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Marketing and Regulatory Programs

Agricultural Marketing Service

Specialty Crops Program

Specialty Crops Inspection Division

AIM Inspection Series

Program Manual

Harmonized GAP Audit Program

Policies and Procedures

July 2022

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Program Manual: Harmonized GAP Audit Program
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INTRODUCTION

This manual is designed to help auditors interpret and apply the U.S. Department of Agriculture's (USDA) Harmonized Good Agricultural Practices (GAP) and USDA Harmonized GAP Plus+ Audit standards and checklists. These instructions are in accordance with official Specialty Crops Inspection (SCI) Division policy. Please contact your immediate supervisor for any information not addressed in this manual. Additional auditor instructions are in the SCI Division Auditor Manual – General Requirements (In-Development).

This manual contains links to various internal and external sources of information. Personnel without Internet or intranet access should contact their immediate supervisor for hard copies of documents as needed.

SCI Division will review and maintain this manual to reflect current GAPs. Submit any recommended changes via email to the SCI Division's Audit Services Branch at SCAudits@usda.gov. All updates will be shared with SCI Division auditors via the AIM update notification process. This publication supersedes previously issued auditing policies and instructions for the Produce GAPs Harmonized Food Safety Standards.

GUIDE FOR ELECTRONIC USAGE

The AIM system of instructional manuals is available electronically in Adobe Acrobat Portable Document Format (PDF) at the following intranet address: https://usdagcc.sharepoint.com/sites/ams/AMS-SCI/SitePages/Home.aspx.

When accessed electronically, AIM materials have hyperlinks and hypertext (visible as underlined blue text) available to the PDF user. Clicking on a hyperlink takes the reader to a web site with information relating to the subject. Hypertext links the reader to a different page within the current manual, or a different manual, with information relating to the subject. For example, the hypertext in the Table of Contents allows a reader to go directly to the section of interest in the manual by clicking on the section title.

PDF offers a variety of tools depending on the Adobe version the reader has. The newer the version, the more tools available. PDF documents are easily searchable for content within a document or within multiple documents. To learn about the variety of PDF search options:

- Click on the "Help" tab on the top of any page in Adobe Acrobat,
- Then click on the "Adobe Acrobat Help" bar,
- Type the word "Search" in the "Search" box, and click on the "Search" button,
- A series of options will become available,
- Click on the "Access Search Features" link and follow the instructions for the type of search you are interested in.

BACKGROUND

History of the Produce GAPs Harmonized Initiative and Standards

In 2009, the Produce GAPs Harmonization Initiative (GHI) was founded to create "one audit by any credible third party, acceptable to all buyers." This initiative was led by a Steering Committee comprised of representatives of more than 30 major fresh produce buying companies, growers, and produce trade associations. The Initiative was designed to reduce the audit burden on the fruit and vegetable industry by developing "harmonized standards" acceptable to all parties that could be used to verify food safety practices for farm, harvest, packinghouse and storage/transportation operations for fresh produce.

The Harmonized Standards were developed by a Technical Working Group (TWG) comprised of more than 150 volunteer technical experts in the areas of food safety, growing, and handling practices for a wide variety of crops and growing regions. The GHI TWG first compared the 13 most commonly accepted fresh produce food safety standards: the California Leafy Greens Marketing Agreement (LGMA), Mushroom GAPs, SENASICA (Mexico's agriculture ministry), Silliker, USDA, Tomato Food Safety Audit Protocol, Community Alliance with Family Farmers, California Strawberry Commission, the Association of Food and Drug Officials (AFDO) Model Code, AIB International, CanadaGAP, GlobalGAP, and Safe Quality Food (SQF) 1000. The comparison identified commonalities and select wording from each standard that best suited a common standard that would meet food safety needs. The TWG developed the Field Operations and Harvesting Harmonized Food Safety standard for all field operations and greenhouses, and the Post-harvest Harmonized Food Safety standard for growing operations with packing facilities onsite. The draft standards were tested by "pilot audits," refined, and then finalized for use by audit organizations.

The Harmonized Standards are based on the U.S. Food and Drug Administration's (FDA) Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. Neither the FDA guide nor the Produce GAPs Harmonized Audit Program apply to products that are processed. FDA considers raw produce that is peeled, cut, and/or chopped to be a processed food that is covered by FDA's Current Good Manufacturing Practices (CGMP). Similarly, this audit program may not be used for processed produce, processed fruit and vegetable products (e.g., canned, dried, or frozen) or for other commodities regulated by FDA such as milk, dairy products, and shell eggs, which also are covered by FDA CGMP. Meat, poultry, and processed egg products are regulated by USDA's Food Safety and Inspection Service (FSIS). The Agricultural Marketing Service (AMS) has no authority to assess conditions for these products.

Specifically, the standards were designed to:

- Achieve global recognition while being specifically applicable to North American operations,
- Include requirements that:
    - Are clearly defined,

  - Consider all microbiological, chemical, and physical hazards reasonably likely to occur.
  - Are risk-based, science-based, attainable, auditable, and verifiable,
  - Recognize and account for regional and crop-specific food safety needs, and
  - Are acceptable to most customers who require general produce food safety practices.
- Be scalable to fresh produce operations of all sizes,
- Be sufficiently non-prescriptive to allow for equivalent food safety practices,
- Be freely available for nonproprietary use by any producer, buyer, or auditor, and
- Be adaptable as science reveals better practices and limits.

Governance of the Harmonized Standard

The Harmonized Standards are "owned" by the fruit and vegetable industry through their participation on the GHI TWG. The GHI TWG is and will remain a volunteer organization of fresh produce stakeholders with open membership. The International Fresh Produce Association (International Fresh) serves as the secretariat and custodian of the standards for the benefit of the industry. The secretariat is responsible for maintaining standards policies, coordinating among support committees, communicating through the website, and serving as the point of contact for questions.

USDA, as a Harmonized Standard licensee, is required to use the International Fresh technical standard verbatim, with no changes in wording permitted. Licensees may include *additional* items in the audit, provided that those items are clearly marked, but they may not delete audit items. Requests to change the standards or the wording of the standards must be presented to the GHI TWG to undergo the established revision process.

The GHI TWG's Calibration Committee is a subset group that provides real time responses to any questions about the standards and the development of official training materials.

USDA Produce GAPs Harmonized Audits

USDA has actively participated in the Harmonization Initiative since its inception, serving on both the GHI TWG and the Calibration Committee. In 2010, in response to a request from industry, USDA became actively involved in conducting a pilot program to audit to the Produce GAPs Harmonized Food Safety Standards. In 2011, USDA was one of the first organizations to provide Produce GAPs Harmonized Food Safety Standards audit services. In 2018, USDA aligned the Harmonized GAP audit services with the requirements of the FDA FSMA Produce Safety Rule.

Additionally, in 2018, the USDA Harmonized GAP Plus+ Audit was created and was formally recognized for Technical Equivalence by the Global Food Safety Initiative (GFSI). In 2021, the Harmonized GAP Audit Services were updated to include addenda for the Tomato Audit Protocol.

USDA Produce GAPs Harmonized audit services are provided to assess a company's efforts to implement a food safety management system that uses a risk-based approach to minimize microbial contamination of fresh fruit, vegetables, and nuts. Audits are not a guarantee that covered products are free from microbial contamination; they indicate the operation has implemented and is following generally accepted food safety practices.

USDA Produce GAPs Harmonized audit services are conducted by Federal or Federal-State licensed auditors. Audits occur on a scheduled basis at least once each year, with unannounced audits conducted according to instructions.

AUDITOR INSTRUCTIONS

Additional Guidance for Conducting Audits

The SCI Division Auditor Manual – General Requirements (In Development) contains general instructions for conducting an audit or providing audit services. Additional guidance for procedures specific to conducting any of the USDA GAP or GHP audits is in current SCI Division AIM documents, including Instructions for the Corrective Action Process, and FPB 703 Fresh Products Branch Good Agricultural Practices and Good Handling Practices (GAP&GHP) Audit Appeals, Complaints and Dispute Process. This manual provides instructions that are specific to conducting Produce GAPs Harmonized Food Safety Standard audits.

Standards

The GAP Harmonization Initiative provides audit standards for Field Operations and Harvesting as well as Post-harvest Operations. International Fresh also offers a combined standard. The official versions of these standards are posted on the International Fresh Produce GAPs Harmonization Initiative website at https://www.freshproduce.com/resources/food-safety/produce-gaps-harmonized-audit-standard/

USDA incorporates the GAP Harmonization Initiative standards into the USDA Harmonized GAP and USDA Harmonized GAP Plus+ Audit programs standards (USDA Harmonized Standards).

In addition to the requirements and their corresponding procedures, verifications, and corrective actions found in the GAP Harmonization Initiative standards, USDA has a designated documentation and mandatory question column in the USDA Harmonized Standards. Both USDA standards also include a Logo Use addendum and Tomato Audit Protocol addenda. The USDA Harmonized GAP Plus+ Audit Standard includes additional requirements to address the GFSI Technical Equivalence requirements.

In the USDA Harmonized Standards, the procedures provide guidance to the auditees on the components that should comprise their operation's procedures. Each verification outlines what the

auditor should verify during the audit. When deficiencies are identified, the corrective action details the action that may be necessary.

Checklists

There are two USDA checklists for the Harmonized GAP Audit Program: the USDA Harmonized GAP Audit checklist and the USDA Harmonized GAP Plus+ Audit checklist. The official copies of the USDA checklists are posted on the USDA Harmonized GAP Audit Program website at https://www.ams.usda.gov/services/auditing/gap-ghp/harmonized. Before conducting an audit, auditors must check the website to ensure that they have the latest version of the checklist(s).

Each checklist includes sections on Auditee Information, Audit Information, Auditor Information, Audit Scope, Other Information, Additional Comments, Internal Use Only, Auditor Completion Instructions, Auditee Information, USDA Acceptance Criteria, the Audit Summary, the body of the checklist for each standard, Duplication of Corrective Action Tab Instructions, and the Corrective Action Report. Instructions on how to use each section and guidance for auditors is included in subsequent sections of this manual.

Auditee Information Section

Provide the following information about each auditee in the Auditee Information section of each checklist.

A. Company Name

Enter the legal business name the auditee wants listed on the USDA website, certificates, and any correspondence. The auditor **must verify** this information each year with the auditee. If the company does business under multiple names, you may include multiple names in this section. You also may use hyphenated names or names listed with a Doing Business As (DBA) designation.

B. Audited Location Address

Enter the physical location(s) at which the onsite audit takes place. If multiple sites are covered by the audit, record this information in the Additional Comments section of the checklist.

1. Global Positioning System (GPS) (Optional)

List the GPS coordinates of the physical audit location(s) if they are available or provided by the company. This section is optional, so if GPS coordinates cannot be determined, mark N/A. Use the Additional Comments section of the checklist if there is more information than will fit in the space provided.

2. Street

List the physical street location of the audit site.

3. City, State, Zip

List the city, state, and zip code of the physical location being audited.

4. Multiple sites covered by this audit?

Check the Yes or No checkbox to designate if more than one site is covered by this audit. Use the Additional Comments section of the audit checklist to provide the further details of each audit site that will not fit in the Audited Location Address fields. List each site as designated by the auditee. For example, an auditee may designate a site by acreage blocks, site names, or crop production areas. An auditor may include a copy of a farm map or a list of audit sites provided by the auditee as long as the map or list is referenced in the audit report.

C. Mailing/Business Address

Use this section to list the mailing/business address for the company being audited. The auditor should verify this information with the auditee at each onsite audit.

1. Same as above

Check this box if the mailing address is the same as the audited location address listed above.

2. Street

List the mailing/business street address of the audit site.

3. City, State, Zip

List the city, state, and zip code of the mailing/business location being audited.

D. Federal Account Number

Must be established prior to scheduling the audit.

E. Company Contact

List the person the auditee designates as their main point of contact for the audit. This person may or may not be the company's food safety manager.

F. Contact Title

List the job title of the person listed in the Company Contact section.

G. Phone Number

List the phone number of the person listed in the Company Contact section. If both office and cell phone numbers are given, list both phone numbers designating the type of phone for each number (cell or office).

H. Fax Number

List the fax number of the person listed in the Company Contact section.

I. E-Mail Address

List the e-mail address of the individual listed as the company contact. If additional e-mail addresses are provided, list them on this line as space permits or in the Additional Comments section. Be sure to include the name of the person associated with each e-mail address recorded.

J. Company uses USDA GAP&GHP Logo on packing or marketing materials?

Select the Yes or No box to designate whether the company uses the USDA GAP&GHP logo on packing or marketing materials. If yes is selected, complete the USDA Logo Use Addendum of the audit checklist. A company must meet eligibility requirements and receive permission from the SCI Division in order to use the logo and complete a SC-652 request for Logo Use Form.

K. Is this company currently subject to the Produce Safety Rule (21 CFR Part 112)?

Select the Yes or No box to designate whether the company is currently subject to the Produce Safety Rule (PSR). It is up to the operation to determine if they are subject to the Produce Safety Rule. If the auditee is subject to the Produce Safety Rule, the auditor will verify implementation of the PSR requirements when assessing compliance with the standard when applicable.

Audit Information

Fill out the Audit Information section of the checklist to specify the following information about the audit. If additional space is needed, use the Additional Comments space on the audit report.

A. <u>Date and Time of the Audit</u>

Provide information that describes the onsite audit being conducted. Describe any offsite desk reviews of the company's food safety plan or other paperwork performed in the Additional Comments section of the audit report. If the audit is stopped on the initial date and then restarted on a later date, then the auditor is required to document a reason.

Example scenario: An audit was conducted for two small neighboring farms. Both farms are managed under similar food safety plans by the same food safety manager. To streamline the audit process for both companies, the food safety manager asks the owners of each company to have the opening meeting, closing meeting and paperwork review conducted by the auditor at the same time.

In this scenario, the Date and Time of the Audit section would be identical on the two reports. A comment explaining why the audit reports show the auditor at two places at the same time will clarify the situation.

Example comment: "This audit was conducted simultaneously with the neighboring farm. Both operations are managed by <<food safety manager name>>. The food safety manager asked, and both companies consented, to have the opening meeting, closing meeting, and paperwork review conducted together. The onsite audit for <<name of operation being audited>> was conducted between <<times>>."

1. Beginning

Date: List the date that onsite audit activities started (mm/dd/yyyy). If the audit is split into two different components, e.g., an initial visit for the farm and secondary visit for the harvest at a later date, list the date range of the initial visit.

Time: List the beginning time of onsite audit activities using standard time format. If an entire initial visit is recorded as in the example above, list the start and end time for that initial visit.

2. Ending

Date: List the date the onsite audit activities concluded (mm/dd/yyyy). If the audit is split into two different components, e.g., initial visit for the farm and secondary visit for harvest at a later date, then the date range for the secondary visit may be listed here.

Time: List the concluding time of onsite audit activities. If an entire secondary visit is recorded as in the example above, list the start and end time for the secondary visit.

B. Description of Operation

List any information that further describes the operation being audited in this section. For example, "Operation is a 40-acre tomato farm in a suburban area surrounded primarily by housing developments. Operation primarily grows heirloom tomatoes for roadside market activities, and supplies product to several local restaurants."

C. Harvest Company Name (if applicable)

List the name of the harvest company if a separate contracted company is used to harvest the crop. If no outside harvest company is used, mark N/A.

D. Other Contractors

List any contractors used by the operation. This might include; portable toilet maintenance companies, pesticide applicators, or cooling unit maintenance companies. If no contractors are used, mark N/A.

E. Commodities Covered by Audit

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 a list of the commodities submitted. 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 must 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/or harvested during the initial audit or subsequent, unannounced verification visits.

F. Commodities Produced During Audit

List all crops that are covered by the audit and are in operation at the time of the audit. A farm is considered “in operation” when fruits or vegetables are being grown, handled or harvested and activities such as thinning fruit, picking, harvesting, or field packing occur. It does not include activities such as pruning which occur when the fruits or vegetables are dormant or ground preparation such as plowing, discing or planting. A facility is “in operation” when any fruit or vegetable handling activity occurs such as sorting, packing, repacking, storing or transporting.

G. Total Acres Covered by Audit

List the total acres of the production area covered in the scope of the audit for the field locations.

H. Total Square Feet Covered by Audit

List the total square footage of the packinghouse and the storage facilities covered in the scope of the audit.

Auditor Information

Use this section to list information for all auditors and auditors-in-training who served on the audit team.

A. Field Office

List the name of the field office of the lead auditor.

B. Auditor Name(s)

List the full name of all auditors, auditors-in-training, evaluators, and observers who served on the audit team. The audit report shall clearly indicate the roles of all participants on an audit, with the name of the lead auditor listed first. This applies for both an auditor or an auditor-in-training whose role is the lead auditor. When a lead auditor is an auditor-in-training, there must be a SCI Division auditor or evaluator listed as well. The role of everyone who was in attendance must be either listed in parenthesis following the name of the individual or in the list of the audit team.

Example 1: John Smith (AIT), John Q. Auditor (Evaluator)
Example 2: Mary Smith (AIT), John Q. Auditor (Evaluator), Sam Stevens (Observer)
Example 3: Mary Smith, John Q. Auditor (Evaluator)

C. Auditor Signature(s)

"Signature on File" should be typed into the electronically submitted Excel workbook. The lead auditor is responsible for obtaining the signature of each member of the audit team and keeping the signed copy on file with the audit report in the local audit office. The lead auditor's signature should appear first on the file copy.

Audit Scope

Check all the boxes of the corresponding audit scope that pertains to the audit. For further instruction, refer to the GAP Audit Program Scope https://www.ams.usda.gov/sites/default/files/media/GAPProgramScope.pdf.

Other Information

This section of the audit report contains the following pertinent audit information.

A. Person(s) Interviewed

Interviewing an appropriate number of people is necessary for the integrity of the audit. The number of people interviewed should be proportional to the size and scope of the operation. Record the first and last name of each person interviewed.

Most workers use their legal names on official documents, while others may use a "nickname". To ensure accuracy with the audit notes, comments, and operation's records, the auditor must use the name the employee uses on all operational paperwork. This is critical in allowing the auditor to make additional accurate verification of other documents during the audit (such as training records).

There are many ways to obtain and verify the correct spelling of an employee's name. An auditor may review the employee's company identification or obtain the full name with correct spelling by reviewing worker's training sign-in logs. The title of the employee does not need to be listed.

B. Audit Requested By

List the name of person requesting the audit report. This may or may not be the same as the company contact for the audit. For example, a buyer who is financially responsible for the audit may request the audit for one of its suppliers who is listed as the company contact.

C. Distribute Audit Report To* (if known)

List additional distribution instructions for the audit report, if any. Only upon written request from the auditee to the auditor can the audit report be distributed to another person, company, or entity. The request must specify that the report can be released to the third party.

*It is not mandatory to supply the names of retail and food service buyers, but it is useful to know that information in the event the auditee asks USDA, in writing, to send a copy of the audit report directly to the buyer(s).

Additional Comments

An audit is a snapshot in time of the company being audited. While the checklist fields are designed to record as much information as possible about the audit, there often will be additional comments that will be very useful to anyone reading the audit report describing observations or circumstances of the audit. Use the Additional Comments section to record any information about the audit that does not have another designated place on the audit report, or for information that does not fit in the space the report allows for a given section.

Internal Use Only

This section is for use of the Audit Services Branch only.

A. Reviewing Official Name

Show the name of the reviewing official who reviewed the audit report.

B. Signature

Place the signature of the reviewing official in this section. Electronic signatures may be used.

C. Date

List the date the audit report is signed by the reviewing official.

D. Audit Results Meets USDA Acceptance Criteria

Check either Yes or No. This section refers only to the USDA Acceptance Criteria for the Produce GAPs Harmonized Food Safety Standard; it does not address meeting the Logo Use Addendum criteria in this checklist.

Auditor Completion Instructions

Assess all questions on the Produce GAPs Harmonized Food Safety Standard USDA checklists in accordance with the Verification Instructions in the Produce GAPs Harmonized Food Safety Standard, which you must have with you when performing audits.

A. Assessment Terms

Assess all questions using one of the following:

1. Compliant (C)

The operation meets the requirements of the Harmonized GAP Standard.

2. Corrective Action Needed (CAN)

The operation does not meet the requirements of the Harmonized GAP Standard; however, the non-conformance is not considered to be an immediate food safety risk.

3. Immediate Action Required (IAR)

The operation does not meet the requirements of the Harmonized GAP Standard and the non-conformance is considered an imminent food safety risk. An imminent food safety risk is present when produce is grown, processed, packed, or held under conditions that promote or cause the produce to become contaminated. Examples of IARs include employees' personal or hygienic practices that jeopardize the safety of

the produce, the presence or evidence of rodents or an excessive number of insects or pests.

4. Not Applicable (N/A)

The question is not applicable to the operation.

B. Auditor Comments

Document all findings related to any question answered CAN or IAR in the Auditor Comment section of the checklist. You may document observations associated with any question on the checklist regardless of whether it is a non-conformity to clarify why a question was answered compliant. Write a comment for each question answered N/A explaining the rationale for that answer. In Appendix V, a table is provided to demonstrate required information the auditor must document in the comment section for certain requirements of the checklist.

C. Tallying the Audit

Once you finish the audit, fill out the score sheet (found in the Audit Summary) by recording the number of C, CAN, IAR, and N/As for each section of the audit. The electronic Excel checklist will tabulate this information automatically, but you must verify the Audit Summary is correct. Note the number of any question answered as CAN or IAR for each section in the last column of the Audit Summary section.

D. Corrective Action Reports

Fill out a Corrective Action Report for each question that was answered CAN or IAR. Refer to SCI Division current guidance on Corrective Action Reports for further instructions.

E. Submittal of the Audit Report for Review

Submit the Checklist (Excel file), the signed Agreement for Participation in Audit Verification Programs (SC-651), and the Request for Audit Services (SC-237A) to SCAudits@usda.gov in accordance with the guidelines in the SCI Division Auditor Manual (In Development). Ensure the most recent SC-651 is on file before or during the opening meeting for the audit. The auditee can use the same SC-651 each year if (1) they are using the most current version of the form; (2) the auditee has maintained good audit standing, (3) the operation's address is accurate, (3) the release information remains unchanged (if applicable); and (4) the signature of the auditee's current management is on file.

Documents Required

The auditing standards require verification of certain policies and procedures (WP), Risk Assessments (A) and records (R). To help auditors identify where documents (DOC) are required,

the Checklist includes a DOC column that designates the type of documentation to verify a WP, R, A or a combination.

A. Policies and Procedures (WP)

A policy is high-level guidance that describes general goals and acceptable procedures for an organization. A procedure is a specified way to carry out an activity or process. Policies and procedures may be communicated in writing or orally. They only need to be written if the standard specifically states that requirement. Use interview techniques to verify that policies and procedures, whether communicated in writing or verbally, are implemented throughout the operation as specified.

B. Record (R)

A record is a document stating results achieved or providing evidence of activities performed. Records may include checklists, service records, billing forms, and water tests.

Records that show errors or deviations from the company's procedures should be noted or copied and included in the audit report. Since such records will not likely support the requirement, assess the requirement as Corrective Action Needed or Immediate Action Required, depending on the severity of the non-conformity.

If you find evidence of falsified records any time during the audit, contact your immediate supervisor for further instructions. The auditor should take detailed notes of the observation and obtain a copy of the falsified document. Falsification of records is considered an egregious offense and will lead to an Immediate Action Required for the audit.

C. Risk Assessment (A)

A risk assessment is a process to identify potential hazards on a farm and/or in a packinghouse as well as the likelihood the hazards will impact the safety of fruits and vegetables. The findings of the risk assessment must be documented.

Auditee Information

This section of the Audit Checklist is designed to provide information to the auditee about the USDA Harmonized Standards and the USDA Produce GAPs Harmonized Audit program. It describes how to access and use the Standard and Checklist, and how to schedule an audit with USDA. You must be familiar with this section and may refer the auditee to this portion of the Audit Checklist when sharing information about the USDA Produce GAPs Harmonized Audit Program.

Audit Summary

The Audit Summary shows the number of questions assessed as C, CAN, IAR, or N/A. The numbers are tabulated automatically in the electronic Excel checklists, however, upon completion of the audit, the auditor should verify them for accuracy to ensure that all questions were answered

and recorded properly. Auditor should list the requirement number for any assessed with CAN or IAR in the last column of the summary table.

The rest of this manual provides guidance on interpreting technical points and acceptance criteria. There are also example scenarios that provide guidance on how to interpret various situations that may be encountered.

GENERAL GUIDANCE FOR ASSESSING REQUIREMENTS

Risk Assessments

Risks must be assessed for potential physical, chemical, and biological hazards throughout the operation. Risk Assessments for the Produce GAPs Harmonized audit focus on food safety and must include:

- Identification of potential physical, chemical, and biological hazards;
- Analysis of any identified hazards;
- Control measures for identified hazards;
- Monitoring and verification of hazard mitigation; and
- Corrective and preventive actions to prevent additional hazards.

Prevailing and Applicable Regulations

The USDA Harmonized Standards can be applied in various countries and localities. The terms "prevailing regulation" and "applicable regulation" refer to regulations that apply specifically to the operation being audited, such as municipal, town, county, state, or Federal regulations. When these terms are used, you must be familiar with the regulations that apply to the auditee's operation.

You may apply either the requirements in the standards or prevailing and applicable regulations; apply whichever guidance is more stringent. For example, Requirement G-3.3 states that "Documentation shall be retained for a minimum period of two years, or as required by prevailing regulation." If a state regulation requires retention of pesticide documentation for a minimum of three years, you would apply the three-year requirement. If a state regulation requires pesticide documentation must be kept for one year, you would apply the two-year requirement in the standard.

For many operations in the United States, the Food Safety Modernization Act (FSMA) Produce Safety Rule will be considered a prevailing regulation. Coverage and applicable sections of the rule are affected by the commodities produced and/or handled by an operation, the activities of the operation, sales, customers, and other factors. Operations are responsible for understanding if and how they are subject to the Produce Safety Rule.

Crop-Specific Guidance Expectations

The Harmonized Standards refer to current industry practices or current industry standards, which are practices or standards that are generally accepted and followed by members of a specific industry. SCI expects that producers will incorporate applicable industry practices and standards into their food safety plans, as appropriate, and auditors will reference applicable industry practices and standards when performing audits.

You should be familiar with industry guidance reviewed by the FDA prior to conducting an audit. Please see Appendix IV: FDA & Industry Guidance Documents of this manual.

The auditee's policies and practices may be based on FDA guidance, or new research or recommendations. Verify that any practice or policy that diverges from GAPs found in FDA-reviewed guidance meets the requirements of the Harmonized Standard and has a credible basis, such as published studies that are peer reviewed and cooperative extension guidance. Most importantly, you must observe implemented practices and policies to verify they minimize food safety hazards.

Questionable Observations

If you observe a questionable practice or policy during an audit:

- Take thorough notes to document your observations; and
- Contact your supervisor or the SCI Audit Services Branch (ASB) immediately if the practice or policy may be considered an IAR; or
- Take thorough notes on the practice or policy if it is not one that may be considered an IAR and seek further guidance from your supervisor or ASB.

If you cannot decide whether a practice you see during an audit is an IAR, advise the auditee of the observations you documented and that you are seeking further guidance.

PROGRAM EXPECTATIONS

USDA Acceptance Criteria for the Produce GAPs Harmonized Food Safety Standard Audit

An operation must meet the following criteria to meet USDA acceptance criteria:

1	No questions are assessed as an “IAR,” Immediate Action Required.
2	Falsification of records is considered an “IAR.”
3	Any applicable question marked with a ● in the MAN column must be assessed as "compliant".
4	Operation must have performed all risk assessments, designated with an "A" in the DOC column, in the Produce GAPs Harmonized Food Safety Standard.
5	If the auditee has been audited against the Produce GAPs Harmonized Food Safety Standard previously, the auditee must have addressed all associated CANs or IARs, following their established corrective action procedure.
6	In each major section (G, F, and P) of the audit, at least 80% of the questions not answered as "N/A" must be answered as compliant.

Meeting or Not Meeting Criteria

If an operation meets the acceptance criteria as outlined above, the operation will receive a certificate stating its conformance to Produce GAPs Harmonized Food Safety Standard as well as being posted to the USDA website. Corrective action reports will still be supplied to the auditee for all non-conformances.

If an operation does not meet the acceptance criteria as outlined above, a corrective action report form will be issued for each non-conformance noted on the audit. The operation has the opportunity to take measures in order to address the issue and schedule a new audit in order to show compliance to the acceptance criteria.

USDA ACCEPTANCE CRITERIA FOR THE HARMONIZED GAP PLUS+ AUDIT

An operation must meet the following criteria to meet USDA acceptance criteria:

1	No questions are assessed as an “IAR,” Immediate Action Required.
2	Falsification of records is considered an “IAR.”
3	Any applicable question marked with a ● in the MAN column must be assessed as "compliant".
4	Operation must have performed all risk assessments, designated with an "A" in the DOC column, in the USDA Harmonized GAP Plus+ Standard.
5	If the auditee has been audited against the USDA Harmonized GAP Plus+ Standard or the Produce GAPs Harmonized Food Safety Standard previously, the auditee must have addressed all associated CANs or IARs, following their established corrective action procedure.
6	In each major section (G, F, and P) of the audit, at least 80% of the questions not answered as "N/A" must be answered as compliant.

Meeting or Not Meeting Criteria

An operation that meets the acceptance criteria as outlined above, the operation will receive a certificate stating its conformance to the Harmonized Standard or USDA Harmonized GAPs Plus+ Standard as well as being posted to the USDA website. Corrective action reports will still be supplied to the auditee for all non-conformances.

If an operation does not meet the acceptance criteria as outlined above, a corrective action report form will be issued for each non-conformance noted on the audit. The operation has the opportunity to take measures in order to address the issue and schedule a new audit in order to show compliance to the acceptance criteria.

GENERAL QUESTIONS

The questions in this section assess the operation's Management Responsibility, Food Safety Plan or Risk Assessment, Documentation and Recordkeeping, Worker Education and Training, Sampling and Testing, Traceability, Recall Program, Corrective Actions and Food Safety Incidents, and Self-Audits, Worker Health/Hygiene and Toilet/Handwashing Facilities, Waste Management, Food Defense, and Food Fraud.

G-1 Management Responsibility

Management must be committed to an operation's food safety program. The following requirements address the essential elements of management responsibility:

Requirement	G-1.1 A food safety policy shall be in place.
Procedure	A written policy shall outline a commitment to food safety, in general terms, how it is implemented and how it is communicated to employees, and be signed by Senior Management.
Verification	The auditor observes the food safety policy, observes that it is signed by Senior Management, and observes that it has been communicated to all employees in a manner that can be understood.
Corrective Action	The operation creates or revises the policy, or its communication to employees, to be in compliance.
Documents Required	Written Policy.
Mandatory	●

Expectation
A food safety policy is the company's written commitment to ensuring the safety of its product and a description of how that is accomplished. This policy must be signed by senior management. The Harmonized Standard doesn't specify how often the food safety policy should be reviewed or revised, but the policy should accurately reflect current senior management and accurate, appropriate policy. If a company has a standard operating procedure (SOP) for updating its food safety policy, the food safety policy must be compliant with the SOP.

The food safety policy may be displayed or communicated in any way that can be demonstrated to be effective, including, being displayed in the front lobby in English and the predominant worker language, shared during annual training, or posted on an employee bulletin board. Throughout the audit, interview employees to verify that the food safety policy has been communicated effectively. All employees should be familiar with the food safety policy as appropriate for that employee's responsibility.

Example Scenarios
Scenario 1: In reviewing an operation's food safety policy, that was implemented/dated three years ago you review a SOP that states the food safety policy shall be updated yearly and/or as needed.
Assessment: Corrective Action Needed

Reason: The operation is not following their Standard Operating Procedure.

Scenario 2: Operation presents their food safety policy which describes their commitment to ensure food safety, it is signed by senior management. The food safety policy is displayed in the employee break room and upon entry into the building (with sign in sheets for visitors, etc.) you conduct interviews throughout the audit with employees that are well versed on the food safety policy and procedures.
Assessment: Compliant.
Reason: Employees are able to accurately describe the company's food safety policies and procedures showing they have been effectively communicated to and are knowledgeable on the subject.

Requirement G-1.1.a	**The food safety policy shall include measurable objectives for meeting the safety needs of the products.**
Procedure	**A written policy shall include measurable objectives, each of which is defined and includes a plan to achieve it. The plan must include the timeline in which the objective will be accomplished, who is responsible for ensuring it is accomplished, and how the progress of completion will be documented and verified.**
Verification	**The auditor observes that the food safety policy contains measurable objectives and that the operation is progressing toward their completion.**
Corrective Action	**The operation adds or revises its measurable objectives.**
Documents Required	**Written Policy.**
Mandatory	

Expectation
The operation must have measurable objectives for meeting the safety needs of their product in their food safety policy. These objectives must be defined and have a plan to achieve it. The plan must include: 1) a timeline in which the objective will be accomplished, 2) a designated individual or individuals who are responsible, and 3) an explanation of how the progress of completion will be documented and verified.

Example Scenarios
Scenario 1: An auditee's food safety plan contains the following objectives: 1) To provide safe food to customers and 2) To satisfy our customers. No additional information on the objectives is provided.
Assessment: Corrective Action Needed
Reason: These objectives are not measurable.

Scenario 2: An auditee's food safety plan contains the following objectives: 1) To have zero product recalls or outbreaks associated with our products and 2) To respond to all customer complaints or feedback within 1 week of receipt. There is no documentation of their progress.
Assessment: Corrective Action Needed.

Reason: Auditees must have a plan to verify and document progress towards their objectives.

Requirement	G-1.2. Management has designated individual(s) with roles, responsibilities and resources for food safety functions.
Procedure	The food safety plan shall designate who has the responsibility and authority for food safety, including a provision for the absence of key personnel. Twenty-four hour contact information shall be available for these individuals in case of food safety emergencies. The organization's senior management shall determine and provide, in a timely manner, the resources needed to implement and maintain the food safety plan.
Verification	Auditor observes that the food safety plan has identified individual(s) for key food safety activities. Auditor verifies that procedures include provisions for when the identified individual is not present. Auditor observes whether senior management has provided the resources needed to implement and maintain the food safety plan.
Corrective Action	Operation identifies individual(s) for key food safety activities in the food safety plan. Operation identities actions to be taken when the identified individual(s) are not present. Senior Management commits resources needed to implement and maintain the food safety plan.
Documents Required	Written policy.
Mandatory	●
PSR	112.23

Expectation
Operations must designate an individual(s) who is responsible for ensuring that its food safety program is being followed. Key personnel and 24-hour contact information must be included in the food safety plan and accessible to relevant employees. The auditor will interview the designee(s) to determine their knowledge of the program. Designees should be able to demonstrate procedures, show applicable records, and knowledgeably answer questions about the program for which they are responsible.

The auditor will include the name(s) of the individual(s) responsible for the Food Safety Plan with their roles/responsibilities in the comments.

Example Scenario
Scenario: There is no alternate designated for food safety.
Assessment: The assessment will depend on whether the lack of an alternate affects effective implementation of the operation's food safety plan.
Reason: An operation that does not designate an alternate, thereby creating reasonable potential for food safety to be left unsupervised requires a corrective action. A small operation that designates only the owner and food safety manager, who are present to oversee all activity, but does not designate an alternate, would be compliant.

Produce Safety Rule

112.23: Operations must assign or identify personnel to supervise (or otherwise be responsible for) the operations to ensure compliance with the requirements of the Produce Safety rule.

Requirement	G-1.2.a. The food safety plan outlines an organizational structure for at least those staff whose activities affect food safety.
Procedure	The food safety plan defines and documents the job functions and responsibilities related to on farm activities of at least those staff whose activities affect food safety.
Verification	Auditor observes documentation of job functions and responsibilities related to on farm food safety activities.
Corrective Action	The operation creates or revises the documentation of job functions and responsibilities related to on farm food safety activities.
Documents Required	Written policy.
Mandatory	

Expectation
The food safety plan must define an organizational structure that shows job functions and responsibilities of workers whose activities affect food safety within the company. For very small companies, an individual worker may be responsible for many job functions.

Example Scenario
Scenario: The auditee does not have an organizational chart, but instead provides a document which lists job titles and their roles in executing the food safety plan.
Assessment: Compliant
Reason: Does not need to be an organizational chart, so long as roles and responsibilities are defined and documented for all employees who may affect food safety.

Requirement	G-1.3. There is a disciplinary policy for food safety violations.
Procedure	There shall be a policy that establishes corrective actions for personnel who violate established food safety policies or procedures.
Verification	Auditor observes the policy and checks for examples of enforcement.
Corrective Action	The operation creates or revises the policy, or its communication to employees, to be in compliance.
Documents Required	N/A.
Mandatory	

Expectation
The operation, whether part of a large farming corporation or a small family farm, must have a disciplinary policy for food safety violations that establishes corrective actions for personnel who violate established food safety policies or procedures. This policy does not have to be written, but it does need to be established, and effectively communicated to and understood by personnel. The corrective actions for personnel food safety violations are established by the operation and not the Harmonized Standard. The auditor will verify by interviews that employees are aware of and can

explain the company's disciplinary policy for food safety violations.

Example Scenarios
Scenario 1: Auditor reviews the food safety policy but does not see any documentation for a disciplinary policy. Employee interviews established that after 3 warnings or corrective actions relating to food safety, employee(s) would be dismissed.
Assessment: Compliant
Reason: Policy does not have to be written; however, it must be understood by employees.

Scenario 2: Several employees of a large operation were interviewed. The interviews confirmed that employees were not made aware of a disciplinary policy.
Assessment: Corrective Action Needed
Reason: Although policy does not have to be written, policy needs to be established and communicated to and understood by personnel.

G-2 Food Safety Plan

The written Food Safety Plan is a critical component of every operation's food safety program. The format of the Food Safety Plan is not specified in order to promote the writing of a plan that is customized to the operation.

Requirement	G-2.1. There shall be a written Food Safety Plan. The plan shall cover the operation. The operation and products covered shall be defined.
Procedure	The Food Safety Plan shall identify all locations of operation covered by the plan and shall identify physical, chemical, and biological hazards reasonably likely to occur and hazard control procedures, including monitoring, verification and recordkeeping, for all provisions covered by this audit.
Verification	Auditor shall observe the Food Safety Plan and verify that the plan has considered potential biological, chemical and physical hazards and has identified preventive controls for hazards that may reasonably affect food safety.
Corrective Action	Operation develops or completes a Food Safety Plan for all locations of operation.
Documents Required	Written Policy.
Mandatory	●

Expectation
The Food Safety Plan is a written document that outlines the company's plan to identify, control, monitor, and verify the mitigation of potential food safety hazards. This includes physical, chemical, and biological hazards that are reasonably likely to affect food safety for water, soil amendments, field sanitation, production environment, and worker practices.

The Food Safety Plan must identify locations, products, and activities of the operation. The plan will establish policies and procedures that will enable the operation to effectively prevent cross-contamination of produce from agricultural inputs, cleaning agents, or personnel who come directly or indirectly into contact with other sites, animals or produce throughout the operation.

The plan must also include the operation's recordkeeping requirements.

The auditor will include the date and/or version of the current Food Safety Plan being audited in the comments.

Example Scenarios
Scenario 1: The Food Safety Plan is generic and does not consider the operation's actual conditions and potential hazards.
Assessment: Corrective Action Needed for lack of a specific plan; or Immediate Action Required if the conditions and potential hazards for that operation are imminent food safety hazards.
Reason: The plan must consider the operation's actual conditions and procedures.

Scenario 2: The Food Safety Plan is generic but considers all of the potential hazards reasonably likely to occur at the operation; procedures in the generic plan are being followed.
Assessment: Compliant.
Reason: The plan addresses all hazards for the operation and is consistent with procedures being

followed.

Scenario 3: The operation's Food Safety Plan is silent about hazards or states that there are no biological hazards likely to occur.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: This contradicts current industry guidance. The operation's contention that there are no hazards is insufficient unless it can provide evidence that its analysis is correct. "We've never had a problem" is not sufficient evidence.

Requirement	G-2.2. The Food Safety Plan shall be reviewed at least annually.
Procedure	Operation shall be responsible for reviewing their food safety plan at least annually, documenting the review procedure and revising the plan as necessary. Updated or revised on date shall be indicated.
Verification	Auditor reviews last Food Safety Plan review.
Corrective Action	Operation reviews Food Safety Plan and documents review.
Documents Required	Record.
Mandatory	

Expectation
The operation must review its Food Safety Plan at least annually. If the operation has an SOP in place that requires more frequent reviews of the plan, verify that the plan is reviewed in accordance with the SOP.

The auditor will include the date the Food Safety Plan was last reviewed in the comments. If Not Applicable is selected, include that the plan is less than a year old.

Example Scenarios
Scenario 1: The operation's Food Safety Plan does not have an effective or revised date.
Assessment: Corrective Action Needed.
Reason: Standard requires that the Food Safety Plan must be reviewed at least annually and that "updated or revised on date shall be indicated."

Scenario 2: The operation's Food Safety Plan is less than a year old.
Assessment: Not Applicable.
Reason: Unless the operation has an SOP that specifies more frequent review, the operation only needs to review its plan annually. The Food Safety Plan must have been in place for a full year before it can be assessed for compliance to this requirement. Place a comment on the audit report indicating that the plan is less than a year old.

Requirement	G-2.2.a. The Food Safety Plan shall be reviewed in the event of any change which may affect food safety.
Procedure	The documented food safety plan review shall include evidence of management's commitment to establish, implement, maintain, and improve food safety and the organization's food safety culture. Elements of a food safety culture include but are not limited to communication about food safety policies and responsibilities, training, Employee feedback on food safety relate issues and performance measurement. Additionally, it shall ensure access to necessary resources to implement plan, including suitably qualified personnel. The plan must include a review of all supplier specifications.
Verification	Auditor shall review documentation for food safety plan review in the event of any change which may affect food safety.
Corrective Action	Operation conducts a review of the food safety plan in the event of any change which may affect food safety, and provides documentation.
Documents Required	Record.
Mandatory	●

Expectation
The plan must be reviewed at least annually. It shall also be reviewed in the event of any change which may affect food safety to ensure the hazards identified and any necessary controls continue to be accurate and appropriate for the operation in light of the changes. The plan shall be updated/revised as necessary based on this review.

The documented Food Safety Plan review shall include evidence of management's commitment to establish, implement, maintain, and improve food safety and the organization's food safety culture. Elements of a food safety culture include but are not limited to communication about food safety policies and responsibilities, training, employee feedback on food safety related issues and performance measurement. The auditor will verify through interviews and observations that workers performing their jobs share values, beliefs and similar mindsets and behaviors toward the importance of food safety in, across and throughout the organization.

Example Scenarios
Scenario 1: Operation had been manually monitoring chemical disinfectant concentration in flume water at a frequency specified in its Food Safety Plan. The operation manually added chemicals when levels dropped below a point specified in its Food Safety Plan. They recently switched to an automatic monitoring and injection system. Auditor observes that the operation's Food Safety Plan was last reviewed eight months ago.
Assessment: Corrective Action Needed
Reason: Food Safety Plan still reflects previous practices, not current practices or conditions.

Scenario 2: Auditor observes that the operation recently expanded its product throughput by fifty percent, adding a new sorting line and packing line. However, the firm did not conduct a review of its Food Safety Plan based on these changes. Auditor asks the Food Safety Manager if they had

considered reviewing their plan. The manager said they considered it but didn't think it was necessary because the building had adequate space to accommodate the new equipment and the equipment was similar to what they already had. Therefore, controls already in the plan are sufficient and the changes weren't likely to affect food safety.
Assessment: Compliant
Reason: In compliance. Changes not likely to affect food safety so no review needed.

Requirement	G-2.3. Operation has an Approved Supplier program for all incoming materials, including packaging.
Procedure	Operation has and maintains a current list of approved raw material suppliers and service providers relevant to food safety. Approved Supplier program includes a procedure for accepting materials from alternate sources.
Verification	Auditor verifies a list of raw material suppliers is maintained and current. Auditor verifies that all materials received from alternate sources has followed established procedure.
Corrective Action	Operation develops an Approved Supplier program and maintains current list. Operation develops a procedure for accepting materials from alternate sources. Operation ceases accepting or shipping materials from non-compliant suppliers.
Documents Required	Record.
Mandatory	●

Expectation
Incoming materials include any materials purchased for use in production. This includes chemicals, produce, packaging material, labeling supplies, equipment used in the packing process, etc.

The auditor will include the date of current approved supplier list in the comments.

Example Scenarios
Scenario 1: An operation has a program in place for approving suppliers, which includes packaging materials, ingredients and cleaning chemicals, but the program is not written.
Assessment: Compliant for Harmonized GAP audit, Corrective Action Needed for Harmonized GAP Plus audit (see G-2.3.a)
Reason: Procedure for approving suppliers does not have to be written; only the supplier list must be written.

Scenario 2: An approved list of raw material suppliers is 18 months old.
Assessment: Compliant.
Reason: This will be compliant as long as it is accurate.

Scenario 3: Approved supplier program does not include source of diesel fuel for tractors.
Assessment: Not Applicable.
Reason: The approved supplier list only needs to include items that could impact food safety.

Scenario 4: An approved supplier list includes XYZ Hardware Store for cleaning supplies. XYZ Hardware Store has been approved by their program as a supplier for the materials purchased.
Assessment: Compliant.
Reason: XYZ Hardware Store is an approved supplier.

Requirement	G-2.3.a. Approved supplier program contains written procedures for the evaluation, approval, and continued monitoring of suppliers.
Procedure	The operation shall document the procedures for evaluation approval, and continued monitoring of suppliers. Results of evaluations, investigations, and follow up actions shall be recorded for each supplier.
Verification	Auditor verifies documentation for procedures for evaluation, approval, and continued monitoring of suppliers as well as records documenting these activities.
Corrective Action	Operation develops procedure and/or records for the evaluation, approval and continued monitoring of suppliers.
Documents Required	Written Policy.
Mandatory	

Expectation
A procedure for the evaluation, approval and continued monitoring of suppliers which have an effect on food safety shall be established, implemented and maintained. The procedure must address procurement in emergency situations to ensure that food still conforms to the documented specified requirements or specifications, and the supplier has been evaluated. The results of evaluations, investigations and follow up actions must be recorded.

Example Scenario
Scenario: The operation's Approved Supplier program requires all growers supplying produce to ABC Packing to have completed a Harmonized GAP Plus+ Field Operation & Harvesting audit. They keep records of all audit reports electronically in file folders on the food safety manager's computer.
Assessment: Corrective Action Needed
Reason: The operation's policy does not include the necessary information and therefore is incomplete. Missing information includes who approves suppliers, when suppliers are approved, how approved suppliers are monitored, how results of evaluations, investigations and follow up actions are recorded for each supplier.

Requirement	G-2.3.b. The operation's Approved Supplier program includes procedures for approving contractors.
Procedure	The operation's program includes the approval of any contractors and food safety related services utilized by the operation to ensure that all specifications are met. The program includes a procedure for accepting services from alternate sources.
Verification	Auditor verifies that a list of contractors is maintained and current. Auditor verifies that any services received from alternate sources has followed established procedure.
Corrective Action	Operation develops an Approved Supplier program and maintains current list. Operation develops a procedure for accepting services from alternate sources. Operation ceases utilizing services from non-compliant suppliers or contractors.
Documents Required	Record.
Mandatory	

Expectation
A procedure for the evaluation and approval of contractors which provide a service which has an effect on food safety shall be established, implemented and maintained. The procedure shall address procurement in emergency situations to ensure that food still conforms to the documented specified requirements or specifications, and the supplier has been evaluated. The results of evaluations, investigations and follow up actions shall be recorded.

Example Scenario
Scenario: The operation contracts a pesticide applicator company and a portable toilet maintenance company. All other work is done in house. The operation's SOP states that the Food Safety Manager must approve all contractors and document their approvals using a Vendor Assessment Checklist. Alternative sources are approved using this same process.
Assessment: Compliant
Reason: The operation maintains a file for all contractors and has a procedure to use their Vendor Assessment Checklist for all contractor approvals.

Requirement	G-2.3.c. Outsourced processes must be identified, documented, and monitored.
Procedure	Outsourced processes (i.e. pest control, sanitation unit maintenance, harvest crews, etc.) must be identified, documented, and monitored.
Verification	Auditor verifies that outsourced processes are documented and monitored.
Corrective Action	Operation identifies, documents and monitors outsourced processes.
Documents Required	Record.
Mandatory	

Expectation
The operation is responsible for ensuring the processes conducted by any contractors and food safety related services utilized by the operation are consistent with the operation's plan, the requirements of this standard and in compliance with the Produce Safety Rule. To ensure that all specifications are met. Operation shall identify, document, and monitor outsourced processes (e.g., pest control, sanitation unit maintenance, harvest crews, etc.) to ensure that its food safety program is being followed.

Example Scenarios
Scenario 1: Operation contracts nightly cleaning and sanitation of packinghouse and equipment. Operation can identify the company that performs this service, provide invoices showing the company name and explains that these procedures are performed after the packinghouse stops operation for the day. The work is supervised by an employee of the contract firm. However, the operation's food safety manager inspects facilities and equipment before the operation resumes the next day to ensure everything is clean and sanitary before packing resumes. Operation explains that if any issues are found, which they say is rare, their own personnel make immediate corrections, and they contact the contract firm.
Assessment: Compliant
Reason: Operation's monitoring appears to be sufficient to ensure food safety objectives.

Scenario 2: Operation identifies and provides documentation for the contract harvest crew that they use. The contract includes requirements for the training of harvest workers and procedures they must follow. Operation relies on the contract firm to conduct training and supervise the crew. Auditor observes that harvest bins contain debris from a previous harvest and that some crew members are leaving the porta potties and returning to work without washing their hands.
Assessment: Corrective Action Needed, possible Immediate Action Required.
Reason: Operation is relying on contract firm to meet requirements written into the contract but does not monitor or provide sufficient oversight to ensure procedures are followed.

G-3 Documentation and Recordkeeping

Documentation and records are an essential part of a Food Safety Plan. Throughout the audit standard each requirement dictates whether or not documents or records will need to be created and maintained.

Requirement	G-3.1. Documentation shall be kept that demonstrates the food safety plan is being followed.
Procedure	Documents and records of procedures, standard operating procedures (SOPs) and policies shall be in place for meeting each of the food safety standards identified in the Food Safety Plan. Records comply with prevailing regulations.
Verification	Auditor reviews Food Safety Plan and verifies that all required documentation is available.
Corrective Action	Operation develops missing documentation or recordkeeping procedures.
Documents Required	Record.
Mandatory	●
PSR	112.161

Expectation
The operation must maintain documentation that demonstrates, at a minimum, that it is following its Food Safety Plan. Verify these documents, which should include, but are not limited to, policies, SOPs, and records.

Example Scenarios
Scenario 1: The operation's SOP states that equipment will be checked for maintenance on a daily basis. There is no log for a day when equipment was not used.
Assessment: Corrective Action Needed.
Reason: The SOP requires a daily check; the lack of log for a day is inconsistent with the operation's SOP.

Scenario 2: The operation has no record of cleaning/sanitizing an automated produce weighing machine on a day that it was used.
Assessment: Corrective Action Needed, unless the lack of the records indicates a potential food safety hazard, which would indicate Immediate Action Required.
Reason: The operation is not complying with its policy for cleaning/sanitizing the weighing machine.

Scenario 3: There is no written SOP for performing cleaning/sanitation of a food contact equipment.
Assessment: Corrective Action Needed.
Reason: The operation must follow its food safety plan regarding documentation.

Produce Safety Rule
112.161: A list of records that are required in the PSR can be found in Appendix II: Records Required for the Produce Safety Rule. All records that are required by the Produce Safety Rule must include the following information, as applicable:
- Name and location of the farm

- Actual values and observations during the observation
- An adequate description of the produce applicable to the record (e.g., name of commodity, lot number or identifier if available)
- Location of area applicable to the record (e.g., specific field or packing shed)
- Date and time of activity documented
- Be created at the time of the activity documented
- Be accurate, legible and indelible
- Be dated, signed or initialed by the person who performed the activity documented.
- Be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

In addition, records required under §§ 112.7(b), 112.30(b)(2), 112.50(b)(2), 112.50(b)(4), 112.50(b)(6), 112.60(b)(2), 112.60(b)(3), 112.140(b)(1), 112.140(b)(2), 112.150(b)(1), 112.150(b)(4), and 112.150(b)(6). Appendix II lists all required records and notes which require review. For records required by the Produce Safety Regulation these records can rely on or add to existing records kept for another purpose.

Requirement	**G-3.2. Documentation shall be readily available for inspection.**
Procedure	**Documents and records may be maintained onsite or at an off-site location, or accessible electronically, and shall be available for inspection in a reasonable timeframe or as required by prevailing regulation. Records shall be protected to prevent unauthorized access or potential falsification.**
Verification	**Auditor verifies that required documentation can be accessed in a reasonable timeframe.**
Corrective Action	**Operation defines in food safety plan where and how documentation is maintained and expected retrieval time.**
Documents Required	**N/A.**
Mandatory	●
PSR	**112.162, 112.166**

Expectation
The auditee must make all documentation readily available for inspection by the auditor. Documentation may be maintained onsite or at an accessible off-site location, and in hard copy (paper) or electronically so long as it is accessible to the auditor in a reasonable timeframe and kept in accordance with prevailing regulations and the company's Food Safety Plan specifications. The standard does not specify whether documents/records must be protected or if "track changes" must be enabled to show modifications to them. If the operation's Food Safety Plan allows records to be maintained without changes tracked, for example, an Excel spreadsheet or a paper record written in pencil, the auditor will verify to the best of their ability that these records are complete, and no falsification of records has occurred for this question to be compliant.

If a document/record is not available at the time of the audit, it is acceptable for the auditee to provide this document/record to the auditor in a timeframe that is reasonable to the auditor. For

example, if the operation keeps water test records at an off-site location and has forgotten to bring them to the onsite audit, it is reasonable to allow the auditee 24 hours to fax or e-mail a copy of these reports to the auditor's office.

Example Scenarios
Scenario 1: A document or record required by the food safety plan is not available for the auditors review during the audit but can be provided to the auditor within 24 hours.
Assessment: Compliant

Scenario 2: A document or record required by the food safety plan is maintained by a subcontractor (e.g., pesticide applicator) and is not accessible by the operation for auditor's review.
Assessment: Corrective Action Needed

Produce Safety Rule:
112.162: Off-site storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite at the farm if they are accessible from an onsite location at the farm.

112.166: All records required under the Produce Safety Rule must be readily available and accessible during the retention period for inspection and copying by FDA upon request, except you have 24 hours to obtain records kept offsite. If electronic records are kept, or if a reduction technique such as microfilm is used to keep true copies of records, FDA must be provided with records in a format that is accessible and legible. If the farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the farm within 24 hours for official review upon request.

Requirement	**G-3.3. Documentation shall be retained for a minimum period of two years, or as required by prevailing regulation.**
Procedure	**Document and record handling policy or procedures require that documentation required by the food safety plan shall be retained for a minimum of two years, or as required by prevailing regulation.**
Verification	**Auditor reviews document handling procedures and verifies that required documentation is available for at least two years, or as required by prevailing regulation.**
Corrective Action	**Operation revises documentation procedures.**
Documents Required	**Record.**
Mandatory	●
PSR	**112.164**

Expectation
Documents must be kept for a minimum period of two years; documents may be kept longer than two years. Be aware of local prevailing regulations to determine if records need to be kept for longer than 2 years. For example, Texas requires restricted use pesticide records to be kept for 30

years. If an operation has 2 years of documents/records available for review and no other prevailing regulation requires documents be kept longer, the operation is in compliance with this requirement.

If Not Applicable is selected, the auditor will include that the business or Food Safety Plan has been in operation for less than two years in the comments.

Example Scenarios
Scenario 1: Records are kept for the entire time the operation has been in business, which is 3 months.
Assessment: Compliant.
Reason: The company has kept records throughout its operations. Assess the records that the operation has been keeping from the time the operation began, and add a comment explaining why less than 2 years of records were assessed.

Scenario 2: Records are kept for the length of time the company has had a food safety plan in place, which is 1-1/2 years.
Assessment: Compliant.
Reason: The company has kept records throughout the lifetime of its food safety plan. Assess the records that the operation has been keeping from the time the food safety plan was implemented, and add a comment explaining why less than 2 years of records were assessed.

Scenario 3: Records were inadvertently destroyed by a natural disaster (e.g., a fire or hurricane).
Assessment: N/A.
Reason: Due to extenuating circumstances beyond the operation's control.
Produce Safety Rule
112.164: Records are required to be kept for at least two years past the date the record was created.

Requirement	G-3.3.a. Food Safety Plan documentation and records shall be securely stored and effectively controlled.
Procedure	The Food Safety Plan, documentation, and any records required to demonstrate the implementation of food safety are securely stored and effectively controlled.
Verification	Auditor verifies that documentation and records are securely stored and effectively controlled.
Corrective Action	Operation stores their documentation and records in a secure location and implements effective controls for these records.
Documents Required	N/A.
Mandatory	

Expectation
Control of documented information required to demonstrate the effective operation and control of processes and the Food Safety Plan shall be established. Records should be stored in a manner to prevent intentional or unintentional changes to records (falsification). Records should be stored to prevent loss, deterioration, or destruction.

Example Scenarios
Scenario: Food safety plan documentation is stored in the operation's Food Safety Manager's office, as well as records that have been completed. When asking to review this week's pre-harvest risk assessment records you find out they are kept with the harvest crew manager in his pickup truck.
Assessment: Compliant or Corrective Action Needed.
Reason: It depends on what the SOP states. If in alignment with the SOP for records storage and the records are controlled within the truck, Compliant. If the SOP states all records, except for records currently in use must be kept in the office, Corrective Action Needed.

G-4 Worker Education and Training

Worker education and training are essential to the effective implementation of a Food Safety Plan. This section addresses practices that must be implemented in an operation and verified at the time of the audit.

Requirement	**G-4.1. All personnel shall receive food safety training, appropriate to their job responsibilities.**
Procedure	**All personnel shall receive training in the food safety policy and plan, food safety procedures, sanitation and personal hygiene appropriate to their job responsibilities. Personnel shall receive training at hire and refresher training at prescribed frequencies, and as needed. Documentation of training is available.**
Verification	**Auditor reviews program of required training and examines training records for evidence of compliance.**
Corrective Action	**Operation shall develop and deliver required training.**
Documents Required	**Record.**
Mandatory	**●**
PSR	**112.21, 112.22 (a)(b); 112.30 (Rec)**

Expectation
All personnel in the operation must receive food safety training appropriate to their job responsibilities. For example, harvest workers should be familiar with the company's safety, sanitation, and personal hygiene procedures specific to their jobs. An equipment operator responsible for the placement of bins in an apple orchard should be trained on food safety procedures related to placement of the harvest bins. All employees should be trained on the company's general food safety policies, sanitation, and personal hygiene.

Auditors will review the training records for each employee to assess training received when employees were hired and refreshers. The operation determines and must specify the frequency of refresher trainings. If an operation is only in production for a limited time each year (e.g., blueberries' 4-week harvest), the company may decide to conduct only one annual training. The

auditor will include the title and topics covered by training and specify the records that show training is current as of the date of the audit in the comments.

Example Scenarios
Scenario 1: A contract sanitation crew has documentation of food safety training from another operation.
Assessment: Compliant if food safety risks and controls for the harvest crew are the same at this operation; if not, then Corrective Action Needed.
Reason: The operation being audited must have reviewed the training received by the harvest crew and ensured it applies to this operation.

Scenario 2: Office staff does not attend food safety training.
Assessment: Corrective Action Needed.
Reason: Every employee at a grower operation must take food safety training. The operation must determine the level and frequency of food safety training for each employee/position.

Scenario 3: Employees say that they received "tailgate" food safety training; training materials are available for review; but there are no records of which individuals were trained or when.
Assessment: Corrective Action Needed.
Reason: The standard requires records of training.

Scenario 4: An operation's "food safety training" for employees is comprised of handing out leaflets on proper practices once a year. No formal training is performed.
Assessment: Compliant.
Reason: So long as there is a record of who received the leaflets and this practice is compliant with the operation's training policies/procedures, then it is compliant with the requirements of the standard.

Produce Safety Rule
112.21: All personnel (including temporary, part time, seasonal and contracted) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, (a) must receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually, (b) must have a combination of education, training and experience necessary to perform the person's assigned duties. (c)Training must be conducted in a manner that is easily understood by personnel being trained. (d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards of the Produce Safety Rule.

112.22: At a minimum, all personnel who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive training that includes the following: (a) Principles of food hygiene and food safety, the importance of health and hygiene, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of produce or food contact surfaces with human pathogens and those food safety requirements as appropriate to the person's job responsibilities. (b) Additionally, harvest workers' training must include recognition when produce should not be harvested, including produce that may be contaminated with known or reasonably foreseeable hazards; the inspection of harvest containers

for cleanliness and condition, and correcting problems with containers or equipment and reporting them.

112.30: Records must be established and kept in accordance with Subpart O. PSR requires that records for training for food safety must contain dates of training, the training topics covered, and the names of people trained.

Requirement	G-4.2. Personnel with supervisory food safety responsibilities shall receive training sufficient to their responsibilities.
Procedure	The individual designated for food safety responsibilities demonstrates knowledge of food safety principles. Food safety designate has completed at least one adequate food safety course/workshop, by job experience or as required by prevailing regulation.
Verification	Auditor reviews the evidence of the individual's training relevant to produce food safety, such as a degree or course certificate or receipt, or attendance at a relevant food safety meeting, company training record, and/or auditor interview.
Corrective Action	Individual must obtain demonstrable food safety training.
Documents Required	Record.
Mandatory	●
PSR	112.22 (c); 112.23

Expectation
The individual designated for food safety responsibilities who has related work experience in food safety, but no formal food safety training will be considered compliant for this question if the company meets USDA acceptance criteria for the audit, and also meets the standard of the prevailing regulation. The Produce Safety Rule is the prevailing regulation that is applicable to this requirement, which requires operations to have at least one supervisor or responsible party for the farm to successfully complete food safety curriculum at least equivalent to curriculum currently recognized by the FDA. One such curriculum is the Produce Safety Alliance training. One method of verifying this requirement is by reviewing the Certificate of Training for the Produce Safety Alliance training provided by the Association of Food and Drug Officials (AFDO), however a PSA certificate is not the only record that demonstrates compliance.

Auditor includes training and/or certifications received which are applicable in the comments section of the audit report.

Example Scenario
Scenario: The designated food safety individual received food safety training at another company that is applicable to his current duties, but not since assuming responsibilities at this operation.
Assessment: Compliant.
Reason: The standard does not require training to have been at this operation, but the individual is able to provide documentation of completed training and demonstrate its relevance to current job

duties.

Produce Safety Rule
112.22 (c): Requires covered operations to have at least one supervisor or responsible party for the farm to successfully complete food safety curriculum at least equivalent to curriculum currently recognized by the FDA.

112.23: FDA requires that the operation assign or identify personnel to supervise (or otherwise be responsible for) the operation to ensure compliance with the requirements of the Produce Safety Rule.

Requirement	**G-4.3. Contracted personnel are held to the relevant food safety standards as they would be as employees.**
Procedure	**Operation shall have procedures and/or records to demonstrate that contracted personnel whose activities can affect food safety have been informed of and, to the extent that can be verified, are in compliance with the relevant requirements of this standard.**
Verification	**Auditor reviews operation's evidence that contracted personnel are trained to the same food safety requirements as employees would be and, if practical during the audit, observes contracted personnel for compliance.**
Corrective Action	**Operation obtains evidence, trains or discontinues using contracted personnel.**
Documents Required	**Record.**
Mandatory	●
PSR	**112.21, 112.22 (a)(b); 112.30 (Rec)**

Expectation
In addition to observing contracted workers when possible, verify the training record of contractors, contracts or letters of guarantee, or statements in the contract/agreement that require contracted personnel to be aware of the audited company's applicable food safety policies and procedures.

Example Scenarios
Scenario 1: Grower utilizes subcontractor for plant protection applications. The subcontractor does not provide evidence of water quality brought on site.
Assessment: Corrective Action Needed
Reason: The subcontractor is not in compliance with water quality standards and requires retraining.

Scenario 2: Grower utilizes farm labor subcontractors and only has copy of current state license for each.
Assessment: Corrective Action Needed

Reason: Farm labor contractor licenses do not necessarily address all onsite food safety training requirements.

Produce Safety Rule
112.21: All personnel (including temporary, part time, seasonal and contracted) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, (a) must receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually, (b) must have a combination of education, training and experience necessary to perform the person's assigned duties. (c)Training must be conducted in a manner that is easily understood by personnel being trained. (d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards of the Produce Safety Rule.

112.22: At a minimum, all personnel who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive training that includes the following: (a) Principles of food hygiene and food safety, the importance of health and hygiene, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of produce or food contact surfaces with human pathogens and those food safety requirements as appropriate to the person's job responsibilities. (b) Additionally, harvest workers' training must include recognition when produce should not be harvested, including produce that may be contaminated with known or reasonably foreseeable hazards; the inspection of harvest containers for cleanliness and condition, and correcting problems with containers or equipment and reporting them.

112.30: Records must be established and kept in accordance with Subpart O. PSR requires that records for training for food safety must contain dates of training, the training topics covered, and the names of people trained.

G-5 Microbiological Sampling and Testing

An operation does not need to conduct microbiological sampling and testing unless it is required in its Food Safety Plan. When microbiological sampling and testing are required, the operation must comply with the requirements in section G-5. If an operation's Food Safety Plan requires microbiological testing that is not food-safety related, verify that the operation is conducting these tests in accordance with its plan. Common microbiological tests performed on the farm include water, soil, surface of equipment, and product testing.

Requirement	G-5.1. Where laboratory analysis is required in the Food Safety Plan, testing shall be performed by a GLP laboratory using validated methods.
Procedure	Operation utilizes laboratories that have, at minimum passed a Good Laboratory Practices (GLP) audit or participates in a Proficiency Testing program, and utilizes BAM, AOAC International or testing methods that have been validated for detecting or quantifying the target organism(s) or chemical(s).
Verification	Auditor reviews operation's evidence that only GLP laboratories and validated methods are used.
Corrective Action	Operation discontinues using non-GLP laboratory and non-validated testing methods.
Documents Required	Record.
Mandatory	

Expectation
Laboratory analysis required in a Food Safety Plan must be performed by a laboratory that: 1) passed a Good Laboratory Practices (GLP) audit or 2) participates in a proficiency testing program. A laboratory does not need to be accredited to meet this requirement, but if it is not, it does have to operate according to GLPs or participate in a proficiency testing program to be in compliance with this requirement.

GLPs are a set of principles that provide a framework within which laboratory studies are planned, performed, monitored, recorded, reported, and archived. These studies generate data that are used to assess the hazards and risks of pharmaceuticals, agrochemicals, cosmetics, food additives, feed additives and contaminants, novel foods biocides, detergents, and other compounds.

Internationally, the Organization for Economic Co-operation and Development (OECD) (www.oecd.org) has developed GLP principles. In the United States, GLPs are regulated by the FDA in 21 CFR 58 and by the Environmental Protection Agency (EPA) in 40 CFR 160, in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and 40 CFR 792, section 5 of the Toxic Substances Control Act (TSCA). Additional information on FDA's GLPs is at: http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/default.htm. Additional information on EPA's GLPs is at: http://www.epa.gov/compliance/good-laboratory-practices-standards-compliance-monitoring-program.

The operation is responsible for providing verification of the GLP status of the laboratory they use for microbiological sampling and testing. Verification may include GLP approval of the lab, a letter from the laboratory that attests to its GLP status, or evidence of GLP approval on the laboratory's website.

Alternatively, a laboratory can provide evidence that they participate in a proficiency testing program for the type of analyte that they will be contracted to test for. Proficiency testing demonstrates that a laboratory is able to provide accurate results for a specific test or test type.

Proficiency testing programs occur on an ongoing basis and would need to be repeated at scheduled intervals as directed by the program. The operation is responsible for collecting and maintaining documentation that demonstrates that any laboratory they use adheres to these requirements.

A laboratory also must use FDA's Bacteriological Analytical Manual (BAM), Association of Official Analytical Chemists (AOAC) International, or other testing methods that have been validated for detecting or quantifying the target organism(s) or chemical(s). The FDA's BAM contains the agency's preferred laboratory procedures for microbiological analyses of foods and cosmetics. More information about BAM is at: http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm. AOAC International is a globally recognized, independent, third-party, non-profit association and voluntary consensus standards developing organization. More information on AOAC standards for microbiological testing methods are at: https://www.aoac.org/.

The operation may perform its own testing if 1) its laboratory operates according to GLPs, participates in a proficiency testing program, or is ISO 17025 certified; and 2) the testing performed is not required in the Food Safety Plan. The operation also may use its own proprietary testing methods if the methods are in compliance with the operation's Food Safety Plan and are documented by the laboratory as being validated for the target organism(s).

Municipal water is regulated by the Environment Protection Agency (EPA) through the National Primary Drinking Water Regulations: Revisions to the Total Coliform Rule; Final Rule, 40 CFR Part 141 and 142. Requirement 141.852 describes the acceptable analytical methods and laboratory certification for drinking water standards. USDA recognizes that these standards meet GLP and validated test methods. If an operation is only using municipal water, the documentation that an operation needs to provide to meet this requirement are the municipality's water test results.

The auditor will include the name of the lab in the comments. If the lab is accredited, include the type of accreditation.

Example Scenarios
Scenario 1: The operation sends all microbiological testing to the State lab and has documentation that the State lab meets the requirements.
Assessment: Compliant.
Reason: The operation has evidence that the laboratory conforms with the requirement.

Scenario 2: The operation sends all microbiological testing to a laboratory that they describe as "ISO 17025 certified," but has no documentation about the laboratory's credentials.
Assessment: Corrective Action Needed.
Reason: The operation must have evidence that the laboratory conforms to the requirement.

Scenario 3: Records indicate that the operation's laboratory is performing testing as required in the food safety plan but is using its own proprietary test methods.
Assessment: Compliant or Corrective Action Needed.
Reason: Compliant if the operation has documentation from the laboratory verifying the method has been validated for the organism and product being tested. Corrective Action Needed if no

documentation is available, or if the method has not been validated by the laboratory for the specific application.

Scenario 4: The microbiological testing required in the Food Safety Plan is not really food safety, but some of the testing was not performed or recorded.
Assessment: Corrective Action Needed.
Reason: Even if they do not require a food safety test, the operation must follow its food safety plan and documentation.

Requirement	**G-5.2. Where microbiological analysis is required in the Food Safety Plan, samples shall be collected in accordance with an established sampling procedure and prevailing regulations.**
Procedure	**Operation utilizes a written sampling protocol when collecting samples for microbiological testing.**
Verification	**Auditor observes that the operation has a sampling protocol for each type of microbiological testing required in the operation's food safety plan.**
Corrective Action	**Operation develops or obtains written sampling protocols for each type of microbiological testing required in their Food Safety Plan.**
Documents Required	**Written policy.**
Mandatory	

Expectation
Verify that the operation has written sampling protocols for all testing required in the Food Safety Plan and in accordance with prevailing regulations. For example, a protocol stating that the "QA will collect one irrigation water sample per week at random" would be in compliance with this requirement. This requirement does not apply to microbiological testing conducted by the operation that is not specified in the Food Safety Plan.

Example Scenario
Scenario: The operation has a written sampling protocol for all testing required in the food safety plan, but not for some other microbiological testing.
Assessment: Compliant.
Reason: The standard only applies to testing required by the food safety plan.

Requirement	G-5.3. Testing, test results and actions taken must be documented.
Procedure	All results for microbiological testing, including lab reports or certificates of analysis, required in the operation's food safety plan shall be recorded and the records maintained for two years or as required by prevailing regulation.
Verification	Auditor reviews operation's recordkeeping of microbiological test results.
Corrective Action	Operation maintains for at least two years test records for all required microbiological tests.
Documents Required	Record.
Mandatory	

Expectation
Tests are not the same as analyses. A test is a procedure for critical evaluation; a means of determining the presence, quality or truth of something; or a basis of evaluation or judgment. An analysis is the separation of something into its constituents in order to find out what it contains, or the identification or separation of ingredients of a substance.

Verify that the operation maintains records for all microbiological tests required by its Food Safety Plan for a minimum of 2 years or as required by prevailing regulation. If the operation has been in production for less than 2 years or implemented its microbiological testing requirements less than 2 years from the start of the audit, the auditor may mark this question as compliant so long as the operation's required microbiological records are present at the time of an audit. If this is the case, include a comment explaining these circumstances. The operation would be compliant with this requirement if they started a new microbiological testing procedure within the last 4 months and they have records for those 4 months.

The auditor will assess this question as Corrective Action Needed if there are incomplete records for microbiological testing as specified in the Food Safety Plan, missing records, or records that are not available for review. Records of required testing must be kept but need not be the original records unless that is specified in the operation's Food Safety Plan. For example, the operation may record only "pass" or "fail" in their in-house records and retain the original test results at the laboratory. If the operation's Food Safety Plan specifies that the laboratory is responsible for maintaining testing records and providing them within 24 hours of being requested, the operation would be compliant with this requirement if the records are made available for review within 24 hours of the onsite audit.

The auditor will include the type of testing required (e.g., soil, water, or Adenosine triphosphate (ATP) swabbing) and the testing method in the comments.

Example Scenarios
Scenario 1: The operation says that weekly microbiological testing was performed throughout the previous month, but records from the second week are missing and unavailable.
Assessment: Corrective Action Needed.

Reason: Testing records are required to be maintained and made available for review.

Scenario 2: The operation began a new microbiological testing procedure 6 months ago and only has records for those 6 months.
Assessment: Compliant.
Reason: The operation has all testing records for the tests that were conducted. Include a comment that testing and records have only been in place for 6 months.

Scenario 3: The operation does not maintain in-house records, of test results; it relies on the laboratory to maintain all records.
Assessment: Compliant or Corrective Action Needed.
Reason: Compliant if the operation can obtain the records in a reasonable timeframe (e.g., 24 hr.). Corrective Action Needed if the records cannot be provided within a reasonable timeframe.

Requirement	**G-5.4. All required testing shall include test procedures and actions to be taken based on the results.**
Procedure	**For all microbiological testing required by the Food Safety Plan, operation has a written testing procedure that includes test frequency, sampling, test procedures, responsibilities and actions to be taken based on results. If finished product is tested for pathogens or other adulterants, operation's procedures require that it shall not be distributed outside the operation's control until test results are obtained.**
Verification	**Auditor reviews the operation's microbiological testing procedures for completeness.**
Corrective Action	**Operation revises testing procedures for completeness and to meet expectation of the food safety plan.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
Verify that the operation has written procedures for all microbiological testing required by the Food Safety Plan. Each written microbiological testing procedure must include test frequency, sampling, test procedures, and actions to be taken based on results.

The operation's procedures must require that all finished product tested for pathogens or other adulterants not be distributed outside of the operation's control until test results are obtained. For Field Operations and Harvesting audits, finished products include any product that is packaged in the field, such as berries packed in clamshells, lettuce packed in cartons, and melons packed in bins.

The operation's plan should specify its control policy for finished products. For example, a company may ship product before receiving test results if the operation can retain control of the lot until the results are obtained and can guarantee 100 percent stock recovery. A Corrective Action Needed is required if the company is not able to complete a total recall if records indicate that pathogen-positive product was shipped.

Additionally, if the operation tests finished product for pathogens, it must have policies and procedures for testing whole lots, not just portions of a lot. For example, corrective action would be needed if the operation holds a portion of a lot for a customer who requires testing and ships the remainder of the lot prior to receiving test results. Action is needed because the pathogen-positive result will reflect the entire lot unless there is scientific rational for why the sublots differ.

Corrective actions for any non-conformance to Requirement G-5.4 must include a revision of testing procedures to ensure they fully meet the Food Safety Plan's requirements. This requirement should be assessed as Immediate Action Required if the operation's corrective action to a positive test result is to retest the lot, the second test result for the lot is "negative," and the operation considers the first test result a false positive. A positive test result cannot be overturned by a negative test result unless the operation demonstrates a laboratory error on the first test. The operation's policy must be changed to require action on the initial test result.

If thresholds are exceeded, the auditor will include the operation's threshold criteria, the test results, and what actions are taken based on the results in the comments.

Example Scenarios
Scenario 1: The Food Safety Plan does not require product testing, and no testing of product is performed.
Assessment: Not Applicable
Reason: The standard does not require product testing unless required by the Food Safety Plan.

Scenario 2: The operation retains records of results of tests required by the Food Safety Plan, but has no documentation of the test frequency, test procedures, responsibilities or actions to be taken based on results.
Assessment: Corrective Action Needed.
Reason: The standard requires that "the operation has a written testing procedure that includes test frequency, sampling, test procedures, responsibilities and actions to be taken based on results".

G-6 Traceability

Traceability, or traceback, is the ability to track food items back to their source. A traceback system cannot prevent the occurrence of a microbiological hazard that may lead to an outbreak of foodborne disease, but can complement good agricultural and management practices intended to prevent the occurrence of food safety problems. Information gained from a traceback investigation also can help identify and eliminate a hazardous risk pathway.

The FDA's Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables also recommends that producers be able to track product forward throughout the marketing chain, including through retail channels to the consumer. Consider any and all reliable methods that an operation may use to track product.

Some crop groups commingle various growers' product prior to packing. This commonly occurs with tree fruit, tomatoes, and potatoes. When commingling occurs, assess whether or not the product can be traced to a reasonably sized group of growers and/or harvest dates.

Requirement	G-6.1. A documented traceability program shall be established.
Procedure	Records that enable reconciliation of product delivered to recipients (one step forward) shall be maintained except for direct to consumer sales. Records shall be maintained that link product with source of the produce or production inputs, e.g., soil amendments, fertilizers, seeds/transplants, agricultural chemicals, homemade preparations (one step backward). Records shall include the date of harvest, quantities, farm identification (field or block), transporter and non-transporter. Additional information may be included. Contents and retention of records shall be consistent with applicable regulations. If using reusable containers, procedures ensure that labels are accurate prior to packing.
Verification	Auditor reviews traceability program and verifies operation's ability to trace product accurately one step forward and one step back.
Corrective Action	Operation establishes an effective traceability program.
Documents Required	Written Policy, Record.
Mandatory	●

Expectation
There is no expectation that traceability must be done a specific way. It is up to the operation to determine the traceability system used in their operation. Auditors must verify that all operations have a traceability program that, at a minimum, allows a traceback investigation to follow the product both forward and backward at least one level in the marketing chain. The traceability program must be used for all fresh produce listed in the audit and grown or harvested by the operation. A traceability program outlines the controls and record keeping internal to an operation – the ability to track where they received a product from and where they moved a product to – tracking the product beyond this is beyond the responsibility of the operation (unless specifically written into the requirements of their Food Safety Plan).

Documentation, either paper or electronic, must be accessible during the audit and in case of a traceback investigation.

Verify "one step forward" by ensuring the operation's records are maintained in a way that allows for reconciliation of all product delivered to recipients, except for direct consumer sales. Reconciliation may include a comparison of the operation's records of where the product was sent, what is in the marketplace, how much product is remaining for sale, how that product will be handled, and how much has been sold or destroyed.

Direct-to-consumer sales are those made by the farm directly to a consumer via farm stand sales, community supported agriculture (CSA) sales, and you-pick operations. In the event that a post-

harvest operation supplies product to a farm stand or CSA, records tracing the product from the post-harvest operation to the farm stand or CSA are required. Operations with only one customer are exempt from the trace-forward requirement.

Verify "one step backward" by ensuring the operation's records are maintained in a way that shows the links between a product and its source or production inputs. Verify that production inputs include any physical factors used in the production of the produce, such as soil amendments, fertilizers, seeds/transplants, agricultural chemicals (pesticides and herbicides), and homemade preparations. Also verify that records include the date of harvest, quantity harvested, farm identification (field or block), and transporter. Operations with only one supplier are exempt from the traceback requirement.

Verify the traceability program is functioning as specified in the Food Safety Plan. This may include verifying additional information used in the traceability of the product such as bin tags, harvest slips accompanying gondolas of fruit, pallet tags, or stickers used on cartons.

One way to verify that the operation's traceability system is effectively established and operating is to trace the product being harvested to its end destination in the operation being audited. For example, when auditing a blueberry growing operation where blueberries are harvested directly into clamshells and placed in flats that are palletized in the field, ask the food safety manager or harvest crew manager to explain the system for designating how the lot being harvested is identified in the field (e.g., row number, block number, or field name) and the meaning of the coding on the stickers used on each pallet. You can then follow the code from a pallet that was previously harvested though the company's records forward to distribution and backward to the agricultural inputs used in the production of that lot.

Example Scenarios
Scenario 1: A tomato operation can trace product forward to all customers and can traceback most agricultural inputs but cannot traceback to where and when transplants are sourced.
Assessment: Corrective Action Needed
Reason: The traceback is incomplete because it does not include all of the required documentation.

Scenario 2: Some of an operation's product is sold to consumers at a farmer's market and the remainder is sold to a broker. Records indicate the product, date and amount sold at/to each, but does not include the names of the consumers who bought at the farmer's market.
Assessment: Compliant
Reason: The standard does not require traceability records on "direct to consumer sales".

Requirement	G-6.1.a. Packaging must include product identification.
Procedure	Operation must include product identification on all packaging. The product identification at a minimum must include the name and address of the farm, packer, or distributor of the produce and meet the requirements of the prevailing regulation.
Verification	Auditor reviews the product identification on all packaging.
Corrective Action	Operation establishes product identification on all packaging.
Documents Required	N/A.
Mandatory	

Expectation
Auditor is responsible for checking packaging used by operation. Packaging identification must include the name and address (street address or post office box, city, state and zip code) of the farm, packer or distributor of the produce, country of origin and meet the requirements of any prevailing regulations.

Example Scenario
Scenario: Operation is packing produce into 5 lb. bags. The 5 lb. bag has a clip with the grower's code, indicating location and date packed and grower's logo. The 5 lb. bag has the product description, distributors name and address on the bag. The 5 lb. bags are packed into master containers with no identification on the master container.
Assessment: Corrective Action Needed, all packaging must be identified.

Requirement	G-6.1.b. If product is intended for export, product meets labeling regulations of the country(ies) the product is being exported to.
Procedure	Product shall be labeled according to the applicable regulations in the country(ies) in which the product is intended to be sold, if known during production.
Verification	Auditor reviews operation's procedure for ensuring adherence to food labeling regulations in country(ies) of destination. If the country of destination is unknown during production, this item is not applicable.
Corrective Action	Operation develops procedures, and diverts non-compliant product to a market in which the product meets standards.
Documents Required	N/A.
Mandatory	

Expectation
This requirement is only applicable if it is known that the product is intended for export. It is the operation's responsibility to know the labeling regulations in the country of destination. These labeling regulations could include allergens, genetically modified organisms (GMOs), warnings, organic, or other claims.

Example Scenario
Scenario: The auditee sells their product through a broker and does not know the final customer for the product.
Assessment: Not Applicable.
Reason: This question is not applicable if it is not known that the final destination is international.

Requirement	**G-6.1.c. If a post-harvest operation supplies product to a farm stand or Community Supported Agriculture (CSA), records tracing the product from the post-harvest operation to the farm stand or CSA are required.**
Procedure	**In the event that a post-harvest operation supplies product to a farm stand or CSA, records tracing the product from the post-harvest operation to the farm stand or CSA are required.**
Verification	**Auditor reviews operation's traceability records.**
Corrective Action	**Operation develops procedures and keeps traceability records for product supplied to a farm stand or CSA.**
Documents Required	**Record.**
Mandatory	

Expectation
Direct-to-consumer sales are those made by the farm directly to a consumer via farm stand sales, community supported agriculture (CSA) sales, and you-pick operations. In the event that a post-harvest operation supplies product to a farm stand or CSA, records tracing the product from the post-harvest operation to the farm stand or CSA are required. Operations with only one customer are exempt from the trace-forward requirement.

Example Scenario
Scenario: The packinghouse has a roadside stand where they sell produce. During the audit it is asked if the operation has records of what product supplies the road-side stand. The auditee states that they don't keep a record, just randomly pull product as they need it.
Assessment: Corrective Action Needed.
Reason: Records tracing the product from the post-harvest operation to the farm stand are required.

Requirement	G-6.2. A trace back and trace forward exercise shall be performed at least annually.
Procedure	The trace back and trace forward exercise shall achieve accurate traceability within 4 hr. or as required by applicable regulations. Trace exercise shall achieve 100% reconciliation of product to recipients.
Verification	Auditor reviews records of most recent trace exercise. If no trace exercise was performed in the past year, the operation will perform the exercise during the audit.
Corrective Action	Operation performs exercise and/or improves traceability program to achieve accurate reconciliation.
Documents Required	Record.
Mandatory	

Expectation
Verify that a traceback or trace-forward exercise has been performed within the past year. If not, the operation must perform a trace exercise during the audit. A traceback or trace-forward exercise is not the same as but, may be a part of a recall or mock recall. Since the traceability program is an internal accounting of where an operation received/sent product, a traceability exercise would test the operation's own ability to track product without needing to contact customers and/or suppliers. Check the status of the trace exercise early in the audit to provide the auditee with as much opportunity as possible to conduct the trace exercise during the audit.

This question may be answered as Not Applicable if the operation ships all of its product to only one customer. Include the date and product(s) of last traceback and trace-forward exercise, and the effectiveness of the reconciliation within the four hours or as required in the comments.

Example Scenario
Scenario: Operation's trace program requires them to obtain 100 percent reconciliation within 2 hours but records indicate the last exercise required 3 hours.
Assessment: Corrective Action Needed.
Reason: While the operation achieved the requirements of the standard, they did not achieve their internal standard.

G-7 Recall Program

A "recall" is an action that returns marketed product to its origin and removes it from the marketplace. A "mock recall" is a practice exercise used to determine where product is shipped, and whether it can be returned to origin or removed from the marketing chain. A recall program is:

- Governed by written procedures,
- Documented by records (including those of a recall or mock recall conducted by the operation),

- Includes a trace exercise, and
- Assigns a designated recall team.

Requirement	G-7.1. A documented recall program, including written procedures, shall be established.
Procedure	The recall program shall have a designated recall team. A mock recall exercise shall be performed at least annually at the operation being audited. The mock recall shall include the trace back and trace forward exercise and shall be completed as stated in the program and in compliance to applicable regulations.
Verification	Auditor reviews records of most recent mock recall performed at the operation.
Corrective Action	Operation develops and implements corrective actions procedures.
Documents Required	Written Policy, Record.
Mandatory	●

Expectation
Verify that the operation has a recall program in place governed by written procedures, with documented records. The written procedures shall include directions on direct customer notification about the product being recalled, including how to withdraw, return, dispose or divert the affected product; public notification about any hazard presented by the product; effectiveness checks to verify that the recall was carried out. The written procedures should define each step of the recall process and clearly describe what needs to be done and who is responsible for carrying out the task.

The operation shall have a designated a recall team, and can demonstrate, through an annual mock recall exercise, that it can identify all affected product, verify contact information for all affected customers and the prevailing public health authority, and comply with all regulatory and legal obligations. The mock recall must include the traceback and trace-forward exercise and must be completed as stated in the recall program and in compliance with applicable regulations. The operation may contact its customers to verify contact information is current but not advise them that their contact is for a mock recall and still be in compliance with this requirement. An actual recall may replace the mock recall.

A designated recall team includes individuals identified in the recall plan who will be assigned tasks during a recall. Typically, the team includes individuals who are the most knowledgeable about the distribution of the product and can obtain the necessary information accurately and quickly. A single person may comprise the “team”; there is no minimum number of team members and the team may include non-company consultants.

This requirement may be answered N/A and the operation can be cleared of recall responsibilities if the operation can produce documentation from its sole customer (e.g., cooperative packinghouse)

specifying that the customer has a recall team and is responsible for performing any recalls of their product. The auditor will include the date of the last actual recall or mock recall in the comments section.

Example Scenarios
Scenario 1: During a mock recall, the operation contacts its customers to verify contact information is current but does not tell them it is for a mock recall.
Assessment: Compliant.
Reason: Verifying contact information is current is expected; advising the customer that the information is needed for a mock recall is not required.

Scenario 2: In reviewing the recall procedures, the auditor does not see any personnel assigned to the recall team. When questioning the Auditee about the recall team he stated, "No one is designated to do recalls."
Assessment: Corrective action needed.
Reason: Operation shall have a designated recall team.

Requirement	**G-7.1.a. The recall program written procedures must include specifications for the recall process including direct customer and public notifications as well as steps for verification and responsibilities.**
Procedure	**These specifications must address internal and external details of the recall process to include:** ➢ **Direct customer notification about the product being recalled, including how to withdraw, return, dispose or divert the affected product.** ➢ **Public notification about any hazard presented by the product** ➢ **Effectiveness checks to verify that the recall was carried out.** ➢ **Definition of each step of the recall process and clearly describe what needs to be done and who is responsible for carrying out the task.**
Verification	**Auditor reviews the written recall procedures for completeness of required specifications.**
Corrective Action	**Operation develops written recall procedures.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
Verify that the operation has a recall program in place governed by written procedures, with documented records. The written procedures shall include directions on direct customer notification about the product being recalled, including how to withdraw, return, dispose or divert the affected product; public notification about any hazard presented by the product; effectiveness checks to verify that the recall was carried out. The written procedures should define each step of

the recall process and clearly describe what needs to be done and who is responsible for carrying out the task.

Example Scenario
Scenario: When reviewing the operation's recall procedures, it is noted that steps are listed which outline what to do with the product that is being recalled and whose responsibility it is to carry out the task.
Assessment: Compliant.
Reason: The written procedures define each step of the recall process and clearly describe what needs to be done and who is responsible for carrying out the task.

G-8 Corrective Actions and Food Safety Incidents

Corrective Actions are taken to rectify a non-conformance with the food safety plan that is observed within the operation or during an audit.

Requirement	**G-8.1. The operation shall have documented corrective action procedures.**
Procedure	**A documented Corrective Action is required for an observation or audit that contains a non-conformance with food safety requirements. The responsibility, methods, and timelines to address Corrective Actions shall be documented and implemented.**
Verification	**Auditor reviews corrective action procedures and examines records for evidence of compliance.**
Corrective Action	**Operation develops and implements corrective action procedures.**
Documents Required	**Written Policy, Record.**
Mandatory	●

Expectation
Verify that operations have a corrective action procedure to address any non-conformance with the Food Safety Plan that is observed at the operation or during an audit. The procedure must be written and must specify the individual(s) responsible for corrective actions, the methods used to document and implement corrective actions, and the timeframe in which corrective actions will be addressed. The operation decides how best to address corrective actions. To address a corrective action, the operation may simply acknowledge that the non-conformance exists and, if it is not a major food safety concern, may choose to accept the risk of not correcting the non-conformance.

Example Scenarios
Scenario 1: A Corrective Action addresses more than one cause for a nonconformity.
Assessment: Compliant.
Reason: The Corrective Action must include cause analysis and address all correctable causes of the nonconformity.

Scenario 2: The operation has written corrective action procedures, but there are no records of corrective actions.
Assessment: Compliant or Corrective Action Needed.
Reason: Compliant if there is no evidence that corrective actions have been needed in the past 2 years. Corrective Action Needed if there is evidence that corrective actions have been needed in the past 2 years but there is no record of them.

Requirement	G-8.1.a Corrective action procedures shall include a procedure to evaluate complaints.
Procedure	For the purpose of preventing recurrence, there shall be a documented corrective action procedure to evaluate food safety related complaints, and to investigate non-conformities. It shall include a plan to address the issue; a plan to prevent recurrence; and demonstration of the evidence of effectiveness. The time frame necessary for corrective action shall be documented. Objective evidence shall demonstrate that the procedure is effective.
Verification	Auditor shall verify the operation has a procedure to evaluate complaints.
Corrective Action	The operation shall develop a procedure for evaluating complaints.
Documents Required	Written Policy.
Mandatory	

Expectation
The operation must have a documented system in place to address complaints from customers. This system must address and evaluate complaints. The system shall include a plan to address the issue, a plan to prevent reoccurrence, and be able to demonstrate evidence of effectiveness. This must include the time frame necessary for corrective actions.

Example Scenario
Scenario: An operation received a customer complaint about a piece of metal being found in a bag of spinach. Following their written procedure for complaints, they recorded this incident in their corrective action log which documents the date the complaint was received, the complaint, and the date the incident occurred, the lot number for the spinach.
Assessment: Corrective Action Needed.
Reason: The operation needs to evaluate and investigate the complaint, have a plan to address the issue, have a plan to prevent reoccurrence, demonstrate that this plan is effective, and establish a timeframe needed for there to be evidence of corrective action.

Requirement	G-8.1.b. Food safety incidents are recorded and assessed to determine severity and risk, and are addressed according to a documented food safety incident management procedure.
Procedure	A food safety incident management procedure shall be in place. Relevant staff shall be aware of their obligations in case of an incident. Incidents which could lead to unsafe or non-conforming product are recorded and assessed in a timely manner to establish their severity and consumer risk. Corrective actions are taken and documented.
Verification	Auditor verifies operation has a food safety incident management procedure, that food safety incidents are recorded and assessed, and risk is addressed by the operation accordingly.
Corrective Action	A food safety incident management mechanism will be implemented. Staff is trained to record and assess the severity of risk and to respond accordingly.
Documents Required	Record.
Mandatory	

Expectation
The operation needs to have a policy which requires that incidents which could lead to unsafe or non-conforming product are recorded and assessed in a timely manner to establish their severity and consumer risk. Corrective actions are taken based on the risk assessment and documented. For example, a worker doesn't wash their hands and starts to handle product. The operation catches it, and takes immediate action to remove the worker from the line, remove the handled product from the line, and cleans and sterilizes the line. This would need to be documented to show what actions were taken, what the disposition of the product was, and what steps were taken to reduce the chance of the incident happening again. If the auditee states that they had no incidences to document, auditor should document this on the audit report.

Example Scenarios
Scenario 1: A harvest worker cuts himself with a knife while harvesting broccoli. The worker stops, notifies the harvesters and harvest crew leader of the contaminated produce. The crew leader follows the operation's SOP for injuries and contamination of produce. This injury and potential contamination are written up in the operation's Incident Management log.
Assessment: Compliant.
Reason: The operation is following their SOPs and Food Safety Plan to manage the incident of the worker's injury.

Scenario 2: Operation is harvesting potatoes when a hydraulic line bursts. Operation stops harvesting, fixes the hydraulic line, segregates the area in the field by marking with do not enter ribbon. Operation continues with harvest but avoids contaminated area. Harvest operator contacts appropriate, personal to remove contaminated soil and product, as stated in the SOP's. Incident is documented. Section of field is taken out of production until testing concludes that area is safe for food production.

Assessment: Compliant
Reason: Operation followed SOP's to remove contaminated product and prevent future contamination.

Requirement	G-8.1.c. The documented incident management procedure is reviewed, tested and verified at least once a year.
Procedure	An annual review is conducted of the overall documented incident management procedure, including a review of records and corrective actions related to any food safety incidents that occurred. If there has been no food safety incident in the previous year, a mock incident management exercise has been conducted by the operation to test the existing system. Any identified deficiencies in the incident management system have been corrected.
Verification	Auditors verify that the operation has conducted an annual review of the operation's incident management procedure. Auditor will verify records.
Corrective Action	Operation implements an incident management review procedure which is tested and verified annually. Training of personnel responsible for implementing the incident management procedure may need to occur.
Documents Required	Written Policy, Record.
Mandatory	

Expectation
Each operation must have a food safety incident management procedure as specified in requirement G-8.1.b. This procedure must minimally be tested and verified by the operation at least once annually. A mock exercise may be used to test this system.

The auditor will include the date of the annual review and the date of the actual incident or mock incident exercise in the comments.

Example Scenarios
Scenario: The operation has a documented incident management procedure. It is reviewed and tested on a quarterly basis.
Assessment: Compliant.
Reason: The minimum requirement is that the food safety incident management plan is tested on an annual basis. This operation reviewed and tested their food safety incident management plan more frequently than required.

Requirement	G-8.2 Non-conforming product on hold for food safety is clearly identified and segregated from other products and packaging materials.
Procedure	Operation has a written procedure to clearly identify and segregate on-hold, quarantined, and rejected product and materials when held for food safety reasons, to prevent commingling with other products or adulteration of products, production area, or packaging materials.
Verification	Auditor reviews procedure, reviews logs and observes all currently on-hold, quarantined, and rejected materials for compliance with procedure.
Corrective Action	Non-compliances are corrected on site. If on-hold, quarantined or rejected materials are not segregated according to procedure, operation shall assess potential for product adulteration. Procedures are developed or revised. Retraining is performed.
Documents Required	Written Policy, Record.
Mandatory	●

Expectation
An operation must have clear, written procedures on how to identify and handle potentially contaminated or non-conforming product (including non-GAP certified product) and product packaging within their operation. These procedures may be a specific holding area while product awaits disposition, but could also be accomplished through labeling/identification, or any other method to prevent unintended use or delivery, or misrepresentation of product.

Example Scenarios
Scenario 1: Lettuce comes in from the field to the cooler. Upon receipt, the shipping manager notices that the top carton of the pallet of lettuce has one box with bird feces on the top. Following the operation's SOP, the pallet is segregated to the operation's hold area for further inspection.
Assessment: Compliant.
Reason: The adulterated product was segregated from non-adulterated product.

Scenario 2: During an audit of a broccoli field, employees were having their break. One employee was observed not washing his hands. Employees returned to their harvesting stations and started harvesting. Auditor informed field supervisor of the employee not washing his hands. Field supervisor stops the harvest and removes/segregates all produce from the harvesting machinery and makes every employee return to wash station to wash hands and disinfect their knives before continuing with harvest. All produce that was suspected to be contaminated was destroyed.
Assessment: Compliant
Reason: Operation was following their SOP's.

G-9 Self-Audits

Self-audits are tools that operations must use for continuous improvement and to assess their compliance with the Produce GAPs Harmonized Food Safety Standard.

Requirement	G-9.1. The operation shall have documented self-audit procedures.
Procedure	Internal audits will be conducted at a minimum annually by an assigned individual utilizing this standard to assist in the self-audit. All aspects of the operation's food safety plan will be audited and a written record of required corrective action will be documented.
Verification	Auditor reviews internal audit procedures and examines records for evidence of compliance.
Corrective Action	Operation develops and implements internal audit procedures.
Documents Required	Record.
Mandatory	

Expectation
Verify that the self-audit evaluated the requirements of the Harmonized Standard. The format of the self-audit is not specified; the operation may use the USDA Produce GAPs Harmonized Food Safety checklist to conduct its self-audit or another format, at its discretion, so long as the self-audit covers all aspects of the operation's Food Safety Plan. The Harmonized Standards requirements must be a part of the self-audit. The operation may also include non-food safety items in their self-audit.

The auditor will include the date and the role/title of the person who performed the annual self-audit in the comments.

Example Scenarios
Scenario 1: Operation uses USDA Produce GAPs Harmonized Plus+ Food Safety checklist to conduct their self-audit, for their Harmonized Plus+ audit.
Assessment: Compliant
Reason: Harmonized Plus+ Checklist covers all aspects of the operation's Food Safety Plan.

Scenario 2: Operation that is preparing for a GAPs Harmonized Plus+ audit is using the GAP/GHP audit checklist for their self-audit.
Assessment: Corrective Action Needed
Reason: The GAP/GHP audit checklist does not cover all aspects of the GAPs Harmonized Plus+ audit criteria.

G-10 Worker Health and Hygiene, and Toilet/Handwashing Facilities

Worker health and hygiene, and the availability, use, and maintenance of toilet/handwashing facilities are essential components to minimizing food safety risks. Operations must take measures to prevent ill or infected persons from contaminating produce with human pathogens.

Requirement	G-10.1. Operation shall have a policy for toilet, handwashing, hygiene, and health.
Procedure	Each operation shall establish written policies for their specific operations, which shall be in compliance with prevailing regulations for Worker Health and Hygiene Practices.
Verification	Auditor ensures that policies for toilet, handwashing, hygiene and health exist.
Corrective Action	Operation develops written policies covering toilets, handwashing, hygiene and health.
Documents Required	Written Policy.
Mandatory	●
PSR	112.129; 112.130; 112.31; 112.32; 112.33

Expectation
Verify the operation has documented policies in place that cover the number, cleanliness, and maintenance of toilet/handwashing facilities, hygiene practices (e.g., handwashing), and employees' health (e.g., human communicable diseases, injuries, and sickness). These policies must be available onsite for your review during the audit. They also must be specific to the operation being audited and in compliance with prevailing regulations for worker health and hygiene.

Information on current Federal regulations are in Appendix I, II, and III of this document; familiarize yourself with state and local regulations related to worker health and hygiene.

Example scenario
Scenario: Operation has a policy that covers workers' hygiene, toilets, and handwashing.
Assessment: Corrective Action Needed
Reason: Policy does not cover workers' health (communicable diseases, injuries and sickness.)

Produce Safety Rule
112.129: (a) The operation must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities. (b) They must be designed, located and maintained to (1) Prevent contamination of produce, food contact surfaces, production and growing areas, water sources and water distribution systems with human waste; (2) Be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use and be kept supplied with toilet paper; (3) Provide for the sanitary disposal of waste and toilet paper. (c) If growing activities take place in a fully-enclosed building, hand-washing stations must be in sufficiently close proximity to toilet facilities to make it practical for people to wash their hands.

112.130: (a) The operation must provide personnel with adequate, readily accessible hand-washing facilities in a fully enclosed building or during harvesting, packing or holding activities. (b) Handwashing facilities must be stocked with soap (or other effective surfactant), running water which has no detectible generic *E. coli* in 100 mL of water and adequate drying devices (such as

single service towels, sanitary towel service or electric hand dryers). (b) The operation must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food contact surfaces, growing and production areas, water sources and water distribution systems with human waste.

112.131: (a) The operation must dispose of sewage into an adequate sewage or septic system or through other means. (b) The sewage and septic systems must be maintained in a manner, as well as (c) Leakages or spills must be managed and disposed in a manner that prevents contamination of produce, food contact surfaces, growing and production areas, agricultural water sources and water distribution systems with human waste.

112.32: All personnel who come into contact with produce or food contact surfaces must maintain adequate personal cleanliness, avoid contact with animals other than working animals, and take appropriate steps to minimize contamination of produce when in direct contact with working animals, wash hands thoroughly, use gloves in intact or sanitary condition, removing or covering jewelry that cannot be adequately cleaned or sanitized and refraining from eating, chewing gum, or using tobacco products in production areas.

112.33: All visitors must be aware of the operation's Health and Hygiene policies and procedures, as well as have access to toilet and hand-washing facilities.

Requirement	**G-10.2. Employees and visitors shall be made aware of and follow all personal hygiene practices as designated by the operation.**
Procedure	**Operation's hygiene policies shall apply to all employees, contractors, visitors, buyers, product inspectors, auditors, and other personnel in the field. The operation shall designate competent supervisory personnel to ensure compliance by all workers, visitors, and field personnel with the requirements in this section.**
Verification	**Auditor observes personnel in field for evidence of compliance. Auditor notes whether s/he was informed of the policy.**
Corrective Action	**Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	●
PSR	**112.32; 112.33**

Expectation
All onsite employees and visitors at the operation must be made aware of and follow all personal hygiene practices required by the operation, including handwashing. Proper sanitation and hygiene practices include maintaining adequate personal cleanliness; avoiding contact with animals other than working animals and taking appropriate steps to minimize contamination of produce when in direct contact with working animals; handwashing; appropriately maintaining/replacing gloves, if used; removing or covering hand jewelry that cannot be sanitized; refraining from eating, chewing

gum or using tobacco products in areas where produce is handled. Not all of these practices are applicable to every operation. The operation should establish and follow those that apply.

The operation must demonstrate reasonable effort to instruct visitors on personal hygiene practices. For example, the operation may require visitors to check-in and enter the premises through the office, they may post signs in the field stating, "all visitors must check in at the office prior to coming onto property." Some companies may ask visitors to sign-in before entering. Each of these is an indication that the facility requires certain hygiene and sanitation practices.

In addition, hygiene requirements must be reinforced through continual periodic reviews of employee/visitor habits, training sessions, requirements for attire/uniforms, and other means. A statement on hygiene by company management at an orientation session, in an employee handbook, or on posted signs is not sufficient. Continual review and follow-up are needed for this to be considered a "required process."

Review company procedures and policies to determine whether there is an established policy and what it covers. Auditors are held to the same standard as a visitor and should be asked to go through the same procedures required of other visitors. If not, this is a good indication that such hygiene practices are not required or appropriately emphasized.

Example Scenarios
Scenario 1: You observe a customer leaving toilet facility without washing hands. Supervisor re-instructs customer on handwashing requirements.
Assessment: Compliant - if the operation had instructed the customer about proper handwashing before the observed event.
Reason: The operation's policy and procedures for monitoring and correcting the improper handwashing are observed to be working.

Scenario 2: The operation has posted signs around the field with "all visitors must check in at the office prior to coming onto property." In the office, visitors are instructed in safe practices. Utility workers are demanding the right to come onto property without notifying the operation, so the operation has no opportunity to instruct or monitor the workers in the field.
Assessment: Compliant.
Reason: The operation has demonstrated a reasonable effort to instruct visitors and has no control over the utility workers.

Produce Safety Rule
112.32: All personnel who come into contact with produce or food contact surfaces must maintain adequate personal cleanliness, avoid contact with animals other than working animals, and take appropriate steps to minimize contamination of produce when in direct contact with working animals, wash hands thoroughly, use gloves in intact or sanitary condition, removing or covering jewelry that cannot be adequately cleaned or sanitized and refraining from eating, chewing gum, or using tobacco products in production areas.

112.33: All visitors must be aware of the operation's Health and Hygiene policies and procedures, as well as have access to toilet and hand-washing facilities.

Requirement	G-10.3. Toilet facilities and restrooms shall be designed, constructed, and located in a manner that minimizes the potential risk for product contamination and are directly accessible for servicing.
Procedure	Toilet and handwashing facilities are situated during operation and servicing, and maintained so as not to pose a hazard to the produce or other opportunity for contamination. Restrooms are located away from produce handling areas whenever possible. If in a building, restrooms should not open directly into product handling areas. Those that do open directly into produce handling areas should have additional measures in place to mitigate risk, such as a self-closing mechanism, a maze-type entrance/exit, or distance.
Verification	Auditor visually verifies that toilet and handwashing facilities are not positioned, leaking or serviced in a manner that poses a risk of produce contamination.
Corrective Action	Toilet or handwashing facility is replaced, repaired or repositioned to be compliant.
Documents Required	N/A.
Mandatory	●
PSR	112.129; 112.130

Expectation

Operations must comply with Federal regulations in the PSR, 21 CFR 112.129 and 112.130, and in the Occupational Safety and Health Standards, 29 CFR, (see Appendix I and III). The design, construction, and location of toilets and handwashing facilities are essential in minimizing the potential risk for product contamination and enabling proper use and servicing. Review all toilet and handwashing facilities pertinent to the operation being audited. Any single toilet or handwashing facility within the operation that does not meet minimum requirements would prevent this requirement from being answered as compliant for the entire operation.

A toilet facility is a fixture maintained within a toilet room for the purpose of defecation, urination, or both. Toilet facilities may be permanent or portable structures. These facilities must be located so they do not serve as a source of contamination, i.e., outside of the production area or in a production area that has already been harvested. Immediate Action is required if a toilet is a source of likely contamination to the crop, e.g., a pit toilet located in the production block or a portable toilet in an orchard so that the physical structure is touching unharvested crop. Additionally, verify that toilet facilities are near and made readily available to the workers and visitors, and are no more than ¼ mile away from farming and harvesting activities.

There may be some situations where farm workers who don't have access to restrooms onsite use nearby facilities at a gas station, fast food restaurant etc. It is expected that if these workers are contacting the harvested crop, they will need to have access to handwashing onsite prior to entering the field to resume their duties.

Verify that toilet facilities are in good repair. A leaking toilet facility may contaminate produce by leaking waste into contact with the crop or by cross contamination if the waste is spread to the production area by a worker (e.g., via the worker's shoes). Observe how the operation addresses the leak to ensure employees are adhering to the operation's procedures for handling leaks. The operation must immediately address any leaks likely to cause contamination of the produce.

Handwashing facilities with soap and towels may be located within or outside the toilet facility. They must be near the toilet facility so employees who contact produce or food contact surfaces have ample opportunity to wash before returning to work. These units must be designed to capture the grey water, which is used water that has not come into contact with the toilet, so they don't contaminate the produce. If grey water is intentionally not captured, Immediate Action will be required.

Damage to toilet and handwashing facilities may occur with use. Assess if the damage to the facility is recent or ongoing and observe how the operation addresses the damage to determine if the employee(s) are adhering to the operation's procedures for handling damage.

This question must be answered N/A if toilet facilities are not required and are not present.

Example Scenarios (Pre-harvest)
Scenario 1: Operation is harvesting produce from four fields. To make toilets and handwashing most accessible and to use fewer units, they have placed portable units outside of the production area where the four fields meet.
Assessment: Compliant
Reason: Toilets are positioned in a manner with easy access to servicing and the harvest crews without posing a risk of contaminating produce. Multiple harvest crews may share the same facilities as long as the ratio of toilets and handwashing facilities to workers meets the regulatory requirements.

Scenario 2: Toilet and handwashing units are located in roadway, adjacent to the field but they have no containment for grey water from handwashing unit. Grey water goes directly onto gravel of roadway.
Assessment: Immediate Action Required
Reason: The grey water is likely to contaminate the product or product contact surfaces. It is a requirement that units are designed to capture all grey water.

Example Scenarios (Post-harvest)
Scenario 1: There is no doorway between the bathrooms and the hallways but there is self-closing door into handling areas.
Assessment: Compliant.
Reason: The self-closing doors and restroom are located in a manner that minimizes the potential risk for product contamination.

Scenario 2: The restroom floor has cracks and chipped areas such that it cannot be easily cleaned.
Assessment: Corrective Action Needed.
Reason: The condition of the floor poses a harborage risk, which can be carried into the produce

handling area.

Scenario 3: A handwashing faucet is the kind that requires turning (not hands free) and has crevices that are not easily cleaned and are visibly dirty.
Assessment: Immediate Action Required.
Reason: The faucet has become a source of contamination.

Produce Safety Rule
112.129: (a) The operation must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities. (b) They must be designed, located and maintained to (1) Prevent contamination of produce, food contact surfaces, production and growing areas, water sources and water distribution systems with human waste; (2) Be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use and be kept supplied with toilet paper; (3) Provide for the sanitary disposal of waste and toilet paper. (c) If growing activities take place in a fully-enclosed building, hand-washing stations must be in sufficiently close proximity to toilet facilities to make it practical for people to wash their hands.

112.130: (a) The operation must provide personnel with adequate, readily accessible hand-washing facilities in a fully enclosed building or during harvesting, packing or holding activities. (b) Handwashing facilities must be stocked with soap (or other effective surfactant), running water which has no detectible generic *E. coli* in 100 mL of water and adequate drying devices (such as single service towels, sanitary towel service or electric hand dryers). (b) The operation must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food contact surfaces, growing and production areas, water sources and water distribution systems with human waste.

Requirement	**G-10.4. Toilet facilities shall be of adequate number, easily accessible to employees and visitors and in compliance with applicable regulations.**
Procedure	**The operation will have verification that the number of toilet facilities and their location relative to employees meets the more stringent of federal, state, or local regulations.**
Verification	**Auditor verifies that the number of available toilet facilities and their location is compliant with prevailing regulation for the number of employees.**
Corrective Action	**Operation obtains a sufficient number of toilet facilities to be compliant.**
Documents Required	**N/A.**
Mandatory	**●**
PSR	**112.129; 112.33(b)**

Expectation

The operation must have an adequate number of toilet facilities that are easily accessible by employees and visitors to promote good sanitary practices of employees in compliance with Federal regulations found in the Occupational Safety and Health Standards, 29 CFR (see Appendix III). Additional requirements for toilet facilities are described in 21 CFR 112.129 and 112.33(b). Specifically, toilet facilities must be designed, located, and maintained to be readily accessible and to prevent contamination of covered produce in growing areas during harvest activities, and, in a fully-enclosed building, during harvesting, packing, or holding activities. Operation must make toilet and handwashing facilities available for visitors. Be aware of state and local regulations that apply to the operation being audited to determine if the operation adheres to these requirements.

Example Scenario (Harvest)
Scenario: Operation has located portable toilets in a clear area surrounded by multiple growing fields. Auditor observes that the distance between the portable toilets and growing fields is well within the OSHA requirements. However, there is a deep ditch with vegetation between toilets and the field being harvested.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: The toilets are not easily accessible. If auditor has reason to believe workers are going into the ditch and relieving themselves there rather than using the toilets, this may be even more serious.

Example Scenarios (Post-harvest)
Scenario 1: Operation has 20 employees and one unisex toilet.
Assessment: Corrective Action Needed.
Reason: Two toilets are the minimum number required for 16 – 35 employees per the federal regulation CFR 1910.141.

Scenario 2: Operation has 10 employees (8 men/2 women) and one unisex toilet.
Assessment: Compliant.
Reason: According to 29 CFR 1910.141 where toilet rooms will be occupied by no more than one person at a time, can be locked from the inside, and contain at least one water closet, separate toilet rooms for each sex need not be provided. Corrective Action Needed if more stringent state or local regulations apply.

Scenario 3: Operation has 30 employees (15 men/15 women) and two toilets.
Assessment: Compliant.
Reason: As long as water closets are distinctively marked for each sex, this is in compliance with CFR 1910.141. Corrective Action Needed if more stringent state or local regulations apply.

Produce Safety Rule
112.129: (a) The operation must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities. (b) They must be designed, located and maintained to (1) Prevent contamination of produce, food contact surfaces, production and growing areas, water sources and water distribution systems with human waste; (2) Be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use and be kept supplied with toilet paper; (3) Provide for the sanitary disposal of waste and toilet paper. (c) If growing activities take place in a fully-enclosed

building, hand-washing stations must be in sufficiently close proximity to toilet facilities to make it practical for people to wash their hands.

112.33: All visitors must be aware of the operation's Health and Hygiene policies and procedures, as well as have access to toilet and hand-washing facilities.

Requirement	**G-10.5. The practice of disposing of used toilet tissue on the floor, in trash receptacles, or in boxes is prohibited except in situations where waste systems are not capable of handling toilet paper.**
Procedure	**Operation shall instruct employees that used toilet tissue shall only be disposed of in the toilet. If toilet paper cannot be disposed of in the toilet, the use of toilet paper disposal containers is acceptable. Containers must be used only for toilet paper or other hygiene products and must be distinguishable from towel waste containers. Operation shall develop SOPs for the sanitary disposal of waste, ensuring adequate monitoring and cleaning frequencies to prevent unsanitary conditions.**
Verification	**Auditor observes restrooms for evidence of compliance. Auditor observes evidence or existence of toilet paper disposal, if applicable.**
Corrective Action	**Retraining is performed and documented.**
Documents Required	**N/A.**
Mandatory	●
PSR	112.129

Expectation
Auditor shall inspect toilet facilities and review policy for operation's requirements for disposing of toilet tissue. In the event of an emergency situation (i.e. earthquake, flooding, other natural disaster etc.), if an operation's toilet facility waste system is not capable of handling toilet paper this should be documented in the policy, along with SOPs for the sanitary disposal of waste. If the operation is using a container for the disposal of toilet paper, the container is restricted to toilet paper use only. Disposal of waste shall be done by incorporating a sanitary procedure for waste disposal, have adequate monitoring of disposal waste and cleaning frequencies to prevent any contamination or become a cross contamination factor to product activities.

If operation is disposing of used toilet tissue in trash receptacles, the auditor will describe the reason and state mitigation measures taken to include monitoring and cleaning frequencies in the comments.

Example Scenario
Scenario: An operation's written policies and employee training include a prohibition against disposing used toilet tissue anywhere except in the toilet. You find used toilet tissue in trash receptacle in one toilet stall.
Assessment: Immediate Action Required.

Reason: All toilet tissue must be disposed of in the toilet, and clearly one or more workers need training.

Produce Safety Rule
112.129: (a) The operation must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities. (b) They must be designed, located and maintained to (1) Prevent contamination of produce, food contact surfaces, production and growing areas, water sources and water distribution systems with human waste; (2) Be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use and be kept supplied with toilet paper; (3) Provide for the sanitary disposal of waste and toilet paper. (c) If growing activities take place in a fully-enclosed building, hand-washing stations must be in sufficiently close proximity to toilet facilities to make it practical for people to wash their hands.

Requirement	**G-10.6. Toilet and wash stations shall be maintained in a clean and sanitary condition.**
Procedure	**Toilet paper shall be available in toilet facility. Wash stations shall include hand wash facilities with water that meets the microbial standard for drinking water, hand soap, disposable towels or other hand drying device, towel disposal container, and a tank that captures used hand wash water for disposal. These stations shall be provided inside or adjacent to toilet facilities, and any location where product handling is taking place. If portable hand wash water tanks are used, they are cleaned and sanitized at a prescribed frequency and the water is changed at a prescribed frequencies adequate to prevent unsanitary conditions. Restrooms shall include hand wash facilities with water that meets the microbial standard for drinking water, hand soap, disposable towels or other hand drying device, and towel disposal container. Gray water is plumbed or captured for disposal.**
Verification	**Auditor observes toilet and handwashing facilities for compliance. Auditor observes checklist or other evidence of a documented system for tracking cleaning of toilets and wash stations.**
Corrective Action	**Toilet or handwashing facility is replaced, repaired or maintained to be compliant.**
Documents Required	**Record.**
Mandatory	**●**
PSR	**112.129; 112.130**

Expectation
The auditor should determine at the beginning of the audit which bathroom and handwashing facilities are included in the scope of the audit. Some smaller operations may or may not include the use of a residential bathroom due to the home being located on the same property as the operation. If included in the scope of the audit, the auditor shall verify that the residential facility meets the requirements of the standard.

It is important to consider the number of people using the facility, the time of day that the observation was made (e.g., just after a break/meal period, or the beginning of the work period), the cleaning schedule, and the overall appearance of the facility.

A single observation of no drying towels at a handwashing station or toilet paper at a toilet facility is not sufficient justification to mark this requirement as Corrective Action Needed. Observe multiple handwashing stations or toilet facilities at various times during the audit to determine whether there is an ongoing effort to keep the stations properly supplied. Cloth towels used by all employees laundered at any frequency are not acceptable "hand drying devices" as they may be sources of cross-contamination meriting a Corrective Action.

All dirty toilet tissue must be flushed into the sewer or septic system, or properly disposed of in a portable toilet. Feminine hygiene products may be disposed of in a lined and closed receptacle in the toilet room. Disposal of dirty/used toilet tissue in a box or other receptacle, or on the toilet room floor is an unsanitary and unacceptable practice that is an Immediate Action Required.

The operation must provide documentation that handwashing water, whether provided by the company or a contractor, meets microbial requirements for drinking water. If water is from a municipal source, current documentation from the municipality is sufficient.

There may be instances when employees are using offsite bathrooms within close proximity to the operation but are not under the operation's control, such as a restroom at a restaurant or gas station. However, it is expected that when the employees return to the operation, they still have access to a handwashing station onsite, so that they may wash their hands before returning to work.

Example Scenarios
Scenario 1: The toilet room has one automatic hand-drying air device that you test, and it does not work.
Assessment: Immediate Action Required
Reason: Hand-drying capability has to be provided.

Scenario 2: You move the towel disposal container and observe the floor below the container is filthy.
Assessment: Corrective Action Needed.
Reason: The entire toilet room must be in clean and sanitary condition.

Scenario 3: While inspecting a field sanitation unit, you inquire about the quality of water for handwashing station. The auditee states that the field sanitation units are supplied by a contractor and the contractor is responsible for the water.
Assessment: Corrective Action Needed
Reason: The operation must provide documentation for handwashing water.

Produce Safety Rule
112.129: (a) The operation must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.

(b) They must be designed, located and maintained to (1) Prevent contamination of produce, food contact surfaces, production and growing areas, water sources and water distribution systems with human waste; (2) Be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use and be kept supplied with toilet paper; (3) Provide for the sanitary disposal of waste and toilet paper. (c) If growing activities take place in a fully-enclosed building, hand-washing stations must be in sufficiently close proximity to toilet facilities to make it practical for people to wash their hands.

112.130: (a) The operation must provide personnel with adequate, readily accessible hand-washing facilities in a fully enclosed building or during harvesting, packing or holding activities. (b) Handwashing facilities must be stocked with soap (or other effective surfactant), running water which has no detectible generic *E. coli* in 100 mL of water and adequate drying devices (such as single service towels, sanitary towel service or electric hand dryers). (b) The operation must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food contact surfaces, growing and production areas, water sources and water distribution systems with human waste.

Requirement	**G-10.7. A response plan is in place for major spills or leaks of field sanitation units.**
Procedure	**A written response plan is developed and implemented in the event of a major leak or spill.**
Verification	**Auditor verifies existence of the plan and interviews the responsible individual for knowledge.**
Corrective Action	**Operation prepares or edits the plan or receives plan from contractors of sanitation units. The responsible individual is retrained.**
Documents Required	**Written Policy**
Mandatory	
PSR	**112.131 (a)(b)(c)**

Expectation

Runoff from toilet facilities from leaks or spills has the potential to contaminate covered produce, soil, and irrigation water. The operation shall have a written plan in place that outlines the steps to respond to a contamination event. The plan should include consideration for the location of the toilet facilities to minimize the potential for contamination from human waste and should facilitate containment and cleaning of any accidental spills or leaks. For example, the operation could locate portable toilet facilities downhill from the growing areas and away from water sources; or could use berms or grades to help protect growing areas and water sources and distribution systems from contamination from uphill toilet facilities. Sewage transport and other service vehicles should have clear access to the toilet facilities to ensure proper collection and disposal of human waste, minimizing the likelihood of spills or leakage.

Example Scenarios

Scenario 1: The sanitation units at an operation are observed to be clean and in good repair. When interviewing the harvest crew manager about what would happen if they were to observe a leak from a unit, they state they would notify management of the leak and log the leaking unit in the daily field assessment. There is no written response plan.
Assessment: Corrective Action Needed
Reason: A written response plan is required.

Scenario 2: Upon arrival at the harvest field, you observe a portable toilet located outside of the orchard tipped over, there are flags around the toilet. The crew foreman states that they have placed flags around the toilet and are following the written Sanitation Unit SOP
Assessment: Compliant
Reason: The operation has a written SOP and the employees have been trained and are following the procedure.

Produce Safety Rule
112.131: (a) The operation must dispose of sewage into an adequate sewage or septic system or through other means. (b) The sewage and septic systems must be maintained in a manner, as well as (c) Leakages or spills must be managed and disposed in a manner that prevents contamination of produce, food contact surfaces, growing and production areas, agricultural water sources and water distribution systems with human waste.

Requirement	**G-10.8. Personnel shall wash their hands at any time when their hands may be a source of contamination.**
Procedure	**Personnel shall wash their hands prior to start of work, after each visit to a toilet, after using a handkerchief/tissue, after handling contaminated material, after smoking, eating or drinking, after breaks and prior to returning to work, after touching animals or waste and at any other time when their hands may have become a source of contamination. Antiseptic hand rubs may not be used as a substitute for soap (or other effective surfactant) and water. Operation management reinforces importance of and compliance with handwashing policy.**
Verification	**Auditor observes personnel in field for evidence of compliance. If handwashing practices are observed to be compliant, auditor will judge management emphasis to be sufficient.**
Corrective Action	**Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	●
PSR	**112.32(b(3))**

Expectation
Thorough handwashing, including cleaning fingernails and cuticles, at the times listed below is critically important to preventing the spread of the many infectious diseases that are transmissible through food.

Appropriate times to wash hands include:

- Before starting work;
- Before putting on gloves (if used);
- After using the toilet;
- Upon return to the work station after any break or other absence from the work station;

The operation must emphasize that handwashing with soap (or other effective surfactant) and running water is required. Hand Sanitizer used alone is **not** an acceptable practice and does not constitute compliance with this requirement. The operation can promote handwashing by regular and periodic reviews of employee habits, training, or other means. A statement on handwashing by company management at an orientation session, in an employee handbook, or on posted signs is not sufficient. Continual review and follow-up are needed for this to be considered a "required process."

Recommended handwashing procedure:

- Wet hands with clean, warm water, apply soap, and work up a lather.
- Rub hands together for at least 20 seconds (i.e., the time it takes to sing the alphabet).
- Clean under fingernails and between the fingers, and rub the fingertips of each hand in the suds on the palm of opposite hand.
- Rinse hands under clean, running water.
- Dry hands with a single-use towel.

Review the company's policy for handwashing prior to observing field harvesting. In addition to observing personnel in the field for evidence of compliance to the company's policy, auditors should interview selected personnel regarding when they are required to wash their hands to verify employee understanding of the company's policy.

This question may only be indicated as N/A where the workers are not working directly with the produce or food contact surfaces, such as pruning or other similar field work. In cases where a supply of toilet facilities is not mandated, handwashing facilities are required under this statement whenever employees are handling food products. If a worker who handles produce does not wash their hands before beginning and returning to work, and there are no immediate corrective actions taken by the auditee, this would be considered an Immediate Action Required condition. If workers have washed their hands before starting work and their hands become covered with a material sprayed on produce prior to harvesting, such as clay product to prevent sunburn, the material

covering their hands would not be considered a source of contamination and the crew would be considered in compliance with this requirement.

Example Scenarios
Scenario 1: Workers on the sorting line have a small container of hand sanitizer with them and use this after sneezing into their hands rather than going to handwashing station 5 minutes away.
Assessment: Immediate Action Required.
Reason: Hand sanitizers are not an alternative for handwashing.

Scenario 2: Operation's policy allows sick workers to handle produce and food contact surfaces as long as they wash their hands and use hand sanitizer.
Assessment: Immediate Action Required.
Reason: The standard does not allow for handwashing or sanitizer use as a mitigation for illness. If a worker is observed showing signs of illness, this observation should be reported for requirement G-10.18. If a worker is observed with exposed cuts, sores or lesions this observation should be reported for requirement G-10.19.

Scenario 3: Operation does not have plumbing or a ready source of potable water, so allows produce handlers to use a microbial hand sanitizer instead of washing.
Assessment: Immediate Action Required.
Reason: The standard requires hands to be washed.

Produce Safety Rule
112.32 (b(3)): Personnel in contact with produce or food contact surfaces must wash hands thoroughly, including scrubbing with soap (or other effective surfactant) and running water that has no detectible *E. coli* in 100 mL of water, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices: Before starting work; Before putting on gloves; After using the toilet; Upon return to the work station after any break or other absence from the work station; As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of produce with known or reasonably foreseeable hazards.

Requirement	**G-10.9. Signage requiring handwashing is posted.**
Procedure	**Signage in applicable languages and/or pictures shall be provided adjacent to hand wash facilities requiring people to wash their hands after each toilet visit.**
Verification	**Auditor verifies that signage is present adjacent to all hand wash facilities and is in appropriate language or pictures to clearly communicate requirements to all employees.**
Corrective Action	**Operation obtains and posts signage to be compliant.**
Documents Required	**N/A.**
Mandatory	

Expectation
Signs are required to be posted in or near the bathrooms to remind/require employees to wash their hands after they use the toilet facility. 21 CFR 110.37 (e)(5) states: "Readily understandable signs directing employees handling unprotected food, unprotected food packaging materials, or food-contact surfaces to wash and where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces."

Signs should require that employees wash hands before going to work or before returning to work from some activity (breaks, meal breaks, etc.) other than handling the produce. Where there are non-English speaking employees on the staff; signs must be posted in the native language of the workers or have appropriate graphics demonstrating and reminding workers of the requirement. Signs should be posted in the native language of the predominant number of workers.

Auditors should ask questions and make observations to determine whether or not this is being followed. Signs that are not posted in close proximity to the handwashing stations will not be considered as adequate. This question may only be answered N/A when there are no requirements for bathroom/toilet facilities, such as when there are less than the minimum number of workers present or in home toilets used only by family members.

Example Scenarios
Scenario 1: Tree crop operation has workers who are primarily English or Spanish speaking. Auditor observes signs in both languages adjacent to all hand washing and toilet facilities.
Assessment: Compliant

Scenario 2: Packinghouse operation has workers who primarily speak Tagalog/Filipino. Auditor observes signs in English that also display images of step-by-step instructions.
Assessment: Compliant
Reason: The signs need to be readily understandable, written in the native language of employees or have appropriate graphics.

Requirement	**G-10.10. Clothing, including footwear, shall be effectively maintained and worn so as to protect product from risk of contamination.**
Procedure	**Operation shall have a policy that employee clothing shall be clean at the start of the day and appropriate for the operation. Clothing shall be replaced if it becomes reasonably likely to serve as a source of contamination of product or food contact surfaces.**
Verification	**Auditor reviews policy and observes compliance with operation's policy.**
Corrective Action	**Operation develops or revises clothing policy. Retraining is performed and documented.**
Documents Required	**N/A.**
Mandatory	**●**

Expectation
Auditors must verify that the operation has a policy that employee clothing, including footwear, must be clean at the start of the day and appropriate for the operation to protect the product from risk of contamination. This policy does not need to be written. Harvest crews and subcontractors should comply with the operation's food safety practices. Observations will need to be made by auditors to verify the effectiveness of the operation's policy.

In operations where workers may come into direct contact with animals, workers must take steps to minimize the likelihood of cross contamination from their shoes and clothing onto produce. This can be accomplished by designating certain outerwear, boots, or other footwear for activities that involve animals, such as mucking stalls or feeding animals.

The standard does not specify the type of footwear or clothing that must be used. However, footwear or clothing that is used need to be consistent with the company Food Safety Policy. As long as footwear is not needed to protect the product from contamination, footwear may include open toed sandals or may not be worn at all. Harvesters may wear stick pins to fasten clothes that are hidden by outerwear or sleeveless shirts so long as the clothing is consistent with the operation's policy and is not reasonably likely to pose a risk to produce safety.

Example scenario
Scenario: Auditor observes employee cleaning out animal stalls. This same employee washes his hands then leaves the barn and continues to the strawberry field to help harvest the product.
Assessment: Immediate Action Required
Reason: Animal feces on the boots from cleaning the animal stalls may contaminate the strawberries.

Requirement	**G-10.11. If gloves are used, the operation shall have a glove use policy.**
Procedure	**If rubber, disposable, cloth or other gloves are used in contact with product, the operation shall have a glove use policy that specifies how and when gloves are to be used, cleaned, replaced and stored. Hands must be washed before putting on gloves. Policy shall be in compliance with current industry practices or regulatory requirements for that commodity.**
Verification	**If gloves are used, auditor observes glove use for compliance with the operation's policy and current industry practices or regulatory requirements.**
Corrective Action	**Operation develops or revises glove policy. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	**●**
PSR	**112.32(b(4))**

Expectation
If an operation uses gloves in handling covered produce or food-contact surfaces, it must have a glove use policy that includes maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so. In developing its policy, the company may consider what types of gloves are being used for what types of tasks, whether gloves are single use or reusable and, if they are reusable, how gloves should be stored when not in use, either short-term (e.g., when using the toilet or during breaks) and longer term and how to identify and replace gloves when they can no longer be maintained in an intact and sanitary condition.

An operation's glove use policy may be written or unwritten. Auditors should interview company personnel to verify that the company's policy is uniform and understood by personnel, this is especially important when the glove use policy is unwritten.

This question may only be assessed as N/A when the operation has no glove use policy, and the auditor observes no gloves are being used at the time of the audit. Include if gloves are used, are optional, or not used. If gloves are used include the type of gloves and confirm the operation has a policy to sanitarily/safely use gloves in the comments.

This question must be assessed as non-compliant if the operation has no glove use policy and the auditor observes that gloves are being used (i.e., when it is cold out and an employee decides to wear gloves to work, an employee decides to wear gloves to work to protect their hands, etc.).

The operation must adhere to the glove use policy they have in place. For example, an operation's glove policy is that workers on the sorting line wear reusable rubber gloves and that workers are responsible for checking their gloves at the start of each shift to ensure the gloves are intact and able to be maintained in a clean and sanitary condition. Gloves that are damaged and no longer able to be maintained in this condition must be replaced before starting work (or at any other time as needed). For example, if gloves are visibly covered in feces or have holes or cracks in them such that soil or contaminants can enter the inside of the glove. Workers should understand and follow the operation's policy. The operation should ensure replacement gloves are available when needed.

If, the Food Safety Plan states that "all product harvesters are to use single use sanitary gloves when contacting product" and the auditor observes one worker harvesting without gloves because "they ran out of gloves," corrective action would be needed unless the operation has a provision for when gloves are not available.

Example Scenarios
Scenario 1: There is no stated glove policy in the plan. The auditor observes produce handlers using gloves appropriately.
Assessment: Corrective Action Needed.
Reason: If gloves are in use, "the operation must have a glove use policy."

Scenario 2: The operation's glove use policy is verbal (not documented) and applies to all product handlers. Auditor questions a product handler about the glove use policy, and the worker cannot describe it.
Assessment: Corrective Action Needed.

Reason: The product handler is not familiar with the company's glove use policy.

Scenario 3: The operation has no glove use policy, and no gloves are observed in use at the operation.
Assessment: Not Applicable, unless current industry practices or regulations require gloves for that crop.
Reason: No gloves are being used.

Scenario 4: One person is seen wearing clean cotton gloves "because it's cold."
Assessment: Corrective Action Needed.
Reason: If gloves are used there needs to be a glove use policy.

Produce Safety Rule
112.32 (b(4)): If an operation chooses to use gloves in handling produce or food contact surfaces, they must maintain gloves in an intact and sanitary condition and replace such gloves when no longer able to do so.

Requirement	**G-10.12. If protective outer garments are worn in the product handling areas, they shall be handled in a manner to protect against contamination. When appropriate, racks and/or storage containers or designated storage area for protective clothing and tools used by employees shall be provided.**
Procedure	**When employees wear protective outer garments, such as aprons and sleeves, the operation shall have a policy that employees shall wear suitable outer garments, not reasonably likely to serve as a source of contamination of product or food contact surfaces. The clothing shall not be left on product, work surfaces, equipment or packaging material but hung on racks or in designated areas. When appropriate, racks shall be available and located so as to avoid potential contamination. In addition, storage containers or designated storage areas shall be provided to ensure tools used by employees are properly stored prior to entering toilet facilities. Operation shall have a policy regarding whether protective clothing can be taken home.**
Verification	**If protective clothing is used, auditor observes use for compliance with the operation's policy and current industry practices or regulatory requirements. Auditor observes whether storage areas are designated, available and used.**
Corrective Action	**Operation develops or revises protective clothing policy or procedures. Operation obtains and positions racks and storage containers as necessary. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	

Expectation
Protective clothing may include aprons, smocks, sleeve guards, or other personal protective equipment. If protective clothing is used by any employee, the operation must have a policy for how and when protective clothing is to be cleaned, replaced and stored. This policy is not required to be written.

It is the auditor's responsibility to verify that any protective clothing used (e.g., aprons, gloves, etc.) are stored in a manner to avoid potential contamination. Examples of storage include but are not limited to racks, shelving, cubbies, etc.

Auditors must verify the operation's policy is being followed and that the policy does not promote storage that will cause contamination of protective equipment or tools. Storage solutions must be large enough to accommodate all workers' protective equipment and tools. Storage that is not large enough may lead to items being improperly stored or to fall to the ground resulting in non-compliance with the operation's policy and this requirement. These storage solutions should also be placed in appropriate areas for their intended use. Racks placed near break areas; far enough away from the areas to not be contaminated will encourage proper worker use.

Example Scenarios
Scenario 1: The operation states that they have no "protective clothing" but the auditor sees workers wearing aprons and sleeve guards during sorting.
Assessment: Corrective Action Needed.
Reason: If protective clothing is used the operation is required to have a policy.

Scenario 2: Workers are observed wearing aprons while eating in the break room.
Assessment: Corrective Action Needed.
Reason: Protective clothing is not being used and stored in a manner to "protect product from risk of contamination."

Scenario 3: Workers wear reasonably clean aprons and protective clothes, but there is no policy for how and when protective clothing is to be used and cleaned.
Assessment: Corrective Action Needed.
Reason: If protective clothing is worn, there must be a policy.

Scenario 4: The operation has racks for protective clothing and tools. However, racks are inadequate to properly hold clothing and tools as evidenced by some that have fallen on the ground.
Assessment: Corrective Action Required.
Reason: Clothing or tools on the ground may be a source of contamination. The operation should improve the storage racks and/or train workers how to use the racks.

Requirement	G-10.13. The wearing of jewelry, body piercings and other loose objects (e.g. false nails) shall be in compliance to company policy and applicable regulation.
Procedure	Operation shall have a policy that personal effects such as jewelry, watches or other items shall not be worn or brought into fresh fruit and production areas if they pose a threat to the safety and suitability of the food. Policy shall be in compliance with current industry practices or regulatory requirements for that commodity.
Verification	Auditor observes personnel in field for evidence of compliance.
Corrective Action	Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	
PSR	112.32 (b(5))

Expectation
The operation must have a policy for the wearing of jewelry, body piercings, and other loose objects. This policy must comply with applicable regulations. The standard does not specify that the operation's policy must be written. Review the policy (either in writing and/or through interviewing employees) and/or training records as well as observe workers to verify compliance with requirement G-10.12. If workers are seen wearing jewelry, body piercings or carrying other personal effects (i.e., cell phones, headphones, earbuds etc.), observe whether they are wearing or using these items is in compliance with the company policy.

Jewelry can be both a safety and a food safety hazard. It can become dislodged from the person wearing it and fall into the food item or the container. It can get caught on machinery and injure the worker. The intricate places on some jewelry, such as watchbands, can be places where microorganisms can reside. Auditors must review the policy and observe employees to determine if the policy is being followed.

Example Scenarios
Scenario 1: Operation's policy states that no personnel are allowed to wear wrist watches or jewelry in the broccoli field while harvesting. Auditor observes field supervisor wearing a wristwatch.
Assessment: Corrective Action Needed
Reason: Operation is not compliant with own policy.

Scenario 2: Auditor interviews employees about wearing jewelry. All employees state that jewelry is not allowed. There is no written jewelry policy.
Assessment: Compliant
Reason: Jewelry policy does not have to be written.

Produce Safety Rule

112.32 (b(5)): The PSR requires that hand jewelry that cannot be adequately cleaned and sanitized must be removed or covered during periods in which workers are handling produce.

Requirement	G-10.14. The use of hair coverings shall be in compliance to company policy and applicable regulation.
Procedure	The operation shall have a policy that addresses use of hair coverings (e.g., hair nets, beard nets, caps), which is in compliance with prevailing regulation.
Verification	Auditor reviews the operation's policy and observes employees for compliance.
Corrective Action	Operation develops policy. Retraining is performed.
Documents Required	N/A.
Mandatory	

Expectation
The operation's policy may be written or unwritten on how hair coverings shall be used. If any employees are wearing hair coverings in the operation, the operation must have a policy. The operation's policy could be that head coverings are optional and that any head coverings worn should be reasonably clean like the rest of their clothes. Verify that all employees are complying with the operation's hair covering policy. If the company requires field workers to wear hair nets in the field, workers must wear hair coverings in the field to be in compliance with this requirement. Additionally, workers should be aware of the operation's policy.

This question may only be answered N/A if there is no policy requiring hair coverings and the auditor observes that no workers are using hair coverings.

Example Scenarios
Scenario 1: The operation requires all packinghouse workers to wear hair nets when handling produce. The auditor observes one worker without a hair net.
Assessment: Corrective Action Needed.
Reason: The policy requires all packinghouse workers to wear hair nets.

Scenario 2: You observe packinghouse workers at a peach operation wearing ball caps and other hats. No hair nets are worn. No workers are without a hat of some kind. The supervisor says that hair nets are not required as long as hats are worn. There is no written policy.
Assessment: Compliant.
Reason: The workers are following the company's hair covering policy.

Requirement	G-10.15. Employees' personal belongings shall be stored in designated areas.
Procedure	Operation shall have a policy for when and how employee's personal belongings shall be stored so as not to be a source of product contamination.
Verification	Auditor observes personnel in field for evidence of compliance.
Corrective Action	Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	

Expectation
The operation must have a policy for when and how employee's personal belongings must be stored. This policy is not required to be written. Make observations and/or interview workers on where and how their belongings are to be stored to verify compliance with the operation's policy. Storage may be in the employee's personal vehicles, buses, or in backpacks if this is designated in the operation's policy and if these storage areas are not observed to be reasonable sources of contamination in the operation.

Example Scenarios
Scenario 1: Field workers are observed wearing backpacks, in which they store their phones and other personal objects. Backpacks are allowed in the company policy.
Assessment: Compliant, unless auditor observes a reasonable potential for contamination.
Reason: The backpacks are allowed in the company policy for storage of personal belongings.

Scenario 2: Packinghouse workers are observed storing their personal belongings on the floor in the toilet area.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: Corrective Action Needed - the floor of the toilet area is not an appropriate storage area because articles could become a source of product contamination. If clothes that are to be worn in the production area are among the belongings stored on the toilet area floor, Immediate Action Required.

Requirement	**G-10.16. Smoking, chewing, eating, drinking (other than water), chewing gum, spitting, urinating, defecating, and using tobacco shall be prohibited except in clearly designated areas.**
Procedure	**Operation shall have policy prohibiting smoking, eating, spitting, chewing gum, tobacco, or drinking (other than water) except in designated areas. Such areas shall be designated so as not to provide a source of contamination. Operation shall have policy prohibiting urinating or defecating in any growing area.**
Verification	**Auditor observes personnel in field for evidence of compliance.**
Corrective Action	**Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	●
PSR	**112.32 (b(6))**

Expectation
The operation must have a policy (either written or verbal) that smoking, eating, chewing gum or tobacco, drinking (other than water), urinating, defecating, or spitting is not permitted in any growing area. Observe and interview employees for the adherence and knowledge of this policy. If any workers do not have knowledge of the company's policy the operation is not in compliance with this requirement.

In addition to observations of personnel in the fields, observe the fields for evidence of contamination by the prohibited activities. Examples of evidence of contamination may include trash or feces located within the field or orchard.

Example Scenario
Scenario 1: Worker is observed smoking in an area that has already been harvested and is no longer in production. Operation's policy permits smoking, eating and chewing gum in harvested areas.
Assessment: Compliant.
Reason: Compliant, if the auditor does not observe a reasonable potential for produce contamination.

Scenario 2: The policy is not written. You question one worker who does not know the policy.
Assessment: Corrective Action Needed.
Reason: The worker was not familiar with the company's policy.

Produce Safety Rule
112.32 (b(6)): Operation shall prohibit eating, chewing gum, or using tobacco products in growing and production areas (however, drinking beverages is permitted in designated areas).

Requirement	G-10.17. Operation shall have a written policy that break areas are located so as not to be a source of product contamination.
Procedure	Break areas shall be designated and located away from food contact/handling zones and production equipment.
Verification	Auditor observes break areas for evidence of compliance with Operation policy.
Corrective Action	Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Policy.
Mandatory	

Expectation
Eating food, chewing gum, drinking beverages, or using tobacco products must be confined to areas other than where food may be exposed or where equipment or utensils are washed. Such activities must be separated from the area where food handling is being carried out.

Contamination of food may occur in any step of the food handling operation. In field handling activities, break areas must be designated in the operation's written policy. These may be vehicular drive areas away from the production/growing area, a previously harvested area, along the edges of the field out of the harvesting zone, and/or drive areas between fields.

Break areas are required by the standard to be located away from production equipment. If you observe eating, drinking, smoking, etc. on production equipment (tractors, combines, sorters, etc.) corrective action will be needed.

Facilities used by employees to take breaks, prepare to go to work, eat lunches, etc. must be clean and separate from the packing area and other areas where produce is handled. Some operators will have a separate room designed and identified for eating, others will identify an area in a corner of the packing house building or somewhere outside of the immediate storage and packing area and supply it with tables. All of these are acceptable. The intent is that workers do not eat or take breaks within the storage and packing area.

Applicable portions of 29 CFR, Part 1910.141 state:

(3) Housekeeping.
(i) All places of employment shall be kept clean to the extent that the nature of the work allows.
(ii) The floor of every workroom shall be maintained, so far as practicable, in a dry condition. Where wet processes are used, drainage shall be maintained and false floors, platforms, mats, or other dry standing places shall be provided, where practicable, or appropriate waterproof footgear shall be provided.
(iii)To facilitate cleaning, every floor, working place, and passageway shall be kept free from protruding nails, splinters, loose boards, and unnecessary holes and openings.

Example Scenarios
Scenario 1: A worker is observed smoking in an area adjacent to the hydrovac cooler while it is in operation. The operation's policy permits smoking only in non-product handling areas.
Assessment: Corrective Action Needed.
Reason: This is a product handling area, even if no product is currently exposed.

Scenario 2: The operation's policy permits eating at sorting line if not in use. The auditor observes workers eating while at a lettuce sorting line that is empty during lunch.
Assessment: Corrective Action Needed.
Reason: Standard requires that "break areas shall be…located away from food contact/handling zones."

Scenario 3: A greenhouse operation policy does not designate specific areas for workers to eat. Workers are observed eating in product staging area.
Assessment: Corrective Action Needed.
Reason: The standard requires that "break areas shall be…located away from food contact/handling zones."

Scenario 4: A driver on a forklift is observed drinking a canned soda in the shipping area. The operation's policy is silent on forklift drivers.
Assessment: Corrective Action Needed.
Reason: The standard requires that "break areas shall be…located away from…production equipment."

Requirement	**G-10.18. Drinking water shall be available to all employees.**
Procedure	**Drinking water, which meets drinking water standards, shall be easily accessible to field personnel and in compliance with applicable regulation. Bottled water or potable drinking water stations with single-use cups and a trash receptacle shall be available to all employees.**
Verification	**Auditor observes evidence of drinking water accessibility and operation's evidence that water supplied to personnel meets drinking water standards.**
Corrective Action	**Operation makes drinking water available to employees, in compliance with prevailing regulation.**
Documents Required	**Record.**
Mandatory	

Expectation
Bottled water use is acceptable in the work area provided it is stored in closed plastic containers away from the product flow zone when not being used. All drinking water must meet the drinking water standards.

This requirement cannot be assessed as and IAR, as there is no food safety risk posed by the noncompliance. Include the drinking water source (i.e., municipal, bottled, well) in the comments.

Example Scenarios
Scenario 1: Operation provides bottled drinking water to field workers. Receipts of purchase are available for review.
Assessment: Compliant
Reason: Workers have access to drinking water.

Scenario 2: Operation provides a drinking water fountain in the worker's locker room. No water is provided in the fields.
Assessment: Corrective Action Needed
Reason: Standard requires that "drinking water shall be easily accessible to all employees".

Requirement	**G-10.19. Workers and visitors who show signs of illness shall be excluded from direct contact with produce or food-contact surfaces.**
Procedure	**Operation shall have a policy that restricts employees, contractors, visitors, buyers, product inspectors, auditors, and other personnel in the operation who show signs of illness (e.g., vomiting, jaundice, diarrhea) from contact with product or food contact surfaces. Policy shall require that any person so affected immediately report illness or symptoms of illness to the management.**
Verification	**Auditor reviews policy and observes field personnel for evidence of compliance.**
Corrective Action	**Operation develops and implements policy. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**Written Policy.**
Mandatory	●
PSR	**112.31**

Expectation
Any person who is ill shall be excluded from direct contact with produce or food-contact surfaces and from food handling areas. Workers and visitors shall be instructed to report illness to management. Illness could be identified by medical examination, personal acknowledgement, or supervisory observation.

Management should be familiar with the signs of illness so that if symptoms are evident, management can take appropriate steps. Signs of illness may include vomiting, jaundice, or diarrhea. Any worker showing signs of illness must be excluded from work assignments that involve direct or indirect contact with fresh produce, and restricted from entering food handling areas. Operations must have a written policy to follow when workers show signs of possible illness.

Auditors should interview managers/supervisors to determine their knowledge of known signs of illness. The auditor should also look for indications of worker illness, such as frequent trips to the toilet facilities by individual employees. For example, a field crew manager should be familiar with

the company's policy for what to do when a worker reports illness to them or when they observe a worker who has obvious signs of illness; a worker should be familiar with the company's policy of what they should do when they are ill.

This question cannot be indicated as N/A.

Example Scenario
Scenario: An operation has a written policy, requiring workers to report illness or symptoms of illness to the management, but the supervisor says it is illegal to ask workers if they are ill.
Assessment: Compliant, unless you see ill worker(s) in contact with produce or food contact equipment.
Reason: The standard requires that the "Operation shall…restricts personnel who show signs of illness"; it does not require operations to ask workers if they are ill.

Produce Safety Rule
112.31: The operation must take measures to prevent contamination of produce and food contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting or diarrhea). This means excluding any person from working in any capacity that may result in contamination of produce or food contact surfaces with human pathogens when the person (by medical examination, the person's acknowledgement or observation) is shown to have or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health. Personnel must notify their supervisor(s) (or responsible party) if they have, or a reasonable possibility that they have an applicable health condition.

Requirement	**G-10.19.a. Workers showing signs of illness shall not be allowed to enter food handling areas.**
Procedure	**The operation must have a written policy that workers showing signs of illness shall not be allowed to enter food handling areas.**
Verification	**Auditors will verify that there is a written policy and that the policy is implemented.**
Corrective Action	**Operation develops and implements a policy on restricting ill workers from food handling areas. Retraining is performed.**
Documents Required	**Written Policy.**
Mandatory	●
PSR	**112.31**

Expectation
Any person who is ill shall not be allowed to enter food handling areas. The operation must have a written policy that workers showing signs of illness shall not be allowed to enter food handling areas.

Example Scenario

Scenario: A worker who was feeling ill was reassigned from the grading line to instead operate a forklift to transport product and packaging in the production area.
Assessment: Corrective Action Needed.
Reason: Workers who are ill must not be allowed to enter food handling areas.

Requirement	**G-10.20. Personnel with exposed cuts, sores or lesions shall not be engaged in handling product.**
Procedure	**Minor cuts or abrasions on exposed parts of the body are acceptable if covered with a non-permeable covering, bandage or glove. Bandages on hands shall be covered with gloves in compliance with operation's glove policy.**
Verification	**Auditor observes personnel in field for evidence of compliance.**
Corrective Action	**Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	●
PSR	**112.31**

Expectation
In addition to observation of field personnel, auditors will interview selected personnel for verification of their knowledge of the company's policy appropriate to their position's responsibilities. This policy does not have to be written but needs to be known by all workers. For example, a field crew manager should be familiar with the operation's policy for what to do when a worker reports or they observe a worker with a cut, sore or lesion; a worker should be familiar with the operation's policy of what they should do if they have an exposed cut sore or lesion, this type of injury may occur during the farming and/or harvesting activities of the operation. See requirement G-10.11 for additional verification requirements if gloves are used to cover minor cuts or abrasions.

Example Scenario
Scenario: A worker on produce sorting line has a cut on their forearm which, on doctor's orders, is not bandaged.
Assessment: Corrective Action Needed.
Reason: The standard requires personnel "with exposed cuts, sores or lesions shall not be engaged in handling product."

Produce Safety Rule
112.31: The operation must take measures to prevent contamination of produce and food contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting or diarrhea). This means excluding any person from working in any capacity that may result in contamination of produce or food contact surfaces with human pathogens when the person (by medical examination, the person's acknowledgement or observation) is shown to have or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health. Personnel must notify their supervisor(s)

(or responsible party) if they have, or a reasonable possibility that they have an applicable health condition.

Requirement	G-10.21. Operation shall have a blood and bodily fluids policy.
Procedure	There shall be a written policy specifying the procedures for the handling/disposition of food or product contact surfaces that have been in contact with blood or other bodily fluids.
Verification	Auditor reviews policy and observes operation for evidence of compliance.
Corrective Action	Operation develops and implements policy. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Policy.
Mandatory	●

Expectation
Verify personnel's knowledge of the company's written procedure for blood and bodily fluids policy is appropriate to their level of work. Also, verify that the blood and bodily fluids policy is implemented by checking paperwork, observing personnel practices and interviewing personnel.

Example Scenario
Scenario: The operation does not have a written policy, but the field supervisor states, "if anyone gets a cut, we buffer and do not harvest two feet around the site and write an incident report". A recent incident report is available for review.
Assessment: Corrective Action Needed
Reason: Standard requires the policy to be written.

Requirement	G-10.22. First aid kits shall be accessible to all personnel.
Procedure	The kits shall be readily available in the vicinity of field work and maintained in accordance with prevailing regulation. The kit materials shall be kept sanitary and in usable condition.
Verification	Auditor observes that provisions exist for first aid kit to be readily available in vicinity of workers and is stocked in accordance with prevailing regulation.
Corrective Action	Operation obtains and stocks a first aid kit and ensures it is readily accessible near field personnel.
Documents Required	N/A.
Mandatory	

Expectation
Observe that the operation has first aid kits readily available to personnel in the vicinity of the field work. These first aid kits must be stocked and ready for use. Check kits to make sure commonly

used items such as band-aids and antibacterial ointment are present. The contents of the first aid kits must not be past their expiration dates. For example, antibacterial ointment with a best used by date two years prior to the audit date would not be ready for use.

Example Scenarios
Scenario 1: The operation has a first aid kit in the foreman's truck. The kit contains bandages, gauze, and antiseptic. The foreman explains that "this is all we are prepared to treat on site; anything more severe goes to the hospital."
Assessment: Compliant.
Reason: First aid kits are accessible to personnel.

Scenario 2: The antiseptic is two months past its expiration date.
Assessment: Corrective Action Needed.
Reason: The auditor is not in a position to evaluate whether being slightly out of date is a public health issue, so should adhere to the manufacturer's recommendations.

Scenario 3: The antiseptic bottle is empty.
Assessment: Corrective Action Needed.
Reason: The first aid kit is not fully stocked.

G-11 Waste Management

Requirement	**G-11.1. Operation has implemented a waste management plan.**
Procedure	**Operation implements procedures for the control, storage and disposal of trash, litter, and waste in areas used for produce handling activities. Such procedures minimize the potential for trash, litter, or waste to attract or harbor pests and protect against contamination of produce, food contact surfaces, areas used for produce handling activities, water sources, and water distribution systems. Waste treatment and disposal systems operate so that they do not constitute a potential source of contamination in produce handling areas.**
Verification	**Auditor verifies the operation has implemented a waste management plan.**
Corrective Action	**Operation implements a waste management plan.**
Documents Required	**N/A.**
Mandatory	

Expectation
Auditor reviews how the operation's waste management plan is implemented and that the operation has procedures in place for controlling, storing and disposing of trash, litter and waste in areas used for produce handling activities. Procedures should minimize the potential of trash, litter or waste and protect against contamination of produce, food contact surfaces, produce handling activities, water sources, and water distribution systems. Auditor verifies through observations, interviews,

and a review of documentation (such as training records, waste disposal invoices, etc.) to determine if the operation's procedures are being followed. Furthermore, interviews with employees shall demonstrate adherence to the operation's waste management plan since no specific written plan is evident in this requirement.

Example Scenario
Scenario: Auditor observes field is littered with garbage during harvest. Auditor notices field is next to I-5, a major freeway, and there are 2 fences around the field.
Assessment: Compliant or Corrective Action Needed
Reason: If garbage is of animal or human origin there is a risk of contamination of the harvestable portion of crop. As long as the farm manages to collect trash they are compliant, provided that the waste management plan also states that any product in contact with the trash is not harvested.

Requirement	**G-11.2. Trash shall not come in contact with produce.**
Procedure	**Trash handling and removal shall not pose a hazard of contamination of produce.**
Verification	**Auditor reviews trash handling procedures for field operation, and observes trash handling practices for evidence of compliance.**
Corrective Action	**Operation revises procedures. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	●
PSR	**112.132**

Expectation
Trash, leaves, trim, culls, and other waste material are removed from the produce handling areas at a frequency sufficient to avoid being a source of contamination. Trash and waste materials should be removed at a frequency as to not attract or harbor pests. Trash and waste should not contaminate agricultural water sources and distribution systems.

Example Scenarios
Scenario 1: Operation provides field sanitation units on a trailer with outside trash receptacles. Trash is found on the ground, as the receptacle was overflowing with trash. Food Safety Plan states that trash will be emptied daily or as needed. Interview with employee about trash removal stated trash is emptied every other day.
Assessment: Corrective Action Needed
Reason: Policy states trash is to be removed daily or as needed.

Scenario 2: Auditor observes trash container in produce handling area is overflowing. Supervisor explains that containers are emptied during breaks, and this situation is unusual. Next break is in an hour.
Assessment: Corrective Action Needed.
Reason: Operation should have a contingency for when more trash accumulates than normal.

Produce Safety Rule
112.132: The operation must convey, store, and dispose of trash, litter and waste to minimize the potential for trash, litter or waste to attract or harbor pests; and protect against the contamination of produce, food contact surfaces, areas used for product activity, agricultural water sources and agricultural water distribution systems with known or reasonably foreseeable hazards. The operation must adequately operate systems for waste treatment and disposal so they do not constitute a potential source of contamination in areas used for product activity.

G-12 Food Defense

After September 11, 2001, protection of the nation's food supply from attacks became a national priority. The President issued a series of directives; Homeland Security Presidential Directives (HSPD's) that outline the security of the United States. HSPD 9 addresses the need to protect the nation's food supply. In response, both the FDA and the USDA issued voluntary food defense guidelines to help food processors identify measures to prevent or mitigate the risk of intentional food contamination. In 2003, the FDA published the Guidance Document *Food Producers, Processors, and Transporters, Food Security Preventative Measures Guidance*.

Food safety differs from food defense in the following way: Food safety is the protection of food products from *unintentional* contamination by pathogens or chemicals. A GAP & GHP program will address reducing the risk of unintentional contamination. Food Defense is the protection of the food supply from *intentional* contamination by chemical, biological, or radiological means by an aggressor.

Because of the wide variety and complexity of operations that we can audit for food defense, auditors should take into consideration the complexity, size, and scope of the facility. In general, farm operations will have different food defense requirements than an enclosed packing shed or wholesale distribution warehouse. For instance, it is not practical for a farm to enclose their entire operation with fencing, where in a packing facility or warehouse operation, it would be more economically feasible.

Due to the wide variations in food defense facilities and procedures, auditors should take the time to review the auditee's food defense plan prior to the audit to become familiar with it. This makes it easier to audit the farm/facility on the day of the audit.

Requirement	G-12.1. Operation shall assess the potential for unauthorized access to growing and/or packing areas and its impact on food safety.
Procedure	Operation shall demonstrate an awareness of site security and, if deemed necessary for food safety, take reasonable measures to minimize the potential for unauthorized access to growing and/or packing areas.
Verification	Auditor interviews the responsible individual for awareness of site security, and security measures, if applicable.
Corrective Action	Security assessment is performed.
Documents Required	Risk Assessment.
Mandatory	●

Expectation
The operation must conduct a written assessment for the operation's vulnerability to unauthorized people accessing the growing, harvesting, packing and storage areas. It should be taken into consideration the degree to how easy it is to access various areas throughout the operation. Are there items in place that make access more difficult, such as locked doors, fencing, observant personnel, physical space constraints, automated equipment etc.?

Example Scenarios
Scenario 1: A citrus orchard with ripe fruit is along a major roadway. Auditor observes a tourist car pulling over to pick fruit. A field manager pulls up to the car and advises them to leave. There are no noticeable "no trespassing" signs at orchard along the road.
Assessment: Compliant
Reason: Observed actions taken, signs are not required.

Scenario 2: Utility workers come onto property without notifying the operation.
Assessment: Compliant
Reason: The operation has no control over the utility workers. Auditor should request more information to determine if the operation has assessed this to be a food safety risk.

Requirement	G-12.2. Operation shall develop an emergency response plan.
Procedure	A response plan is in place in the event of a security event potentially impacting food safety. Action taken to reduce risk to product shall be documented by means of an incident report or other record of response.
Verification	Auditor interviews the responsible individual for knowledge of the emergency response plan and, if applicable, reviews incident response records.
Corrective Action	Emergency response plan is developed.
Documents Required	Written Policy, Record.
Mandatory	

Expectation
Auditor reviews operation's policy for emergency response plan for security issues that involve/impact food safety and interviews responsible individual(s) for knowledge and effectiveness of emergency response plan. Actions taken to reduce potential risk to product shall be documented by means of an incident report or other record of response. An example of a security breach may be an instance ranging from a computer being hacked to unauthorized entry into fields, produce packing facilities, storage or holding facilities.

An operation must make efforts to identify potential risks to food safety due to trespassers on the property. It is not reasonable to expect an operation to account for all possible risk scenarios, however an operation must address other types of risk (such as common, routine weather events) under consideration of hazards within the Food Safety Plan within G-2.1; physical, chemical, or biological risks within F-1.1; or pre-harvest risk within F-9.1)., or a combination of these. The requirements within G-12.2 focus on security events that potentially impact food safety.

Example Scenarios
Scenario 1: Two months prior to the audit, a drunk driver ran off the road and into the operation's produce field. The food safety manager shares an incident report, describing the measures taken to isolate and not harvest affected sections of the field. No fences or other preventive measures were implemented
Assessment: Compliant.
Reason: The operation took reasonable steps to reduce food safety risk. An operation should not be expected to implement additional preventive measures (e.g. fencing/barriers) for isolated incidents.

Scenario 2: Packinghouse's storage was broken into and had produce stolen. Operation shows auditor the new locks added to better secure the building, but no incident report is available.
Assessment: Corrective Action Needed.
Reason: Action taken to reduce risk to product "shall be documented by means of an incident report or other record of response". In addition to documented corrective actions, an operation should also assess potential risk to food safety due to trespassers on the property.

Requirement	G-12.3.a. Initially and at least annually thereafter, the operation shall evaluate and document the risks associated with security (food defense), including unintentional security risks.
Procedure	A review or new assessment shall be conducted seasonally and any time there is a change made to the system or a situation occurs that provides the opportunity for the intentional or unintentional introduction of a hazard. The risk assessment shall address potential physical, chemical, and biological hazards.
Verification	Auditor reviews the risk assessment for completeness of consideration of potential hazards
Corrective Action	Operation develops or updates the risk assessment.
Documents Required	Risk Assessment.
Mandatory	●

Expectation
The purpose of a food security risk assessment is to identify areas in an operation that are vulnerable to breeches in security that may result in physical, chemical, or biological contamination of produce. The review or new security assessment must be conducted seasonally and any time a change is made to the system or there is a situation that occurs that provides for the introduction of a hazard.

The auditor will include the date the food defense assessment was conducted in the comments.

Example Scenario
Scenario: Packinghouse's storage was broken into and had produce stolen. Operation shows auditor the new locks added to better secure the building, a new risk assessment was not conducted.
Assessment: Corrective Action Needed
Reason: **"**The review or new security assessment must be conducted seasonally and any time a change is made to the system or there is a situation that occurs that provides for the introduction of a hazard".

Requirement	G-12.3.b There shall be a written food defense plan to mitigate risks identified in the food defense risk assessment.
Procedure	The food defense plan shall include the following: preventive controls, monitoring and verification procedures, corrective actions, and documentation. The plan shall be reviewed following any changes made to the food defense risk assessment and adjusted accordingly to incorporate such changes. Evidence of management commitment to the food defense plan shall be documented. Training and/or retraining of personnel having oversight or performance duties shall be documented.
Verification	Auditor reviews the food defense plan for accuracy and completeness relative to the risk assessment.
Corrective Action	Operation develops or updates the food defense plan.
Documents Required	Written Policy, Record.
Mandatory	

Expectation
The food defense plan must include preventive controls, monitoring, verification, corrective actions and documentation.

Example Scenario
Scenario: The operation has a documented food defense plan. The auditor observes food defense practices and procedures throughout the packinghouse. When reviewing training records there are no records for training on food defense.
Assessment: Corrective Action Needed.
Reason: The training of personnel having oversight or performance of duties related to food defense shall be documented.

G-13 Food Fraud

Food fraud is the deliberate and intentional substitution, addition, tampering or misrepresentation of food, food ingredients or food packaging, labeling, product information or false or misleading statements made about a product for economic gain that could impact consumer health. This could be done by the operation or by an individual employee.

Requirement	G-13.1.a. The operation shall initially and at least annually thereafter, evaluate and document the risks associated with food fraud.
Procedure	A review or new assessment shall be conducted seasonally and any time there is a change made to the system or a situation occurs that could provide an opportunity for the misrepresentation of product.
Verification	Auditor reviews the risk assessment for completeness of consideration of potential hazards.
Corrective Action	Operation develops or updates the risk assessment.
Documents Required	Risk Assessment.
Mandatory	●

Expectation
A food fraud vulnerability assessment shall be conducted to identify potential vulnerability and prioritize food fraud mitigation measures. The risk assessment shall be conducted at least annually, and any time there is a change made to the operation or a situation occurs that could provide an opportunity for the misrepresentation of the product.

The vulnerability assessment should be exhaustive and consider a wide range of hazards. Food fraud can cover across all activities of a business and so the scope of the hazard identification step should cover them all. It is important to address the difference between the hazard (a potential source of harm, risk (the probability of loss or injury from a hazard), and vulnerability (susceptibility to a risk): many hazards will have a low or very low likelihood and therefore not represent a risk; likewise, the susceptibility of a company or system to a risk is not only linked to the severity of this risk but more to the company's awareness of their weakness and how they manage it.

Examples of food fraud include:

- Selling gala apples as pink lady apples
- Packaging material sold as food grade made of non-food grade materials
- Selling non GAP-certified produce, as GAP certified
- International produce marketed as domestic
- Non-organic produce being sold under the USDA organics label

The auditor will include the date the food fraud assessment was conducted in the comments.

Example Scenarios

Scenario 1: The operation's food fraud risk assessment contained all items to properly evaluate their mushroom operation, except that it was written two years prior to the audit and was not reviewed or updated.
Assessment: Corrective action needed.
Reason: Food fraud risk assessment needs to be reviewed, or a new assessment conducted each season.
Scenario 2: Inspector notices an incident on the incident report that relates to food fraud, mislabeled packaging; however, when reviewing the food fraud risk assessment there is no mention of the assessment of the risk.
Assessment: Corrective action needed.
Reason: Anytime a situation occurs a review or new assessment must be done.

Requirement	**G-13.1.b. There shall be a written food fraud plan to mitigate risks identified in the food fraud risk assessment.**
Procedure	**The food fraud plan shall include the following: preventive controls, monitoring and verification procedures, corrective actions, and documentation. The plan shall be reviewed following any changes made to the food fraud risk assessment and adjusted accordingly to incorporate such changes. Evidence of management commitment to the food defense plan shall be documented. Training and/or retraining of personnel having oversight or performance duties shall be documented.**
Verification	**Auditor reviews the food fraud plan for accuracy and completeness relative to the risk assessment.**
Corrective Action	**Operation develops or updates the food fraud plan.**
Documents Required	**Written Policy, Record.**
Mandatory	

Expectation
A food fraud vulnerability is the susceptibility or exposure to a food fraud risk, which is regarded as a gap or deficiency that could place consumer health at risk if not addressed. Based upon the food fraud vulnerability assessment, a documented food fraud plan shall be established specifying the measures which shall be maintained and implemented to mitigate the public health risks from the identified food fraud vulnerabilities. The food fraud plan will need to be updated at any time where the food fraud risk assessment identifies a new potential risk, or where the mitigation strategies are deemed to be insufficient or ineffective to address the current risks.

It is important to note that auditors are not expected to detect fraud or affirm that an anti-fraud program is capable of "preventing fraud".

The focus of the auditor should be in assessing the approach taken by the company:

- Is it companywide?

- Is it built by a multi-disciplinary team?
- Is it clearly documented and reviewed regularly?
- What's the source of information used to support the assessment?

The auditor shall verify that the operation is properly enacting their food fraud plan.

Example Scenario
Scenario 1: Operation's food fraud plan does not address all the risks stated in the policy.
Assessment: Corrective action needed.
Reason: Food fraud plan is to mitigate risks identified in the food fraud risk assessment.

FIELD OPERATIONS AND HARVESTING

Field Production

F-1 Field History and Assessment

The following requirements address the evaluation and documentation of field risks.

Requirement	F-1.1. The food safety plan shall, initially and at least annually thereafter, evaluate and document the risks associated with land use history and adjacent land use including equipment and structures.
Procedure	When land use or adjacent land use indicates a possibility of physical, chemical or biological contamination, preventive controls shall be performed and documented to mitigate food safety risk. The assessment is re-performed, and documented, at least annually and upon significant events, for environmental conditions or risk awareness that has changed since the last assessment. The assessment shall address flooding and shall include indoor growing facilities and structures such as green houses and hydroponics.
Verification	Auditor reviews food safety plan to verify that risks associated with field history, adjacent land use and indoor growing facilities have been evaluated at least annually and preventive controls implemented for identified risks.
Corrective Action	Operation evaluates and documents risks associated with land use history, adjacent land use, and indoor growing facilities and implements preventive controls for identified risks.
Documents Required	Risk Assessment.
Mandatory	●

Expectation
Review the operation's Food Safety Plan to verify that the operation has conducted a written assessment at least annually to evaluate, identify, and implement preventative controls for identified risks associated with field history, adjacent land use, and indoor growing facilities.

The operation is responsible for assessing and documenting the land use history and adjacent land use prior to the land being used for the production of fresh produce. The assessment shall consider significant events, which include the potential for flooding events. Growers may use a standard risk assessment form provided by one of their shippers, a self-developed assessment, or an assessment template from another source so long as it addresses all of the operation's risks. Auditors must verify that the risk assessment is accurate when visiting the fields.

The auditor will include the date and the role/title of the person who conducted the last assessment in the comments.

Example Scenarios
Scenario 1: The operation states the field being audited has been in fresh produce production for more than 20 years. The assessment does not include how the field was used prior to that.
Assessment: Compliant or Corrective Action Needed.
Reason: Compliant, unless you note significant risk from previous land use.

Scenario 2: The operation's assessment includes onsite risks but does not consider risks from adjacent land use.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: Potential risks from adjacent land use must be considered and the consideration documented in the assessment. Either CAN (no imminent food safety hazard) or IAR (lack of recognition of a risk has resulted in an immediate food safety risk).

Scenario 3: The annual assessment of risk states "no change" from the previous year's assessment. The prior assessment is available and compliant. Both the initial assessment and the "no change" assessment are dated to demonstrate that the assessment has been conducted annually.
Assessment: Compliant.
Reason: Risk has been evaluated annually.

Requirement	**F-1.1.a. Operation has performed and documented a risk assessment of each production area prior to the harvest of that location. The risk assessment must include potential cross contamination between production sites.**
Procedure	**A system shall be established to maintain the record of agricultural activities undertaken at each production unit and records shall be available to demonstrate that sites (on farm and adjacent sites) have been evaluated with regards to potential food safety hazards. The risk assessment must include potential cross contamination between production sites.**
Verification	**Auditors verify the operation has performed and documented a risk assessment of each production area.**
Corrective Action	**The operation shall perform and document a risk assessment for each production area. Training of appropriate personnel may need to take place to on conducting and recording this assessment.**
Documents Required	**Risk Assessment.**
Mandatory	●

Expectation
A risk assessment must be performed and documented by the operation for each production area, prior to the harvest of that location. The risk assessment must include potential cross contamination between production sites. The time and frequency this assessment is conducted is defined by the operation in their risk assessment procedure. Verify the risk assessment has been conducted, the risk assessment is documented, and the risk assessment addresses the risks of the operation. Observations will be important for the auditor to verify the accuracy of this requirement.

The auditor will include the date and the role/title of the person who conducted the last assessment in the comments.

Example Scenarios
Scenario 1: An auditee plants each field on their farm once per year, in the same crop every year. The field history risk assessment contains a list of each field, what was planted there last year, what surrounds the field, and any identified hazards. Auditee signs off on each field, each year that there are no hazards from prior use, or the use of surrounding areas.
Assessment: Compliant.

Scenario 2: The risk assessment concludes that there are no potential cross-contamination hazard risks from employees moving between production sites, as the fields are in production at different times of the year.
Assessment: Compliant (unless auditor observations prove otherwise).
Reason: The operation has addressed cross-contamination between production sites.

Requirement	**F-1.1.b. Operation has identified control measures to all significant hazards identified during risk assessment.**
Procedure	**Workers shall be trained on what the food safety hazards are and how to manage them. There shall be responsibilities assigned to maintain records on the food safety hazards and their management.**
Verification	**Auditor verifies that control measures for all significant hazards identified during the risk assessment are implemented.**
Corrective Action	**Operation trains workers on the maintenance of the food safety hazards identified and how to manage and record the management of these hazards.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
The operation must have a management plan for any risks that are identified during the risk assessment. Workers must be trained on what the risks to the operation are, how to manage these risks, and how to keep records appropriate to their job responsibilities.

Example Scenario
Scenario: Auditee has recorded all risks and has documented mitigation strategies for all significant hazards. Employees have not been trained on the mitigation strategies.
Assessment: Corrective Action Needed.
Reason: Worker training is required.

Requirement	F-1.2. For indoor growing and field storage buildings, building shall be constructed and maintained in a manner that prevents contamination of produce.
Procedure	Building and equipment structures and surfaces (floors, walls, ceilings, doors, frames, hatches, etc.) shall be constructed in a manner that facilitates cleaning and sanitation and does not serve as harborage for contaminants or pests. Chill and cold storage loading dock areas shall be appropriately sealed, drained and graded. Fixtures, ducts, pipes and overhead structures shall be installed and maintained so that drips and condensation do not contaminate produce, raw materials or food contact surfaces. Water from refrigeration drip pans shall be drained and disposed of away from product and product contact surfaces. Drip pans and drains shall be designed to assure condensate does not become a source of contamination. Air intakes shall not be located near potential sources of contamination.
Verification	Auditor observes building and equipment for evidence that the building can be cleaned and maintained to prevent product contamination.
Corrective Action	Building deficiencies are corrected. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	●
PSR	112.122; 112.126

Expectation
Observe that indoor buildings and equipment can be cleaned and maintained to prevent product contamination. A hoop house is not considered an indoor growing building and should be evaluated for compliance when evaluating the field in requirement F-1.1. Greenhouses with dirt floors that are not reasonably likely to result in contamination of the edible portion of the crop are compliant with requirement F-1.2 unless you observe that the condition of the greenhouse poses a contamination risk (e.g., burrowing of rodents in the dirt floor).

If an auditee states that certain parts of the operation are not part of the audit, clearly document what buildings and/or structures are exempt from the audit. For example, if the operation says that the greenhouse is "not part of this audit" and prohibits the auditor from inspecting the greenhouse, exclude the greenhouse from being audited but assess it as a potential source of risk to the crops that are included in the scope of the audit. Another example would be exclusion of a "field storage facility" that is used for equipment and tools, but not food handling. This structure would not be applicable to Requirement F-1.2 unless the auditor observes that the facility poses a food safety risk to produce.

Example Scenarios
Scenario 1: The "indoor growing building" is a hoop house.
Assessment: Not Applicable

Reason: Hoop houses should be in compliance with field operations standards.

Scenario 2: The operation is storing product onsite in a temporary storage facility and auditor observes that a pest control program is in place. You observe excessive rodent damage to product.
Assessment: Immediate Action Required.
Reason: Pest control program in place is not effective.

Produce Safety Rule
112.122: Buildings subject to the requirements of the Produce Safety Rule include (a) any fully or partially-enclosed building used for growing, harvesting, packing and holding activities, including minimal structures that have a roof but do not have any walls and (b) storage sheds, buildings or other structures used to store food contact surfaces (such as harvest containers and food-packing materials).

112.26: (a) All buildings must meet the following requirements (1) buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for growing, harvesting, packing and holding activities to reduce the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must provide sufficient space for placement of equipment and storage of materials and permit proper precautions to be taken to reduce the potential for contamination of produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems or other effective means. (2) There must be adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building. (b) Measures to prevent contamination of produce and food contact surfaces in the buildings must be implemented, as appropriate, considering the potential for such contamination through: Floors, walls, ceilings, fixtures, ducts or pipes: and drip or condensate.

Requirement	**F-1.3. Sewage or septic systems are maintained so as not to be a source of contamination.**
Procedure	**After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, operation takes appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate produce, food contact surfaces, areas used for produce handling, water sources, or water distribution systems.**
Verification	**If a significant event has occurred, Auditor reviews steps taken by operation to verify sewage or septic system is not a source of contamination.**
Corrective Action	**Sewage or septic systems deficiencies are corrected. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	●
PSR	**112.131**

Expectation
The operation is responsible for being aware of events that could cause a problem with sewage or septic systems, and is responding appropriately to make sure any contamination risks are addressed. The auditor must ask the operation about any recent events and whether they have ensured that their sewage and septic systems are operating in a way that will not contaminate produce, surfaces, and water sources and systems.

Example Scenarios:
Scenario 1: The grower lives adjacent to the harvest field and his personal septic system has malfunctioned. The surface grade is away from the field however the house is on an elevated surface above the field.
Assessment: Compliant.
Reason: Provided grading is away and as long as any discharge (including cross-contamination) didn't affect the crop.

Scenario 2: Auditee states septic system is checked after an earthquake.
Assessment: Depends/Compliant.
Reason: Compliant if the auditee also has records for microbial compliance of any potentially affected water sources following the event. Corrective Action Needed if records for microbial compliance are not provided.

Produce Safety Rule
112.131: (a) The operation must dispose of sewage into an adequate sewage or septic system or through other adequate means. (b) The operation must maintain sewage and septic systems, and (c) The operation must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of produce, food contact surfaces, areas used for growing, harvesting, packing and holding activities, agricultural water sources and agricultural water distribution systems with known or reasonably foreseeable hazards. (d) this includes after a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system.

F-2 Agricultural Chemicals/Plant Protection Products

Pre-harvest materials include pesticides, growth regulators and fertilizers. Post-harvest materials would include waxes, fumigants and fungicides. Personnel in each area being audited should have a working knowledge of the use of these materials, if they are using them. This would include what the application material would be used for (fertilizer, wax, fungicide, etc.), the appropriate strength level, and what to do if there is a spill or the strength is improperly mixed.

Applicators who hold current State licenses will meet the requirements of this question. However, if there are no restricted use materials being used which require the auditee to hold a pesticide license, then review training documents that prove the applicators have received training on the proper use of the materials. These requirements may only be assessed as N/A when no pre-harvest and/or post-harvest materials are used in the scope of the operation being audited.

The use of specific chemical brands or formulations tends to be regional. Growers in the same geographic region will often work with the same chemical salespeople and cooperative extension advisors. Trends may become evident for commonly used chemicals. In these situations, it will become apparent when a new chemical is being used, these are chemicals auditors will want to selectively sample for verification of compliance with the following requirements.

Requirement	**F-2.a. The operation has a current list of agricultural chemicals that are used and approved for the crops being grown.**
Procedure	**An agricultural chemical list is available for the commercial brand names and active ingredient composition or beneficial organisms of agricultural chemicals (including post-harvest chemicals such as biocides, waxes and plant-protection products) that are approved for crops being grown within the scope of the audit for the last 12 months.**
Verification	**Auditor shall verify the operation's list of agricultural chemicals that are used and approved for the crop being grown and for crops grown within the scope of the audit for the last twelve months.**
Corrective Action	**Operation will keep a list of agricultural chemicals used and approved.**
Documents Required	**Record.**
Mandatory	

Expectation
The operation has a current list of agricultural chemicals that are used and approved for the crops being grown. This list shall include the commercial brand names and active ingredient composition or beneficial organisms of the chemicals. This list must be updated annually and current for the last 12 months.

Example Scenario
Scenario: Operation's chemical records include a list of agricultural chemicals listed only by the brand names of chemicals. You verify that all chemicals in the operation are on the list.
Assessment: Corrective Action Needed
Reason: List of chemicals must include the brand name and the active ingredient composition.

Requirement	F-2.1. Use of agricultural chemicals shall comply with label directions and prevailing regulation.
Procedure	Agricultural chemicals, including post-harvest chemicals such as biocides, waxes and plant protection products, must be registered for such use as required by prevailing regulation, and used in accordance with label directions including application rates, worker protection standards, personal protection equipment, container disposal, storage, and all requirements specified for chemical or compound. Chemicals that are not registered pesticides may be permitted for food contact use if allowed under regulations of the prevailing agency. Records of chemical agricultural use are maintained, and include crop date and location of application, chemical used, application rate and method, and preharvest interval.
Verification	Auditor reviews agricultural chemical use records for evidence of compliance with approved uses or label directions.
Corrective Action	Operation develops and maintains agricultural chemical use records and maintains evidence of proper use of each chemical use. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Record.
Mandatory	●

Expectation
Agricultural chemicals must be registered for use as required by prevailing regulations and used in accordance with label directions, including application rate, workers' protection standards, personal protective equipment, container disposal, storage, and all requirements specified for the chemical or compound. Note that this standard requires records of compliance with agricultural chemicals; this will include regulated and non-regulated chemicals.

The directions for use on an agricultural chemical label, describe how the product may legally be used and how the product must not be used. Generally speaking, the necessary information includes:

- The pest(s) that the product may be used to control
- The sites where the product may be used
- The application methods that are required or preferred
- How much pesticide should be applied and the rate of application
- Whether there are any restrictions on use: weather, time of day, season of the year, contamination of sensitive areas, exposure of nontarget species, etc.

- The application methods that are prohibited
- How often pesticide should/may be applied
- All restricted entry intervals (REIs) pertaining to existing uses, as applicable
- Maximum application rates per treatment and per year
- Pre-harvest intervals (PHIs)
- Storage and disposal
- Any other requirements as necessary

The directions for use reflect EPA's determination that the use of the product in such a manner does not cause unreasonable adverse effects on the environment or human health under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The general rule to go by is the label on an agricultural chemical is the law; if the label says you can use it, you can use it.

The directions for use are organized and carefully worded so they can be understood by the person expected to use or to supervise the use of the agricultural chemical. The directions for use indicate whether any actions mentioned are required, prohibited, encouraged, or discouraged when using the product and background information may also be provided.

Charts, tables, and graphics may be seen in many labels' directions for use and they provide accurate information in a clear, concise, and complete manner. For example, an instructional statement such as this may be seen: "To make spray solution, mix 1 to 2 pints of this product in 100 gallons of water. Apply 100 to 200 gallons of diluted spray solution per acre to trees depending on tree size and the coverage obtained with the spray equipment used." Labels for agricultural products usually express the application rate in terms of pints/acre for liquid formulations, or pounds/acre for solid formulations. The directions for use for an agricultural pesticide used in a spray solution also must include the spray volume/unit area or other measurement of coverage, depending on the type of formulation. Labels for residential/household use products express the application rate in smaller units, such as ounces, teaspoons/gallon, or pounds/square foot.

In emergency situations, Section 18 of FIFRA authorizes EPA to allow States to use a pesticide for an unregistered use for a limited time. There are four types of emergency exemptions: specific, quarantine, public health, or crisis. An applicator will need to have a copy of the Section 18 allowing special use on hand. Current and recent actions under Section 18 are detailed in the FIFRA Section 18 Emergency Exemptions Database. This database is found at: https://iaspub.epa.gov/apex/pesticides/f?p=124:2::::::.

It is an acceptable practice for the operation to not have any application records onsite if the records are retained by the pesticide application company and the operation can obtain any record requested by the auditor within 24 hours of the audit.

Example Scenarios
Scenario 1: The operation has no application records for a restricted use pesticide. They say that they are compliant with prevailing regulation because they would not be allowed to purchase any product that is not legal.
Assessment: Immediate Action Required.
Reason: Application records for restricted use pesticides are required by law.

Scenario 2: You observe that a container of sprout inhibitor has spilled in the potato storage area. The operation has not taken any action because it has just been noticed. The operation immediately takes corrective action (following its Spill Procedure SOP) to clean the area according to label directions and removing potentially affected product.
Assessment: Compliant
Reason: The operation has a procedure and is following it.

Requirement	**F-2.1.a. Agricultural chemical records include the target organism(s) and justification for application.**
Procedure	**The name of the pest(s), disease(s) and/or weed(s) treated and justification for the application is documented in all agricultural chemical application records.**
Verification	**Auditors shall verify the operation's records for agricultural chemicals used for target organism(s) and justification for application.**
Corrective Action	**Operation will keep agricultural chemical records which include the target organism(s) and justification for application.**
Documents Required	**Record.**
Mandatory	

Expectation
Auditor reviews operation's chemical application records for the target organism(s), name of pest(s), disease(s) and or weed(s) and compares the application of chemical to the approved chemical product label to verify that the chemical is approved for application of product to the target organism(s). All chemical labels are required to show approval-for-use on target organisms. Chemical labels and/or records may be accessed by computer. In addition, auditors should make themselves aware of their State's chemical application regulations.

Requirements F-2.1.a and F-2.1.b (see next requirement) have similar record-keeping requirements, however auditors should be aware that it is not necessary for the operation to maintain records for compliance to these requirements on the same form or in the same location. The example scenario that follows demonstrates a particular situation where both requirements are located as part of the same record. Auditors should assess each requirement independently for compliance.

Example Scenario
Scenario: Auditor is reviewing operation's chemical application records for a chemical used for control of the Strawberry Clipper. Auditor then reviews the chemical label to verify that Strawberry Clipper is listed as a target organism.
Assessment: Compliant.
Reason: Strawberry Clipper is listed on the chemical label as a target pest.

Requirement	**F-2.1.b Records of post-harvest biocides, waxes and plant protection products include the identity of the harvested crop, location, application dates, treatment, product name, and dose rate.**
Procedure	**Records of agricultural chemical applications shall be available and include: crop type and/or variety, location, application date, dose rate (a.i./ha), application rate (l/ha), product trade name, active ingredient and method of application.**
Verification	**Auditors shall verify that records for post-harvest biocides, waxes and plant protection products include the harvested crop, location, application dates, treatment, product name, and dose rate.**
Corrective Action	**Operation shall include the harvested crop, location, application dates, treatment, product name, and dose rate of post-harvest biocides, waxes and plant protection products in their records.**
Documents Required	**Record.**
Mandatory	

Expectation
Auditor reviews operation's chemical application records to ensure products include the identity of the harvested crop, crop location, application dates, treatment method and type, name of product, and dose rate applied. Auditor shall review product label to verify that the chemical is approved for application as stated in this requirement. All chemical labels are required to show active ingredients, target organism, acceptable uses, application rates, acceptable application methods, and instructions. Chemical labels and/or records may be accessed by computer.

Example Scenarios
Scenario: Auditor reviews the chemical label and the operation's record-keeping for use of the chemical against Strawberry Clipper, a weevil that causes damage to the buds of strawberries.
Assessment: Compliant.
Reason: The operation's records for this chemical and its application include the harvested crop, location of crop, date of application, rate of application, and method of application.

Requirement	F-2.1.c. Use of biological controls shall comply with label directions and prevailing regulation.
Procedure	Only biological controls which are authorized for the cultivation of the specific crop will be used. Any biological control will be used according to the manufacturer's direction.
Verification	Auditor reviews biological controls use records for evidence of compliance with approved uses or label directions.
Corrective Action	Operation develops and maintains biological controls use records and maintains evidence of proper use of each biological control. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Record.
Mandatory	

Expectation
Biological control is the intentional introduction of insects or other organisms into an agricultural operation with the specific intention to control a specific pest. Some types of biological controls include a natural enemy of the target pest, a pathogen or parasite to attack the target pest, and a competitor of the target pest (which can outperform the target pest and reduce its ability to thrive). It is important for an operation to consider any restrictions for introducing biological controls and to be aware that using pests/pathogens/parasites as biological controls may have unintended consequences.

Example Scenario
Scenario: The auditee introduces spotted lady beetles into their potato fields to control the population of Colorado potato beetles. No records are kept since "spotted lady beetles are naturally occurring".
Assessment: Corrective Action Needed
Reason: Records of biological controls must be kept so that it can be determined whether they are being used according to both the directions and any regulations for application.

Requirement	F-2.1.d. Operation keeps records of agricultural chemical applications used on nursery stock, transplants and other propagation material produced on site.
Procedure	Records shall be available of the use of agricultural chemicals on propagation materials.
Verification	Auditor shall verify operation's records of agricultural chemical applications on propagation materials.
Corrective Action	Operation keeps complete records of agricultural chemical applications on propagation materials.
Documents Required	Record.
Mandatory	

Expectation
(In addition to Requirement F-2.1):
If an operation produces propagation materials, they must keep and maintain records of agricultural chemical applications. If an operation brings in propagation materials, this requirement will be assessed as N/A.

Example Scenarios
Scenario 1: All nursery stock is purchased from a third-party supplier. No agricultural chemical records or letter of guarantee was provided by the third-party supplier.
Assessment: Not Applicable
Reason: Nursery stock is not produced on site and therefore is not applicable for this question, however, should be covered in the approved supplier program

Scenario 2 Transplants are produced in the greenhouse on site. Chemical records are available.
Assessment: Compliant
Reason: Necessary records are available.

Requirement	**F-2.2. If product is intended for export, agricultural chemical use, including post-harvest chemicals, shall consider requirements in the intended country of destination.**
Procedure	**The operation shall have procedures, such as pre-harvest interval and application rate sufficient to meet the MRL entry requirements of the country(ies) in which the product is intended to be traded, if known during production.**
Verification	**Auditor reviews operation's procedure for complying with agricultural chemical restrictions in countries of destination. If the country of destination is unknown during production, this item is not applicable.**
Corrective Action	**Operation develops procedures, and diverts non-compliant product to a market in which the product meets standards.**
Documents Required	**N/A.**
Mandatory	

Expectation
If the country of intended export is known, review the operation's procedure for complying with agricultural restrictions in countries of destination. Review records of chemical use to verify compliance with the destination country's requirements, as presented by the auditee.

This question may be answered N/A if the country of destination is unknown during production.

Example Scenarios
Scenario 1: The operation has evidence of training about Maximum Residue Levels (MRLs). Chemical application records from growers which include Pre-Harvest Interval (PHI) and rates

appropriate for sale in the U.S. are maintained. The operation sells to brokers and does not know country of destination for product.
Assessment: Not Applicable.
Reason: The operation does not know the country of destination.

Scenario 2: The operation has not adjusted application rates or PHI for country of destination, which is known and has a lower MRL than U.S. This operation does not do residue testing and has no information to demonstrate that rates and PHI will or will not meet MRL of country of destination.
Assessment: Corrective Action Needed.
Reason: The operation has not considered the requirements for the country of destination.

Requirement	**F-2.3. Agricultural chemicals shall be applied, by trained, licensed or certified application personnel, as required by prevailing regulation.**
Procedure	**Operation maintains records demonstrating that all personnel responsible for chemical applications are trained and/or licensed, or supervised by licensed personnel, in compliance with prevailing regulation.**
Verification	**Auditor reviews records demonstrating that application personnel are licensed and/or trained in compliance with prevailing regulation.**
Corrective Action	**Operation utilizes application personnel who are appropriately licensed and/or trained.**
Documents Required	**Record.**
Mandatory	

Expectation
Applicators who hold current State licenses will meet the requirements of this question. However, if there are no restricted use materials being used which require the auditee to hold a pesticide license, auditors must review training documents to verify that the applicators have received training on the proper use of the materials. The comment should include the applicator and/or personnel name, license number and expiration date.

Records demonstrating that application personnel are licensed and/or trained in compliance with prevailing regulations may include:

- Current copies of private pesticide handler license for each employee applying chemicals
- Training records of employees applying agricultural chemicals
- Letter from subcontractor stating that all applicators/ handlers are licensed if letter provides evidence that specific applicators/handlers were licensed at the time of application.

Example Scenarios

Scenario 1: The operation does not have copies of the employees' licenses onsite but can access records, stating that records are maintained online by The Department of Agriculture.
Assessment: Compliant
Reason: The records are accessible for auditor review.

Scenario 2: Operation has record of annually providing pesticide application and handling training to employees. Auditor is aware that prevailing regulation requires that operator must be licensed.
Assessment: Corrective Action Needed
Reason: The standard requires application personnel to be licensed and/or trained in compliance with prevailing regulation.

Requirement	**F-2.3.a. Operator demonstrates knowledge of preparing and calculating agricultural chemical mixes.**
Procedure	**The responsible person must be able to calculate and prepare the required application mix according to the label instructions and to prevent over or under application.**
Verification	**Auditors shall verify agricultural chemical mixes are calculated properly. Responsible person(s) for applying agricultural chemicals should be interviewed.**
Corrective Action	**Retraining of responsible persons may be needed.**
Documents Required	**N/A.**
Mandatory	

Expectation
The auditor can determine if the operator preparing and calculating agricultural chemical mixes is knowledgeable through observation of the operator preparing the chemical mix, interviewing the operator, or reviewing training and application records to make an assessment of compliance. Auditors should keep in mind that this requirement has no record requirement, however an auditee could provide mix records if available. If mix records are not available, auditors should interview the operator about how mixes are prepared, then review labels to ensure that chemical mixing and preparation complies with label directions. If an outside chemical applicator is used, the auditor should review the letter of guarantee or the spray records.

Example Scenarios
Scenario 1 Operator is not available to be interviewed, but the operation provides mix records to demonstrate how chemicals were prepared. Mix records comply with label directions.
Assessment: Compliant
Reason: The mix records were able to show that chemicals were mixed in compliance with label directions.

Scenario 2: Chemicals are mixed off-site by a chemical application company. No records are available.

Assessment: Corrective Action Needed
Reason: CAN, if no additional documentation is available. If a letter of guarantee and commercial applicator's licenses are on file would be assessed as Compliant.

Requirement	**F-2.4. Water used with agricultural chemicals shall not be a potential source of product or field contamination.**
Procedure	**Water used to dilute or deliver agricultural chemicals shall be from a source in compliance with the Water System Risk Assessment and Water Management Plan, consistent with current industry practices or regulatory requirements for that commodity.**
Verification	**Auditor reviews the Water System Risk Assessment for evidence that water used with agricultural chemicals has been considered, and that agricultural chemical use policies are in compliance with the Water System Risk Assessment.**
Corrective Action	**Operation revises the Water System Risk Assessment. Operation uses a water source in compliance with the Water System Risk Assessment. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**Record.**
Mandatory	
PSR	**112.41**

Expectation
All water used with agricultural chemicals must be of known quality, must be of appropriate microbial quality for its use. The water source used for chemical applications must be included in the Water System Risk Assessment and Water Management Plan. Not all chemical applications require the use of potable water, however, the water must be of microbial quality appropriate for its intended use.

For more information on the Water System Risk Assessment and Water Management Plan see requirements and guidance in sections F-4.1 and F-5.1 of this manual.

The auditor will include water source used for agricultural chemical sprays in the comments. If applicable, include mitigation methods.

Example Scenario
Scenario: Operation utilizes an industry-specific Water Risk Assessment addressing all possible water sources: holding pond, open canal, direct pump from river, and closed system from mountain reservoir. Operation uses direct pump from river and records indicate they are in compliance with industry recommendations.
Assessment: Compliant
Reason: Compliant for this audit requirement. If auditor has reason to believe the Water Risk Assessment is not accurate, that would be reflected in audit item F-4.1.

Produce Safety Rule
112.41: All agricultural water must be safe and of adequate sanitary quality for its intended use.

Requirement	F-2.4.a. Equipment used to apply agricultural chemicals shall be kept in good condition and verified annually to ensure accurate application.
Procedure	The agricultural chemical application machinery has been verified for correct operation within the last 12 months and this is certified or documented either by participation in an official scheme (where it exists) or by having been carried out by appropriately trained and/or licensed (where required) personnel.
Verification	Auditors shall verify the operations records have been maintained within the last 12 months to ensure accurate application of agricultural chemicals. Observation should be made that application equipment is in good condition if maintained by the operation.
Corrective Action	Equipment used for application of agricultural chemicals will be brought to a level of good condition and records of its annual maintenance will be maintained by the operation.
Documents Required	Record.
Mandatory	

Expectation
Auditor conducts a visual inspection on chemical application equipment to ensure that chemical application equipment is in good condition. Auditor reviews yearly calibration records for chemical application equipment. It is not uncommon for an operation to calibrate their equipment multiple times during the season. Calibration needs to be carried out by properly trained or licensed personnel. Records need to be maintained for calibration. Auditors should keep in mind that chemicals may be applied during different farm activities, such as product going into storage and/or products being packed. Equipment must be cleaned and maintained so as not to be a source of contamination. In addition, equipment used to apply agricultural chemicals should be included on the operation's equipment list.

Example Scenarios
Scenario 1: Sprayer is rented by the operation on an annual basis. The rental contract states that equipment is calibrated annually.
Assessment: Compliant
Reason: The contract is their record. Could be assessed as Corrective Action Needed if auditor observes that the equipment is not in good condition or being properly maintained. Best practice would include the last date of calibration.

Scenario 2: Applicator is calibrated annually onsite by a trained employee, but records of calibration are not available.
Assessment: Corrective Action Needed
Reason: The standard requires a record be kept of verification activities such as calibration.

Scenario 3: While auditing a potato farm, inspector notices a spray arm going across a conveyor that is unloading fresh dug product from a farm truck into a storage facility. Auditor questions the farm's representative about the chemical being applied and the calibration records for the equipment used. Representative can only produce documentation for ratio of water to chemical applied.
Assessment: Corrective Action Needed
Reason: All chemical applying equipment needs to be calibrated and recorded.

Requirement	**F-2.5. Agricultural chemical disposal shall not be a source of product or field contamination.**
Procedure	**Operation shall have procedures for disposal of waste agricultural chemicals and for cleaning of application equipment that protects against contamination of product and growing areas.**
Verification	**Auditor observes chemical handling records for evidence of compliance.**
Corrective Action	**Operation develops and implements procedures. Steps are taken to mitigate any contamination events.**
Documents Required	**Record.**
Mandatory	

Expectation
Review chemical handling records for evidence of compliance. Additionally, observe how chemicals and containers for disposal are being stored by the operation to verify that this is in compliance with the operation's Food Safety Plan and applicable regulations. Chemical container disposal methods should comply with what is required by the chemical label. Examples of disposal statements found on various types of pesticide containers include:

- **Metal containers (non-aerosol):**
  Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of container in a sanitary landfill, or by other procedures approved by state and local authorities.

- **Paper and plastic bags:**
  Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

- **Glass containers:**
  Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

- **Fiber drums with liners:**
  Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary

landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

- **Plastic containers:**
  Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

- **Compressed gas cylinders:**
  Return empty cylinder for reuse (or similar wording).

Example Scenarios
Scenario 1: Operation has lockable, designated area for empty/used agricultural chemical containers and participates in a semi-annual recycling program. However, operation does not have a written procedure.
Assessment: Compliant
Reason: The standard does not require procedures to be written.

Scenario 2: The operation applies excess chemical to dirt road adjacent to production area.
Assessment: Corrective Action Needed
Reason: CAN unless prevailing regulation and manufacturer expressly permit it.

Requirement	**F-2.5.a. Agricultural chemicals approved for use on the crops being grown are stored separately from agricultural chemicals used for other purposes.**
Procedure	**Only the agricultural chemicals currently in the approved agricultural chemicals list are kept in the storage area. Agricultural chemicals used for purposes other than application on crops within the rotation for the last 12 months are clearly identified and stored separately within the plant protection products storage area.**
Verification	**Auditors shall verify that only chemicals approved for use on crops being grown by the operation are stored in a designated storage area.**
Corrective Action	**Operation will establish a designated storage for approved agricultural chemicals for use on the crops being grown separated from agricultural chemicals used for other purposes.**
Documents Required	**Record**
Mandatory	

Expectation
Containment of hazardous materials is required for the protection of the environment from contamination as well as for the protection of employees who work in areas where hazardous materials are stored and used. Auditor inspects storage of agriculture chemicals used on crops to ensure that other types of agriculture chemicals are stored separately. Auditors should be familiar with their state's regulation for chemical storage. "Separately", as stated in this requirement, does

not necessarily mean in another location or different storage area. The primary requirement is that an operation must have approved and non-approved agricultural chemicals in designated areas. An operation's employees must know where the chemicals are to be stored and auditors must verify compliance by interviewing employees who are responsible for chemical storage. This requirement is intended to prevent unintended use of non-approved chemicals.

Example Scenarios
Scenario 1: Chemicals, including both those approved for use in food production and those not approved for produce use, are stored in one chemical storage shed, comingled on shelves. Auditee states that employees are trained on which ones are to be used in produce activities and which ones are not.
Assessment: Corrective Action Needed
Reason: Chemicals approved for use on crops being grown by the operation must be stored separately from chemicals used for other purposes.

Scenario 2: Chemicals, including both those approved for use in food production and chemicals used for other purposes are stored in one chemical storage shed. Approved chemicals are stored on the north side of the shed, non-approved chemicals are stored on the south side of the shed. Auditor verifies chemical locations and that employees have been trained on storage locations.
Assessment: Compliant
Reason: The chemicals are stored in different areas of the chemical shed and can be considered separate, if it allows employees to differentiate between approved and non-approved chemicals.

F-3 Water System Description

Requirement	**F-3.1. A water system description shall be available for review.**
Procedure	**Water sources and the production blocks they may serve shall be documented and current. The description shall include one or more of the following: maps, photographs, drawings (hand drawings are acceptable) or other means to communicate the location of water source(s), permanent fixtures and the flow of the water system (including holding systems, reservoirs or any water captured for reuse). Permanent fixtures include wells, gates, reservoirs, valves, returns and other above ground features that make up a complete irrigation system shall be documented in such a manner as to enable location in the field or in hydroponic, aeroponic or aquaponics operations.**
Verification	**Auditor reviews water system description or map, and verifies accuracy during inspection.**
Corrective Action	**Operation develops or corrects the water system description or map.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation

Water system descriptions must describe the sources and distribution of water in an operation. All water sources and distribution systems used by the operation for farming need to be documented. Water system descriptions may include maps, photographs, drawings, written descriptions, etc. Verify that the operation has a written water system description and the completeness and accuracy of the water system description in the process of the farm review.

Example Scenarios
Scenario 1: The operation has a Google Earth map of the fields with well and permanent fixture locations marked in pen.
Assessment: Compliant
Reason: As long as the map is accurate and there are no omissions this would be compliant.

Scenario 2: The water system description does not include an onsite pond. Operation says that the pond is not used for irrigation but may be used to dilute agricultural chemicals or wash out chemical containers.
Assessment: Corrective Action Needed or Immediate Action Required
Reason: The water used for other agricultural purposes are part of the water system. IAR - If the source of water may reasonably lead to product contamination.

Scenario 3: Operation has no written description, but only has one well.
Assessment: Corrective Action Needed
Reason: Standard requires that all "water system descriptions must be available for review", even simple systems should be documented.

Requirement	**F-3.2. The water source shall be in compliance with prevailing regulations.**
Procedure	**Water shall be sourced from a location and in a manner that is compliant with prevailing regulations.**
Verification	**Auditor determines whether the water source is compliant with regulations relevant for the intended use of the water.**
Corrective Action	**Operation discontinues use of the source until compliant with regulations. Affected produce is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	

Expectation
The water source (municipal, well, or surface water) must be in compliance with prevailing regulations. The auditor should be familiar with what source water is being used and any applicable local and state regulations for that water source. Often for wells and surface water there are local regulations for water use. This may include how much water may be used, i.e. if a permit is needed to pull water from a canal or stream.

Example Scenario

Scenario: Operation is sourcing irrigation water from a trout stream onsite. The operation states there are no local regulations regarding using the stream for irrigation.
Assessment: Compliant
Reason: Unless the auditor is aware of contradictory information this is compliant with prevailing regulations.

Requirement	F-3.3. Water systems shall not be cross-connected with human or animal waste systems.
Procedure	Water systems intended to convey untreated human or animal waste shall be separated from conveyances utilized to deliver water.
Verification	Auditor reviews water system for cross-connections with human or animal waste conveyances.
Corrective Action	Operation discontinues use of the system until they are separated.
Documents Required	N/A.
Mandatory	●
PSR	112.133(d)

Expectation
A cross-connection is any place in the water system where a water line may be connected with piping that may carry other liquids. These may include fertilizer, human waste, animal waste, etc. The standard specifies that no cross-connections with human or animal waste conveyances may be present. If cross-connections with human or animal waste conveyances are observed, then Immediate Action will be required.

Example Scenario
Scenario: Irrigation system is cross-connected to a system that distributes liquefied dairy manure to an adjacent grain field. System uses a gate valve to prevent dairy manure from cross-contaminating the irrigation water.
Assessment: Immediate Action Required
Reason: The standard requires that "Water systems intended to convey untreated human or animal waste shall be separated from conveyances utilized to deliver agricultural water".

Produce Safety Rule
112.133(d): Plumbing must be adequately installed and maintained to not allow backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for harvesting, packing or holding activities, for sanitary operations, or for use in hand-washing facilities.

F-4 Water System Risk Assessment

Water use in crop production involves numerous field operations including irrigation, applications of pesticides and fertilizers, cooling, and frost control. Inadequate water quality has the potential to be a direct source of contamination and a vehicle for spreading localized contamination in the field,

facility, or transportation environments. Wherever water comes in contact with fresh produce, its quality dictates the potential for pathogen contamination. If pathogens survive on the produce, they may cause food borne illness.

Water can be a carrier of many microorganisms including pathogenic strains of *Escherichia coli*, *Salmonella* spp., *Vibrio cholerae*, *Shigella* spp., *Cryptosporidium parvum*, *Giardia lamblia*, *Cyclospora cayetanensis*, *Toxiplasma gondii*, and the Norwalk and Hepatitis A viruses. Even small amounts of contamination with some of these organisms can result in food borne illness.

The quality of water, how and when it is used, and the characteristics of the crop influence the potential for water to contaminate produce. In general, the quality of water in direct contact with the harvestable portion of produce may need to be of better quality compared to uses where there is minimal contact. Other factors that influence the potential for contact with waterborne pathogens, and their likelihood of causing food borne illness, include the condition and type of crop, the amount of time between contact and harvest, and post-harvest handling practices.

Produce that has a large surface area (such as leafy vegetables) and those with topographical features (such as rough surfaces) which foster attachment or entrapment may be at greater risk from pathogens, if they are present, especially if contact occurs close to harvest or during post-harvest handling. Some sectors of the produce industry use water containing antimicrobial chemicals to maintain water quality or minimize surface contamination.

Water usage on the farm includes irrigation and chemical applications of the product. Consider the water source and usage when assessing the following requirements.

USDA AMS requires that growers incorporate testing into their water management plan.

Since finalizing the Produce Safety Rule, FDA has received feedback that some of the standards in subpart E need further scientific research. In response to these concerns, FDA is reviewing subpart E which has delayed its implementation. Further guidance will be provided in the future once Subpart E is finalized and regulatory implementation begins.

Requirement	**F-4.1. An initial risk assessment shall be performed and documented that takes into consideration the historical testing results of the water source, the characteristics of the crop, the stage of the crop, and the method of application.**
Procedure	**A review or new assessment shall be conducted seasonally and any time there is a change made to the system or a situation occurs that could introduce an opportunity to contaminate the system. The risk assessment shall address potential physical, chemical, and biological hazards and hazard control procedures for the water distribution system.**
Verification	**Auditor reviews the risk assessment for completeness of consideration of potential hazards.**
Corrective Action	**Operation develops or updates the risk assessment.**
Documents Required	**Risk Assessment.**
Mandatory	●

Expectation
A water risk assessment should take into consideration the source water quality, method of delivery, and timing of delivery. Municipal water sources are viewed as the least likely to be contaminated. Surface water has the highest risk of contamination. If surface water is being used from a source which is not contained within the operation's boundaries (e.g., river, stream) the operation should make every effort to be aware of upstream activities and identify potential sources of contamination.

Farming operations must have knowledge of the quality of their water source in order to determine whether or not the product could become contaminated. Sources such as wells should be in good condition and properly capped and elevated. Land should be sloped away from the wellhead to prevent runoff contamination into the well. Backflow prevention devices should be installed. Sources such as surface irrigation should be assessed for possible contamination from raw human and animal wastes, sewage water discharges, contamination from adjacent land and contamination from wildlife presence or manure runoff.

Application methods include irrigation (overhead-sprinkler, flood-surface, furrow, drip-trickle, humidifiers, humidicelles, etc.), frost protection, and agricultural chemical application. Drip irrigation methods or those where the water does not touch the crop are less likely to promote potential contamination than flood irrigation methods. Irrigation with sprinkler methods, or chemical application where the water sprinkles or drenches the crop can have higher risk for causing contamination, especially if the water quality is unknown.

The timing in the crop cycle when water is applied should be addressed in the assessment of risk. Water applied weeks before harvest poses less risk than water applied to the edible portion of the crop near harvest. It is never the intent that potable or microbially safe water should be used in

every water application on the farm. Chemical applications or irrigation that occur prior to the crop being planted or if the crop is dormant (such as tree fruit) does not require potable water. However, chemical or irrigation applications that occur just prior to the crop being harvested must use microbially safe water.

Review the operation's risk assessment to verify that potential physical, chemical and biological hazards and hazard control procedures have been addressed to take into account the historical testing results of the water source, the characteristics of the crop, the stage of the crop, and the method of application. Include the date and the role/title of the person who conducted the last assessment in the comments.

Example Scenario
Scenario: A row crop operation is sourcing irrigation water from an open pond onsite. The operation has no testing data but claims there are no risks because their children swim in it.
Assessment: Corrective Action Needed
Reason: The operation must have a credible risk assessment.

F-5 Water Management Plan

Requirement	**F-5.1. There shall be a water management plan to mitigate risks associated with the water system on an ongoing basis.**
Procedure	**The water management plan shall include the following: preventive controls, monitoring and verification procedures, corrective actions, and documentation. The plan shall be reviewed following any changes made to the water system risk assessment and adjusted accordingly to incorporate such changes. Training and/or retraining of personnel having oversight or performance duties shall be documented.**
Verification	**Auditor reviews the water management plan for accuracy and completeness relative to the risk assessment.**
Corrective Action	**Operation develops or updates water management plan.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
All operations must have a written water management plan. The management plan must include preventative controls, monitoring and verification procedures, corrective actions, and documentation. The standard does not specify the frequency of a plan review; however, the plan must be reviewed whenever changes in risk assessment occur. The operation must train personnel in a manner consistent with the water management plan.

USDA AMS requires that growers incorporate testing into their water management plan.

The USDA GAP program believes that it is important to know the quality of water that is being used in on your operation even if it is unlikely to contact the edible portion of the crop. It is a requirement for all USDA GAP audits that water testing be performed (or water authority documentation provided) on all water used in the operation.

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. While the standard does not set a numerical threshold that water tests should meet, it is expected that the auditee establishes criteria for their water source based on industry standards/prevailing regulations/historical testing for when the source is at a normal level of risk versus when there may be elevated risk of contamination based on high numbers of indicator organisms. The minimum testing frequency is as follows, unless otherwise justified in the water risk assessment:

- **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.

Corrective actions, including what to do in the event a water test exceeds maximum threshold levels, must be established in the water management plan. Having corrective actions pre-established allows an auditee to take quick and decisive action if water tests results are above allowable levels.

Example Scenario
Scenario: Hydroponic greenhouse operation pulls its water from both well and municipal sources. In addition, it recycles water from the greenhouse operation, which it treats using a validated UV filtration system. The operation tests the well and municipal water but does not test the recycled water after it is UV treated.
Assessment: Compliant.
Reason: The requirement intends to ensure that operations have management plans for water and incorporate policies and procedures according to their own risk assessment. Provided the Auditor's review of the water management plan demonstrated completeness relative to the risk assessment,

this scenario is compliant. There are no specific requirements of F-5.1 requiring the operation to test the water after treatment.

Requirement	F-5.2. Water testing shall be part of the water management plan, as directed by the water risk assessment and current industry standards or prevailing regulations for the commodities being grown.
Procedure	As required, there shall be a written procedure for water testing during the production and harvest season, which includes frequency of sampling, who is taking the samples, where sample is taken, how the sample is collected, type of test and acceptance criteria. If all water is sourced from a municipal source, the municipal testing is sufficient. The frequency of testing and point of water sampling shall be determined based on the risk assessment and current industry standards or prevailing regulations for commodities being produced.
Verification	Auditor verifies that a water testing program is in compliance with the risk assessment and current industry standards or prevailing regulations and is included in the water management plan.
Corrective Action	Operation develops a testing program consistent with risks identified in the risk assessment and with current industry standards or prevailing regulations for the commodities being grown.
Documents Required	Written Policy.
Mandatory	●

Expectation
It is important for auditors to be familiar with the regulatory requirements and industry standards that are applicable to the operation being audited. A list of industry guidance recognized by the FDA can be located in Appendix IV of this manual.

The FDA has currently extended the compliance dates for Subpart E (Agricultural Water) of the FSMA Produce Safety Rule, therefore we do not consider the water testing requirements as prevailing regulations and are not requiring that auditees adhere to them. When the FDA clarifies their water testing standards and sets enforcement dates these will be considered prevailing regulations for all covered farms/commodities, and therefore will be required as part of the water management plan for all covered Harmonized and Harmonized GAP Plus+ auditees.

A water management plan must be written and must include the frequency of sampling, who takes samples, where samples are taken, how the sample is collected, the type of test, and the acceptance criteria for the test. The auditor's comment on the report should include the water test dates and/or results for field operations.

Water samples should be taken from a location which most accurately represents the water which will be used on the specialty crop. For example, a grower who pumps irrigation water out of a river should collect their water sample as close as possible to the intake pipe in the river. If an auditee uses equipment which may reduce risk (e.g., a filter) or introduce risk (e.g., old pipes, or pipes with

dead legs) the auditee may wish to take their water sample from the end of their distribution system to capture the effects that the system has on the water quality. This should be reflected in their risk assessment and water testing procedure.

If a water test can be taken from a location which represents the water used by two different operations, then yes both farmers can use the same water test(s), but both auditees will be expected to have copies of the test results in their own Food Safety Plans. However, if there are significantly different risks in the source where it is pulled by each grower then they will each need to take their own water tests.

Examples

- Two growers pull irrigation water from the same pond which straddles their property line. Each grower has their own pump with intake pipes floated towards the center of the pond. These growers could pull a representative sample from the middle of their pond and share the test results.

- Two growers each pull irrigation water from the same stream. There are two farms separating the growers who also have access to the stream including a cattle farm. In this case the growers would each need to collect their own water samples as the risk to the water source may change as it moves through the other farms.

The auditor will include frequency of testing and threshold criteria for water test results in the comments.

Requirement	**F-5.3. The testing program shall be implemented consistent with the water management plan.**
Procedure	**Testing shall be performed and documented according to procedures described in the water management plan.**
Verification	**Auditor reviews testing records for compliance with the written plan.**
Corrective Action	**Operation shall revise testing to be in compliance with the written plan. The corrective actions noted in the water management plan shall be followed until the conditions have been mitigated and the non-conformity has been resolved.**
Documents Required	**Record.**
Mandatory	●

Expectation

Verify that the water testing program is implemented consistent with the written water management plan. Sampling must be consistent with protocol used for collecting samples for microbiological testing (see requirement F-5.2). Also, verify the operation's testing frequency and sampling frequency.

If an auditee sources potable water from a local water authority (municipality, county, etc.) they must provide a copy of the most recent annual water report, or other documentation showing that the water is being monitored for potential contamination by the local authority. This documentation is often available on the water authority's website or by contacting them directly.

The auditor will include the water test dates, water application method (i.e., drip, overhead, furrow) and source (i.e., well, surface, municipal) in the comments and also include target organism and present/absent or quantified number from most recent water test results.

Requirement	**F-5.4. If water is treated to meet microbiological criteria, the treatment is approved and effective for its intended use, and is appropriately monitored.**
Procedure	**Treatment is approved for its intended use (e.g., EPA-registered antimicrobial pesticide, or registration as required by the prevailing regulation of the country of use) and is delivered in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria. Treatment is monitored at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria.**
Verification	**Auditor verifies that water treatment is approved for its intended use, reviews documentation that it is used effectively to meet the intended microbiological criteria, and reviews monitoring records for compliance with the operation's established procedure and acceptance criteria.**
Corrective Action	**Operation discontinues use of unapproved treatments, uses approved treatments in an effective manner, and monitors the treatment at an adequate frequency.**
Documents Required	**Record.**
Mandatory	●

Expectation

For all chemicals used, including water treatment chemicals, an auditee must have access to the chemical's label. The label needs to show that the chemical has been approved for how the auditee is using it – there are different label approvals for cleaning and sanitizing food contact surfaces, for produce washing, and for treating water.

Additional documentation will be based on the sanitizer and should demonstrate that the auditee is following the label directions for what needs to be monitored. Monitoring criteria may include concentration, contact time, pH, ORP, free chlorine, water temperature, turbidity, and whether or not the product is rinsed with potable water after the use of the sanitizer.

If water is treated to meet microbiological criteria, verify that the treatment is approved for its intended use. The operation must have documentation that clearly states the uses for which the treatment is appropriate and how it is to be used effectively to meet the microbiological criteria.

If water treatment is used by the operation, the auditor should document the treatment and the parameters for monitoring the effectiveness of the treatment in the comments section of the audit report. For chemical treatments include the chemical name and EPA Registration Number.

Example Scenarios
Scenario 1: Farm irrigates with water that does not meet microbial thresholds; water is treated with Peracetic Acid (PAA). PAA is not recognized by EPA to treat irrigation water.
Assessment: Corrective Action Needed
Reason: Not necessarily a food safety risk, but the label is the law, and it's not approved for irrigation water. The label may permit use for cleaning or to control algae.

Scenario 2: The water treatment records are incomplete with missing periods of time, as long as 7 days. Current operation at the time of the audit is acceptable but treatment records do not support consistent acceptable treatment.
Assessment: Corrective Action Needed
Reason: Treatment must be monitored at an adequate frequency so records should not be incomplete.

Requirement	**F-5.5. If post-harvest handling is used to achieve microbial criteria, operation has documentation supporting its use**
Procedure	**If die-off or removal rates or other methods (e.g., commercial washing) are used to achieve microbial criteria of water used during growing, operation has scientific data or information used to support its effectiveness. Documentation includes the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing.**
Verification	**Auditor verifies documentation for completeness.**
Corrective Action	**Operation obtains documentation on, or discontinues use of, unsupported methods, uses approved methods in an effective manner, and maintains required documentation.**
Documents Required	**Record.**
Mandatory	**●**

Expectation
While water treatment is a common way to meet microbial criteria for water used in agriculture, there are also other methods, and the science and accepted methods may change over time, such as an alternative microbial die off rate being used in combination with water test results for cured

onions. If an operation is using post-harvest handling methods to meet microbial standards, they must have documentation and/or scientific data to show that it is effective. Verify records to see that the operation is putting their documented methods into practice appropriately.

Requirement	F-5.6. If Operation uses an alternative approach to regulatory microbiological testing, Operation has scientific data or information to support the alternative.
Procedure	If operation uses an alternative testing method, frequency or criteria to regulatory requirements, operation has documentation supporting the alternative.
Verification	Auditor verifies documentation for completeness.
Corrective Action	Operation obtains documentation on, or discontinues use of, the alternative.
Documents Required	Record.
Mandatory	●

Expectation
An operation may use a different method, frequency or criteria for water testing than the regulatory requirement states. If so, they need to have documentation supporting the use of those alternative methods. Where regulatory microbial testing for water is absent, this question shall be assessed as N/A due to the fact that there is no valid baseline from which to deviate.

If post-harvest handling is used, include the die-off or removal rate, time interval, log reduction and dates relevant to these activities in the comments.

F-6 Animal Control

While it is not possible to completely exclude animal life from all fresh produce production areas, many field programs include elements to protect crops from animal damage. Growers should review existing practices and conditions to assess the potential for significant amounts of uncontrolled deposits of animal feces coming into contact with crops. Good agricultural practices for minimizing hazards from livestock include but are not limited to:

- Exclusion of domesticated animals from fresh produce fields, vineyards and orchards during the growing season. This would include pet dogs, goats, sheep, cows, horses, fowl, domesticated or feral cats, etc.

- Depending on the operation, good management practices may include keeping livestock confined (e.g., in pens or yards) or preventing their entry into fields by using physical barriers such as fences.

- Ensure that animal waste from adjacent fields or waste storage facilities does not contaminate the production area.

Growers should determine whether surrounding fields and farms are used for animal production. They may need to consider measures to ensure that animal waste from adjacent fields or waste storage facilities does not contaminate the produce production areas during heavy rains, especially if fresh produce is grown in low-lying fields or orchards. Measures might include physical barriers, such as ditches, mounds, grass/sod waterways, diversion berms, and vegetative buffer areas that prevent flowing or splashing water from contaminating crops.

High concentrations of wildlife (such as deer, wild pigs or waterfowl in a field) or domesticated animals (such as cows, sheep, horses, or fowl) may increase the potential for microbial contamination by significant or uncontrollable amounts of fecal material.

Control of wild animal populations in the field may be difficult, especially where crop production areas are adjacent to wooded areas, open meadows, and waterways.

Fencing, vegetation removal, and destruction of habitat may result in adverse impact to the environment. As always, do not make any recommendations or suggestions on how to control wildlife. You should refer the auditee to check for local, state and federal laws that protect riparian habitat, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors.

Requirement	**F-6.1. The operation has a written risk assessment on animal activity in and around the production area.**
Procedure	**There shall be a written assessment of the growing fields and adjacent land, prior to each growing season, focusing on domestic and wild animal activity including grazing and feeding operations, noting crop characteristics, type and approximate number of animals, proximity to the growing field, water sources, and other relevant factors.**
Verification	**Auditor reviews the written assessment to ensure it has been performed for this season and is complete.**
Corrective Action	**Operation performs and documents assessments.**
Documents Required	**Risk Assessment.**
Mandatory	●
PSR	**112.83**

Expectation
Verify that the operation has a written risk assessment on animal activity in and around the production area. The risk assessment must address domesticated and wild animal activity on adjacent lands, their proximity to growing fields and water sources, and other relevant factors.

Currently, there is no conclusive science to validate the exact distance needed between crop production areas and sources of potential contamination. You will need to use your best judgment and observe the presence of dairy or livestock production facilities, including feedlots (beef, swine, chickens, etc.). Concentrated feeding operations are defined by EPA and will have bare ground not

covered by vegetation. When these types of facilities are near the crop production area, factors such as topography, wooded areas, or other natural barriers must be taken into consideration when answering this question. For enclosed greenhouses the auditor should consider the type of barriers in place (grass, slope, trees, etc.).

Manure is a major source of potential contamination. Manure storage areas should be constructed to contain any potential leaching and runoff from entering the crop production areas. Where it is possible that manure lagoons from adjacent or close dairy or livestock facilities can be a possible source of contamination, operations must take some measures to prevent the contamination. Lagoons must be of sufficient construction to prevent leaking or overflowing or operations must protect the crop growing area. Measures might include physical barriers, such as ditches, mounds, grass/sod waterways, or diversion berms. In locations where the farming operation is on higher elevation ground than the lagoon, there will be little need for such barriers, as the elevation is a barrier itself.

Manure containment should also consider potential drift and distance from dried manure piles or vented air facilities, such as chicken houses to nearby production areas where wind could have the potential to spread the manure. Traffic patterns should be considered concerning vehicles traveling to and from the manure storage area which may spread human pathogens to production areas nearby through the stirring up of dust, transporting animals or the manure itself. At a minimum, pest control programs should monitor for rodents and other burrowing animals in manure storage and production areas as these animals may serve as a conduit for human pathogen spread and contamination.

In certain cases, it is possible that livestock may have access to the source of the water supply (wellhead area or pond/stream) or to the delivery system (canal/ditch). Where this is the case, operators should take measures to keep such livestock away.

The auditor will include the date and the role/title of the person who conducted the last assessment in the comments.

Example Scenario
Scenario: Row crop operation states in their food safety plan that there are no contamination risks from animal. The auditor notices one horse in the backyard of an adjacent property. The operation says that it is the only horse in the area.
Assessment: Compliant.
Reason: Compliant as long as there is a risk assessment of the horse and there are adequate barriers to prevent and detect intrusion of the horse onto the property.

Produce Safety Requirement
112.83: If there is a reasonable probability that grazing animals, working animals or animal intrusion will contaminate produce, the operation must assess the relevant areas used for growing, harvesting, packing and holding activities as needed during the growing season (based on the produce grown; the practices and conditions; and the observations and experience. If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), the operation must evaluate whether the produce can be harvested. The operation

must take all measures reasonably necessary to identity and not harvest produce that is reasonably likely to be contaminated with a known hazard and that is visibly contaminated with animal excreta.

Requirement	F-6.2. The operation routinely monitors for animal activity in and around the growing area during the growing season.
Procedure	There shall be scheduled monitoring of growing fields and adjacent land for evidence of animal activity. A frequency of monitoring and assessment shall be established based on production factors, such as the crop, geography, and other conditions.
Verification	Auditor reviews monitoring records to ensure the frequency of monitoring is consistent with the schedule.
Corrective Action	Operation develops and implements a monitoring schedule.
Documents Required	Record.
Mandatory	
PSR	112.83

Expectation
Monitoring should include a visual examination for evidence of potential contamination of covered produce by animals in the relevant areas. Examples of animal activity to consider when examining for evidence of potential contamination include the presence of significant numbers of animals, animal excreta, nests, and signs of pecking, feeding, rooting, trampling, grazing, or bedding. For example, personnel performing monitoring of partially enclosed buildings could look for bird nesting and landing areas in overhead areas, such as the rafters, eaves, powerlines and cables or roofs.

Regularly completed "notes," "scouting lists," or "crop maintenance reports" may include this information. This task does not need to be completed on a daily basis, but a regular schedule that shows the producer has an awareness of the animal populations in the production areas. This question may only be answered N/A for fully enclosed greenhouses and aeroponic growing structures.

Example Scenarios
Scenario 1: The tree crop operation has no records of monitoring for animals because their food safety plan says that there are no risks of contamination from animals.
Assessment: Corrective Action Needed
Reason: The standard requires that there "shall be scheduled monitoring of growing fields and adjacent land for evidence of animal activity".

Scenario 2: The blueberry operation has no established frequency for monitoring for animal activity in the field, but procedures require animal activity to be recorded when observed. There are three records of animal activity in the past two months.
Assessment: Corrective Action Needed
Reason: A schedule has not been established.

Scenario 3: A green pepper operation has procedures to inspect fields each morning for deer and large animal activity. There are no procedures to inspect for rodent, bird or amphibian activity.
Assessment: Compliant or Corrective Action Needed
Reason: Compliant if the risk assessment concludes, and observations support, that rodents, birds and amphibians do not pose a contamination risk. Otherwise, the risk assessment is incomplete and CAN because monitoring is insufficient.

Produce Safety Rule
112.83: If there is a reasonable probability that grazing animals, working animals or animal intrusion will contaminate produce, the operation must assess the relevant areas used for growing, harvesting, packing and holding activities as needed during the growing season (based on the produce grown; the practices and conditions; and the observations and experience. If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), the operation must evaluate whether the produce can be harvested. The operation must take all measures reasonably necessary to identity and not harvest produce that is reasonably likely to be contaminated with a known hazard and that is visibly contaminated with animal excreta.

Requirement	**F-6.3. Based on the risk assessment, there shall be measures to prevent or minimize the potential for contamination from animals, including domesticated animals used in farming operation.**
Procedure	**The operation shall have risk-appropriate actions to prevent or minimize the potential for contamination of produce with pathogens from animal feces, including from domesticated animals used in farming operations. There shall be a written record of any mitigation or corrective actions. Preventive measures and corrective actions shall comply with all local, state and federal regulations concerning animal control and natural resource conservation.**
Verification	**Auditor reviews preventive measures and corrective action plans.**
Corrective Action	**Operation develops and implements risk-appropriate corrective actions for animal intrusions reasonably likely to contaminate produce in the field.**
Documents Required	**Written Policy, Record.**
Mandatory	●
PSR	**112.81; 112.83; 112.84**

Expectation
Farming operations are never going to be able to completely exclude wild and/or domesticated animals from entering crop production areas. However, every effort should be made to limit the access to the production areas. Ideally, when there are only a few animals on adjacent land, there is a low risk of contamination. Occasional entry by normally seldom seen animals is tolerable.

When needed, measures should be taken to reduce the entry into crop production areas by wild and domesticated animals, including poultry and pets. This can be accomplished many ways, which can

include such items as noise cannons or scare balloons to scare away birds and migratory waterfowl, or fencing or other barriers to limit wildlife access.

Example Scenarios
Scenario 1: The blueberry operation has records indicating that deer are periodically observed in the fields. There are no subsequent actions recorded. The operation says that they chase the deer away when they see them.
Assessment: Corrective Action Needed
Reason: The standard requires that "there shall be written record of any mitigation or corrective actions".

Scenario 2: The operation uses horses for cultivating fields. The operation's procedures require that horses walk on a lane parallel and separate from the growing rows, and that horse feces are collected and removed from the field. Auditor does not observe any contamination within the growing rows from the horses.
Assessment: Compliant

Produce Safety Rule
112.81: Operations must take steps to minimize opportunities for wild and domestic animals, including working animals to contaminate produce. Requirements in outdoor growing areas and in partially enclosed buildings include monitoring for evidence of animal intrusion and evaluating whether a crop can be harvested. These requirements do not apply to produce grown in a fully-enclosed building or to fish used in aquaculture operations. It should be understood that federal, state, or local environmental laws or policies may regulate certain species of animals, and that producers may have limited options for their control.

112.83: Operations which have a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce must assess the relevant areas used for growing, harvesting, packing or holding activity for evidence of potential contamination of produce as needed during the growing season (based on the produce; the practices and conditions; and the observations and experience); and if significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), the operation must evaluate whether the produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.

112.84: The Produce Safety Rule does not require farms to take actions that would constitute a "taking" of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531-1544); to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

<u>F-7 Soil Amendments</u>

Soil amendments are any chemical, biological, or physical material intentionally added to the soil to improve the chemical or physical condition of the soil in relation to plant growth or to improve the capacity of the soil to hold water.

Animal manure and human fecal matter represent a significant source of potential contamination. Properly treated manure or biosolids can be an effective and safe fertilizer. Untreated, improperly treated, or re-contaminated manure or biosolids used as a fertilizer, used to improve soil structure, or that enters surface or ground waters through runoff, may contain pathogens of public health significance that can contaminate produce. Crops in or near the soil are most vulnerable to pathogens that may survive in the soil. Low growing crops that may be splashed with soil during irrigation or heavy rainfall are also at risk if pathogens in manure persist in the soil. Produce where the edible portion of the crop generally does not contact soil is less at risk of contamination provided that produce that does contact the ground (e.g., windfalls) is not harvested. As with agricultural water, physical characteristics of produce that foster entrapment or attachment also affect risk.

When auditing a mushroom operation, the substrate and/or logs used to grow mushrooms must be evaluated in this section. A determination must be made whether the substrate was adequately treated through a pasteurization or other appropriate process. Refer to the Mushroom Good Agricultural Practices Program Guidelines for recommended industry practices to control potential food safety hazards in mushroom production.

Growers using manure or biosolids need to follow good agricultural practices to minimize microbial hazards. Growers also need to examine their specific growing environment to identify obvious sources of fecal matter that could be a source of contamination. The following requirements in section F-7 focus on minimizing risk of soil amendments to fresh produce.

Another type of soil amendment that may be used is green manure. The most common form of green manure is in the form of a cover crop that is grown in the crop's off-season and then incorporated by tilling into the soil in the early spring. Green manure may also come from collected lawn

trimmings or other plant waste.

Requirement	F-7.1. The food safety plan shall address soil amendment risk, preparation, use, and storage.
Procedure	If animal-based soil amendments or biosolids are used, records of composition, dates of treatment, methods utilized and application dates must be documented. Evidence of processing adequate to eliminate pathogens of human concern, such as letter of guarantee, certificate of analysis (COA) or any test results or verification data (e.g., time and temperature) demonstrating compliance with process or microbial standards, shall be documented. Such soil amendments must be produced, handled, stored, and applied in accordance with applicable federal, state, or local requirements.
Verification	Auditor reviews soil amendment records for completeness and evidence of compliance with prevailing regulations. If biosolids are used, it shall be noted.
Corrective Action	Operation discontinues use of untreated or undocumented animal-based soil amendments or biosolids. Operation develops and implements policies to obtain treatment information for all animal-based soil amendments.
Documents Required	Risk Assessment, Record.
Mandatory	●
PSR	112.52; 112.54; 112.55; 112.56; 112.60

Expectation
Soil amendments are any chemical, biological, or physical material intentionally added to the soil to improve the chemical or physical condition of the soil in relation to plant growth or to improve the capacity of the soil to hold water. Biosolids are permitted when in compliance with applicable federal, state, or local regulations; records of composition, dates of treatment, methods utilized, and application dates must be documented.

Agricultural teas are soil amendments and are considered treated if the biological materials of animal origin used to make the tea have been processed to completion by one of the approved FDA methods (see requirement F-7.2) and the water used was not surface water nor had any detectable generic *E. coli* in 100 mL water. Treated agricultural teas cannot contain any tea additives, such as molasses.

Operations must implement management plans (e.g., timing of applications, storage location, source and quality, transport, etc.) that significantly reduce the likelihood that soil amendments being used contain human pathogens. Effort must be taken to minimize the time interval between soil amendment application and time to harvest. Operations must use soil amendment application techniques that control, reduce or eliminate likely contamination of surface agricultural water and/or nearby production areas. Equipment used for soil amendment handling, preparation, distribution or applications must effectively reduce the potential for cross contamination or use an

effective means of equipment sanitation before subsequent use. Storage of soil amendments must minimize the potential for dispersion into the environment through wind-dispersion or run-off. Movement of workers and visitors between soil amendment storage and preparation areas must be controlled to prevent cross contamination to fresh produce.

For mushroom operations, every effort to prevent of cross-contamination of non-substrate materials and mushrooms with unpasteurized substrate materials must be taken. Operations must receive and store raw manure and unpasteurized substrate materials as far away as possible from receiving areas where harvest containers, packaging materials, spawn, and other sanitary supplies are received or where final product is shipped. Fill and grade areas where standing water can accumulate to permit adequate drainage. Runoff must be collected or diverted through the use of barriers such as concrete blocks, soil berms, pits, or lagoons to prevent contamination of final product, packaging materials and production areas. Substrate used in mushroom production must be prepared based on scientific principles that reduce potentially harmful microorganisms to acceptable levels. Records of documentation from suppliers of raw materials and packaging materials and/or substrate preparation records must be reviewed.

If no soil amendments are used by the auditee, this requirement may be assessed as N/A. The auditor will include the date and the role/title of the person who conducted the last assessment in the comments.

Example Scenarios
Scenario 1: The operation has no COAs for soil amendments because they do not use components of animal origin. Records of compost sources indicate that this is accurate.
Assessment: Compliant.
Reason: The standard is silent on organic soil amendments that do not contain materials of animal origin.

Scenario 2: The operation obtains its compost from the municipality, which composts lawn litter. The municipality offers no guarantees or test results for the compost. The operation does not test the compost.
Assessment: Corrective Action Needed.
Reason: Lawn litter is usually uncontrolled and can contain dead animals or animal manure. The municipality or the operation must compost the lawn litter by a validated process, or the operation must obtain test results to verify composting is adequate to destroy pathogens of human health concern.

Produce Safety Rule
The requirements of the Produce Safety Rule for soil amendments apply to biological soil amendments of animal origins (BSAAO). A BSAAO consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. BSAAOs do not contain any form of human waste.

112.52: The operation must handle, convey and store any BSAAO in a manner and location such that it does not become a potential source of contamination to produce, food contact surfaces, areas used for growing, harvesting, packing and holding activities, water sources, water distribution

systems and other soil amendments. Agricultural teas that are BSAAO may be used in water distribution systems provided that all other requirements of the rule are met. Treated and un-treated BSAAOs must be handled so that the untreated amendment does not contaminate the treated one. If the operation believes that the treated amendment has been contaminated it must be handled as if untreated.

112.54: The FSMA Produce Safety Rule establishes two treatment levels, each with an associated microbial standard. The BSAAO treatment level determines how and when growers can apply the BSAAO to produce fields. (a) A scientifically valid controlled physical process, chemical process, biological process, or a combination of processes that has been validated to satisfy the microbial standard of 112.55(a), or a scientifically valid process that meets the microbial standard in 112.55(b). Two such process are aerated static compost (maintained in aerobic conditions at a minimum of 131°F for three consecutive days, followed by adequate curing) or turned (windrow) composting (maintained in aerobic conditions at a minimum of 131°F for 15 days, with a minimum of five turnings, followed by adequate curing)

112.55: (See Appendix I Subpart F, to view the table)

112.56: The operation must apply BSAAO treated in accordance with 112.54(a) in any manner, with a minimum application interval of 0 days. The operation must apply BSAAO treated in accordance with 112.54(b) in a manner that minimizes the potential for contact with produce during and after application, with a minimum application interval of 0 days. Untreated BSAAO must be applied in a manner that does not contact produce during application and minimized the potential for contact with produce after application. The minimum application interval has not yet been set by the FDA.

112.60: Records of any treated BSAAO received from a third party, documentation (such as a Certificate of Conformance) must be kept at least annually which show the process used to treat the amendment used a scientifically valid process has been carried out with appropriate monitoring and that the BSAAO has been handled, conveyed and stored in a manner and location to minimize the risk of contamination. For operations treating their own BSAAO, records must document that process controls (for example, time, temperature and turnings) were achieved.

Requirement	**F-7.2. If a soil amendment containing raw or incompletely treated manure is used, it shall be used in a manner so as not to serve as a source of contamination of produce.**
Procedure	**If such a product is used, there shall be documentation on the composition, and time and method of application. Such use will be consistent with current industry practices or regulatory restrictions for that commodity. Untreated human waste shall not be used.**
Verification	**Auditor reviews records for any soil amendment use that may contain raw or incompletely treated manure.**
Corrective Action	**Operation discontinues use, or develops and implements policies to safely use animal-based soil amendments that may contain raw or incompletely treated manure. Produce grown without such controls are either diverted to thermal-processed products or destroyed.**
Documents Required	**Record.**
Mandatory	●
PSR	112.52; 112.53

Expectation
The following guidelines must be followed when using raw or incompletely treated manure so that it will not be a source of contamination. These include the following:

- When raw manure is applied, it is incorporated at least 2 weeks prior to planting and a minimum of 120 days prior to harvest and is not used on crops that are harvested within 120 days of planting.

- **DO NOT** harvest vegetables or fruits until 120 days after raw manure application.

- Rates, dates, and locations of manure applications must be documented.

- If it is necessary to apply manure or slurry to vegetable or fruit soil, incorporate it at least two weeks prior to planting and observe the 120-day pre-harvest interval. If the 120-day waiting period is not feasible, such as for short season crops like lettuce or leafy greens, apply only properly composted manure.

Assess whether raw manure is properly used, according to the recommendations. Review manure application records to adequately answer this question. If both raw and treated manure are used, the treated manure must be properly treated, composted, or exposed to reduce the expected levels of pathogens. Any untreated manure that is stored onsite must be stored in a way that ensures that it does not leach or runoff into adjacent crop production areas. Auditors must investigate to verify that raw manure cannot contaminate treated manure.

There are various methods used to treat manure so that it is safer as a fertilizer than raw manure. The auditee should have selected a scientifically valid process that reduces pathogens. Here are two options:

- Static composting: aerobic, minimum 131°F (55°C) for 3 days, followed by curing with proper insulation.

- Turned composting: aerobic, minimum of 131°F (55°C) for 15 days, minimum 5 turnings, followed by curing with proper insulation.

Growers may use other treatment methods if they meet the same microbial standards and provide the same public health protection as static or turned composting methods. These methods can come from published scientific literature that verifies the effectiveness of the process.

Example Scenario
Scenario: Carrot operation applies animal-based compost immediately prior to planting. They have documentation of the composition and composting procedures (consistent with current industry practices), and time and method of application.
Assessment: Compliant.
Reason: There are no industry or regulatory restrictions for carrots on application of fully composted manure.

Produce Safety Rule
112.52: The operation must handle, convey and store any BSAAO in a manner and location such that it does not become a potential source of contamination to produce, food contact surfaces, areas used for growing, harvesting, packing and holding activities, water sources, water distribution systems and other soil amendments. Agricultural teas that are BSAAO may be used in water distribution systems provided that all other requirements of the rule are met. Treated and un-treated BSAAOs must be handled so that the untreated amendment does not contaminate the treated one. If the operation believes that the treated amendment has been contaminated it must be handled as if untreated.

112.53: Operations may not use human waste for growing produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.

F-8 Vehicles, Equipment, Tools and Utensils

Transport vehicles, bulk hauling vehicles (tractors, wagons), as well as harvesting equipment, tools, utensils (knives, pruners, machetes) will be considered in section F-8.

Requirement	F-8.1. Equipment, vehicles, tools, utensils and other items or materials used in farming operations that may contact produce are identified.
Procedure	Operation maintains a list of equipment, vehicles, tools, utensils and other items or materials that may pose a risk of produce contamination during normal use.
Verification	Auditor reviews the list for completeness.
Corrective Action	Operation develops a list of equipment, vehicles, tools and utensils that may pose a risk of produce contamination during normal use.
Documents Required	Record.
Mandatory	

Expectation
The operation must maintain a current and accurate list that has identified all vehicles, equipment, tools, and utensils that may contact produce during growing, harvesting, packing and holding activities. If the equipment list is absent, incomplete, or not verified as accurate for the current year, this will be assessed as a Corrective Action Needed.

Example Scenario
Scenario: You observe that the operation's list of equipment does not include a tractor. The operation explains that the tractor does not contact produce and is not likely to pose a risk of produce contamination during normal use, so does not have to be on the list.
Assessment: Compliant.
Reason: If accurate, the operation has assessed the risk of the tractor during normal use.

Requirement	F-8.2. Equipment, vehicles, tools and utensils used in farming operations which come into contact with product are in good repair, and are not a source of contamination of produce.
Procedure	The operation shall develop, implement, and schedule repair, cleaning, sanitizing, storage and handling procedures of all food contact surfaces to reduce and control the potential for contamination. Records must include the date and method of cleaning and sanitizing equipment. As necessary for food safety, vehicles and equipment shall be properly calibrated, operated, maintained, and used as intended. Equipment traffic flow is prevented from traveling through an untreated manure area into the harvesting field. These procedures shall be documented. Product contact tools, utensils and equipment shall be made of materials that can be cleaned and sanitized. Procedures include equipment and vehicles that are in the field infrequently.
Verification	Auditor observes production and harvest vehicles, equipment, tools and utensils which may come into contact with produce for evidence of food safety risks. Auditor reviews maintenance, cleaning and sanitation records that demonstrate compliance with procedures.
Corrective Action	Operation develops maintenance, cleaning and sanitation procedures for equipment, vehicles, tools and utensils that may pose a risk for produce contamination and disposition.
Documents Required	Written Policy, Record.
Mandatory	
PSR	112.123; 112.140

Expectation
Operation must establish and keep documentation of dates and procedures for cleaning and, as appropriate, sanitizing equipment, vehicles, tools, and utensils. Auditors verify through interviewing and/or reviewing a written policy that these procedures are implemented. Auditors review records for compliance with procedures for maintenance, cleaning and sanitation of harvest vehicles, equipment, tools, and utensils which may come in contact with produce.

Equipment, vehicles, and tools should be kept as clean as possible, and cleaned on a scheduled basis to prevent contamination. Truck beds must be washed or otherwise cleaned whenever they become dirty. Ensure that transportation vehicles are clean. Dirty vehicles can contaminate produce with harmful microbes. Review equipment to verify this factor.

The auditee's food safety manual must show the schedule for cleaning and, if appropriate, sanitizing vehicles, equipment, tools, and utensils which may come in contact with produce. It is understandable that these implements are going to get dirty from constant, repeated use during the course of production or harvest and auditors should not answer this as a Corrective Action Needed just because a harvester is using a dirty knife. However, this will not be compliant if there is no documented procedure for a scheduled cleaning of the implements.

Example Scenarios
Scenario 1: A spinach harvester is on the equipment list. Records demonstrating maintenance of the harvester in the past year are missing. You observe the harvester and do not see any overt contamination risks.
Assessment: Corrective Action Needed.
Reason: Maintenance records are required.

Scenario 2: It is apparent, through visual observation of traffic flow routes, that movement of people or equipment is occurring from an area spread with raw manure to the harvesting field.
Assessment: Immediate Action Required.
Reason: Contamination from the manure is reasonably likely to have occurred.

Produce Safety Rule
112.123: The operation must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and (b) Equipment and tools must be: (1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and (2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests. (c) Seams on food contact surfaces of equipment and tools that are used must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms. (d)(1) The operation must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in growing, harvesting, packing and holding activities as frequently as reasonably necessary to protect against contamination of produce. (2) The operation must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of produce. (e) If using equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact produce, you must do so in a manner that minimizes the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards.

112.140: The operation must establish and keep documentation of the date and method of cleaning and sanitizing of equipment used in the growing, harvesting, packing and holding activities.

Requirement	**F-8.2.a. All equipment and instruments which have an effect on food safety shall be identified, adequately maintained and calibrated at a frequency sufficient to assure continuous accuracy.**
Procedure	**The operation shall have a list of equipment and instruments that have an effect on food safety (e.g. thermometers, pH meters, scales, chemical application devices). This equipment shall be adequately maintained and calibrated at a frequency sufficient to assure continuous accuracy. A record of calibration shall be maintained.**
Verification	**Auditor reviews equipment and instrument list and calibration records.**
Corrective Action	**Operation develops a list of equipment and instruments. Calibration will be performed and recorded.**
Documents Required	**Record.**
Mandatory	●
PSR	**112.124**

Expectation
Instruments or controls used by an operation to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, to control or prevent the growth of microorganisms of public health significance, must be accurate and precise as necessary and appropriate in keeping with their purpose; adequately maintained; and adequate in number for their designated uses.

Accurate means the recorded measurements represent the true value of what is being measured while precise means individual measurements are close to each other when being taken under the same conditions. Both accuracy and precision are necessary to ensure measurements are valid and reliable. The appropriate degree of accuracy and precision needed will vary depending on the nature of the instrument and its specific use.

Instruments must be maintained to ensure they are functioning properly for their intended use. They must also be sufficient in number for their intended use. Operations must maintain a list of all measuring and monitoring equipment that has an effect on food safety. Examples of equipment that may have a bearing on food safety include scales, thermometers, pH meters, chemical application/monitoring equipment, etc. For such devices, there should be a calibration and maintenance schedule and they must be calibrated following a procedure outlined by the operation. Auditors should review an operation's records of equipment and instruments which have an effect on food safety.

Produce Safety Rule
112.124: Instruments or controls used to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be accurate and precise as necessary and appropriate in keeping with their purpose, adequately maintained; and adequate in number for their designated uses.

Requirement	F-8.2.b. Calibration of equipment is traceable to a recognized standard.
Procedure	Calibration of measuring and monitoring equipment (thermometers, pH meters, scales, chemical application or monitoring devices) is performed using a recognized standard or method.
Verification	Auditor reviews the calibration procedures to determine if they follow a recognized standard or method.
Corrective Action	Operation develops calibration procedures which are traceable to a recognized standard or method.
Documents Required	Written Policy.
Mandatory	

Expectation

In the United States, many instrument and control vendors and manufacturers provide instructions and recommended frequencies for calibration procedures. The National Institute of Science and Technology (NIST) sets standards for traceable instruments or other recognized reference solutions or instruments for the United States. Other recognized standard-setting organizations include International Organization for Standardization (ISO), American National Standards Institute (ANSI) and ASTM International (formerly known as American Society for Testing and Materials). In addition to the standardization bodies listed, other recognized standards may include calibration of thermometers using ice water and calibration of a piece of equipment according to the manufacturer's instructions.

The auditor will include the recognized standards used for calibration in the comments.

(See section G-5 for more guidance).

Requirement	F-8.2.c. A cleaning and sanitation program for food contact surfaces shall be established, implemented and maintained. The program shall include measures for monitoring to verify effectiveness.
Procedure	An implemented cleaning and sanitation program shall be established, including SOPs. Procedures must include frequency, approved cleaning and sanitizing agents, and methods of cleaning and sanitizing chemical use. The SOP must justify the frequency of cleaning, demonstrate that the cleaning and sanitizing methods are effective on the surfaces that they are used on, are being used at appropriate concentrations as required by the label. Operation shall demonstrate effectiveness in minimizing the potential for cross contamination from cleaning and sanitizing. Records of sanitizer chemical concentrations shall be maintained.
Verification	Auditor reviews the cleaning and sanitation program procedures and records for inclusiveness of frequency approval and proper use of cleaning and sanitizing agents, and methods of cleaning and sanitizing agent use. Auditor reviews chemical records regarding use of approved chemicals used for cleaning and sanitizing.
Corrective Action	Operation develops and implements program procedures for cleaning and sanitation. Operation identifies chemicals approved-for-use in the cleaning and sanitation program and establishes and maintains records of all cleaning and sanitizer concentrations. Retraining of cleaning and sanitation program policies and procedures are performed and documented.
Documents Required	Written Policy, Records
Mandatory	

Expectation

The emphasis on this requirement is to verify that the cleaning methods and frequencies are appropriate and effective for the operation. The type and concentration of the cleaning agent or detergent should be selected based upon the type of soil, residue, or material targeted for removal. The recommended manufacturer instructions on use, such as physical scrubbing and contact time, as well as concentration, should be followed and records kept to document that the correct procedure was followed.

There are many methods that can be employed to determine if cleaning and sanitation are effective. Visual inspection is a longstanding method that, with a flashlight or blacklight, can provide an assessment of the equipment and surfaces for buildup of organic materials, areas that were missed or damage to equipment. Another common rapid approach used in many facilities to assess sanitary conditions after cleaning is measurement of levels of adenosine tri-phosphate (ATP) on surfaces or in rinse water (e.g., closed systems). ATP can provide an indirect overall estimation of microbial contamination and residual organic matter that may still be present to assess the cleaning effectiveness. Use of ATP swabs should be in accordance with the manufacturer's directions. Another tool is environmental monitoring for microbial organisms by swabbing designated

production areas or equipment and materials used in production. Operations may include additional environmental sampling for generic *E. coli* or total plate count (TPC) or other microbial indicators to verify sanitation.

(See requirement P-3.1.a for more information on environmental monitoring).

Example Scenario
***S*cenario 1:** No cleaning procedures are written in the Food Safety Plan. Operation uses subcontractor for nightly cleaning and sanitizing of facility.
Assessment: Corrective Action Needed
Reason: Procedures should be obtained from the subcontractor and included in the Food Safety Plan.

Scenario 2: In a visual inspection it is observed that a number of the reusable harvest bins have a buildup of organic material prior to the start of the day's production in which cleaning and sanitation have been previously completed.
Assessment: Corrective Action Needed
Reason: Based on the visual inspection, cleaning was not effectively completed.

Scenario 3: An operation has written SOPs describing the frequency, approved cleaning and sanitizing agents, and methods of cleaning and sanitizing chemical use. There are records showing the cleaning is being performed in accordance with the written SOP, however there are no procedures for ATP testing or microbiological sampling.
Assessment: Compliant
Reason: As long as the auditor does not observe dirty or soiled food contact surfaces prior to use in production and the operation is in compliance with their written SOP, they are meeting the requirement. ATP swabbing or microbiological testing is not required for compliance.

Requirement	**F-8.3. Vehicles, equipment, tools and utensils shall be controlled so as not to be a source of chemical hazard.**
Procedure	**Operation shall have a written procedure to address the spills and leaks (fuel, oil, hydraulic fluids) which might occur during equipment operation in the field.**
Verification	**Auditor observes production and harvest vehicles, equipment, tools and utensils which may come into contact with produce for evidence of food safety risks.**
Corrective Action	**Operation repairs leaks and cleans any food contact surfaces. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**Written Policy.**
Mandatory	

Expectation

Auditor reviews operation's policy to ensure policy has written procedures that address chemical hazard spills and leaks such as: fuel, oil, hydraulic fluids, and/or chemical spills. Auditors should perform a thorough visual inspection of harvest vehicles, equipment, tools and utensils that may come in contact with the product for leaks/chemical hazards that may cause food safety risks.

Example Scenarios
Scenario 1: Maintenance of a spinach harvester is performed annually, consistent with the manufacturer's recommendation. Records of maintenance are available. You observe the harvester, in season but not currently in use. There appears to be leakage of oil. The operation has no plans to repair the leak.
Assessment: Corrective Action Needed
Reason: The leak from the hose is a potential source of chemical contamination.

Scenario 2: The operation has a bone yard of vehicles, tools, and utensils. They do not appear to be included in maintenance schedules for spills and leaks.
Assessment: Not Applicable.
Reason: This audit item only applies to "spills and leaks which might occur during equipment operation in the field."

Requirement	**F-8.4. Vehicles, equipment, tools and utensils shall be controlled so as not to be a source of physical hazard.**
Procedure	**Operation has a glass and brittle plastic policy that addresses glass on production equipment and in growing area. Inspections performed in compliance with the policy shall be documented.**
Verification	**Auditor observes production and harvest vehicles, equipment, tools and utensils which may come into contact with produce for evidence of food safety risks and for compliance with the glass and brittle plastic policy.**
Corrective Action	**Operation develops policy. Retraining is performed. Source of food safety risk is mitigated.**
Documents Required	**N/A.**
Mandatory	

Expectation
Any exposed glass fixtures (including flood lights or brake/driving lights) on harvesting equipment should be protected to reduce the potential for contamination of the crop. This question is meant to cover mechanical harvesters or machinery that sits directly over the un-harvested crop. Protection can include such practices as using plastic or wire covers, or enclosed fixtures.

The standard does not require written procedures only that inspections be recorded, and equipment be in compliance with the operation's glass and brittle policy.

Workers may drink water in the field if they use a shatter-resistant plastic container. Water containers in break areas should be made of unbreakable plastic materials.

Example Scenarios
Scenario 1: You observe that items made of breakable glass or brittle plastic (e.g., drinking water containers, watches, vehicle headlights) are in use in or adjacent to growing fields.
Assessment: It depends.
Reason: You will need to determine whether the glass or plastic location is compliant with the operation's policy and if it is a potential hazard.

Scenario 2: Operation is repairing tools in the lettuce field and shards of metal are observed on the ground. The operation immediately buffers the area where the tools were being repaired.
Assessment: Compliant.
Reason: The operation is following their procedures for controlling physical hazards.

Requirement	**F-8.5. Cleaning and sanitizing procedures do not pose a risk of product contamination.**
Procedure	**Equipment cleaning and sanitizing operations shall be conducted away from the product and other equipment to reduce the potential for contamination. Water used for cleaning and sanitizing shall meet the microbial standards for drinking water.**
Verification	**Auditor reviews cleaning and sanitizing procedures for steps to prevent contamination of produce, and observes operation's evidence of compliance.**
Corrective Action	**Operation develops and implements procedures. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	

Expectation
Auditor reviews SOP's for cleaning of equipment. Equipment cleaning must use water that meets microbial standards for drinking water. Auditor evaluates where equipment cleaning and sanitizing procedures are to be done. Cleaning and sanitizing are to be implemented away from production areas. If the operation is using high pressure when cleaning, care should be taken to not spread contamination from one surface (e.g., floors, floor drains) to another, which can occur through splashing or aerosolizing.

Consideration should be taken to capture the waste water from the washing process as to minimize the potential for runoff from these locations to areas used to grow, harvest, store, cool and pack produce or food contact equipment, agricultural water sources, and agricultural water distribution systems. An operation could, for example, choose to clean harvesting bins downhill from these areas or capture the wash water in a drainage area to prevent runoff.

Example Scenarios
Scenario 1: A citrus operation is washing a large pesticide spray machine with uncontrolled surface water. The spray machine does not contact produce during normal operation, so the

operation says that the water that is used to clean the machine does not pose a risk for product contamination.
Assessment: Compliant.
Reason: If accurate, the equipment does not have a food contact surface.

Scenario 2: A blueberry operation is washing a harvester with uncontrolled surface water. The harvester has surfaces that contact produce during normal operation.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: Corrective Action Needed - if the source of water used to wash food contact surfaces or its treatment must be changed to bring it into compliance with the microbial standards for drinking water. Immediate Action Required - if produce may have become contaminated.

Requirement	**F-8.6. Water tanks are cleaned at a sufficient frequency so as not to be a source of contamination.**
Procedure	**There shall be a written procedure for cleaning water tanks, such as those used for dust control, the water from which may contact produce in the field.**
Verification	**Auditor reviews water tanks cleaning procedures for steps to prevent contamination of produce, and observes operation's evidence of compliance.**
Corrective Action	**Operation develops and implements procedures. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
Water tanks on the farm may be in many forms and are often overlooked. Water tanks may be used for drinking water, chemical applications or dust control. Auditors should review written procedures for steps that prevent product contamination and make observations of operation's evidence of compliance. Cleaning should not be initiated near crop production areas.

Example Scenarios
Scenario 1: You observe water tanks dedicated for dust abatement on roads adjacent to the growing field (so the water is reasonably likely to contact produce). No written cleaning procedures or records for cleaning the water tank are available for review. The tanks appear to be clean.
Assessment: Corrective Action Needed.
Reason: The standard requires "written procedure" and "evidence of compliance."

Scenario 2: You observe a water wagon, used for application of citrus canker chemicals, with accumulated soils and algae. It is evident that written cleaning procedures or their performance are inadequate to prevent contamination of produce.
Assessment: Corrective Action Needed or Immediate Action Required.

Reason: Corrective Action Needed - because while the operation has procedures and records, the procedures are inadequate "so as not to be a source of contamination." Immediate Action Required - if the water may have contaminated the produce and created an immediate food safety risk.

Scenario 3: You observe dirty water tanks. The operation says that the tanks are dedicated for washing non-food contact equipment and the water from the tanks is not reasonably likely to contact produce.
Assessment: Not applicable, if accurate.
Reason: The water tanks are not used for washing food contact equipment and the water is not reasonably likely to contact produce.

Requirement	**F-8.7. All cleaning agents shall be approved for their intended use on food contact surfaces.**
Procedure	**All chemicals used for cleaning or sanitizing of food contact equipment, tools, utensils, containers and other food contact surfaces shall be approved for that use, according to the chemical manufacturer or supplier and all federal, state and local requirements, and shall be used in a manner consistent with the approved use.**
Verification	**Auditor reviews cleaning and sanitizing chemicals purchasing practices or procedures, storage area, and use procedures to verify compliance.**
Corrective Action	**Operation ceases use of unapproved chemicals. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	

Expectation
Cleaning is a prerequisite for effective sanitization. Cleaning is the removal of organic matter, using appropriate detergent chemicals under recommended conditions. Organic matter from food residues such as oils, grease, and protein not only harbor bacteria but can actually prevent sanitizers from coming into physical contact with the surface to be sanitized. In addition, the presence of organic matter can inactivate or reduce the effectiveness of some types of sanitizers.

For cleaning to be performed properly, the right cleaning agents must be selected for the job. Cleaning agents commonly used include detergents, solvent cleaners, acid cleaners, and abrasive cleaners. Sanitization follows cleaning. Sanitization is the application of heat or chemicals to a properly cleaned (and thoroughly rinsed) food-contact surface, yielding a 99.999% reduction of representative pathogenic microorganisms of public health importance. Auditor must review evidence that cleaning agents being used are safe for food contact surfaces.

Compressed air or other gases that are mechanically introduced into food or used in the process to clean food-contact surfaces or equipment must be filtered and oil-free. Compressed air must also be dried and filtered to exclude microorganisms and moisture prior to use.

All post-harvest water needs to meet the microbial standards for drinking water. For the purposes of USDA GAP audits, this is considered to be no detectable generic *E. coli*. This would include water used to create steam for cleaning.

Example Scenarios
Scenario 1: The operation uses household multi-purpose cleaner that was purchased to clean food contact surfaces. The cleaner was purchased from a local grocery store. Surfaces are not rinsed before use. According to the label, cleaner was not meant to clean food contact surfaces.
Assessment: Immediate Action Required.
Reason: The cleaning chemical needs to be labeled for the appropriate use.

Scenario 2: The operation has a bulk cleaning material with an EPA registration number written on the container but does not have a product label. The operation has on location the label declaration for approved use on food contact surfaces.
Assessment: Compliant.
Reason: The cleaning material is approved for used on food contact surfaces.

Scenario 3: The operation purchases a cleaning agent approved for use on floors, but they are using it on food contact surfaces also.
Assessment: Immediate Action Required.
Reason: Immediate Action Required unless the agent is also expressly approved for use on food contact surfaces. This chemical is not being used for its intended purpose and is not approved for cleaning food grade surfaces.

Scenario 4: Operation uses disinfectant wipes to wipe down product grading line at the end of each shift.
Assessment: Immediate Action Required.
Reason: Wipes are not labeled for use on food contact surfaces.

Harvesting

F-9 Preharvest Assessment

Requirement	F-9.1. A preharvest risk assessment shall be performed.
Procedure	The Operation shall have a preharvest assessment procedure, which describes when the assessment is performed and that it includes an evaluation of conditions that may be reasonably likely to result in physical, chemical, or biological contamination of the produce, and demonstrates that the Operation is in compliance with the food safety plan. Results of the evaluation shall be documented.
Verification	Auditor reviews most recent preharvest assessment for completeness and consistency with the food safety plan.
Corrective Action	Operation develops and implements a preharvest assessment procedure.
Documents Required	Risk Assessment.
Mandatory	●
PSR	112.112

Expectation
The farm operation must have completed a pre-harvest assessment on each production area prior to harvesting any crop being certified by the audit. Take care not to interpret the assessment but rather to verify the fact that an assessment has been made. The assessment may include statements that address the following items as applicable:

- 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 such as condition of the weather and/or crops.

Also consider, did it address the following areas:

- Intrusion by animals

- Flooding
- Potential contamination materials
- Condition of water source and distribution system
- Unexpected adjacent land activity that will pose a risk to food safety
- Worker hygiene and sanitary facilities

The date of the assessment and the projected date of harvest along with a signature or initials, must be included. The assessment may be documented in various forms such as a self-completed audit checklist or a separate pre-harvest checklist. This question cannot be answered N/A. The comment should include the date and the role/title of the person who conducted the pre-harvest risk assessment.

Example Scenario
Scenario: A row crop operation uses the same checklist for the pre-season risk assessment, and performs the assessment one week before harvesting. Results are recorded. The pre-season checklist addresses all of the pre-harvest concerns identified in the Food Safety Plan. The plan recognizes that a one-week pre-harvest interval for the assessment is acceptable.
Assessment: Compliant.
Reason: All parameters of the pre-harvest risk assessment have been met.

Produce Safety Rule
112.112: The operation must take all measures reasonably necessary to identify, and not harvest, produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all produce to be harvested, regardless of the harvest method used.

<u>F-10 Water/Ice Used in the Harvesting and Post-harvest Operations</u>

Post-harvest Water is any water that contacts the crop during the harvest process or at any time after harvest, and any water that is applied to food contact surfaces. Post-harvest water includes fluming, washing produce, cooling (after harvest), ice, cleaning food contact equipment, cleaning bins and/or packaging, and handwashing water.

All post-harvest water must meet the microbial standards for drinking water. For the purposes of USDA GAP audits, this is considered to be no detectable generic *E. coli*.

The EPA National Primary Drinking Water Regulations: Revisions to the Total Coliform Rule (RTCR) considers *E. coli* to be an indicator of fecal contamination. If water used for post-harvest

purposes shows detectable *E. coli* immediate corrective action will be needed as this exceeds the EPA Maximum Contaminant Level (MCL) for *E. coli*.

The RTCR uses total coliforms as an indicator of system operation and condition rather than an immediate public health concern. Detectable total coliform no longer has a MCL, however, are now used to trigger an assessment of the system. For the purposes of the GAP audits, detectable total coliform in a post-harvest water test would need to be evaluated following a company's corrective action process.

Requirement	**F-10.1. Operation has procedures for water used in contact with product or food contact surfaces.**
Procedure	**Standard Operating Procedures (SOPs), including water-change schedules, shall be developed for all uses of water. Microbial and/or physical/chemical (e.g., test strips) testing shall be performed, as appropriate to the specific operation to demonstrate that acceptance criteria have been met.**
Verification	**Auditor observes existence of water use SOPs.**
Corrective Action	**Operation develops the SOPs.**
Documents Required	**Written Policy, Record.**
Mandatory	●

Expectation
Auditor's review of SOPs verifies procedures for managing the quality of water for all uses that contact produce or food contact surfaces, including water change schedules. SOP's should state what, when, how and why microbial or other testing is performed and if it is appropriate to the specific operation(s) to demonstrate acceptance criteria.

Example Scenarios
Scenario 1: An operation has no SOPs or acceptance criteria for ice used for top icing of broccoli.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: Corrective Action Needed - if SOPs and acceptance criteria for food-contact ice needs to be developed. Immediate Action Required - if the ice being used may reasonably have contaminated broccoli.

Scenario 2: A cherry operation soaks foam pads in water, then places pads on top of cherries for transport. The water used is in compliance with operation's Water Management Plan.
Assessment: Compliant.
Reason: The operation is following its procedure for the water being used.

Requirement	F-10.2. Water use SOPs address the microbial quality of water or ice that directly contacts the harvested crop or is used on food-contact surfaces.
Procedure	If water or ice directly contacts the harvested crop or is used on food-contact surfaces such as in the field, as the final wash step prior to consumer packaging, or as a cooling aid in consumer package, operation's water use SOP requires the water or ice when applied meets the microbial standards for drinking water, as defined by prevailing regulation. Water may be treated (e.g., with chlorine) to achieve microbial standards or to prevent cross-contamination. Ice and water shall be sourced/ manufactured, transported, and stored under sanitary conditions. Special considerations or variances may be appropriate for some crops, e.g. cranberries and watercress, where deliberate flooding of the field is part of production and harvest practices.
Verification	Auditor reviews operation's policy regarding water quality and its transport, and observes evidence that water or ice that contacts harvested crop or food contact surfaces meets the microbial standards for drinking water.
Corrective Action	Operation discontinues using water or ice that does not meet the microbial standards of drinking water. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Record.
Mandatory	●

Expectation
It is important to know the quality of the water which is being used to make the ice. This can be documented through a sales receipt, a COA/letter of guarantee from the supplier, or a water test.

There should be cleaning and maintenance procedures for all tools and equipment that is used for handling, transporting, and/or storing ice. These items should also not be used for other purposes which cause them to become contaminated by bacteria or chemicals without being cleaned and sanitized in between being used and stored in a manner to prevent contamination. If ice is made on site there should be a cleaning schedule and cleaning/maintenance procedures for the equipment used to make the ice.

Consideration should be given to how and where iced product is stored. As the ice used on product begins to melt it can drip onto anything stored below and potentially carry contamination present on the product, packing, pallets, or storage equipment and shelving. If possible, iced product should not be stored above other items to eliminate this route of potential cross contamination. Dripping ice can also create pooled water on floors if there is not sufficient drainage, which can be a reservoir for microorganisms as well as a hazard for employees.

Water quality consistent with EPA microbial requirements for drinking water, or similar standards, is recommended by the FDA's Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. While water quality management may vary throughout all operations, packers should follow best practices to minimize the potential for the introduction or spread of pathogens by water used at and after harvest.

Water that meets the microbial standards for drinking water is considered "safe and sanitary." Municipal water supplies are regulated by law and are required to be potable. Well water may or may not be potable but should be microbially safe. Surface water is subject to various uncontrollable influences and should be considered unsafe without further testing and/or effective treatment. Untreated surface water must not be applied to the finished product or food contact surfaces. Auditors review water tests to determine that the water is microbially safe.

The comment should include the water source for harvest operation and the water's test results.

Example Scenarios
Scenario 1: Operation has an SOP that includes an annual lab test of their well water that is used for all produce and equipment cleaning. Copies of the report from the certified lab are available for the last three years and the results meet the requirements for drinking water standards.
Assessment: Compliant.

Scenario 2: An operation is using surface water to wash harvest totes. Their SOP requires that they treat the water with 0.1% calcium carbonate as a disinfectant.
Assessment: Corrective Action Needed.
Reason: 0.1% calcium carbonate is not an effective water antimicrobial.

Requirement	F-10.3. If water is re-used, SOPs address antimicrobial treatment.
Procedure	Operation's water use SOPs require re-used water to be treated using an approved antimicrobial to prevent it from becoming a source of contamination, according to prevailing regulation or industry specific standards for the commodity.
Verification	Auditor reviews water use SOP for completeness, and observes water treatment records for adequacy and consistency of treatment.
Corrective Action	Operation discontinues using re-circulated water that is not treated sufficiently to prevent contamination of the produce. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Record.
Mandatory	●

Expectation
If an auditee is using recirculated or reused water, it is expected that the water will be treated with a sanitizer to prevent cross contamination of product/lots and to maintain the sanitary quality of the water.

Water sanitizers are intended to sanitize the water, not sanitize the product. Sanitizing the water may not remove microorganisms from an already contaminated product but will help prevent the water from spreading that contamination onto every other product that is contacted by the water.

Treatments of water, including sanitizers must be registered for that use. Registration information should be on the label, but in some cases the label information is included in the paperwork that comes with the product. Growers may need to find additional information from the manufacturer that specifically lists allowable contact with fresh produce or food contact surfaces.

For more information on sanitizers, the Produce Safety Alliance has created an Excel tool for Label Sanitizers for Produce available on their resources webpage. This tool shows the different uses for which each sanitizer has been approved, the active ingredient(s), product information, and whether it can be used in organic operations.

A schedule must be established for changing batch water and/or a process in place for minimizing the build-up of organic material in the water. Reused and batch water can be easily contaminated by incoming loads of produce which could introduce hazards such as pathogens. Organic material can also bind to sanitizers, making them less effective.

The specific schedule for changing water will depend on how much produce an operation is washing/cooling, what type of produce, type of equipment (e.g., large scale vs. small scale, if filters are used), soil conditions and type of sanitizer. Measuring and monitoring turbidity in wash water can be one way in which an operation determines the frequency to change the batch water based on these various operating parameters.

The auditor will include the type of antimicrobial treatment used and the parameters of use (i.e., ranges of pH, ppm free chlorine) in the comments.

Example Scenarios
Scenario 1: The water treatment is not recorded or monitored during the day. Water is used to flume tomatoes from harvest areas to packing facilities in greenhouse is treated with 100 ppm total chlorine.
Assessment: Corrective Action Needed.
Reason: Total chlorine is not an effective way to monitor chlorine in flume systems. Water treatment records are required by the standard.

Scenario 2: Cherries are hydrocooled with re-used fresh water that is from a source that meets drinking water standards. The water is not treated with an antimicrobial but is replaced daily.
Assessment: Corrective Action Needed.
Reason: Standard requires “re-used water to be treated using an approved antimicrobial to prevent it from becoming a source of contamination.”

Scenario 3: Water used to flume potatoes is re-circulated and is treated with citric acid. Citric acid use is recorded and monitored electronically.
Assessment: Corrective Action Needed.
Reason: Unless the operation has documentation demonstrating otherwise, citric acid is not an approved antimicrobial for pathogens of public health concern.

Requirement	F-10.4. Water use SOPs address condition and maintenance of water-delivery system.
Procedure	The water-delivery system shall be maintained so as not to serve as a source of contamination of produce, water supplies or equipment with pathogens, or to create an unsanitary condition.
Verification	Auditor reviews the SOP for inclusion of condition and maintenance of water-delivery system, and observes maintenance records for evidence of compliance.
Corrective Action	Operation revises SOP and implements maintenance procedures.
Documents Required	Record.
Mandatory	●

Expectation
Examples of water delivery systems include reservoirs, canals, ditches, pumps, hoses, and other facilities that move water. Auditor needs to review SOP for condition and maintenance of water delivery system and visually inspect water-delivery system for evidence of compliance.

Example Scenarios
Scenario 1: An operation uses a sand filter in their water system used for food contact water. The sand filter is back flushed whenever the water flow rates drop. The water system is not tested for microbial indicators.
Assessment: Corrective Action Needed.
Reason: The water system is not being maintained so as not to serve as a source of contamination of produce.

Scenario 2: The operation has recently replaced a ball valve with a gate valve of galvanized materials and restarted the line. The water is tested for microbial indicators and found to be compliant with drinking water standards. The operation has not assessed whether changing the type of valve will create a potential for contamination of the water system, regardless of current test results.
Assessment: Corrective Action Needed.
Reason: The operation has not evaluated the valve for the potential for contamination of the water system.

Requirement	F-10.5. If applicable to the specific commodity, water use SOPs address control of wash water temperature.
Procedure	For produce demonstrated as being susceptible to microbial infiltration from wash water, wash water temperature differentials during immersion shall be considered.
Verification	If applicable to the commodity being wash auditor reviews the SOP for inclusion of water temperature control, and observes monitoring and records for evidence of compliance.
Corrective Action	Operation revises SOP to address and control wash water temperature.
Documents Required	Record.
Mandatory	

Expectation
Infiltration can occur if warm produce is placed in water that is cooler than the produce. This temperature change creates a pressure differential, allowing water, and contaminants on the surface or in the water, to be pulled into the fruit or vegetable through the stem end, scars, cracks, cuts, or bruises. Once pathogens are inside the produce, surface washing cannot reduce their levels.

For crops which are susceptible to water infiltration, special attention to the water temperature in the dump tank and flumes and the temperature of the product is required. If contaminated water infiltrates the product, it is very difficult if not impossible to remove the contamination. The water may need to be heated or cooled and/or the product heated or cooled to prevent infiltration of water into the product.

The general recommendation for commodities that are susceptible to water infiltration, is that water temperature should be maintained within 10°F of incoming product pulp temperature to minimize water infiltration. As more research has been done on infiltration, in addition to temperature of the water and fruit, it has been found that the depth of the water, the time the commodity spends in the water, produce wounding (including stem scars) and maturity of produce also are factors in water infiltration.

For tomatoes specifically, there is guidance that states wash water should be at least 10°F above average pulp temperature of the tomatoes when entering the water. There is greater flexibility on commodities other than tomatoes (which need to follow the tomato specific guidance) that are susceptible to water infiltration to rely more on what is in the operation's Food Safety Plan to describe how they are preventing infiltration versus strictly adhering to the within 10 degrees stated in the GAP manual.

For papayas specifically, guidance recommends that water temperature in dump tanks to be maintained at least 5°C warmer than the pulp temperature of the papaya to limit infiltration

of water. Papaya should not be immersed in wash tanks for more than 2 minutes or submerged more than 30 cm to minimize potential for infiltration. These recommendations assume that the antimicrobial levels in the water are being maintained and monitored.

If the commodity is susceptible to microbial infiltration, auditors will include the required temperature differential in the comments.

Example Scenario
Scenario 1: There is no written SOP for monitoring a tomato operation's flume water temperature where the tomatoes are washed.
Assessment: Corrective Action Needed.
Reason: There are current industry practices for tomatoes, SOPs are expected to be written.

F-11 Containers, Bins and Packaging Materials

Requirement	**F-11.1. Operation has written policy regarding storage of harvesting containers.**
Procedure	**Harvesting containers shall be stored in a manner so as not to serve as a source of contamination to the extent feasible and appropriate.**
Verification	**Auditor observes whether operation has a policy regarding storage of harvesting containers used in the field. Auditor observes current practices for compliance with policy.**
Corrective Action	**Operation develops the policy. Retraining is performed and documented.**
Documents Required	**Written Policy.**
Mandatory	
PSR	**112.123(b)(2)**

Expectation
Operations must have a written policy regarding the storage of harvesting containers. These containers are required to be stored in a manner so that they are not to serve as a source of contamination to the extent feasible and appropriate. It is not a requirement that harvesting containers be stored indoors. If a grower stores harvesting containers (bins) outdoors and can demonstrate they are "not a source of contamination" this is acceptable.

Example Scenarios
Scenario 1: The operation has a written SOP for the storage of harvesting containers but doesn't follow the policy based on observation.
Assessment: Corrective Action Needed.
Reason: The operation is not following their policy for the storage of harvesting containers. A policy is only effective if it is being followed.

Scenario 2: Harvest containers are stored outdoors on a clean hard surface, under a mesh "roof."
Assessment: Compliant.

Reason: The container storage procedure is consistent with current industry practice.

Produce Safety Rule
112.123(b)(2): Equipment and tools must be stored and maintained to protect produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.

Requirement	**F-11.2. Operation has written policy regarding inspection of food contact containers prior to use.**
Procedure	**Food-contact totes, bins, packing materials, other harvest containers, and pallets shall be visually inspected, clean, intact and free of any foreign materials prior to use. Containers shall be sufficiently maintained so as not to become a source of contamination.**
Verification	**Auditor observes whether operation has a policy regarding inspection of food contact containers and observes current practices for compliance with policy.**
Corrective Action	**Operation develops the policy. Retraining is performed and documented.**
Documents Required	**Written Policy.**
Mandatory	
PSR	**112.123(d)(1)**

Expectation
The written policy should include procedures for inspecting food contact containers, the frequency of these inspections, the personnel involved, and conditions that should be reported to a supervisor, or responsible party to determine appropriate corrective actions to protect covered produce.

The standard is silent on the frequency of inspection. This should be determined by the operation based upon several factors such as the type of material of the containers, the construction, how the containers are used, cleaned, stored, the age of the containers and frequency of use. There could be different inspection frequencies for different food contact containers.

Ideally, inspections should be performed after each cleaning activity and before using food contact containers to ensure that the cleaning activity was effective in removing residue from previous activities and that the equipment and tools remain clean during periods of storage.

Single-use food-packing materials should be inspected upon receipt or immediately before use to protect against contamination of your covered produce.

The audited location should be following recommendations for harvest containers, which include:

- Keep harvest containers as clean as practicable to prevent cross-contamination of fresh produce.

- Harvest containers used repeatedly during a harvest should be cleaned after each load is delivered and prior to reuse.

- If the containers are stored outside, they should be cleaned and sanitized before being used to haul fresh produce.

- Workers should not stand inside bins.

Example Scenarios
Scenario 1: The operation power washes plastic harvest bins prior to use. Operation's written policy considers the person who does the washing as being the "inspector."
Assessment: Compliant.
Reason: The plastic harvest bins are being inspected in accordance with the operation's written policy.

Scenario 2: The operation has an SOP requiring visual inspection of harvest containers prior to use. Auditor observes that some bins are not in good repair, and one bin is visibly soiled.
Assessment: Corrective Action Needed.
Reason: The SOP is not being implemented consistently.

Produce Safety Rule
112.123(d)(1): The operation must inspect, maintain, and clean, and when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in growing, harvesting, packing and holding activities as frequently as reasonably necessary to protect against contamination of produce.

Requirement	F-11.3. Operation has written policy regarding acceptable harvesting containers.
Procedure	The types and construction of harvest containers and packing materials shall be appropriate to the commodity being harvested and suited for their intended purpose.
Verification	Auditor observes whether operation has a policy regarding what types of containers and packing materials are acceptable for use during harvest, and observes current practices for compliance with the policy.
Corrective Action	Operation develops the policy. Retraining is performed and documented.
Documents Required	Written Policy.
Mandatory	●
PSR	112.116; 112.123(a)(c);

Expectation
Auditor reviews written policy regarding acceptable harvesting containers. Containers must be acceptable for commodity being packed. Materials of harvest containers should be considered whether they can be adequately cleaned or properly maintained under the conditions of their use

and throughout the period of their use, considering stress and strain during use; environmental conditions during use or storage (e.g., wet, humid, dry); and the process of, and treatments used during, cleaning and, when applicable, sanitizing.

Example Scenarios
Scenario 1: A citrus operation harvest crew uses canvas bags, which are cleaned and stored in accordance with operation's SOP.
Assessment: Compliant.
Reason: The canvas bags are in compliance with the operation's SOP.

Scenario 2: An operation doesn't have written policy on the types of containers appropriate for harvest use.
Assessment: Corrective Action Needed.
Reason: The standard requires a "written policy regarding acceptable harvesting containers."

Produce Safety Rule
112.116: Requires that operations use food-packing material that is adequate for its intended use. Materials must be cleanable or designed for single use and must be unlikely to support growth or transfer of bacteria. If operations reuse food-packing material, the operation must take adequate steps to ensure that food-contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

112.123: (a) The operation must use equipment and tools that are of adequate design, construction and workmanship to enable them to be adequately cleaned and properly maintained. (b) Seams on food contact surfaces of equipment and tools used must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles and organic material and thus minimize the opportunity for harborage or growth of microorganisms.

Requirement	**F-11.4. Operation has written policy prohibiting use of harvest containers for non-harvest purposes.**
Procedure	**Food-contact totes, bins and other harvest containers designated for harvesting shall not be used for other purposes unless clearly marked or labeled for that purpose.**
Verification	**Auditor observes whether operation has a policy prohibiting use of harvest containers for other uses unless otherwise labeled, and observes current practices for compliance with the policy.**
Corrective Action	**Operation develops the policy. Retraining is performed and documented.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation

The operation must have a written policy concerning harvest containers and appropriate uses within the operation. The auditor will observe practices to ensure that the operation is complying with the written SOP.

Example Scenarios
Scenario 1: Harvest containers are observed as storage for bagged fertilizer without a clear marking or designation.
Assessment: Corrective Action Needed.
Reason: Containers must be prominently marked for this use and workers must not use these for picking and transporting produce.

Scenario 2: The policy is written but fails to clearly establish marking requirements for non-harvest uses of harvest containers.
Assessment: Corrective Action Needed.
Reason: The policy needs to establish marking requirements for non-harvest uses of containers.

Scenario 3: Field workers are observed storing personal effects in harvest containers. The harvest containers are temporarily marked "not for harvest." There is no written policy permitting temporary marking.
Assessment: Corrective Action Needed.
Reason: There must be a written policy on marking containers for non-harvest purposes.

F-12 Field Packaging Materials

Requirement	**F-12.1. Operation shall have a written policy that visibly contaminated, damaged or decayed produce is not harvested, or it is culled.**
Procedure	**Employees are trained that only sound produce appropriate for the intended use is harvested, and that produce that has been visibly contaminated or otherwise damaged to an extent that it poses a microbial food safety hazard is not harvested or is culled.**
Verification	**Auditor reviews written policy and evidence of employee training. Auditor inspects the harvest or sorting operation for evidence of compliance.**
Corrective Action	**Operation develops the policy. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**Written Policy.**
Mandatory	●
PSR	**112.112**

Expectation
Employees responsible for harvesting activities should be trained in the operation's written policy concerning produce visibly contaminated (such as with animal feces or excreta) is not harvested. Harvest personnel must be instructed on appropriate actions to be taken when observations of

produce that is contaminated occurs. If contamination is widespread, efforts must be taken to cordon off the affected areas. The auditor shall review the SOP and validate the operation's compliance with the policy.

Example Scenarios
Scenario 1: You observe that produce with minor damage or decay is being harvested. The written policy says that decayed/damaged produce will be removed during sorting. You also observe that decayed/damaged produce is culled during sorting.
Assessment: Compliant.
Reason: The decayed/damaged produce is culled during sorting.

Scenario 2: A peach operation has written policy that damaged fruit is harvested but is placed into a bin designated for processing.
Assessment: Compliant.
Reason: The damaged fruit is following the operation's policy if it is not damaged to an extent that it poses a microbial food safety risk.

Scenario 3: An auditor observes hail damaged fruit that has healed over prior to being harvested.
Assessment: Compliant.
Reason: The standard prohibits harvest only if "damaged to an extent that it poses a microbial food safety hazard."

Produce Safety Rule
112.112: The operation must take all measures reasonably necessary to identify, and not harvest, produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all produce to be harvested, regardless of the harvest method used.

Requirement	F-12.2. Product that contacts the ground shall not be harvested unless the product normally grows in contact with the ground.
Procedure	Operation has considered and developed written policies regarding produce that comes in contact with the soil (e.g., drops) and to avoid, to the degree practicable, contact of cut surfaces of harvested produce with soil. Policy shall be consistent with industry standards or prevailing regulations.
Verification	Auditor reviews written policy and evidence of employee training. Auditor inspects the harvest or sorting operation for evidence of compliance.
Corrective Action	Operation develops the policy. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Policy.
Mandatory	●
PSR	112.113, 112.114

Expectation
Dropped produce is produce that has unintentionally dropped to the ground prior to harvest. Dropped produce could have bruises, punctures, or other injuries which can create potential pathways for pathogens to contaminate the produce and multiply. A written policy which explains whether dropped product can be harvested is required. Employees must be trained on this policy. Interview employees to verify their understanding of the dropped product policy.

Auditors will include the type of growing method and if the product grown in contact with the ground (e.g., tomatoes staked, or vine grown) in the comments.

Example Scenarios
Scenario 1: Auditor observes harvest crews picking mushrooms close enough to the growing medium that some harvested mushrooms have growing medium on them.
Assessment: Compliant.
Reason: Mushrooms normally grow in contact with the growing medium.

Scenario 2: Auditor observes strawberries being harvested that are in contact with the plastic mulch under the plants.
Assessment: Compliant.
Reason: Strawberries normally grow in contact with the ground or with plastic mulch.

Scenario 3: Auditor observes a peach harvester putting a peach that she has just dropped on the ground into her harvest sack.
Assessment: Corrective Action Needed.
Reason: Peaches are not grown in contact with the ground.

Produce Safety Rule
112.113: requires operations to handle harvested covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards – for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil.

112.114: prohibits the distribution of dropped covered produce. This prohibition applies to dropped produce that contacts soil when it falls as well as dropped produce that falls onto another surface, such as plastic mulch. The prohibition for dropped covered produce does NOT include: root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).

Requirement	**F-12.3. Harvest procedures shall include measures to inspect for and remove physical hazards.**
Procedure	**Operation shall have procedures to detect glass/plastic breakage and remove possible physical contamination such as glass, metal, rocks, or other hazardous items, during harvesting operations.**
Verification	**Auditor inspects the harvest or sorting operation for evidence of hazard control.**
Corrective Action	**Operation develops the procedure. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	

Expectation
Harvest procedures for inspecting and removing physical hazards are not required to be written. Harvest employees who are responsible for the food safety procedures must be trained on the procedures for inspecting and removing physical hazards appropriate to their job responsibilities (see requirement G-4.1).

Example Scenarios
Scenario 1: A strawberry harvest crew has no written procedures for physical hazard control. The field-pack operation says that the harvesters are trained to look for and not harvest any strawberries that have foreign objects on them. You observe evidence that harvesters have been trained and appear to be following the procedure.
Assessment: Compliant.
Reason: Harvest crew workers are familiar with and follow the operation's verbal policy regarding physical hazards.

Scenario 2: A field-packed Romaine lettuce operation is using a mechanical harvester, which they say has gaps and other automated mechanisms to remove glass, metal and other physical hazards. You see an insect in the harvested product.
Assessment: Compliant.
Reason: The insect is not a physical hazard.

Requirement	**F-12.4. Cloths, towels, or other materials that pose a risk of cross-contamination shall not be used to wipe produce, unless risk mitigation procedures are in place.**
Procedure	**Operations shall not use cloths or other cleaning materials to clean produce, unless there is a procedure to reduce risk of cross-contamination.**
Verification	**Auditor reviews whether operation uses cloths or other produce cleaning materials and, if so, how operation prevents cross-contamination between uses.**
Corrective Action	**Operation ceases use of produce cleaning cloths, or develops procedure to prevent cross-contamination. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	

Expectation
If cleaning materials (cloths, paper towels, etc.) are used repeatedly for cleaning, special steps must be taken to ensure they do not become a source of contamination. For example, an operation can choose to use one-use paper towels (once and done) to prevent cross contamination. Operations must have a procedure for when to discontinue using or change a cleaning material.

For papayas specifically, sponges or wash mitts must be changed out at least once per shift, or sooner if the sponge becomes visibly dirty or otherwise contaminated. During use, sponges should be dipped in the papaya wash water with adequate antimicrobial control or a separate antimicrobial solution for a few seconds between each papaya to reduce the potential for cross-contamination between fruit.

Auditors should interview and observe employees for compliance of the procedure. The comment should include the type of cloth, towel, or other cleaning material and procedure for preventing cross contamination.

This requirement may not be answered Not Applicable. If the operation is not using materials to wipe produce then this requirement would be assessed as Compliant.

Example Scenarios
Scenario 1: A cucumber harvester is seen wiping dirt from some cucumbers on his apron prior to putting them in the harvest bin.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: Corrective Action Needed as the apron could serve as a risk for contamination. If you observe evidence that the practice has resulted in product contamination, then it would be an Immediate Action Required.

Scenario 2: Operation states in their policy that it is acceptable to wipe produce if necessary with a one-time use paper towel. Policy states this may only be done if a leaf or plant debris is adhered to product. While conducting a field packing audit the auditor witnesses an employee wiping away bird droppings and placing product in container for shipment.
Assessment: Immediate Action Required
Reason: Policy states one-time use paper towels may only be used on leaf or plant debris. If the representative/field supervisor also sees this and removes product and retrains employee to follow procedure this question may be assessed as compliant.

Requirement	**F-12.5. Packaging materials shall be appropriate for their intended use.**
Procedure	**The product contact packaging shall be appropriate to the commodity being harvested and suited for its intended purpose.**
Verification	**Auditor observes evidence (e.g., information from supplier, customer specification, industry standards, prevailing regulation) that the packaging does not create an unsafe condition.**
Corrective Action	**Operation discontinues use of the packaging until information can be obtained demonstrating safe use. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	●
PSR	**112.116**

Expectation
When selecting material for packaging it's important to consider if the material is reusable or designed for a single use. It should also be unlikely to support growth or transfer of bacteria, taking into consideration the handling, maintenance, and storage practices of the operation. An operation should not reuse food-packing materials that are designed for single use. Although some single-use food-packing materials, such as fiberboard or foam, could be sufficiently sturdy for multiple uses, they may not be cleanable after use and, when reused, could then serve as a source of contamination or support bacterial growth or transfer. Twist ties or rubber bands used for herbs bunches etc. are considered packing materials and must be assessed under this requirement.

Example Scenarios
Scenario 1: A tomato operation is field-packing tomatoes directly into cardboard boxes which are being reused from other tomato lots. All boxes are labeled with the tomato operation's name and date of harvest.
Assessment: Corrective Action Needed.
Reason: The Tomato Metrics prohibits re-use of cardboard or fiberboard boxes for field-packing because of potential cross-contamination from other lots.

Scenario 2: A strawberry operation is field-packing strawberries directly into new plastic clamshells. The operation has an invoice from a national packaging supplier for "strawberry clamshells."
Assessment: Compliant.

Reason: The packaging is appropriate to the crop being harvested.

Produce Safety Rule
112.116: Requires that operations use food-packing material that is adequate for its intended use. Materials must be cleanable or designed for single use and must be unlikely to support growth or transfer of bacteria. If operations reuse food-packing material, the operation must take adequate steps to ensure that food-contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

Requirement	**F-12.6. Packaging shall be stored in a manner that prevents contamination.**
Procedure	**Packaging storage shall be designed to maintain packaging dry, clean and free from dirt or residues so it remains fit for the purpose. Particular care shall be taken to prevent packaging from becoming a harborage for rodents and other vermin. Packaging shall be stored separately from hazardous chemicals, toxic substances and other sources of contamination.**
Verification	**Auditor inspects packaging storage area for evidence of compliance.**
Corrective Action	**Operation designates a storage area and practices that reduce risk of contamination. Affected packaging is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	
PSR	**112.123(b)(2)**

Expectation
Packaging materials that are not ready for immediate use should be stored in a way that protects them from contamination by any source (pests, rodents, dirt, water condensation, etc.). Packaging stored outside should be covered in some manner to protect against contamination. Observe where and how packaging is stored. Containers which are stored in a manner that may lead to contamination by any reasonable means will result in Corrective Action Needed.

Example Scenario
Scenario: You observe rolls of mesh bags, to be used for potato packaging, wrapped in plastic and stored in an open, designated part of the potato storage building. The plastic wrapping has some dust on it, but is dry, intact and bags inside the wrapping appear clean.
Assessment: Compliant.
Reason: Packaging is stored in a manner that prevents contamination.

Produce Safety Rule
112.123(b)(2): Equipment and tools must be stored and maintained to protect produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.

Requirement	F-12.7. Operation has written policy regarding whether packaging materials are permitted in direct contact with the soil.
Procedure	If produce is packed in field, operation has considered and developed written policies regarding placement of packaging materials directly on the soil, or whether a physical buffer (e.g., buffer bin or slip sheet) is required. Policy shall be consistent with industry standards.
Verification	Auditor observes whether operation has a policy regarding placement of packaging materials used in the field in direct contact with soil. Auditor observes current practices for compliance with policy.
Corrective Action	Operation develops the policy. Retraining is performed and documented.
Documents Required	Written Policy.
Mandatory	
PSR	112.113

Expectation
Produce that is packed in the field must have a policy stating the operation's procedures for packaging. Policy must state if packaging materials are allowed to come in direct contact with the soil or if there is a buffer zone between the soil and the packaging. Auditor should observe employee practices to ensure that policy is being followed.

Produce Safety Rule
112.113: You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or foreseeable hazards. – for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil.

Requirement	F-12.8.a. The operation has implemented a product release procedure.
Procedure	Operations follow product release written procedure to ensure that all potential hazards have been addressed prior to transport. Release records must be kept.
Verification	Auditor observes product release procedure is being followed and release records are kept.
Corrective Action	Operation develops a written release procedure release procedure. Release records are kept.
Documents Required	Written Policy.
Mandatory	

Expectation
Product release procedures are the steps taken before harvested product is permitted to leave the field (released). Operation develops a product release policy. Auditor reviews the operation's written policy, makes observations that product release policy is being followed, and reviews records of product release.

Example Scenario
Scenario 1: The operation has a written procedure that the harvest crew foreman visually inspects each load of bell peppers before cartons are loaded for transport to the cooler. The harvest crew foreman is also responsible for visually inspecting the truck before product is loaded. This inspection and the number of cartons shipped from the field is included in the daily harvest log for each truck loaded. Quality assurance checks each load when received at the cooler and verifies the count of the product entering it into the inventory system if found acceptable to ship. If any food safety concerns are found the product is segregated to a separate area of the loading dock. All records associated with the operation's written policy were available.
Assessment: Compliant
Reason: Operation was observed following their written policy and records were available to review.

F-13 Post-harvest Handling and Storage (Field Prior to Storage or Packinghouse)

Requirement	**F-13.1. Harvested produce is handled in a manner such that it is not likely to become contaminated.**
Procedure	**Operation has a policy, in compliance with current industry practices or regulatory requirements for that commodity, regarding handling, walking, stepping, or lying on harvested produce, food contact surfaces or packaging materials, or coming in contact with produce that has not been handled in compliance with these standards, or that may otherwise result in contamination.**
Verification	**Auditor reviews policy and produce handling practices for evidence of compliance.**
Corrective Action	**Operation develops the policy. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	●
PSR	**112.113**

Expectation
The operation must evaluate their practices during harvesting, packing, and holding, to identify conditions that could increase the likelihood of contamination. Steps must be taken to handle produce in a manner to minimize contamination of the product. The auditor observes the operation's practices to evaluate if food contact surfaces or the product itself is directly contaminated or has a high likelihood of contamination. Produce and chemicals need to be separated in a manner that is practical and reasonably would not result in contamination of the produce or food contact surfaces.

This policy does not have to be written. To determine if this question is compliant, the auditor observes if the actions practiced by the operation are compliant with company policies (including glove policy).

Example Scenario
Scenario 1: You observe workers walking on open bins of harvested iceberg lettuce.
Assessment: Immediate Action Required.
Reason: The practice is reasonably likely to result in product contamination.

Scenario 2: You see a bottle of stainless-steel cleaner that is used to clean sorting tables lying on an open bin of washed pears.
Assessment: Corrective Action Needed.
Reason: The cleaner is not stored separately from the produce.

Produce Safety Rule
112.113: The operation must handle harvested produce during growing, harvesting, packing and holding activities in a manner that protects against contamination with known or reasonably foreseeable hazards – for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil.

Requirement	**F-13.1.a. When product is field packed, collection, storage, and distribution points are maintained in a clean and hygienic condition.**
Procedure	**Areas of collection/storage/distribution points shall be identifiable on farm during harvesting. There shall be visual evidence that these areas are kept clean. Where there is temporary storage on farm, rodent and other animal control measures shall be present.**
Verification	**Auditors shall verify through observation that when products are field packed, collection, storage and distribution points are maintained in a clean and hygienic condition.**
Corrective Action	**Operation will implement practices that during field packing of produce that collection, storage and distribution points are maintained in a clean and hygienic condition.**
Documents Required	**N/A.**
Mandatory	

Expectation
Operations must make every effort to ensure cleanliness in the post-harvest handling and storage of their produce. When field packing is performed, operations must implement practices that are conducive to maintaining produce collection, storage and distribution points in a clean and hygienic condition. Auditors should be able to visually observe that collection, storage and distribution points are clearly identifiable during harvesting and that these areas are clean. If an operation has temporary storage or staging areas, animal control measures should also be implemented.

Example Scenarios
Scenario 1: Strawberries are field packed into plastic clamshells. Clamshells are placed in cardboard boxes and stacked in the shade under trees near the field for temporary storage until they can be picked up. There is visible bird activity in the trees.

Assessment: Corrective Action Needed or Immediate Action Required
Reason: CAN due to the potential for contamination from the birds. IAR if there is evidence that the birds have contaminated product.

Scenario 2: Lettuce is field packed. Packed product is moved out of the field and temporarily stored on the back of a flatbed truck in the parking area of the operation until the buyer's trucks arrive. The parking area is free of litter and waste, and there is no indication of pest or animal activity.
Assessment: Compliant
Reason: The products distribution point is observed in a clean and hygienic condition.

Requirement	**F-13.2. Materials that come in contact with the produce shall be clean and in good repair.**
Procedure	**Operation has a policy that pallets, produce bins, totes and materials that come in contact with the produce or the containers during handling or storage shall be cleaned and, if practicable, sanitized sufficient so as not to be a source of contamination.**
Verification	**Auditor observes current practices for compliance with policy.**
Corrective Action	**Operation develops the policy. Retraining is performed and documented. Affected materials are evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	●
PSR	**112.123**

Expectation
Food containers shall be clean, in good repair, and not cause contamination. Auditors observe the condition of pallets and containers being used and those stored for future use. Auditors interview the operation's personnel to determine what is done with broken or dirty pallets or containers.

Example Scenario
Scenario: You observe operators placing produce into broken bins.
Assessment: Corrective Action Needed.
Reason: These containers are not in good repair.

Produce Safety Rule
112.123: The operation must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and (b) Equipment and tools must be: (1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and (2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests. (c) Seams on food contact surfaces of equipment and tools that are used must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of

microorganisms. (d)(1) The operation must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in growing, harvesting, packing and holding activities as frequently as reasonably necessary to protect against contamination of produce. (2) The operation must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of produce. (e) If using equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact produce, you must do so in a manner that minimizes the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards.

F-14 Equipment Sanitation & Maintenance

Requirement	**F-14.1. The operation shall have a policy, written procedures, and a checklist to verify cleanliness and functionality of shipping units (e.g., trailer).**
Procedure	**Shipping units shall be clean, functional and free of objectionable odors before loading, in compliance with current industry practices or regulatory requirements for that commodity. Refrigeration units, if used, must be in working order.**
Verification	**Auditor reviews cleaning and inspection procedures and inspects produce transport vehicles for cleanliness.**
Corrective Action	**Operation develops the policy. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**Written Policy, Record.**
Mandatory	●
PSR	**112.125**

Expectation
All parties involved in the transport of fresh produce should help ensure that sanitation requirements for conveyances are maintained throughout the transportation chain. Trucks and transport containers must be inspected for cleanliness, odors, and debris before the loading process begins. Cleaning and sanitizing, as well as associated documentation, may be included in contracts for transportation.

Drivers and operators should be aware of the contents of previously carried loads and consider this information when determining current usage. For example, trucks recently used to transport animals or animal products would increase the risk of contaminating fresh produce if not properly cleaned prior to produce loading. Conveyances may not be in like-new or sterilized condition; however, conveyances must be visibly clean.

Review auditee documentation to verify that there is an active policy in place addressing carrier condition. The auditee must maintain records verifying that the overall physical condition of conveyances is being checked.

For operations that use a dedicated fleet of trailers that transport only produce, with no backhaul of non-produce items, the auditee must maintain records verifying the overall physical cleanliness of the vehicles. However, unless required by the operation's Food Safety Plan, transport history or wash tickets do not need to be maintained for these vehicles.

Example Scenarios
Scenario 1: An operation's products are transported by the customer's trucks. The operation has no control over their condition. You see dirt and debris in one truck prior to loading.
Assessment: Corrective Action Needed.
Reason: The operation should not load a dirty truck regardless of ownership.

Scenario 2: An operation's written procedure requires trailers to have transport history for immediate past 3 loads or to be washed. You observe one truck being loaded without wash ticket "because we have to get this load to the customer now."
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: A Corrective Action is Needed because the operation is not following their procedure. If you observe a reasonable opportunity for contamination an Immediate Action is Required.

Produce Safety Rule
112.125: Equipment used to transport produce must be adequately clean before use in transporting produce and adequate for use in transporting produce.

Requirement	F-14.2. Loading/unloading procedures and equipment shall minimize damage to and prevent contamination of produce.
Procedure	Personnel responsible for the loading and unloading of produce shall take steps to minimize the potential of physical damage to produce, which can introduce and/or promote growth of pathogens. Loading/unloading equipment shall be cleaned and well maintained and of suitable type to avoid contamination of the produce.
Verification	Auditor observes loading/unloading procedures for evidence of practices that result in excessive damage to produce. Auditor observes loading/unloading equipment for suitability and condition.
Corrective Action	Operation revises procedures. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	

Expectation
All fresh produce must be carefully packed and loaded to minimize physical damage and to reduce the potential for contamination during transport. A shipper should have an SOP describing the use of acceptable safe loading practices.

Produce which is damaged during harvesting, packing, or transportation is more susceptible to microbial contamination than undamaged product. Precautions should be taken to minimize or prevent shifting of the load during transit. Load bracing, straps/belts, and pallet wrapping are examples designed to keep containers in place. Shippers should strive to organize each load with a realistic attempt at securing packages and preventing spillage during transit.

Example Scenario
Scenario: Cartons of tomatoes are placed on wooden pallets and plastic-strap wrapped, then loaded onto trailers by forklift. The forklifts are old but generally in good repair.
Assessment: Compliant.
Reason: The forklift is observed to not cause damage to the produce.

POST-HARVEST OPERATIONS

Each requirement in the Post-harvest Operations Checklist is taken verbatim from the Produce GAPs Harmonized Food Safety Standard. The checklist is designed as a working tool to report the verification of each requirement and report any comments that will create a clear picture of the observations made by the auditor.

The instructions in this section are designed to give the auditor additional guidance on utilizing the standard. A copy of the audit standard being assessed shall be accessible to an auditor while performing all audit activities.

P-1 Product Sourcing

Requirement	**P-1.1. The operation has a policy and takes affirmative steps to ensure that all fresh produce that are packed or stored in the operation are grown following requirements in *Field Operations and Harvesting* harmonized standard.**
Procedure	**The operation requires all raw product suppliers to provide evidence of food safety/GAP programs and compliance. Such evidence must include sufficient documentation to demonstrate that the supplier complies with the requirements in *Field Operations and Harvesting* harmonized standard.**
Verification	**Auditor reviews policy and verifies that operation's evidence of supplier compliance with food safety/GAP programs is in compliance with the operation's policy.**
Corrective Action	**Operation obtains required documentation. Operation ceases accepting or shipping product from non-approved suppliers, until sufficient documentation demonstrating compliance is received by the operation.**
Documents Required	**Record.**
Mandatory	

Expectation
The operation needs to ensure that all fresh products that are packed or stored in the operation are grown following the requirements of the Field Operations and Harvesting harmonized standard. How the operation ensures these requirements are met is up to each individual operation. This requirement is not specifying that the auditee must have a Field Operations and Harvesting audit conducted by USDA to meet this requirement. The operation may choose to ensure compliance by having auditees complete a third-party audit, internal audit, letter of guarantee, or by other means.

Example Scenarios
Scenario 1: The operation has a contract in place that requires a new leafy greens grower to comply with the Field Operations and Harvesting Harmonized Standards but has no written evidence of compliance with the Standards.
Assessment: Corrective Action Needed.

Reason: A contract is not sufficient evidence to demonstrate that the supplier complies with the requirements and the operation has no historical evidence.

Scenario 2: The operation has records of compliance for the previous year's tomatoes, but their grower has not had an audit yet this year, so the operation does not have any current evidence of compliance.
Assessment: Compliant.
Reason: The standard does not require the operation to have the grower's audit results, just to receive evidence from the supplier. There is historical evidence of compliance and the operation has no indication that the grower is not in compliance.

Scenario 3: A vertically integrated operation has no evidence at the packinghouse that their growing operation is in compliance with the requirements of the Harmonized Standards.
Assessment: Corrective Action Needed.
Reason: The operation must have evidence of compliance, even if part of the same company.

P-2 Agricultural Chemicals

Requirement	**P-2.1. Use of agricultural chemicals shall comply with label directions and prevailing regulation.**
Procedure	**Agricultural chemicals applied post-harvest (e.g., biocides, waxes and plant protection products) must be registered for such use as required by prevailing regulation, and used in accordance with label directions including application rates, worker protection standards, personal protection equipment, container disposal, storage, and all requirements specified for the chemical or compound. Chemicals that are not restricted pesticides may be permitted for food contact use if allowed under regulations of the prevailing agency. Records of chemical use are maintained.**
Verification	**Auditor reviews post-harvest agricultural chemical use records for evidence of compliance with approved uses or label directions.**
Corrective Action	**Operation develops and maintains evidence of proper use of each chemical use. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**Record.**
Mandatory	●

Expectation
Post-harvest chemicals must be registered for use as required by prevailing regulations and used in accordance with label directions, including application rate, workers' protection standards, personal protective equipment, container disposal, storage, and all requirements specified for the chemical or compound. Note that this standard requires records of compliance with post-harvest chemicals; this will include regulated and non-regulated chemicals.

The directions for use, on a post-harvest chemical label, describe how the product may legally be used and how the product must not be used. Generally speaking, the necessary information includes:

- The organism(s) that the product may be used to control
- The sites where the product may be used
- The application methods that are required or preferred
- How much of the chemical should be applied and the rate of application
- The application methods that are prohibited
- Maximum application rates per treatment and per year
- Storage and disposal
- Any other requirements as necessary

The directions for use reflect EPA's determination that the use of the product in such a manner does not cause unreasonable adverse effects on the environment or human health under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The general rule to go by on labeling is the label on a post-harvest chemical is the law, if the label says you can use it, you can use it.

The directions for use are organized and carefully worded so that they are understood by the person expected to use or to supervise the use of the agricultural chemical. The directions for use indicate whether any actions mentioned are required, prohibited, encouraged, or discouraged when using the product and background information may also be provided.

Charts, tables, and graphics may be seen in many labels' directions for use and they provide accurate information in a clear, concise, and complete manner.

Post-harvest chemicals may include products used to control fungus or bacteria prior to final packaging, cleaning chemicals, water treatment chemicals to prevent cross contamination in wash water, bait in pest control devices, lubricants for equipment, etc.

(See Field and Harvest F-2.1)

Requirement	P-2.1.a. Compressed air or other gases that are mechanically introduced into food or used in the process to clean food-contact surfaces or equipment must be appropriate for its use.
Procedure	Compressed air or other gases that are mechanically introduced into food or used in the process to clean food-contact surfaces or equipment must be filtered and oil-free. Compressed air must also be dried and filtered to exclude microorganisms and moisture prior to use. These processes must be regularly monitored. Compressed air or other gases must be adequately stored and handled.
Verification	Auditor reviews records of monitoring and/or maintenance of the compressed air or other gases. Auditor observes the use, storage, and/or handling of the compressed air or other gases.
Corrective Action	Operation develops and maintains compressed air or other gas records and associated maintenance records. Retraining is performed.
Documents Required	Record.
Mandatory	●

Expectation
Compressed air or other gases that are mechanically introduced into food or used in the process to clean food-contact surfaces or equipment must be filtered and oil-free. Compressed air must also be dried and filtered to exclude microorganisms and moisture prior to use.

Example Scenario
Scenario: The operation is using compressed Nitrogen/CO2 mix for their modified atmosphere packaging. The gas mixture is food grade appropriate, and the machinery is equipped with filters.
Assessment: Compliant.
Reason: The compressed gas is being used in accordance with the label and is filtered.

Requirement	P-2.2. If product is intended for export, pre- and post-harvest agricultural chemical use shall consider requirements in the intended country of destination.
Procedure	The operation shall have procedures, such as review of pre-harvest intervals and adjustment of post-harvest application rates, sufficient to meet the MRL entry requirements of the country(ies) in which the product is intended to be traded, if known during post-harvest handling.
Verification	Auditor reviews operation's procedure for complying with agricultural chemical restrictions in countries of destination. If destination is unknown during post-harvest handling, this item is not applicable.
Corrective Action	Operation develops procedures, and diverts non-compliant product to a market in which the product meets standards.
Documents Required	N/A.
Mandatory	

(See Field and Harvest F-2.2)

Requirement	P-2.3. Agricultural chemicals shall be applied by trained, licensed or certified application personnel, as required by prevailing regulation.
Procedure	Operation maintains records demonstrating that all personnel responsible for chemical applications are trained and/or licensed, or supervised by licensed personnel, in compliance with prevailing regulation.
Verification	Auditor reviews records demonstrating that application personnel are licensed and/or trained in compliance with prevailing regulation.
Corrective Action	Operation utilizes application personnel who are appropriately licensed and/or trained.
Documents Required	Record.
Mandatory	

(See Field and Harvest F-2.3)

P-3 Facility

Requirement	P- 3.1. Operation has initially and at least annually thereafter, performed and documented a hazard analysis of the packinghouse, and addresses all identified hazards.
Procedure	Records shall be available to demonstrate that the packinghouse has been evaluated with regards to potential food safety hazards associated with the packinghouse and the activities taking place within. Workers shall be trained on what the food safety hazards are and how to manage them.
Verification	Auditors verify the operation has performed and documented a hazard analysis of the packinghouse Auditor verifies that control measures for all significant hazards identified during the analysis are implemented.
Corrective Action	The operation shall perform and document a hazard analysis for the packinghouse. Training of appropriate personnel may need to take place on conducting and recording this assessment. Operation trains workers on the maintenance of the food safety hazards identified and how to manage and record the management of these hazards.
Documents Required	Risk Assessment.
Mandatory	●

Expectation
A hazard analysis is the process of collecting and evaluating information on hazards and the conditions leading to their presence to determine which hazards are significant for food safety and therefore should be addressed in a Hazard Analysis and Critical Control Point (HACCP) plan or Food Safety Plan. Hazards are any biological, chemical (including radiological), or physical agent

that has the potential to cause illness or injury. The hazard analysis must include two elements: (1) a hazard identification and (2) a hazard evaluation to determine whether the hazard requires a control measure.

A hazard analysis identifies and evaluates hazards and helps to determine if control measures are needed to prevent, eliminate, or further reduce potential contamination. All activities that take place in the packinghouse should be assessed such as: receiving and storage of raw material, processing, packing, storage, and distribution. Additionally, it is important to identify the various equipment and food contact surfaces that are used in the operation when outlining the steps in the hazard analysis.

The risk assessment should be reviewed/updated when operational changes occur within the packinghouse. The comment should include the date and the role/title of the person who conducted the most recent hazard analysis.

Example hazards include:
Biological:

- Bacteria: *Listeria monocytogenes*, *Salmonella*, *E. coli*
- Viruses: Hepatitis A, norovirus
- Parasites: *Cryptosporidium*, *Cyclospora*

Chemical:

- Pesticide residues
- Sanitation chemicals
- Lubricants

Physical:

- Glass
- Metal
- Stones

Example Scenarios
Scenario 1: Operation performed and documented a risk assessment of the packinghouse when they first began using it 5 years ago. They have not updated the risk assessment since, but they state that the risks have not changed.
Assessment: Corrective Action Needed

Reason: The requirement requires an annual hazard analysis be performed and documented.

Scenario 2: A risk assessment has been conducted for the packinghouse which was updated two months before the time of the audit. During the audit the auditor observes that there is a tomato packing line that was not included in the risk assessment. The food safety manager states that they just started packing tomatoes on that line two weeks ago.
Assessment: Corrective Action Needed
Reason: The hazards have not been assessed for that packing line.

Requirement	**P- 3.1.a. If microbiological hazards requiring a control are identified in the hazard analysis of the packinghouse an environmental monitoring program shall be established.**
Procedure	**The operation has established an environmental monitoring program based on the risks identified in the hazard analysis. The program shall address microbiological risks and include procedures for sampling, testing and frequency. Acceptable results shall be clearly defined and include procedures for when unacceptable results have occurred. Records of environmental monitoring sampling, testing and any corrective actions shall be kept.**
Verification	**Auditor reviews the environmental monitoring program and records and observes current practices for compliance with policy.**
Corrective Action	**Operation develops an environmental monitoring program. Retraining is performed and documented. Records of environmental monitoring and corrective actions are kept.**
Documents Required	**Written Policy, Record.**
Mandatory	

Expectation
If an operation determines that a microbiological hazard requires a control, then a risk-based approach must be in place to define the microbiological environmental monitoring program. Examples of produce operations where microbiological hazards may be identified in the hazard analysis that could potentially require a control are:

- Bagged salad mix or bagged spinach
- A raw agricultural commodity exposed to the environment after washing before packaging
- Commodities following industry guidelines

This program must establish, implement and maintain procedures to reduce the risk of cross-contamination.

The program must identify the target organism, the test method, the frequency of testing, the areas to be tested, the acceptance criteria and actions to be taken in the event samples exceed acceptance

criteria. The target organism could be the environmental pathogen of concern or an appropriate indicator organism.

Environmental pathogens are those pathogens capable of surviving and persisting within the manufacturing processing, packing, or holding environment such that food may be contaminated if not properly controlled. Those pathogens of concern in the produce industry are often *Salmonella* in dry environments and *Listeria monocytogenes* in wet environments. Pathogenic *E. coli* is not considered an environmental pathogen that would be monitored in an environmental monitoring program.

The environmental monitoring program parameters should be established based on risk. Factors to consider when setting the parameters include whether the product receives a reduction step, what points along production where the product has exposure to the environment after the reduction step and before packaging, whether the product is handled in a wet, verses a dry environment, whether the product supports growth of the environmental pathogen, and the shelf life of the product and storage conditions. International Fresh has published *Listeria* guidance for industry with information on how to develop an environmental monitoring program for produce operations.

The Food Safety Preventive Controls Alliance (FSPCA) provides teaching examples of food safety plans and hazard analysis performed for a blueberry packing operation, a whole tomato packing operation and a fresh cut leafy greens salad operation. These teaching examples demonstrate when an environmental monitoring program is appropriate as determined by the hazard analysis and provides example environmental monitoring programs.

Example Scenarios:
Scenario 1: A strawberry operation which field packs strawberries into clamshells, cools and stores the product on site. Their hazard analysis determined that they do not need a microbial environmental monitoring program. The operation concluded that any microbial exposure in the facility would be controlled through their cleaning SOP's.
Assessment: Compliant
Reason: Operation's that handle only pre-packaged produce, i.e., produce not exposed to the environment are reasonably unlikely to be vulnerable to microbial contamination in the facility.

Scenario 2: An apple operation's environmental monitoring program establishes that drains shall be swabbed for *Listeria* spp. quarterly, however the program does not define the acceptable results. Auditor reviews most recent swab results and all are negative for *Listeria* spp.
Assessment: Corrective Action Needed
Reason: The environmental monitoring program shall establish acceptable results and corrective action steps to be taken when results are out of compliance. Routine sampling may be performed weekly, monthly or quarterly depending on the amount of product produced, risk and facility history. There is no "right" answer as to frequency and number of swabs. It is up to the operation to make that determination. However, the operation must comply with their own policy.

Requirement	P-3.2. Building shall be located, designed, constructed and maintained in a manner that prevents contamination of produce during handling, storage, and cooling.
Procedure	Product flow is designed to minimize risk of cross-contamination. Building and equipment structures and surfaces (floors, walls, ceilings, doors, frames, hatches, etc.) shall be constructed in a manner that facilitates cleaning and sanitation and does not serve as harborage for contaminates or pests. Drop ceilings shall enable cleaning and monitoring for pest activity. Chill and cold storage loading dock areas shall be appropriately sealed, drained and graded, as appropriate for the operation. Fixtures, ducts, pipes and overhead structures shall be installed and maintained so that drips and condensation do not contaminate produce, raw materials or food contact surfaces. Drip pans and drains shall be designed to assure condensate does not become a source of contamination. Water from refrigeration drip pans shall be drained and disposed of away from product and product contact surfaces. Floors are designed to minimize and/or facilitate the removal of standing water. Air intakes shall not be located near potential sources of contamination.
Verification	Auditor observes building and equipment for evidence that the building can be cleaned and maintained to prevent product contamination.
Corrective Action	Building deficiencies are corrected. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	
PSR	112.126

Expectation

Consideration should be given to the activities that occur within the building, the volume and frequency of activity within the building, the number, size, and placement of equipment and tools used or stored within the building, and the number of people (e.g., personnel, supervisors, visitors, contractors) using the building at any given time to determine if the size and construction of the building is adequate. For a building to be suitable in size, it should have enough space for the operation's activities to be conducted without contact between produce or food contact surfaces and building materials, non-food contact surfaces, or clothing. The placement of equipment should be such that personnel can easily perform inspections, maintenance, and cleaning and sanitizing activities.

Consideration should be given to the flow of the product throughout the operation to minimize the potential for cross contamination. For example, the areas where final product is packaged for distribution is not immediately adjacent to areas where incoming field product is being washed, thus minimizing the potential for wash water to splash up and contact the finished product.

Produce and food contact surfaces must be protected from dripping condensate using practices such as: routing condensate to drains, drip pans, or areas away from produce and food contact surfaces; not storing covered produce or food contact surfaces under or near areas identified as likely condensate areas or "drip zones"; covering produce and food contact surfaces to protect them from condensate; or controlling the humidity in the building (e.g., through ventilation) to minimize the formation of condensate. The operation should limit the amount of standing water that pools on the floor for long periods of time. This water could harbor pathogens such as *Listeria monocytogenes*, which thrives in wet, cool environments.

It is the auditees responsibility to ensure that buildings are designed, constructed, and maintained properly to facilitate cleaning and sanitation and does not serve as a harborage for contaminates or pests and prevents a food safety risks to products during handling.

Example Scenarios
Scenario 1: The packinghouse has three finished walls and bird netting on the fourth.
Assessment: Compliant.
Reason: The structure is built to facilitate cleaning and sanitation and does not serve as harborage for contaminants or pests during staging and cooling.

Scenario 2: You observe the condensate drain from the refrigeration unit inside the cold room is piped into a floor drain.
Assessment: Compliant.
Reason: The facility is designed in a manner that prevents product contamination.

Produce Safety Rule
112.26: (a) All buildings must meet the following requirements (1) buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for growing, harvesting, packing and holding activities to reduce the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must provide sufficient space for placement of equipment and storage of materials and permit proper precautions to be taken to reduce the potential for contamination of produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems or other effective means. (2) There must be adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building. (b) Measures to prevent contamination of produce and food contact surfaces in the buildings must be implemented, as appropriate, considering the potential for such contamination through: Floors, walls, ceilings, fixtures, ducts or pipes: and drip or condensate.

Requirement	P-3.3. Adequate lighting shall be provided in all areas.
Procedure	Lighting in all areas shall be sufficient to enable cleaning, sanitation, repairs, etc.
Verification	Auditor observes, directly or by other evidence, that sufficient lighting is provided to the worker to clearly see the task being performed.
Corrective Action	Operation installs adequate, lighting.
Documents Required	N/A.
Mandatory	

Example Scenarios
Scenario 1: Covered lights are available on the perimeter of open-air facility (i.e., roof but no walls) but not directly over product lines. Owner states that facility only runs during daylight hours.
Assessment: Compliant.
Reason: As long as interviews substantiate daylight only for running and maintenance and cleaning activities.

Scenario 2: Lights are located appropriately to enable cleaning, sanitation, repairs, etc. and are not directly over food handling areas. Light fixtures are not covered nor are shatterproof bulbs being utilized.
Assessment: Compliant for P-3.3 however corrective action needed for P-3.4.
Reason: The lighting is adequate. The material the lighting is made out of is potentially hazardous which does not comply with the requirement of P-3.4.

Requirement	P-3.4. Only essential glass and brittle plastic shall be present in the building.
Procedure	Light bulbs, fixtures, windows, mirrors, skylights and other glass and brittle plastic in the building or in the product path entering or exiting the building shall be of the safety type, or shall be otherwise protected to prevent breakage. If glass or brittle plastic must be used, there shall be a written glass and brittle plastic control policy, including a glass and brittle plastic register.
Verification	Auditor observes glass and brittle plastic use in building, and glass and brittle plastic control policy and glass and brittle plastic register for compliance.
Corrective Action	Operation develops a glass and brittle plastic control policy or eliminates all glass and brittle plastic in the building.
Documents Required	Record.
Mandatory	

Expectation
This question pertains to glass light bulbs and any other glass products that may be located above the product flow zone. Overhead lighting, regardless of height above the product, that may be

susceptible to breakage should be protected from falling onto conveyor lines or into product containers such as bins or final packages. Other glass items, either in whole or broken form, must be contained or prevented from falling into product.

In the case of lighting equipment (fluorescent, incandescent, krypton vapor, etc.), there are many commercially available products and lighting equipment/types that may be used. In some cases, lighting fixtures may cover or enclose the bulb; in other cases, the bulbs may be coated with some medium that retards breakage and shattering; in other cases, shields to cover the fixture are available. Operators must take preventive measures to effectively prevent glass, broken or whole, from falling into the flow of product. Observe the lighting or other glass being used in the operation and determine whether it is possible that falling pieces may contaminate the produce. This question can only be answered N/A when there is no glass over any of the product flow zones.

Example Scenarios
Scenario 1: Lights in the storage building are unshielded glass. Products being stored below the lights are sealed and palletized with plastic wrapping.
Assessment: Corrective Action Needed.
Reason: The standard requires glass to be of the safety type or must be otherwise protected to prevent breakage.

Scenario 2: Lights on the forklift that is used in the storage area are unshielded glass. Product in this area is in exposed open top boxes.
Assessment: Corrective Action Needed.
Reason: The standard requires glass to be of a safety type or otherwise protected. This assessment could be an Immediate Action Required if there is a reasonable probability that the glass could break into the boxes.

Requirement	P-3.5. Catwalks above product zones are protected to prevent produce or packaging contamination.
Procedure	Where workers walk over product contact surfaces, those walkways are solid surface or have catch trays installed, are protected by kick plates, product covers or other barriers.
Verification	Auditor observes catwalks over product zones for evidence of protective measures.
Corrective Action	Operation retrofits catwalks or product zones to protect against potential contamination. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	

Example Scenarios
Scenario 1: An equipment-access catwalk above a product conveyor is made of steel grid material without kick plates. You observe that personnel access to the catwalk is controlled and infrequent during product handling. There is signage at both entry points that instruct personnel to change into

designated footwear that is only worn in the catwalk area. You observe the footwear and its use by employees, including properly maintained footbaths at both entries to catwalk, is compliant with the operation's policy.
Assessment: Immediate Action Required.
Reason: Designated footwear is not a sufficient protection against materials falling onto the conveyor, and sanitizer from the footbath and footwear is reasonably likely to drip onto the conveyor.

Scenario 2: Same as Scenario 1, but catch pan is installed underneath catwalk. You observe the catch pan extends the entire length of the catwalk, is wider than the catwalk, and is clean and contains no debris.
Assessment: Compliant.
Reason: The catch pan provides protection to the product from the catwalk.

Requirement	P-3.6. If applicable, operation has a written Allergen Control Program.
Procedure	The Allergen Control Program lists the allergens in use or storage at the operation specific to country regulations. If applicable, procedures address identification and segregation of allergens during storage and handling as based on a risk assessment conducted by the operation.
Verification	Auditor reviews Allergen Control Program and inspects operation for evidence of allergen use and storage.
Corrective Action	Operation develops and implements an Allergen Control Program or eliminates allergens from the operation.
Documents Required	Risk Assessment, Written Policy.
Mandatory	●

Expectation
FDA has identified nine major food allergens: milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, soybean and sesame.

If applicable, the comment should include that the auditor verified there are no allergens present.

See the FDA allergen guidance document for more information on allergen regulations.

Example Scenarios
Scenario 1: The operation has no allergen control program and there is no evidence that they handle allergens.
Assessment: Not Applicable.
Reason: If the operation states that no allergens are handled and you observe this to be correct this requirement is Not Applicable.

Scenario 2: The operation has no allergen control program and the only allergens on property are peanuts in the break room vending machine.
Assessment: Compliant.

Reason: Allergens in the break room are not reasonably likely to enter the production area if break area and handwashing policies are followed.

Scenario 3: The operation has no allergen control program, and they handle celery. Celery seed is considered an allergen in Australia.
Assessment: Immediate Action Required or Not Applicable.
Reason: Immediate Action Required if product from the operation is destined for the European Union or other country that considers celery an allergen. Not Applicable if destined for a country that does not consider celery an allergen.

Scenario 4: The operation has no allergen control program, and the operation is co-packing fruit baskets with walnuts that they receive pre-sealed in plastic packets. They do not handle exposed walnuts.
Assessment: Corrective Action Needed.
Reason: The operation needs an Allergen Control Program in case of accidental exposure.

P-4 Pest and Animal Control

Requirement	**P-4.1. Operation has procedures to manage pests to the extent appropriate to the operation.**
Procedure	**Operation has a written pest control program, performed by a trained pest control operator (or licensed where required by prevailing regulation). The written program includes policies and procedures applicable to that operation, such as storage of outside equipment or other factors dealing with pest harborages, and maps of the location of pest traps outside and inside the operation. Operation maintains a pest-control log that includes dates of inspection, inspection reports and steps taken to eliminate any problems. Applications of pesticides (e.g., insecticides, rodenticides) shall be performed in compliance with local, state, and federal pesticide regulations.**
Verification	**Auditor reviews pest control program, pest control operator's credentials, and inspects operation for pest activity.**
Corrective Action	**Operation develops, documents and implements an effective pest control program.**
Documents Required	**Written Policy.**
Mandatory	**●**
PSR	**112.128**

Expectation
All packing and storage facilities should establish a pest control program to reduce the risk of contamination by rodents and other animals, including pets. This program should include regular and frequent monitoring of affected and treated areas to accurately assess the program's effectiveness. A pest control log must be maintained that includes inspection dates, inspection reports, and procedures implemented to eliminate any problems.

Generally, all traps and bait stations will be marked and flagged by numbers or some type of coding system. It is likely that there will also be a map of the premises that 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.

Be aware of and look for an organized method of pest detection and elimination. The comment should identify who manages the pest/animal control program.

Example Scenarios
Scenario 1: The operation has contracted with a pest control firm but doesn't have a written plan available.
Assessment: Corrective Action Needed.
Reason: A written plan is required.

Scenario 2: The operation has a written pest management plan with contract requiring the pest control company to maintain logs detailing dates and observations during inspections. The logs are not maintained onsite.
Assessment: Compliant if logs are available during the audit.
Reason: The operation has written the contract into their pest management plan and logs are accessible even though they are maintained off-site.

Scenario 3: During the audit, the auditor observes two rodent traps in the finished product storage area with decaying rodents.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: The decaying rodents indicate that the maintenance of the pest management program is not conducted at a frequent enough basis. If an imminent food safety risk is present to the produce this would be considered an Immediate Action Required.

Produce Safety Rule
112.128: The operation must take those measures reasonably necessary to protect produce, food contact surfaces and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate. For fully-enclosed buildings, measures must be taken to exclude pests from the buildings. For partially-enclosed buildings measures must be taken to prevent pests from becoming established in the buildings (such as by use of screens or by monitoring for the presence of pest and removing them when present).

Requirement	P-4.2. Operation restricts animals from food handling areas.
Procedure	Domesticated animals are prohibited from packhouse, cooling, and storage facilities unless procedures are in place for their safe presence. Procedures are in place to exclude wild and feral animals to the degree practical and to monitor for and mitigate contamination from animal excreta.
Verification	Auditor looks for evidence of animals or animal activity.
Corrective Action	Operation develops, documents and implements an effective animal control program.
Documents Required	N/A.
Mandatory	●
PSR	112.127; 112.134

Expectation
The facility should consider the use of screens, wind curtains, bird deterrent tape and traps to minimize risk of product contamination. Pet dogs, cats, or other animals should not be allowed in the packing and storage facilities. Review the facility's SOPs to determine if there is a proactive effort to exclude animals and pests from the facility. When guide dogs or similar animals are present, SOPs must include corrective measures.

Example Scenarios
Scenario 1: An operation has security dogs within a constrained area outside the building adjacent to the perimeter of the property.
Assessment: Compliant.
Reason: Working animals are maintained in a manner as to minimalize risk to the product.

Scenario 2: During the audit, you observe evidence indicating the presence of multiple bird nesting sites in the rafters, over the product handling and packing area.
Assessment: Immediate Action Required.
Reason: The active presence of the birds must be removed, and a plan established to prevent the reoccurrence of the nesting sites.

Scenario 3: The packinghouse is an open structure (three walls and a roof) with no barriers to animal entry. Produce, trash, and other animal attractants are only present during work hours (removed nightly). Employees are trained to chase away any animals trying to enter the structure during work hours, and product contact surfaces are cleaned and sanitized before starting work. Employees are also trained to ensure pests do not become established in the structure.
Assessment: Compliant.
Reason: The operation has policies and procedures to restrict animals from the food handling area and prevent pests from becoming established in the structure.

Produce Safety Rule
112.127: Operations must take reasonable precautions to prevent contamination of produce, food

contact surfaces, and food-packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by: (1) excluding domesticated animals from fully-enclosed buildings where produce, food contact surfaces, or food-packing material is exposed; or (2) separating domesticated animals in a fully enclosed building from an area where growing, harvesting, packing or a holding activity is conducted on produce by location, time, or partition. (b) Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food contact surfaces, or food-packing materials.

112.134: If the operation has domesticated animals, there must be a system maintained to control animal excreta and litter in a way to prevent contamination of produce, food contact surfaces, areas used for growing, harvesting, packing and holding, agricultural water sources, or agricultural water distribution systems.

Requirement	**P-4.3. If used, pest control devices, including rodent traps and electrical flying insect devices, are located so as to not contaminate produce or food handling surfaces.**
Procedure	**Only non-toxic traps and pest control devices are used inside the packing house or storage building.**
Verification	**Auditor reviews pest control program and placement of pest control devices.**
Corrective Action	**Operation removes or repositions pest control devices to be compliant.**
Documents Required	**N/A.**
Mandatory	

Expectation
Pest control devices, including indoor rodent traps (e.g., catch-and-release traps, snap traps, glue boards); outdoor rodent traps and bait stations anchored to the perimeter of the building; insect glue boards; light traps; and electronic flying-insect killers, may be placed in areas of high pest activity, suspected points of entry, and nesting sites, but should be placed away from covered produce, food contact surfaces, and food-packing materials. Operations using pesticides and pesticide devices must follow all applicable Federal, state, and local laws.

Example Scenarios
Scenario 1: Electrified insect traps are located adjacent to the raw product handling and packing areas and multiple fragments of insects appear to be scattered throughout the general area.
Assessment: Corrective Action Needed or possible Immediate Action Required.
Reason: IAR if auditor observes insect fragments on product or food contact surfaces. Otherwise CAN; traps must be relocated so as to pose no threat of contamination of the product or food handling surfaces.

Scenario 2: The operation uses bait stations inside the open shipping area. The operation's food safety manager explains that no exposed product is stored or handled in the area; all product is

palletized by the time it reaches shipping.
Assessment: Corrective Action Needed.
Reason: Bait stations must not be used in produce handling areas, packaged or not.

P-5 Equipment, Tools and Utensils

Requirement	**P-5.1. All food contact equipment, tools and utensils are designed and made of materials that are easily cleaned and maintained.**
Procedure	**The operation shall develop, implement, and schedule repair, cleaning, sanitizing, storage and handling procedures of all food contact surfaces to reduce and control the potential for contamination. These procedures shall be documented. Product contact tools, utensils and equipment shall be made of materials that can be cleaned and sanitized. Seams between food contact surfaces are smooth and cleanable.**
Verification	**Auditor observes food contact surfaces for design and materials that can be easily cleaned and maintained. Auditor reviews cleaning, sanitizing, storage and handling procedures.**
Corrective Action	**Operation develops and implements procedures. Operation replaces all non-compliant food contact equipment, tools and utensils.**
Documents Required	**Written Policy.**
Mandatory	●
PSR	**112.123**

Expectation
Food contact tools, equipment and utensils must be of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained. Seams on food-contact surfaces of equipment and tools must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms. They must be stored and maintained to protect from contamination, including preventing the equipment and tools from attracting and harboring pests.

Example Scenarios
Scenario 1: You observe post-harvest tools and utensils around the post-harvest work area during lunch time on a day when there is no harvest activity.
Assessment: Compliant.
Reason: As long as the observed storage of tools and utensils is permitted by the operation's storage and handling procedures and the auditor does not observe a reasonable potential for contamination.

Scenario 2: Product contact tools and utensils appear to be suitable, clean, sanitary, and stored appropriately, but there are no written procedures.
Assessment: Corrective Action Needed.
Reason: The standard requires procedures to be written.

Scenario 3: You observe a trim knife in use has been repaired with a weld that is corroding/cracking.
Assessment: Corrective Action Needed.
Reason: The condition of the food-contact knife is a risk of pathogen harborage or metal contamination. This assessment could be an Immediate Action Required if the auditor observes that the condition of the knife is severe enough to pose an immediate food safety risk.

Produce Safety Rule
112.123: The operation must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and (b) Equipment and tools must be: (1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and (2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests. (c) Seams on food contact surfaces of equipment and tools that are used must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms. (d)(1) The operation must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in growing, harvesting, packing and holding activities as frequently as reasonably necessary to protect against contamination of produce. (2) The operation must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of produce. (e) If using equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact produce, you must do so in a manner that minimizes the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards.

Requirement	**P-5.2. Equipment is installed in a way that provides access for cleaning.**
Procedure	**Cooling, packing and other food contact equipment is installed away from walls and otherwise positioned so as not to inhibit access for proper cleaning.**
Verification	**Auditor observes positioning of all food contact equipment for compliance.**
Corrective Action	**Operation relocates the equipment to be compliant.**
Documents Required	**N/A.**
Mandatory	
PSR	**112.123(b)(1)**

Expectation
Equipment must be installed to facilitate cleaning of the equipment and of all adjacent spaces. Maintenance and cleaning personnel should have easy access to all food contact surfaces, protective coverings or barriers, equipment framework, any movable parts, and other relevant parts. Maintenance and cleaning personnel should also have access to adjacent spaces, such as the floors,

walls, ceilings, and other equipment and tools in the immediate vicinity. Observe the installation of equipment and visually assess the operation's activities to confirm practices.

Consider the potential for installed equipment to accumulate moisture, organic material, or other potential sources of contamination that could contact, drip or drain onto covered produce or food contact surfaces. Also consider the potential for surrounding surfaces to transfer moisture, organic material, or other potential sources of contamination onto covered produce or food contact surfaces of your equipment and tools.

Example Scenarios
Scenario 1: You observe that there is walk around space on all sides of food contact equipment but are not able to observe washing procedures to verify how washing equipment accesses equipment. You observe the equipment is clean.
Assessment: Compliant.
Reason: The equipment is installed in a way that provides access for cleaning and you did not observe deficiencies in cleaning.

Scenario 2: A produce flume, 4 foot wide, is installed with 2 inches clearance from the concrete floor. The operation uses a high-pressure hose to clean under the flume.
Assessment: Corrective Action Needed.
Reason: The flume has not been installed to provide access for proper cleaning.

Produce Safety Rule
112.123: The operation must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and (b) Equipment and tools must be: (1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces.

Requirement	**P-5.3. Equipment lubrication is managed so as not to contaminate food products.**
Procedure	**Only food-grade lubricants are used on food processing and packaging equipment or on any other equipment where incidental food contact may occur, unless the equipment manufacturer specifies only a non-food grade lubricant. Lubricant leaks are fixed or catch pans are installed to prevent product contamination.**
Verification	**Auditor reviews purchase or maintenance records to verify all lubricants used are food grade. Auditor observes lubrication points to verify leaks are controlled.**
Corrective Action	**Operation replaces non-food grade lubricants. Operation fixes lubricant leaks or installs catch pans. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	

Expectation
Auditors will consider if the operation uses a closed system. A closed system is a physical system that does not interact with other systems, it prevents contamination and spillage. In many operations auditors will observe various types of open mechanical systems, such as chains moving conveyor belts. It is important that auditors verify that food grade lubricant is used in open systems to reduce possible contamination. Catch or drip pans are often used in systems where lubricant could possibly leak or drip. Observe that catch or drip pans are properly maintained and placed so that they are not overflowing and are located to catch any leaking lubricant.

Example Scenario
Scenario: Leaking lubrication is noticed on the drive motor fitting for conveyor B. There is no catch pan in place under the drive motor, which is located over conveyor C, which contains exposed product. There are streaks on Conveyor C, demonstrating that lubricant has dripped onto the conveyor. The supervisor explains that it is food grade lubricant.
Assessment: Immediate Action Required.
Reason: Contamination with food grade lubricant is still adulteration.

Requirement	**P-5.4. All instruments used to measure temperature, pH, antimicrobial levels and/or other important devices used to monitor requirements in this section shall be adequately maintained and calibrated at a frequency sufficient to assure continuous accuracy.**
Procedure	**Records shall be kept. If an ORP system is used, an independent measurement shall be used to verify compliance. Test methods or test strips used to monitor requirements shall be appropriate to their use, sufficiently sensitive to their intended purpose and available in adequate numbers for their designated use.**
Verification	**Auditor reviews calibration and verification procedures and records.**
Corrective Action	**Operation develops, documents and implements calibration and verification procedures and records.**
Documents Required	**Record.**
Mandatory	●
PSR	**112.124**

Expectation
Calibration is essential when using various equipment within the Food Safety Plan. Companies must calibrate when necessary or by defined date as may be required by the manufacture. Employees must be properly trained in how to calibrate their specific equipment. Training may consist of documentation provided by the manufacture or participation in classroom environment.

The auditor will include the instruments/equipment being calibrated, the method of calibration and the frequency of calibration in the comments.

Example Scenarios

Scenario 1: The operation calibrates ORP and pH meters daily before initial production using manufacturer's recommended procedures. Chlorine levels are verified using free chlorine test strips of appropriate sensitivity and precision, and within manufacturer's expiration date. Records are kept.
Assessment: Compliant.
Reason: The operation calibrates the ORP and pH meters and records are kept of calibration activities.

Scenario 2: The operation has switched to chlorine dioxide but continues to use ORP controller and chlorine test strips.
Assessment: Immediate Action Required.
Reason: Unless operation has demonstrated that the ORP controller and chlorine test strips are appropriate for monitoring chlorine dioxide.

Scenario 3: Wash water temperature is monitored with an in-line coil thermometer. Temperature is recorded daily. There are no calibration records.
Assessment: Corrective Action Needed.
Reason: Coil thermometers are notorious for losing calibration, and the standard requires calibration records to be kept.

Produce Safety Rule
112.124: Instruments or controls used to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be accurate and precise as necessary and appropriate in keeping with their purpose, adequately maintained; and adequate in number for their designated uses.

Requirement	P-5.4.a. Calibration of equipment is traceable to a recognized standard.
Procedure	Calibration of measuring and monitoring equipment (thermometers, pH meters, scales, chemical application or monitoring devices) is performed using a recognized standard or method.
Verification	Auditor reviews the calibration procedures to determine if they follow a recognized standard or method.
Corrective Action	Operation develops calibration procedures which are traceable to a recognized standard or method.
Documents Required	Written Policy.
Mandatory	

Expectation
(See F-8.2.b)

Requirement	P-5.5. Foreign material control devices are inspected and maintained.
Procedure	If included in the Food Safety Plan, foreign material control devices shall be included as part of a Preventive Maintenance Schedule or other program and maintained to ensure effective operation. Calibration checks shall be performed according to written procedure or manufacturer's recommendations.
Verification	Auditor inspects any foreign control devices and maintenance and calibration check records for compliance.
Corrective Action	Operation develops written procedures for inspection, calibration checks and maintenance of foreign material control devices. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Record.
Mandatory	

Expectation
A HACCP plan is the foundation of effective foreign material control as it identifies the raw materials and process steps where contamination is likely to occur. Using the HACCP risk assessment, as well as industry standards, guidelines, regulations, and scientific studies, the facility can identify the steps in the process where foreign material control is needed. At the manufacturing level, devices commonly used to control foreign material include metal detection, X-ray, optical sorting equipment, mechanical sorting equipment (sieves, screens, filters, and magnets), bone separators, and visual inspection. Farm processing may include de-stoners, gravity tables, air separation, and visual inspection. This list is not exhaustive, and the devices needed in each facility will depend on the product being made and the manufacturing process.

Once an operation has identified the required devices, a strong program to control foreign material is necessary. Components of this program include standard operating procedures for activities, corrective action procedures for any deviations that occur, and employee training. Also essential for critical control points is the validation of the system.

If metal detection equipment is used, the auditor will include the frequency the equipment is being checked in the comments.

Example Scenarios
Scenario 1: The metal detector is calibrated by a contract service provider annually. The operation checks detection sensitivity and kick-out daily with wand provided by the contractor. Records are kept. The production records indicate no metal has ever been detected in product.
Assessment: Compliant.
Reason: The detection checks are at a frequency required in the Food Safety Plan and by manufacturer recommendations.

Scenario 2: A lemon packing operation has no metal detector on-line or in the Food Safety Plan. The operation says washing, roller gaps and visual sorting make foreign material control unnecessary.
Assessment: Not Applicable, if accurate.
Reason: The standard does not require foreign material control devices.

Scenario 3: Same as Scenario 2 except the Food Safety Plan says that metal control is unnecessary because of washing and sorting, but they have a metal detector on the packing line "because customers require it." The detector is not working.
Assessment: Not Applicable.
Reason: The Food Safety Plan does not require a metal detector. Not Applicable, unless auditor observes reasons why there is metal contamination risk.

Requirement	**P- 5.5.a. Metal detection equipment, if utilized shall be checked at a scheduled frequency as outlined in the operation's food safety/HACCP plan using iron, non-iron and stainless steel testing wands.**
Procedure	**These systems should be frequently checked to ensure that they are working correctly (recorded). Foreign material issues should be noted and corrective actions implemented as written in the food safety program.**
Verification	**Auditors shall review equipment records to ensure frequency is according to established food safety plan.**
Corrective Action	**Procedure is developed and implemented at an established frequency. Training is implemented.**
Documents Required	**Record.**
Mandatory	

Example Scenario
Scenario: The food safety manual states that the metal detector will be verified with Safe line 2.5 mm Fe, 2.0 mm non-ferrous, and 3.0 mm 316 Stainless wands on an hourly basis. You observe the metal detector check log and notice that calibrations are recorded every two hours.
Assessment: Corrective Action Needed
Reason: The operation is not in compliance with their own policy.

P-6 Maintenance and Sanitation

Requirement	P-6.1. A Preventive Maintenance and/or Master Cleaning Schedule, with related SOPs, shall be established.
Procedure	There is a written cleaning and sanitation schedule for all food and non-food contact surfaces including floors, drains, walls, ceilings and other surfaces that may pose a source of product contamination. Roof leaks shall be promptly identified, controlled and repaired. Operation has procedures for cleaning and sanitation of cooling equipment. Drip pans and drains shall be maintained to assure condensate does not become a source of contamination. If standing water exists, it is removed from floors and floors cleaned in a manner and at a frequency sufficient to prevent creation of a source of contamination.
Verification	Auditor reviews Preventive Maintenance and/or Master Cleaning Schedule, observes building and equipment for evidence that the building is cleaned and maintained to prevent product contamination. Auditor reviews building maintenance records for evidence of repairs.
Corrective Action	Operation develops a Preventive Maintenance and/or Master Cleaning Schedule, with related SOPs. Building deficiencies are corrected. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Policy, Record.
Mandatory	●

Expectation
Buildings, fixtures, and other physical facilities of the plant must be monitored and maintained in a clean and sanitary condition and must be kept in repair to prevent food from becoming adulterated. All areas of the operation should be considered in the Preventive Maintenance and Master Cleaning schedules.

For the Master Cleaning schedule, the operation must identify the cleaning and/or sanitation for the facility, including the food handling areas and equipment, specify how often the tasks are conducted, responsibilities for the tasks, and how completion of the tasks is documented.

A Preventive Maintenance (PM) program will include the regular and routine maintenance of equipment and other facility infrastructure in order to keep them in suitable condition for production. The timing of tasks would be based on the equipment manufacturer's recommendations. The program requires planning and scheduling maintenance of equipment before a problem occurs. Examples of items that would be included in the preventive maintenance program would be the replacement of filters or screens, changing oil or applying lubrication, and the inspection and replacement of production line rollers.

Operations should regularly inspect and maintain equipment to avoid conditions that can support microbial growth. Examples of harborage areas are cracked hoses, torn rubber door seals, standing water, dirty conveyor belts, brushes and rusty equipment. Condensation in packing, cooling and

storage areas should be eliminated or minimized. Equipment associated with food contact surfaces must be cleaned, sanitized, and inspected after maintenance repairs. When construction, dismantling, or re-positioning of equipment is done as part of maintenance activities, control measures are in place to minimize food safety risks. Verify through interviewing and/or reviewing a written policy that these procedures are implemented. Review records for compliance with procedures for maintenance, cleaning and sanitation.

All post-harvest water needs to meet the microbial standards for drinking water. For the purposes of USDA GAP audits, this is considered to be no detectable generic *E. coli*. This would include water used to create steam for cleaning.

Example Scenarios
Scenario 1: There are noticeable water stains on the ceiling over product contact surfaces but no standing water on the floor. There is a record of maintenance correcting the source of the water stains.
Assessment: Compliant.
Reason: The problem was documented and has been corrected.

Scenario 2: The operation's master cleaning schedule indicates that walls, drains and ceilings are cleaned once a year. Records are available demonstrating compliance. Annual cleaning is deemed to be sufficient to prevent product contamination.
Assessment: Compliant.
Reason: Cleaning records are maintained.

Scenario 3: SOPs are written for cleaning and sanitizing equipment and are located in the office 4 miles away. Your observations and interviews demonstrate operation's compliance with written procedures.
Assessment: Compliant.
Reason: SOPs are in place and appropriate for the operation.

Requirement	**P-6.1.a. Routine housekeeping practices must be implemented.**
Procedure	**Routine housekeeping practices must be implemented. These could include sweeping, mopping, emptying trash and cull piles, cleaning up spills, and keeping storage areas neat and tidy.**
Verification	**Auditor verifies operation for evidence of routine housekeeping.**
Corrective Action	**Operation implements routine housekeeping.**
Documents Required	**N/A.**
Mandatory	

Expectation
Maintenance and sanitation are key to preventing unintentional cross contamination to the product. Basic, routine housekeeping practices are the foundation to an effective sanitation program. Such practices could include sweeping, mopping, emptying trash and cull piles, cleaning up spills, and

keeping storage areas neat and tidy. Once basic housekeeping practices are in place, a preventive maintenance and master cleaning program can be established.

Requirement	P-6.1.b. Maintenance activities shall not introduce food safety risks.
Procedure	Procedures for maintenance activities are compliant with all food safety requirements and do not create potential sources of chemical, microbiological, or physical contamination.
Verification	Auditor verifies maintenance activities do not introduce food safety risks.
Corrective Action	Operation implements maintenance activities in a manner that will not introduce a food safety risk.
Documents Required	N/A.
Mandatory	

Expectation
Equipment associated with food contact surfaces must be cleaned, sanitized, and inspected after maintenance activities and repairs. When construction, dismantling, or re-positioning of equipment is done as part of maintenance activities, control measures are in place to minimize food safety risks.

Example Scenario
Scenario: The auditor observes maintenance being performed on one of the packing lines. There was no opportunity to observe if cleaning and sanitation was performed afterwards. Cleaning and sanitation records do not indicate cleaning after maintenance is performed.
Assessment: Corrective Action Needed.
Reason: Equipment must be cleaned and sanitized after maintenance activities.

Requirement	P-6.2. Any temporary repairs on food contact surfaces are constructed of food grade material. Operation has a procedure to ensure that permanent repairs are implemented in a timely manner.
Procedure	Operation has procedures to ensure temporary repairs are compliant with all food safety requirements, and do not create potential sources of chemical, microbiological or physical contamination. Permanent repairs are implemented as soon as practical; operation establishes timelines and responsibilities for completion.
Verification	Auditor observes temporary repairs, if present, and operation's plans for timely completion.
Corrective Action	Operation develops and implements a temporary repair procedure. Operation immediately fixes any non-compliant temporary repairs. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	

Expectation
Operation has procedures both to ensure temporary and permanent repairs are compliant with all food safety requirements and do not create potential sources of chemical, microbiological or physical contamination. Seams on food contact surfaces of equipment and tools must be either smoothly bonded or maintained to minimize accumulation of dirt, filth, food particles and organic material. Materials used for temporary and permanent repairs shall be constructed of food grade materials. No carpet or materials that cannot be cleaned or do not dry shall be used. Repairs shall be inspected and followed by cleaning and sanitation as established by the cleaning procedures outlined in requirement P-6.1.

Example Scenarios
Scenario 1: Plastic is used for a temporary repair and was secured with clips that do contact the product. The operation explains that they are actively looking for a permanent solution.
Assessment: Compliant.
Reason: The plastic and clips are approved for food contact, and are to be cleaned and sanitized, and are not reasonably likely to pose a physical hazard.

Scenario 2: Duct tape is used for a temporary repair and no timeline or plan for a permanent fix is available.
Assessment: Immediate Action Required.
Reason: Tape presents an opportunity for pathogen harborage and can become a source of foreign material. Additional concerns include whether the tape is approved for food contact and can be cleaned/sanitized. Further, operation has not established a timeline or responsibilities for completion.

Requirement	**P-6.3. All cleaning agents shall be approved for their intended use on food contact surfaces.**
Procedure	**All chemicals used for cleaning or sanitizing of food contact equipment, tools, utensils, containers and other food contact surfaces shall be approved for that use, according to the chemical manufacturer or supplier and all federal, state and local requirements, and shall be used in a manner consistent with the approved use.**
Verification	**Auditor reviews cleaning and sanitizing chemicals purchasing practices or procedures, storage area, and use procedures to verify compliance.**
Corrective Action	**Operation ceases use of unapproved chemicals. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	

Expectation
Cleaning is a prerequisite for effective sanitization. Cleaning is the removal of organic matter, using appropriate detergent chemicals under recommended conditions. Organic matter from food

residues such as oils, grease, and protein not only harbor bacteria but can prevent sanitizers from coming into physical contact with the surface to be sanitized. In addition, the presence of organic matter can inactivate or reduce the effectiveness of some types of sanitizers, making sanitization ineffective.

For cleaning to be performed properly, the right cleaning agents must be selected for the job. Cleaning agents commonly used include detergents, solvent cleaners, acid cleaners, and abrasive cleaners. Sanitization follows cleaning. Sanitization is the application of heat or chemicals to a properly cleaned (and thoroughly rinsed) food-contact surface, yielding a 99.999% reduction of representative pathogenic microorganisms of public health importance. Auditor must review evidence that cleaning agents being used are safe for food contact surfaces.

Compressed air or other gases that are mechanically introduced into food or used in the process to clean food-contact surfaces or equipment must be filtered and oil-free. Compressed air must also be dried and filtered to exclude microorganisms and moisture prior to use.

All post-harvest water needs to meet the microbial standards for drinking water. For the purposes of USDA GAP audits, this is considered to be no detectable generic *E. coli*. This would include water used to create steam for cleaning.

Example Scenarios
Scenario 1: The operation uses household multi-purpose cleaner that was purchased to clean food contact surfaces. The cleaner was purchased from a local grocery store. Surfaces are not rinsed before use. According to the label, cleaner was not meant to clean food contact surfaces.
Assessment: Immediate Action Required.
Reason: The cleaning chemical needs to be labeled for the appropriate use.

Scenario 2: The operation has a bulk cleaning material with an EPA registration number written on the container but does not have a product label. The operation has on location the label declaration for approved use on food contact surfaces.
Assessment: Compliant.
Reason: The cleaning material is approved for used on food contact surfaces.

Scenario 3: The operation purchases a cleaning agent approved for use on floors, but they are using it on food contact surfaces also.
Assessment: Immediate Action Required.
Reason: Immediate Action Required unless the agent is also expressly approved for use on food contact surfaces. This chemical is not being used for its intended purpose and is not approved for cleaning food grade surfaces.

Scenario 4: Operation uses disinfectant wipes to wipe down product grading line at the end of each shift.
Assessment: Immediate Action Required.
Reason: Wipes are not labeled for use on food contact surfaces.

Requirement	P-6.4. Cleaning equipment and tools are clean, in working order and stored properly away from product handling area.
Procedure	Equipment, utensils and tools used for cleaning or sanitizing, including food contact and non-food contact surfaces, are maintained in a manner sufficient to avoid becoming a source of produce contamination and are stored away from product handling areas.
Verification	Auditor reviews practices or procedures for use and storage of cleaning and sanitizing equipment, tools and utensils, and observes storage area for compliance.
Corrective Action	Operation develops written procedures for maintaining and storing cleaning and sanitizing equipment, tools and utensils. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	

Example Scenarios

Scenario 1: Operation uses rags, brooms/mops, and floor polisher as cleaning equipment, which are cleaned after use and stored on racks/shelves in a room away from production. Cleaning and sanitizing chemicals for food contact surfaces and bathrooms are stored separately in a locked cabinet.

Assessment: Compliant.

Reason: Cleaning equipment and tools are stored properly away from product handling areas.

Scenario 2: Brooms, mops, and brushes are color coded for bathrooms, outside areas, production areas, drains, etc. You find them stacked together on the floor of the storage room.

Assessment: Corrective Action Needed.

Reason: Stacking together defeats the purpose of color coding.

Requirement	P-6.5. Food contact surfaces shall be cleaned, sanitized and maintained according to the Food Safety Plan.
Procedure	Prior to use, the lines used for washing, grading, sorting, or packing shall be cleaned and sanitized as appropriate per risk assessment or prevailing regulations. Records must include the date and method of cleaning and sanitizing equipment. When in use, the lines shall be maintained so as not to be a source of contamination with pathogens.
Verification	Auditor reviews cleaning and sanitizing and records and observes food contact surfaces to verify compliance.
Corrective Action	Operation develops written cleaning and sanitizing procedures and records consistent with the Food Safety Plan. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Record.
Mandatory	●
PSR	112.123

Expectation
Determine if the facility has a policy for cleaning and sanitizing all surfaces that come into contact with the product. This may be verified through questioning of the workers, through a written policy or records of the cleaning process. Review maintenance, cleaning and sanitation records that demonstrate compliance with procedures. If you observe that cleaning and sanitizing is not sufficient this question must be answered as CAN or IAR depending on the severity.

Example Scenarios
Scenario 1: Open air packing facility utilizes an approved food contact surface cleaner and rags to wipe down white conveyor belts which transport fruit to sorters and packers.
Assessment: Compliant.
Reason: Compliant if the product is validated by manufacturer for this use and used according to label instructions.

Scenario 2: A power wash system, with water only, is used to blow off produce particles on conveyor belts in enclosed facility. Per written procedures, a cleaning crew follows up with rags and sanitizing solution for belts only (i.e., belts are run at slow speed and wiped down in place). Particles of blueberries and stems remain between belt and edges of machine.
Assessment: Immediate Action Required.
Reason: Cleaning is chronically insufficient since produce residues have accumulated and have become a source of contamination.

Scenario 3: No cleaning procedures are written in the Food Safety Plan. The operation uses subcontractor for nightly cleaning and sanitizing of facility, food contact and non-contact surfaces.
Assessment: Corrective Action Needed.
Reason: Procedures should be obtained from the subcontractor and included in the Food Safety

Plan.

Produce Safety Rule
112.123: The operation must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and (b) Equipment and tools must be: (1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and (2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests. (c) Seams on food contact surfaces of equipment and tools that are used must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms. (d)(1) The operation must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in growing, harvesting, packing and holding activities as frequently as reasonably necessary to protect against contamination of produce. (2) The operation must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of produce. (e) If using equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact produce, you must do so in a manner that minimizes the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards.

Requirement	P-6.5.a. A cleaning and sanitation program for food contact surfaces shall be established, implemented and maintained. The program shall include measures for monitoring to verify effectiveness.
Procedure	An implemented cleaning and sanitation program shall be established, including SOPs. Procedures must include frequency, approved cleaning and sanitizing agents, and methods of cleaning and sanitizing chemical use. The SOP must justify the frequency of cleaning, demonstrate that the cleaning and sanitizing methods are effective on the surfaces that they are used on, are being used at appropriate concentrations as required by the label. Operation shall demonstrate effectiveness in minimizing the potential for cross contamination from cleaning and sanitizing. Records of sanitizer chemical concentrations shall be maintained.
Verification	Auditor reviews the cleaning and sanitation program procedures and records for inclusiveness of frequency approval and proper use of cleaning and sanitizing agents, and methods of cleaning and sanitizing agent use. Auditor reviews chemical records regarding use of approved chemicals used for cleaning and sanitizing.
Corrective Action	Operation develops and implements program procedures for cleaning and sanitation. Operation identifies chemicals approved-for-use in the cleaning and sanitation program and establishes and maintains records of all cleaning and sanitizer concentrations. Retraining of cleaning and sanitation program policies and procedures is are performed and documented.
Documents Required	Written Policy, Record.
Mandatory	

Expectation
(See Requirement F-8.2.c)

Requirement	P-6.6. Transporting equipment shall be maintained to prevent contamination of products being transported.
Procedure	Pallet jacks, carts, trolleys and forklifts, shall be maintained to prevent contamination of products being transported and are listed on the Preventive Maintenance and/or Master Cleaning Schedules.
Verification	Auditor observes transporting equipment and reviews Schedules and records for evidence of compliance.
Corrective Action	Operation develops and implements Preventive Maintenance and/or Master Cleaning Schedules.
Documents Required	Record.
Mandatory	
PSR	112.123(e)

Expectation
Transporting equipment should be kept as clean as possible and cleaned on a scheduled basis to assist in preventing contamination. All equipment used to transport should be washed or otherwise cleaned whenever they become dirty. Dirty vehicles can contaminate produce with harmful microbes, as well as forklifts and pallet jacks that are not maintained and potentially leaking oil or other fluid onto facility floor.

Some operations may establish standard procedures and logs to ensure clean and maintained equipment. Review records and documentation to verify that a schedule is being followed. This also may be verified through questioning of the workers. This requirement should not be assessed as compliant if there is no documented procedure for a scheduled cleaning/maintenance of the transport equipment.

Example Scenarios
Scenario 1: A forklift used to transport cased, palletized lettuce heads is visibly soiled and has flaking paint on the fork and platform areas that touch pallets.
Assessment: Corrective Action Needed.
Reason: The condition of the forklift is a contamination risk for the pallets and other areas of the operation, and possibly product through holes in the cases. Immediate Action Required if auditor observes evidence of product contamination.

Scenario 2: A maintenance and sanitation schedule lists all forklifts as having weekly inspection and service however pallet jacks are on a monthly frequency. Pallet jacks are clean, but forklifts are visibly soiled.
Assessment: Corrective Action Needed.
Reason: The cleaning schedule for forklifts should be adjusted.

Produce Safety Rule
112.123: The operation must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; (e) If using equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact produce, you must do so in a manner that minimizes the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards.

Requirement	P-6.7. Waste materials and their removal are managed to avoid contamination.
Procedure	Trash, leaves, trim, culls, waste water and other waste materials are removed from the produce handling areas at a frequency sufficient to avoid becoming a source of produce contamination.
Verification	Auditor observes waste control procedures in produce handling areas.
Corrective Action	Operation develops a written waste control procedure. Operational deficiencies are corrected. Retraining is performed and documented.
Documents Required	N/A.
Mandatory	●
PSR	112.132

Expectation
The standard is silent on the type of waste containers required or the frequency for trash removal. The operation should select waste containers that are appropriate for their waste collection and storage activities. For example, look to see that waste containers are not prone to spills, leaks, or overflow and that the waste is being removed at an appropriate frequency, that the volume of waste being generated is able to be contained.

Example Scenarios
Scenario 1: Most of the waste from hand trimming and culling cabbage is carried away by conveyor, but you observe some trim waste on the floor around workers. The supervisor explains that waste is swept away during breaks and area is cleaned and sanitized nightly.
Assessment: Compliant.
Reason: Waste materials are managed to avoid becoming a source of contamination.

Scenario 2: You observe trash container in produce handling area is overflowing. The supervisor explains that containers are emptied during breaks, and this situation is unusual. The next break is in an hour.
Assessment: Corrective Action Needed.
Reason: Operation should have a contingency for when more trash accumulates than normal.

Produce Safety Rule
112.132: (a) All trash, litter and waste in areas used for growing, harvesting, packing and holding of produce must be conveyed, stored and disposed of to minimize the potential to attract or harbor pests and protect against contamination of produce, food contact surfaces, areas used to grow, harvest, pack or hold produce, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards. (b) Adequate systems for waste treatment and disposal must be operated so that they do not constitute a potential source of contamination in growing, harvesting, packing and holding areas.

Requirement	**P-6.8. Outside garbage receptacles/dumpsters are closed and located away from building entrances and the area around such sites is reasonably clean.**
Procedure	**Waste containers and compactors are located away from produce handling areas, are closed or have lids (except for waste collection/cull trailers in active use), are emptied on a scheduled basis or as needed, and weeds and other pest harborage are minimized around container.**
Verification	**Auditor observes waste container location and management practices.**
Corrective Action	**Operation relocates waste containers. Building deficiencies are corrected. Retraining is performed and documented.**
Documents Required	**N/A.**
Mandatory	
PSR	**112.132(a)**

Expectation
Open garbage receptacles/dumpsters attract pests such as birds, vermin, flies, and wildlife because of odors and discarded food products. All containers with lids should be kept closed whenever they are not in use or should be so located that they are a reasonable distance from the storage building entrances in order that pests will not be drawn to the building. They should be emptied regularly.

This question will be a Corrective Action Needed when open or un-lidded receptacles or dumpsters are close to the facility entrances and it is likely pests will enter the building. The area surrounding the dumpsters or garbage receptacles needs to be maintained in a clean and orderly manner. Keep in mind that there may be a small amount of garbage spilled on the outside area surrounding the garbage receptacle or dumpster because of how it may be dumped. When the garbage sits or accumulates or there is no action being taken to clean the spillage, this question must be answered as Corrective Action Needed.

Example Scenarios
Scenario 1: Waste containers are stored inside the facility, along product movement flow lines and are overflowing with waste.
Assessment: Corrective Action Needed, and possible Immediate Action Required.
Reason: Corrective Action Needed, and possible Immediate Action Required if auditor observes reasonable potential for waste to contact product or product contact surfaces.

Scenario 2: You observe the outside area where waste containers are stored to be clean, in good condition, but there are odors coming from the containers.
Assessment: Compliant.
Reason: Compliant if the odor is the only objectionable condition and the waste containers are away from the production area. Waste odors may only take a few hours to develop and are not necessarily an indication of a food safety risk.

Produce Safety Rule
112.132: (a) All trash, litter and waste in areas used for growing, harvesting, packing and holding of produce must be conveyed, stored and disposed of to minimize the potential to attract or harbor pests and protect against contamination of produce, food contact surfaces, areas used to grow, harvest, pack or hold produce, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

Requirement	**P-6.9. The plant grounds are reasonably free of litter, waste culls, vegetation, debris and standing water.**
Procedure	**Operation has procedures to maintain the grounds surrounding the building in a manner to minimize sources of contamination, such as litter, vegetation, waste culls, debris and standing water that may be pest attractants or harborages. Equipment and materials stored outside are stored away from the building perimeter. Outside storage areas are included in pest control program. Vegetation that does not serve as an attractant or harborage is permitted.**
Verification	**Auditor observes the grounds for compliance.**
Corrective Action	**Operation removes the attractants and harborages, and develops procedure to maintain grounds in compliance.**
Documents Required	**N/A.**
Mandatory	
PSR	**112.132**

Expectation
Grounds in the immediate vicinity of all storage areas should be kept clear of waste, litter and improperly stored garbage. The area around the facility should be maintained in a way to discourage the breeding, harboring and feeding of pests, such as rodents and reptiles.

If the grounds are not reasonably free of litter, waste, culls, vegetation, debris or standing water or the type and/or location is such that the debris represents a possible risk of microbial contamination or is sufficient to attract pests to the area, this question should be answered Corrective Action Needed.

Piles of wood, such as pieces of broken pallets, garbage or waste collected or scattered along the storage grounds, food products, food wrappers, cigarette butts, or soda or drink containers scattered across the storage grounds, are all examples of possible reasons to answer this question Corrective Action Needed and Immediate Action Required if excessive.

(See Post-harvest Operations Requirement P-9)

Example Scenarios
Scenario 1: The facility grounds are not on the cleaning schedule but are clean and maintained at the time of inspection.
Assessment: Compliant.

Reason: No schedule is required by the standard.

Scenario 2: There is an empty water bottle, food wrapper, and a puddle (it rained two days ago) near the parking lot, 25 feet from the main building. Grounds closer to the building are well kept.
Assessment: Compliant.
Reason: The observed trash and puddle are not an unreasonable condition.

Scenario 3: The facility has no procedure to prevent pest harborage for equipment stored near the buildings. There is notable rodent and insect activity observed.
Assessment: Corrective Action Needed.
Reason: While the standard does not require written procedures, it does require a procedure. Observation of rodent and insect activity demonstrates actual practices are insufficient.

Produce Safety Rule
112.132: (a) All trash, litter and waste in areas used for growing, harvesting, packing and holding of produce must be conveyed, stored and disposed of to minimize the potential to attract or harbor pests and protect against contamination of produce, food contact surfaces, areas used to grow, harvest, pack or hold produce, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards. (b) Adequate systems for waste treatment and disposal must be operated so that they do not constitute a potential source of contamination in growing, harvesting, packing and holding areas.

Requirement	**P-6.10. Sewage or septic systems are maintained so as not to be a source of contamination.**
Procedure	**After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, operation takes appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate produce, food contact surfaces, areas used for produce handling, agricultural water sources, or agricultural water distribution systems.**
Verification	**If a significant event has occurred, Auditor reviews steps taken by operation to verify sewage or septic system is not a source of contamination.**
Corrective Action	**Sewage or septic systems deficiencies are corrected. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**
Mandatory	●
PSR	**112.131; 112.133**

Expectation
Plumbing for sewage and liquid disposable waste should be intact and free from leaks to prevent contamination of surrounding areas (e.g., packing area floors, growing area soil, agricultural water sources and distribution systems, such as irrigation systems). The sewage or septic system should be inspected periodically to evaluate that it is in good working order and free from damage. If

applicable, the drain field of the septic system should be properly functioning, with no visible leakage. Evidence of a sewage or septic system failure might include soggy patches of land around the septic tank or drain field, slow draining sinks or drains, sewage odors, gurgling noises from the plumbing drain lines, or effluent backup coming from drains, sinks or toilets.

After a significant event, such as flooding or an earthquake, the operation must inspect the entire system to the extent that it is accessible to identify and correct any defects with the system. When the inspection after a significant event indicates defects in the system, the operation must also consider whether they can continue to perform growing, harvesting, packing, and holding activities in a manner that does not contaminate the produce. Temporary measures may be needed to ensure the adequate sanitary conditions are available to prevent possible contamination.

Example Scenario
Scenario 1: Auditee states septic system is checked after a significant event. Shows evidence of compliance via service invoice after a significant event.
Assessment: Compliant
Reason: Invoice serves as the record of their septic system being checked after a significant event.

Produce Safety Rule
112.131: Sewage must be disposed into an adequate sewage or septic system or through other adequate means. Sewage and septic systems, leakages or spills of human waste, which includes after a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, must be maintained in a manner that prevents contamination of produce, food contact surfaces, growing, harvesting, packing or holding areas, agricultural water sources and their distribution systems with known or reasonably foreseeable hazards.

112.133: The plumbing must be of an adequate size and design and be installed and maintained to distribute water under pressure as needed, in sufficient quantities, in all areas where used in growing, harvesting, packing and holding activities for sanitary operations or for hand-washing and toilet facilities. It must be able to convey sewage and liquid disposable waste in a manner to prevent contamination of produce, areas used to grow, harvest, pack and hold produce or agricultural water sources. The plumbing must not allow backflow from or cross connection between piping systems that discharge waste water or sewage and piping systems that carry water used for growing, harvesting, packing and holding of produce, for sanitary operations or for use in handwashing.

Requirement	P-6.11. The sewage disposal system is adequate for the process and maintained to prevent direct or indirect product contamination.
Procedure	The human waste and gray water sewage system has sufficient capacity to handle the operation's peak flows and not cause direct or indirect product contamination. Cross-connections with product contact water systems are prohibited. Floor drains are adequate, functional, free of obstruction, and are properly maintained and cleaned to prevent them from becoming sources of contamination.
Verification	Auditor observes operation for evidence of compliance.
Corrective Action	Operation suspends operation until sewage disposal system functions so as to prevent risk of product contamination. Affected product and product handling areas are evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	●
PSR	112.131; 112.133

Expectation
A cross-connection is a connection between a water source or distribution pipe (e.g., drinking water, water used for handwashing, water used for cooling covered produce) and a liquid waste pipe (e.g., sink drain, sewage line, floor drain line). Cross-connections with product contact water systems are prohibited.

Drainage systems involving water contact with produce, such as from flumes or dump tanks, should flow into a floor drain with an air gap or with a backflow or back siphonage prevention device to prevent contamination of the flume system or dump tank if a backup occurs in the drainage system.

Evidence of a sewage system failure might include slow draining sinks or drains, sewage odors, gurgling noises from the plumbing drain lines, or effluent backup coming from drains, sinks or toilets.

Example Scenario
Scenario: A hydrocooler waste line is plumbed in the same line with the operation's floor drains. You observe the hydrocooler waste line becomes plugged and water backs up onto operation's floor.
Assessment: Immediate Action Required.
Reason: Even rare backflow could contaminate the facility structures and equipment, which could lead to product contamination.

Produce Safety Rule
112.131: Sewage must be disposed into an adequate sewage or septic system or through other adequate means. Sewage and septic systems, leakages or spills of human waste, which includes after a significant event (such as flooding or an earthquake) that could negatively impact a sewage

or septic system, must be maintained in a manner that prevents contamination of produce, food contact surfaces, growing, harvesting, packing or holding areas, agricultural water sources and their distribution systems with known or reasonably foreseeable hazards.

112.133: The plumbing must be of an adequate size and design and be installed and maintained to distribute water under pressure as needed, in sufficient quantities, in all areas where used in growing, harvesting, packing and holding activities for sanitary operations or for hand-washing and toilet facilities. It must be able to convey sewage and liquid disposable waste in a manner to prevent contamination of produce, areas used to grow, harvest, pack and hold produce or agricultural water sources. The plumbing must not allow backflow from or cross connection between piping systems that discharge waste water or sewage and piping systems that carry water used for growing, harvesting, packing and holding of produce, for sanitary operations or for use in handwashing.

P-7 Post-Harvest Water/Ice

Requirement	**P-7.1. A water system description shall be prepared.**
Procedure	**Water sources and the operations they serve shall be documented and current. The description shall include one or more of the following: maps, photographs, drawings (hand drawings are acceptable) or other means to communicate the location of water source(s), permanent fixtures and the flow of the water system (including holding systems, reservoirs or any water captured for re-use). Permanent fixtures include wells, gates, reservoirs, valves, returns, backflow prevention and other above ground features that make up a complete water distribution system shall be documented in such a manner as to enable location in the operation.**
Verification	**Auditor reviews water system description or map, and verifies accuracy during operation inspection.**
Corrective Action	**Operation develops or corrects the water system description or map.**
Documents Required	**Record.**
Mandatory	●

Expectation
Water system descriptions must describe the sources and distribution of water in an operation. All water sources and distribution systems used by the operation need to be documented. If a water source (e.g., a pond on the property) is not used by the operation and the auditor can verify that this information is accurate, the source does not have to be included in the operation's description. Water system descriptions may include maps, photographs, drawings, written descriptions, etc. Auditors will need to verify that the operation has a written water system description and verify the accuracy of the water system description in the process of the review.

Example Scenarios

Scenario 1: An operation has a diagram of all internal piping and fixtures, but only a verbal description that the water comes from an onsite well.
Assessment: Corrective Action Needed.
Reason: A water system documentation must include all water sources.

Scenario 2: The water system description does not include one leg of distribution piping. The operation says that the water is not used for product handling purposes.
Assessment: Corrective Action Needed.
Reason: The water system description must be the "complete water distribution system," although the documentation can state that the water carried by the distribution piping is not used for product handling purposes.

Scenario 3: The operation has no written description, but only uses municipal water.
Assessment: Corrective Action Needed.
Reason: A water system description is still required.

Requirement	**P-7.2. Documented scheduled assessment of water system including delivery equipment shall be performed.**
Procedure	**The water-delivery system shall be maintained so as not to serve as a source of contamination of produce, water supplies or equipment with pathogens, or to create an unsanitary condition. Water installations and equipment are constructed and maintained to prevent back siphonage backflow and cross connections between product contact water and waste water. Routine checks verify that back siphonage and backflow prevention units are functioning properly (annual or as needed to maintain continuous protection). Results are documented.**
Verification	**Auditor reviews maintenance records and examines water system for compliance with water system maintenance program, including backflow prevention and cross-connections.**
Corrective Action	**Operation corrects deficiencies in ability of water system to reliably distribute safe water and schedules water system assessments. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**Record.**
Mandatory	●
PSR	**112.133(d)**

Expectation
The operation must conduct scheduled and routine inspections of their agricultural water systems, to the extent they are under the operation's control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto produce or food-contact surfaces. The operation must adequately maintain their water systems to prevent the water system from being a source of contamination to produce, food-contact surfaces, areas used for harvesting, packing, holding activities, or water sources.

The operation's water system should be of an adequate size and design and be adequately installed and maintained to distribute water under pressure as needed, in sufficient quantities, in all areas where used for activities, for sanitary operations, or for hand-washing and toilet facilities; properly convey sewage and liquid disposable waste; avoid being a source of contamination; and not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for contact with produce or food contact surfaces. Operation must correct any significant deficiencies in ability of water system to reliably distribute safe water (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections).

The operation should have the backflow prevention device checked by a plumber. The auditor reviews water system inspection and/or routine check documentation. It is not expected that an auditor test that the backflow prevention devices are functioning properly. However, if any obvious damage or other evidence that indicates that the system is not functioning properly is observed this must be documented in the audit report and assessed as a Corrective Action Needed or Immediate Action Required based on the risk observed.

The auditor will include frequency of water delivery system assessment in the comments.

Example Scenario
Scenario: You observe a leak at one of the water supply connections to the equipment wash tank and there are rust stains indicating that this has been present for a period of time. The maintenance records do not indicate there is a leak and there is no repair history.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: Corrective Action Needed because there is a leak from the wash tank. This may possibly be considered an Immediate Action Required if there is a reason to believe that the leak is reasonably likely to result in contamination of the water going into the wash tank.

Produce Safety Rule
112.133(d): Plumbing must be adequately installed and maintained to not allow backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for harvesting, packing or holding activities, for sanitary operations, or for use in hand-washing facilities.

Requirement	P-7.3. Water use SOPs address the microbial quality of water or ice that directly contacts the harvested crop or is used on food-contact surfaces.
Procedure	If water or ice directly contacts the harvested crop or is used on food-contact surfaces, operation's water use SOP requires that water or ice when applied meets the microbial standards for drinking water, as defined by prevailing regulation or country in which the product is intended to be traded, whichever is more stringent. Water may be treated (e.g., with chlorine) to achieve the microbial standards or to prevent cross-contamination. Ice and water shall be sourced/manufactured, transported, and stored under sanitary conditions.
Verification	Auditor reviews operation's policy regarding water quality and its transport, and observes evidence that water or ice that contacts harvested crop or food contact surfaces meets the microbial standards for drinking water.
Corrective Action	Operation discontinues using water or ice that does not meet the microbial standards of drinking water. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Record.
Mandatory	●

Expectation
(See Requirement F-10.2)

The auditor will include the water source for post-harvest operation and the water's test results in the comments.

Example Scenarios
Scenario 1: An operation has an SOP that includes an annual lab test of their well water that is used for all produce and equipment cleaning. Copies of the report from the certified lab are available for the last three years.
Assessment: Compliant.
Reason: The results demonstrate compliance with the microbial standards of the drinking water standard.

Scenario 2: An operation uses city water for all activities in the facility but has nothing on file to prove that it meets the microbial requirements of the drinking water standards.
Assessment: Corrective Action Needed.
Reason: The operation should have documentation of compliance from the city.

Scenario 3: Well water is used within the operation for the cleaning of food contact bins. The operation states that they perform testing, but no documentation of the tests or results is available.
Assessment: Corrective Action Needed.

Reason: The operation must have evidence that the water source meets the microbial standards for drinking water.

Scenario 4: An operation only tests the microbial quality of the water and does not perform tests for chemicals.
Assessment: Compliant.
Reason: The Standard only requires compliance to the microbial standards for drinking water.

Requirement	**P-7.4. Operation Food Safety Plan includes produce washing process, if used.**
Procedure	**If produce is washed, an initial risk assessment of the washing process shall be performed that takes into consideration the commodity, type of wash system, type of sanitizer, and water quality.**
Verification	**Auditor reviews Food Safety Plan and operational procedures to determine if washing process has been considered.**
Corrective Action	**Operation revises Food Safety Plan to include produce washing process.**
Documents Required	**Risk Assessment, Written Policy.**
Mandatory	●

Expectation
If produce is washed, an initial risk assessment shall be conducted to identify the risks associated with the washing process which includes the commodity, type of wash system, type of sanitizer and water quality.

The operation must consider the risks associated with the washing process of the produce through the complete wash system. The risk assessment must include the water quality at the start of use and water management strategies such as water treatments used to reduce cross-contamination risks by the water. Treatment methods may vary depending on type of wash water system, such as single pass water verses recirculated and reused water.

Key water quality variables should be included the risk assessment. These key variables include pH, temperature and turbidity. The water plan must include procedures that identify the appropriate parameters required to maintain the water system. The plan must also include how and when to monitor these variables. If using reused water, procedures must include how frequently the water should be changed. Change schedules will be influenced by the organic load introduced by the commodity, volume of produce, type of produce, operating conditions, type of equipment and type of antimicrobial product used.

The operation must identify the approved antimicrobial product and establish the appropriate concentration and monitoring procedures to ensure continuous control of potential hazards in the wash water process. The antimicrobial product must be approved for use in postharvest water systems and reduce human pathogens of concern. Procedures must include corrective actions

needed when monitoring demonstrates the system was out of compliance with parameters established in the plan.

If applicable, comment must include a description of the washing process identifying the type of wash system and type of sanitizer used for each product.

Example Scenarios
Scenario 1: An overhead spray bar is used to wash incoming product. The water source was tested by a lab and the results state it is of drinking water quality. The water is re-used and treated with sodium hypochlorite appropriately and is recorded in a timely manner. The date on the box of sodium hypochlorite test strips used to test the water indicates the test strips are two months beyond the expiration date.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: CAN, if operation can find a box of test strips within the expiration date, checks the water with the good box of test strips, and the water is within the appropriate range. IAR, if a good box of test strips or other adequate method of monitoring the water cannot be found.

Scenario 2: An overhead spray bar is used to wash incoming potatoes. The water is of drinkable quality, is not re-used, and is not treated.
Assessment: Compliant, if considered in the Food Safety Plan.
Reason: The water used is of appropriate quality for its intended use.

Requirement	**P-7.5. If used, water antimicrobial treatments shall be monitored sufficiently to assure continuous control.**
Procedure	**Microbial, physical or chemical testing shall be performed, as appropriate to the specific operation, to demonstrate that acceptance criteria have been met.**
Verification	**Auditor reviews monitoring records for compliance with the operation's established procedure and acceptance criteria.**
Corrective Action	**Operation establishes monitoring program that assures continuous control of water antimicrobial treatment to meet acceptance criteria.**
Documents Required	**Record.**
Mandatory	●

Expectation
For all chemicals used, including water treatment chemicals, an auditee must have access to the chemical's label. The label needs to show that the chemical has been approved for how the auditee is using it – there are different label approvals for use on food contact surfaces, for produce washing, and for the treatment of water.

Additional documentation will be based on the sanitizer and should demonstrate that the auditee is following the label directions for what needs to be monitored. Monitoring criteria may include concentration, contact time, pH, ORP, free chlorine, water temperature, turbidity, and whether the product is rinsed with potable water after the use of the sanitizer.

The comment should include the frequency of microbial, physical, or chemical testing monitoring.

Example Scenarios
Scenario 1: The operation has a policy for monitoring the level of chlorine in the wash water but does not keep records of monitoring activity.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: Corrective Action Needed because records are required. Possible Immediate Action Required if chlorine levels may have dropped or risen to unsafe levels.

Scenario 2: Monitoring records are missing entries.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: Corrective Action needed because monitoring must be at sufficient frequency to ensure continuous control and records are required. Missing entries could be poor record keeping. They could also reflect times when monitoring was not being done as prescribed in company procedures. Possible Immediate Action Required if chlorine levels may have dropped or risen to unsafe levels.

Requirement	**P-7.6. Re-used water that contacts product or food contact surfaces shall be treated using an approved antimicrobial process or chemical treatment.**
Procedure	**Re-used water shall be treated using an antimicrobial treatment sufficient to prevent cross-contamination, unless prevailing regulation or commodity specific standards provide an alternative. Treatments shall be in compliance with prevailing regulation or the country in which the product is intended to be traded, whichever is more stringent.**
Verification	**Auditor reviews water treatment process and evidence of compliance with regulation and the operation's established procedure.**
Corrective Action	**Operation suspends operation until water treatment functions so as to prevent risk of product contamination. Affected product and product handling areas are evaluated for potential contamination and disposition.**
Documents Required	
Mandatory	●

Expectation
The USDA GAP program considers water which contacts more than one batch or lot to be re-used water. This can include both water which is continuously pumped through a system (e.g., a flume, or a spray bar where the water is collected and passed through more than once) or stagnant water which is not drained between lots (e.g. dump tank or wash sink). Since re-used water contacts multiple batches/lots it has the potential to spread contamination across all the product and therefore should be carefully considered in a post-harvest water risk assessment.

If an auditee is using re-used water, it is expected that the water will be treated with a sanitizer to prevent cross contamination of product/lots, unless prevailing regulation or commodity specific standards provide an alternative.

For more information on sanitizers, the Produce Safety Alliance has created an Excel tool for Label Sanitizers for Produce available on their resources webpage. This tool shows which of the different uses each sanitizer has been approved for, the active ingredient, produce information, and whether it can be used in organic operations.

It is important to remember that these water sanitizers are intended to sanitize the water, not sanitize the product. Sanitizing the water may not remove microorganisms from an already contaminated product but will help prevent the water from spreading that contamination onto every other product that is contacted by the water.

The comment should include the type of antimicrobial treatment used and the concentration/critical limits.

Example Scenarios
Scenario 1: Re-used water is treated with a concentration of antimicrobial agent that is lower than the recommended label rate for the intended use.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: Corrective Action Needed unless the operation has validation data demonstrating efficacy at the lower rate. Possible IAR if use rates are not sufficient to prevent cross-contamination.

Scenario 2: Same as Scenario 1, but with a concentration that is greater than the recommended rate.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: Corrective Action Needed because the antimicrobial treatment is not being used in accordance with instructions. Possible Immediate Action Required if residues on produce exceed legal limits.

Scenario 3: Same as Scenario 1, but with an antimicrobial agent not approved for food use.
Assessment: Immediate Action Required.
Reason: Treating with a chemical not approved for food use renders the food adulterated.

Requirement	P-7.7. Operation has documentation demonstrating regulatory approval of the wash water antimicrobials in use.
Procedure	Only wash water antimicrobials or antimicrobial systems registered or approved by EPA, FDA or the prevailing regulatory agency for their specific intended use may be used in the dump tank wash water, on the spray line or other food contact purposes.
Verification	Auditor reviews documentation for appropriateness of use.
Corrective Action	Operation obtains documentation or discontinues use of the antimicrobial system and implements use of appropriate antimicrobial system. Affected product is evaluated for potential contamination and disposition.
Documents Required	Record.
Mandatory	

Expectation
(See requirement F-10.3)

Example Scenarios
Scenario 1: An FDA or EPA approval of the antimicrobial in use for the wash water cannot be found on the label and cannot be produced.
Assessment: Immediate Action Required.
Reason: Inappropriate use of an unauthorized antimicrobial.

Scenario 2: A label for the wash water antimicrobial in use is present, but its use in the water for the category of produce being washed is not on the label.
Assessment: It depends.
Reason: This may be Compliant, CAN, or IAR. Listing produce types is not required. Thus, labels for antimicrobial chemicals used in wash water may not always specify the category of produce that is allowed to be washed. However, all chemicals approved by FDA for washing produce are listed in 21 CFR part 173.315

Scenario 3: A label for the sodium hypochlorite product used in the wash water is present. The chemical is approved for use by the proper authority, however, the dose rate in use is below the acceptable minimum range provided on the label.
Assessment: Immediate Action Required.
Reason: Immediate Action Required if the use rate in the wash water produces levels below the minimum acceptable range.

Requirement	P-7.8. If wash water antimicrobial is used, it shall be used in accordance with established operational procedure and manufacturer instructions.
Procedure	Records shall be kept. Operation shall have a procedure that includes minimum limits for antimicrobial in wash water for food safety. Procedure shall include how to control, monitor and record use of wash water antimicrobial as needed to assure compliance with minimum limits. Operation shall have a procedure as to what corrective actions are taken if criteria are not met.
Verification	Auditor reviews operational procedures and antimicrobial use and corrective actions records for compliance.
Corrective Action	Operation develops, documents and implements procedures for use of the antimicrobial system in compliance with manufacturer instructions. Affected product is evaluated for potential contamination and disposition.
Documents Required	Record.
Mandatory	

Expectation
(See requirement F-10.2 and F-10.3)

Example Scenarios
Scenario 1: The operation's HACCP plan states a Critical Limit of "50 ppm total chlorine minimum" in the wash tank. They monitor ORP and automatically add chlorine and adjust pH as needed, according to manufacturer's recommendations. Electronic records can be downloaded from the ORP controller.
Assessment: Corrective Action Needed.
Reason: Operation should be measuring free chlorine, not total chlorine. ORP monitoring and records are inconsistent with the stated Critical Limit. HACCP plan does not indicate monitoring of pH.

Scenario 2: Operation washes incoming produce twice: the first tank uses potable water but no sanitizer; the second tank uses potable water and 50 ppm free chlorine. The chlorine level is monitored in the second tank every half hour, and records indicate compliance with the 50 ppm limit.
Assessment: Immediate Action Required.
Reason: The first tank must contain sufficient antimicrobial to prevent cross-contamination, or switch to a non-immersion, non-reused (single pass) spray system. If cross-contamination occurs in the first tank, there is no assurance that the antimicrobial in the second tank can correct the contamination.

Scenario 3: The operation monitors antimicrobial levels every hour. Records indicate that antimicrobial levels are monitored as specified in the Food Safety Plan and are always within the operation's established limits.
Assessment: It depends.

Reason: The standard is silent on the minimum frequency for monitoring antimicrobial levels. If records demonstrate that the monitoring frequency adheres to the plan and is sufficient, then the frequency is compliant. If records demonstrate frequent corrective actions because limits are exceeded, then Corrective Action Needed to adjust the frequency.

Requirement	P-7.9. If applicable to the specific commodity, water use SOPs address control of immersion water temperature.
Procedure	For produce that is immersed in water and demonstrated as being susceptible to microbial infiltration from water, water temperature differentials during immersion shall be controlled in accordance with prevailing regulation or industry guidelines.
Verification	If applicable to the commodity being immersed, auditor reviews the SOP for inclusion of water temperature control, and observes monitoring records for evidence of compliance.
Corrective Action	Operation revises SOP to address and control water temperature.
Documents Required	Record.
Mandatory	

Expectation
(See requirement F-10.5)

Example Scenarios
Scenario 1: There is no written SOP for monitoring the flume temperature of the water for tomatoes.
Assessment: Corrective Action Needed.
Reason: Standard Operating Procedures are expected to be written.

Scenario 2: Cantaloupes are washed with a cold-water spray bar. The water contains an approved antimicrobial.
Assessment: Not applicable.
Reason: This item only applies to produce that is immersed.

Requirement	P-7.10. Water change schedules shall be developed for all uses of water where water is re-used.
Procedure	Operation shall have procedures for changing water that is re-used, such as recirculated water, flumes and dump tanks.
Verification	Auditor observes water use procedures and evidence of compliance.
Corrective Action	Operation develops water use procedures. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	

Expectation
A schedule must be established for changing batch water or a process in place for minimizing the build-up of organic material in the water. Recirculated and batch water can be easily contaminated by incoming loads of produce which could introduce hazards such as pathogens. Organic material can also bind to sanitizers, making them less effective.

The specific schedule for changing water will depend on how much produce an operation is washing/cooling, what type of produce, type of equipment (e.g, large scale vs. small scale, if filters are used), soil conditions and type of sanitizer. Measuring and monitoring turbidity in wash water can be one way in which an operation determines the frequency to change the batch water based on these various operating parameters.

The auditor will include the frequency of the re-used water change schedule for each commodity in the comments.

Example Scenarios
Scenario 1: You observe the dump tank has lettuce leaves mixed with broccoli florets in turbid water. There is no documentation or records of water change schedule. No protocol is available regarding breaks between products. The operation explains that all produce washed on the same day has the same lot code.
Assessment: Corrective Action Needed.
Reason: The operation has no procedures for changing water.

Scenario 2: The operation has a "maximum turbidity" standard for wash water. The operation adds fresh water to maintain turbidity below the standard. All wash water is dumped daily.
Assessment: Compliant.
Reason: A water change schedule is in place.

Scenario 3: The operation has a water change schedule for dump tanks, once a day, and for final rinse tanks, twice a day. There is no information in records for some of the scheduled water changes. Operation explains that product volume was unusually high on those days and they didn't want to lose production time by stopping to change the water.
Assessment: Corrective Action Needed.
Reason: The operation did not follow its procedures for changing water.

Requirement	P-7.11. Debris, damaged and/or visibly contaminated produce shall be removed from wash areas/dump tanks to the extent possible.
Procedure	Operation has procedures to determine how and when debris, damaged and/or visibly contaminated produce shall be removed from wash areas/dump tanks.
Verification	Auditor reviews procedures and observes wash areas for evidence of compliance.
Corrective Action	Operation develops, documents and implements a wash area control program. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	

Expectation
The operation shall have a policy to handle debris and damaged and/or visibly contaminated produce in the wash areas and dump tanks. This policy is not required to be written. Auditor interviews the auditee to review the procedures concerning debris and damaged product removal. The auditor observes the operation and determines if they are in compliance with the operation's procedures.

P-8 Containers, Bins and Packaging

Requirement	P-8.1. Specifications for all packaging materials that impact on finished product safety shall be provided and comply with prevailing regulations.
Procedure	The methods and responsibility for developing and approving detailed specifications and labels for all packaging shall be documented. A register of packaging specifications and label approvals shall be maintained and kept current.
Verification	Auditor reviews documentation on methods and responsibilities for packaging materials and label approvals.
Corrective Action	Operation revises labels and packaging materials to be compliant with prevailing regulations.
Documents Required	Record.
Mandatory	
PSR	112.116

Expectation
(See Requirement F-12.5)

Example Scenario
Scenario: Operation has a register of approved packaging and labels for all products. They are packing a new product this week and the register has not been updated.

Assessment: Depends on how the register is worded.
Reason: Compliant if the register and labels are still current. Corrective Action Needed if the new product is not considered in the register, i.e., the register lists individual products.

Produce Safety Rule
112.116: Food-packing material must be adequate for its intended use, which includes being cleanable or designed for single use and unlikely to support growth or transfer of bacteria. If food-packing material is reused, adequate steps must be taken to ensure that food contact surfaces are clean, such as by cleaning food packing containers or using a clean liner.

Requirement	**P-8.2. Operation has a written procedure for inspecting incoming packaging materials.**
Procedure	**All packaging materials are inspected for evidence of contamination upon arrival. Results are recorded.**
Verification	**Auditor reviews procedure and examples of packaging for compliance.**
Corrective Action	**Operation creates or revises policy. Contaminated or adulterated packaging material is rejected or discarded. Retraining is performed.**
Documents Required	**Written Policy, Records.**
Mandatory	
PSR	**112.123(d)(1)**

Expectation
Auditor reviews the operation's written policy on inspecting incoming packaging materials and reviews the records for compliance against their own policy. If applicable, the auditor also observes the operation receiving and inspecting packaging materials to determine if the policy is being carried out as intended.

Example Scenario
Scenario: An operation has a written procedure to inspect packaging at receiving, but there are no records that the inspection was completed.
Assessment: Corrective Action Needed
Reason: The operation has a written procedure, but it also needs to have a documented record that the inspection was completed.

Produce Safety Rule
112.123(d)(1): Food contact surfaces, equipment and tools used in growing, harvesting, packing and holding must be inspected, maintained and cleaned and when necessary appropriately sanitized all food contact surfaces of equipment and tools used, as frequently as reasonably necessary to protect against contamination of produce.

Requirement	P-8.3. Operation has written policy regarding storage and post-storage handling of product-contact containers.
Procedure	Product-contact containers, as appropriate to the specific Operation (e.g., harvest bins, totes, crates, sacks, buckets, finished product clam shells, bags or packaging films), shall be stored, or handled (e.g., cleaned prior to post-storage use), in a manner so as not to serve as a source of contamination.
Verification	Auditor observes whether operation has a policy regarding storage and handling of product-contact containers used in the operation. Auditor observes current practices for compliance with policy.
Corrective Action	Operation develops the policy. Retraining is performed and documented.
Documents Required	Written Policy.
Mandatory	
PSR	112.123(b)(2)

Expectation
(See requirement F-12.6)

Example Scenarios
Scenario 1: A celery operation has written instructions stating that all product containers are stored in enclosed warehouse on pallets and wrapped in plastic until use.
Assessment: Compliant.
Reason: Operation has a written policy on the storage of all product containers and is observed to be in compliance.

Scenario 2: Same as Scenario 1, but you see several product containers stored unwrapped in a clean area of the warehouse.
Assessment: Corrective Action Needed.
Reason: CAN - Unless the product containers are about to be used, the practice is not in compliance with the written instructions. Either the practice or the instructions must be corrected.

Scenario 3: The facility has nothing in writing, and auditor observes unassembled cases on dusty, overhead shelves.
Assessment: Corrective Action Needed.
Reason: A written policy is required. A "dusty" shelf is not a compliant storage area.

Scenario 4: An operation manager states that they re-use clamshell containers. A written procedure is available showing that clamshells are cleaned and sanitized before use.
Assessment: Compliant.
Reason: The operation has evidence that clamshells can be cleaned and reused safely.

Produce Safety Rule

112.123(b)(2): Equipment and tools must be stored and maintained to protect produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.

Requirement	**P-8.4. Materials that come in contact with the produce shall be clean and in good repair.**
Procedure	**Operation has written procedures for cleaning and, if practicable, sanitizing of pallets, produce bins, totes and materials that come in contact with the produce during handling or storage so as not to be a source of contamination. Procedures require that cleaning and sanitizing be documented.**
Verification	**Auditor reviews SOP, cleaning logs and records, interviews responsible individuals for knowledge of the SOP and observes containers, employees and records for evidence of compliance.**
Corrective Action	**Operation develops the policy. Retraining is performed and documented. Affected materials are evaluated for potential contamination and disposition.**
Documents Required	**Written Policy, Records.**
Mandatory	
PSR	**112.123**

Expectation
Perform a visual assessment of the growing, harvesting, packing and holding areas to identify tools, equipment, packing and packaging materials, and other food contact surfaces that are likely to or intended to contact produce. These materials should be kept clean and in good repair. It is recommended that the materials be made of non-porous materials such as stainless steel, PVC, or nylon instead of porous materials such as foam, carpet, wood or fabric. The assessment should include a determination that the equipment have sufficient space for cleaning. The materials and food contact surfaces of equipment and tools should have minimal pits, corrosion, cracks, crevices, partially open seams, poorly bonded welds, rough areas or other damage.

Example Scenarios
Scenario 1: Operation uses wood produce bins for bulk shipping of apples. Their written policy states the bins are inspected prior to use to ensure they are clean and in good repair. Record of inspections are available for review.
Assessment/Reason: Compliant as long as the bins appear clean and in good repair.

Scenario 2: Operation's written policy states all product contact material are cleaned and sanitized prior to use however, there are no records being kept.
Assessment: Corrective Action Needed
Reason: The standard requires that all cleaning and sanitizing activities are documented.

Produce Safety Rule

112.123: The operation must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and (b) Equipment and tools must be: (1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and (2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests. (c) Seams on food contact surfaces of equipment and tools that are used must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms. (d)(1) The operation must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in growing, harvesting, packing and holding activities as frequently as reasonably necessary to protect against contamination of produce. (2) The operation must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of produce. (e) If using equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact produce, you must do so in a manner that minimizes the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards.

Requirement	**P-8.5. Operation has written policy regarding whether product-contact containers are permitted in direct contact with the ground or floor.**
Procedure	**If produce does not normally contact the ground during production, Operation has considered and developed written policies regarding placement of product-contact containers directly on the ground or floor, or whether a physical buffer (e.g., buffer bin or slip sheet) is required, or use of containers constructed to prevent contact of the produce or produce contact surfaces with the ground. Policy shall be consistent with industry standards.**
Verification	**Auditor observes whether operation has a policy regarding placement of product-contact containers in direct contact with the ground. Auditor observes current practices for compliance with policy.**
Corrective Action	**Operation develops the policy. Retraining is performed and documented.**
Documents Required	**Written Policy.**
Mandatory	

Example Scenarios
Scenario 1: The operation has a written procedure for keeping all cartons off the ground. You observe two cartons labeled to hold discarded product, on loading dock directly on the ground.
Assessment: Corrective Action Needed.
Reason: The requirement only applies to food-contact cartons, but practice is not compliant with written procedure.

Scenario 2: A strawberry operation does not change the container in which product is field packed and keeps all containers off the dirt floor of the packinghouse by using slip sheets. Written

procedure is available and auditor observes compliant implementation.
Assessment: Compliant.
Reason: The operation is following their written procedure.

Requirement	**P-8.6. Operation has written policy regarding inspection of food contact containers and bins prior to use.**
Procedure	**Food-contact totes, bins, packing and packaging materials, other harvest containers, and pallets shall be visually inspected, clean, intact and free of any foreign materials prior to use. Containers shall be sufficiently maintained so as not to become a source of contamination.**
Verification	**Auditor observes whether operation has a policy regarding inspection of food contact containers and observes current practices for compliance with policy.**
Corrective Action	**Operation develops the policy. Retraining is performed and documented.**
Documents Required	**Written Policy.**
Mandatory	
PSR	**112.123(d)(1)**

Expectation
Facilities must keep food contact containers as clean as practicable to prevent cross-contamination of fresh produce. Any food contact containers used repeatedly during harvest or production should be cleaned after each load is delivered and prior to reuse. If the containers are stored outside, they should be cleaned and sanitized before being used to haul fresh produce. Workers should not stand inside bins.

(See Requirement F-11.2)

Example Scenarios
Scenario 1: The operation has SOP requiring visual inspection of stored bins to ensure they are clean, intact and free of foreign materials prior to use.
Assessment: Compliant.
Reason: The operation has a written SOP.

Scenario 2: Operation obtains a shipment of RPCs (reusable plastic container), which are cleaned and inspected by the supplier. The operation's SOP excludes these RPCs from inspection prior to use.
Assessment: Corrective Action Needed.
Reason: RPCs are often received with labels and other debris on them and an operation should not assume they are clean without inspection.

Produce Safety Rule
112.123(d)(1): Food contact surfaces, equipment and tools used in growing, harvesting, packing and holding must be inspected, maintained and cleaned and when necessary appropriately sanitized

all food contact surfaces of equipment and tools used, as frequently as reasonably necessary to protect against contamination of produce.

Requirement	P-8.7. Operation has written policy regarding acceptable product-contact containers.
Procedure	The types and construction of product-contact containers and packing materials shall be appropriate to the commodity being handled and suited for their intended purpose. Produce shall only be stored in clean and sanitary containers.
Verification	Auditor observes whether operation has a policy regarding what types of containers and packing materials are acceptable for use, and observes current practices for compliance with the policy.
Corrective Action	Operation develops the policy. Appropriate product-contact containers are obtained. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Policy.
Mandatory	●
PSR	112.116

Expectation
(See requirement F-12.5)

Example Scenarios
Scenario 1: A brussels sprouts packing operation uses Reusable Plastic Containers (RPCs), which are cleaned and stored in accordance with operation's SOP.
Assessment: Compliant.
Reason: The operation has a written policy and operates in accordance with the policy.

Scenario 2: The operation uses only new, web-style bags from a single supplier for packing onions. The operation has no written policy on the types of containers appropriate for product packaging.
Assessment: Corrective Action Needed.
Reason: The policy must be written, even if only one type of packaging is used.

Scenario 3: A packinghouse has changed crops and uses existing containers and packing materials to pack the "new" crop.
Assessment: Corrective Action Needed
Reason: The written policy does not demonstrate that the type of packaging has been considered for the new crop.

Produce Safety Rule
112.116: Requires that operations use food-packing material that is adequate for its intended use. Materials must be cleanable or designed for single use and must be unlikely to support growth or transfer of bacteria. If operations reuse food-packing material, the operation must take adequate

steps to ensure that food-contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

Requirement	P-8.8. Operation has written policy prohibiting use of product-contact containers for non-product purposes unless clearly marked or labeled for that purpose.
Procedure	Food-contact totes, bins and other product-contact containers shall not be used for other purposes unless the operation has a policy or procedure that clearly designates approved non-product contact uses and how the containers are to be marked or labeled for that purpose. Food-contact totes, bins and other packing containers and equipment that are no longer cleanable shall not be used for packing but can be used for other non-food uses if clearly marked/labeled.
Verification	Auditor observes whether operation has a policy prohibiting use of product-contact containers for other uses unless otherwise labeled, and observes current practices for compliance with the policy.
Corrective Action	Operation develops the policy. Retraining is performed and documented.
Documents Required	Written Policy.
Mandatory	

Expectation
(See Requirement F-11.4)

Example Scenarios
Scenario 1: Finished product container on packing line is observed containing waste plastic and other non-produce trash without a clear marking or designation.
Assessment: Corrective Action Needed.
Reason: Product containers are observed being used for items other than produce without being clearly marked or designated.

Scenario 2: Policy is written but fails to clearly establish marking requirements for non-product uses of packing containers.
Assessment: Corrective Action Needed.
Reason: The written policy must clearly establish marking requirements for non-product use.

Scenario 3: Workers are observed storing personal effects in packing containers. The packing containers are temporarily marked “not for product.” There is no written policy permitting temporary marking.
Assessment: Corrective Action Needed.
Reason: Policy must be written.

Requirement	P-8.9. Pallets shall be kept clean and in good condition as appropriate for their intended use.
Procedure	Operation inspects pallets prior to use for conditions that may be a source of produce contamination. Pallets that are not cleanable are removed from use. Pallets and other wooden surfaces are properly dried after being washed.
Verification	Auditor observes pallets for compliance.
Corrective Action	Operation removes noncompliant pallets from use.
Documents Required	N/A.
Mandatory	
PSR	112.123(d)(2)(e)

Expectation
Auditor reviews the condition of pallets and containers being used and those stored for future use. Auditor interviews the operator to determine what is done with broken or dirty pallets. When operators use dirty or broken pallets or do not clean and/or repair pallets this question must be a Corrective Action Needed.

(See requirement F-13.2)

Example Scenarios
Scenario 1: You observe pallets being used that have minor damage that does not affect the holding ability or integrity of the pallet. The pallets are being stacked in racks above other pallets holding product.
Assessment: Corrective Action Needed.
Reason: Pallets shall be kept in good condition as appropriate for their intended use; pieces of wood have the potential to fall into produce if stored on top of or over other product.

Scenario 2: The operation's pallet use policy is not written, but employees say that damaged, unclean, or otherwise unusable pallets cannot be used and will be segregated. Pallets appear to be in compliance.
Assessment: Compliant.
Reason: The operation has a policy which is understood by employees.

Produce Safety Rule
112.123(d)(2): All non-food-contact surfaces of equipment and tools used during harvesting, packing and holding must be maintained and clean as frequently as reasonably necessary to protect against contamination of produce. (e) Equipment such as pallets, forklifts, tractors and vehicles such that they are intended to or likely to contact produce, must do so in a manner that minimizes the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards.

P-9 Storage

Requirement	P-9.1. Product storage areas and conditions shall be appropriate to the commodities stored.
Procedure	Produce storage locations and conditions shall not pose a risk of produce contamination, consistent with industry standards or prevailing regulation.
Verification	Auditor observes storage area for evidence that stored produce is protected from contamination.
Corrective Action	Operation designates and maintains storage areas to prevent contamination of produce.
Documents Required	N/A.
Mandatory	
PSR	112.126

Expectation
(See requirement P-3.2)

Example Scenarios
Scenario 1: Condensate line from cooling unit in produce storage room is draining onto the floor.
Assessment: Immediate Action Required.
Reason: Condensate draining onto the storage room floor creates an unacceptable food safety risk.

Scenario 2: The walls on either side inside of the doorway to the produce storage room are damaged/punctured from forklift traffic. There are no maintenance records of when the damage occurred, or plans to repair it.
Assessment: Corrective Action Needed.
Reason: Damage is sufficient to allow entry or harborage of pests, water, or other contaminants.

Produce Safety Rule
112.126(a)(1): Buildings must be suitable in size, construction and design to facilitate maintenance and sanitary operations for growing, harvesting, packing and holding activities to reduce the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must provide sufficient space for placement of equipment and storage of materials and permit proper precautions to be taken to reduce the potential of contamination. Effective design may include separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems or other effective means. (2) Adequate drainage must be provided in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building. (b) Measures must be implemented to prevent contamination of produce and food contact surfaces in buildings, as appropriate, considering the potential for such contamination through: (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and (2) Drip or condensate.

Requirement	P-9.2. Iced produce is handled so as not to serve as a source of contamination.
Procedure	Protective measures are provided in areas where iced product is stored over food items in order to prevent melting ice from contaminating product below.
Verification	Auditor inspects any iced product on premises for compliance.
Corrective Action	Operation develops written procedures to handling and storage of iced product. Operational deficiencies are corrected. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Procedure.
Mandatory	
PSR	112.113

Expectation
Many vegetable products are frequently packed with ice or crushed ice put on the tops of the cartons or pallets to keep them cold. This would include broccoli and sweet corn. In storage where pallets are stacked more than one high or when there are racks to stack pallets one above the other, the iced product should be stored on the bottom. If a product is stored beneath an iced product, it must be protected from the dripping of melting ice. Auditors must review the storage, ask appropriate questions about storage of products packed with ice and assess the results.

Example Scenarios
Scenario 1: Iced product is stacked in produce storage area. A cover sheet on each pallet drains water away from the container below it. Visual inspection confirms that water is not dripping onto other produce.
Assessment: Compliant.
Reason: Iced product is handled so as not to serve as a source of contamination.

Scenario 2: Iced product is stored only in the bottom rack in the produce storage area. The area is drained so that water does not accumulate.
Assessment: Compliant.
Reason: The iced product is stored so as not to serve as a source of contamination.

Scenario 3: The operation does not receive or pack iced produce.
Assessment: Not applicable.
Reason: The operation does not have iced product to assess.

Scenario 4: Iced broccoli is stacked on upper shelf. Product in cartons is stored directly below. Melting ice is dripping from the upper broccoli cartons.
Assessment: IAR if there is evidence that melting ice from above iced product has contacted the cartons/product stored below. CAN: If there is no evidence that melting ice is contacting the product below.

Reason: Dripping ice from product stored above has become a source of contamination.

Produce Safety Rule
112.113: An operation must handle harvested produce during growing, harvesting, packing and holding activities in a manner that protects against contamination with known or reasonably foreseeable hazards--for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil or it is a reasonably foreseeable hazard that ice will melt.

Requirement	**P-9.3. Non-product storage areas shall be maintained so as not to be a source of product or materials contamination**
Procedure	**Areas designated to store materials, whether indoors or out, shall be clean, well ventilated, and designed to protect materials and produce form contamination.**
Verification	**Auditor observes storage area for evidence that stored materials are protected from contamination.**
Corrective Action	**Operation designates and maintains storage areas to prevent contamination of non-product materials.**
Documents Required	**N/A.**
Mandatory	
PSR	**112.126(a)(1)**

Example Scenarios
Scenario 1: A "bone yard" storage area for unused equipment and parts is outside, behind the building and is unprotected from the weather. The area is paved and fenced but otherwise not maintained.
Assessment: Compliant.
Reason: The area does not serve as a source of product contamination unless there is evidence of pest harborage.

Scenario 2: Packaging and other dry materials are stored in a locked trailer outside the main building. The trailer has a small vent on the roof that is screened to exclude pests. The trailer walls are rusting but intact. Materials inside are stacked on pallets or racks, off the floor.
Assessment: Compliant.
Reason: Packaging and other dry materials are stored in a manner that protects them from contamination.

Produce Safety Rule
112.126(a)(1): Buildings must be suitable in size, construction and design to facilitate maintenance and sanitary operations for growing, harvesting, packing and holding activities to reduce the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must provide sufficient space for placement of equipment and storage of materials and permit proper precautions to be taken to reduce the potential of contamination. Effective design may include separation of operations in which contamination is

likely to occur, by one or more of the following means: Location, time, partition, enclosed systems or other effective means.

Requirement	P-9.4. Materials and packaging materials shall be protected from contaminants.
Procedure	Materials stored in uncovered areas shall be protected from condensate, sewage, dust, dirt, chemicals, allergens or other contamination. Materials shall be stored off the floor/ground on pallets, slip sheets or stands and covered where applicable.
Verification	Auditor observes stored materials for protection from contamination.
Corrective Action	Operation develops and implements written procedures for materials storage. Operational deficiencies are corrected. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	
PSR	112.126

Example Scenarios
Scenario 1: Packaging and other raw materials are stored in a designated, enclosed area on racks but are not covered to protect from contamination. No contamination is seen.
Assessment: Compliant.
Reason: Materials and packaging are protected from contaminants unless you observe a reasonable likelihood of contamination of the materials as stored.

Scenario 2: Partly used packaging film, is returned for storage in an enclosed room. The packaging film is covered in a plastic bag and stored on a rack.
Assessment: Compliant.
Reason: Packaging film is protected from contaminants.

Scenario 3: Partly used packaging film is covered in a plastic bag and stored on a pallet outdoors in a designated area with a roof to protect from rain. The bag is dusty but adequately sealed to prevent contamination.
Assessment: Compliant.
Reason: The bag provides protection for the film from contaminants.

Produce Safety Rule
112.126(a)(1): Buildings must be suitable in size, construction and design to facilitate maintenance and sanitary operations for growing, harvesting, packing and holding activities to reduce the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must provide sufficient space for placement of equipment and storage of materials and permit proper precautions to be taken to reduce the potential of contamination. Effective design may include separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems or other effective means. (2) Adequate drainage must be provided in all areas where normal

operations release or discharge water or other liquid waste on the ground or floor of the building. (b) Measures must be implemented to prevent contamination of produce and food contact surfaces in buildings, as appropriate, considering the potential for such contamination through: (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and (2) Drip or condensate.

Requirement	**P-9.4.a. The operation has a procedure to ensure that purchased materials, work in progress and finished products are used in the correct order, and within the allocated shelf life when applicable.**
Procedure	**The operation clearly outlines a procedure in which work in progress, finished products, purchased materials, such as packing materials, cleaning chemicals and any other materials that may have an impact on food safety, shall be used in accordance with the allocated shelf life, i.e. materials used on a first in first out basis or in the correct order as established by the policy or procedure.**
Verification	**Auditor observes the procedure for stock management is implemented effectively.**
Corrective Action	**Operation develops and implements effective procedures for stock management.**
Documents Required	**Written Policy.**
Mandatory	

Expectation
The operation shall establish a stock management system. This system shall include a procedure that describes appropriate policies are established to ensure that purchased materials, work in progress and finished products are used in the correct order, and within the allocated shelf life when applicable. These purchased materials such as raw incoming product, packaging, cleaning chemicals and any other materials that may have an impact on food safety should be included in the stock management procedures. The operation will determine the correct order of usage. The auditor will verify that the operation is following their procedure correctly.

Example Scenario
Scenario: The auditor interviews the production manager to explain the operation's procedure to ensure that products are used in the correct order prior to their expiration. The manager explains their inventory system of using a combination of FIFO and quality evaluation. However, the procedure is not written.
Assessment: Corrective Action Needed.
Reason: The procedure needs to be written and clearly outline the steps necessary to ensure that purchased materials, work in progress and finished products are used in the correct order, and within the allocated shelf life.

Requirement	P-9.5. Adequate space shall be maintained between rows of stored materials to allow cleaning and inspection.
Procedure	Materials shall be stored away from walls and ceilings. Written procedures shall be followed to guarantee the proper cleaning, inspection and monitoring for pest activity in storage areas.
Verification	Auditor reviews the procedures and observes the storage area to determine whether storage practices allow cleaning, inspection and monitoring for pest activities.
Corrective Action	Operation develops and implements a written procedure, and moves material into compliance.
Documents Required	Written Procedure.
Mandatory	
PSR	112.123(b)(1)

While not part of this requirement, many companies allow at least 18 inches between the wall and product as used in other programs including, the Department of Defense, USDA Grain Inspection, Packers and Stockyards Administration (GIPSA), USDA Plant Survey's, and as recommended in many state and extension publications to allow for adequate pest control and to conduct inspections. Observe the storage area to determine if storage practices allow cleaning, inspection, and monitoring for pest activity and follow the operation's food safety procedure.

Example Scenarios
Scenario 1: Materials are stored on racks that reach to the ceiling (20 feet), are one pallet deep and are bolted to the back wall. There is a 12 inch clearance under the racks. The areas under the racks are clean.
Assessment: Corrective Action Needed.
Reason: Written procedures are required and the actual practices need to maintain sufficient space between pallets and the wall and pallets and the ceiling to allow inspection.

Scenario 2: Written procedures require an 8 inch clearance between racks and between the racks and the wall. Spacing is in compliance. Racks can be moved for cleaning and pest inspections.
Assessment: Compliant.
Reason: The operation is following their written policy which allows adequate space.

Produce Safety Rule
112.123(b)(1): Equipment and tools must be installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces.

Requirement	P-9.6. All chemicals shall be stored in a secure separate area. All chemicals shall be properly labeled.
Procedure	Chemicals, including cleaning maintenance compounds and lubricants, when not being used, are stored away from product handling areas and in a manner that inhibits unauthorized access. Food-grade and nonfood-grade lubricants are kept separate from each other.
Verification	Auditor observes that chemicals are properly labeled and storage practices protect against product contamination.
Corrective Action	Operation designates a secure area for storage of chemicals. Unlabeled chemicals are labeled or properly discarded. Retraining is performed and documented.
Documents Required	N/A.
Mandatory	

Example Scenarios

Scenario 1: Chemicals are stored in a locked, vented cabinet. All facility and equipment cleaning and sanitizing chemicals are stored together on the top shelf, lubricants are stored on the bottom shelf. All are in original containers with manufacturers' labels. The cabinet appears clean and orderly.
Assessment: Compliant as long as chemicals are stored according to label and regulatory requirements; e.g., storage of incompatible products.
Reason: Chemicals are stored in a secure separate area.

Scenario 2: Food grade lubricants are used on most equipment in the facility, except for one that requires special non-food grade lubricant. All are stored on the same shelf, but the special lubricant is clearly marked non-food grade.
Assessment: Corrective Action Needed.
Reason: Special labeling does not provide sufficient separation.

Scenario 3: Chemicals are stored in original containers or transferred to labeled secondary containers and stored on designated open shelves in the maintenance area, which is locked with limited access.
Assessment: Compliant.
Reason: Chemicals are stored in a secure separate area.

Requirement	P-9.7. When produce is cooled, it is cooled to temperatures appropriate to the commodity according to current established regulatory or industry standards.
Procedure	When required for food safety or by industry guidelines, steps are taken to minimize temperature increases and minimize the time between produce receipt and cooling at the operation. The product temperature and equipment control mechanisms are calibrated and monitored at a defined frequency and temperatures are kept appropriate to the commodity. Records are maintained.
Verification	Auditor reviews cooling procedures for commodities requiring temperature control, and reviews temperature logs for evidence of compliance.
Corrective Action	Operation develops and implements procedures to monitor cooling procedures in compliance with current established regulatory or industry standards.
Documents Required	Record.
Mandatory	
PSR	112.124

Expectation
If the operation determines that produce should be cooled to a certain temperature to control a microbiological hazard, then the operation must take steps to ensure that the product is cooled appropriately. The operation shall provide records of compliance with the established guidelines. Records include temperature measurements and equipment calibration. Auditor verifies compliance. If temperature control is required, the auditor will list the temperature range for each commodity in the comments.

Example Scenario
Scenario: An operation stores celery at 32 to 36°F. They say that the temperature range came from the UC Davis Post-harvest website. Daily monitoring records indicate compliance with the range.
Assessment: Not applicable, unless temperature control of celery is in operation's Food Safety Plan (then compliant).
Reason: Typically, cold storage of celery and other raw agricultural commodities is for quality purposes, not food safety.

Produce Safety Rule
112.124: Instruments or controls used to measure, regulate or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance must be accurate and precise as necessary and appropriate in keeping with their purpose, adequately maintained and adequate in number for their designated uses.

Requirement	**P-9.8. Where temperature control is required for food safety, cooling facilities shall be fitted with temperature monitoring equipment or suitable temperature monitoring devices.**
Procedure	**Temperature monitoring equipment shall be located in all temperature controlled areas, and shall be located so as to accurately monitor the temperature. Temperature measuring devices shall be monitored and calibrated on a scheduled basis or as needed.**
Verification	**Auditor observes evidence that temperatures are being monitored, and reviews calibration records and procedures for temperature monitoring equipment.**
Corrective Action	**Operation establishes and implements temperature monitoring procedures.**
Documents Required	**Record.**
Mandatory	
PSR	**112.124**

Expectation
The requirement is only applicable for this audit for operations that include temperature as a requirement for food safety in their Food Safety Plan. Currently, there are no regulatory requirements or crop specific guidance for food safety for raw agricultural commodities.

Example Scenario
Scenario: The only available thermometer in a cooler is directly across from the evaporator fan and indicates 37ºF. The core temperatures of cantaloupes in the cooler range as high as 44ºF.
Assessment: Depends on whether Food Safety Plan identifies storage area temperature as important for food safety.
Reason: If not, then N/A. If yes, then judgment depends on whether thermometer is accurately measuring the room temperature, regardless of measured core temperature. If inaccurate, then Corrective Action Needed to ensure room temperature is measured accurately.

Produce Safety Rule
112.124: Instruments or controls used to measure, regulate or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance must be accurate and precise as necessary and appropriate in keeping with their purpose, adequately maintained and adequate in number for their designated uses.

Requirement	P-9.9. Cooling equipment shall be maintained so as not to be a source of product contamination.
Procedure	Cooling equipment (e.g. hydrocoolers, air coolers), shall be inspected, all debris removed, and cleaned and sanitized according to written sanitation SOPs.
Verification	Auditor reviews cooling equipment maintenance and sanitation procedures and inspects equipment for compliance with procedure.
Corrective Action	Operation develops and implements effective maintenance and sanitation procedures.
Documents Required	Written Policy, Record.
Mandatory	●
PSR	112.123

Expectation
The comment should include the date last maintenance or cleaning was conducted.

Refrigerated storages should be cleaned on a scheduled basis. This will reduce the amount of dust and dirt build-up and further reduce the possibility of contamination. Auditors should review the cleaning schedule documentation. Below is guidance for cooling from FDA's Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.

Various methods are available for cooling produce, including water, ice, and forced air. The method used depends on the fruit or vegetable and the resources of the operator. In most instances, cooling with air (such as vacuum coolers or fans) will pose the lowest risk.

The benefits of chilling to remove field heat and the temperature requirements for optimum keeping quality vary for different types of produce. Adequate refrigeration, in conjunction with crop characteristics, is an important safeguard against many pathogens. Further, good quality, intact produce is most resistant to microbial contamination and growth. Thus, maintaining temperatures that promote optimum product quality may reduce the risk of microbial hazards.

Air cooling equipment and cooling areas should be monitored, periodically cleaned and inspected. Potential sources of contamination should not be located near air intakes.

Chilling equipment, such as hydrocoolers, and containers holding produce during chilling operations should be clean and sanitary. Field soil should be removed as much as possible from produce and containers prior to chilling. Interiors of hydrocoolers should routinely be cleaned and sanitized.

Example Scenarios
Scenario 1: A dripping evaporator unit pan is observed, the unit is located above a traffic lane, not above stored produce. The splash area below the unit is marked off with yellow paint and signage reading "No Storage Permitted."

Assessment: Immediate Action Required.
Reason: This situation provides too high a risk of spreading contamination to other areas and stored produce.

Scenario 2: An evaporator drain pan is misaligned and dripping liquid onto the floor below and near palletized produce. The storage pallet is visually wet but the stored whole produce cases appear dry.
Assessment: Immediate Action Required.
Reason: The visible appearance of the cases is insufficient to assure that contamination is not occurring and pathogens are known to survive on dry cardboard.

Produce Safety Rule
112.123: The operation must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and (b) Equipment and tools must be: (1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and (2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests. (c) Seams on food contact surfaces of equipment and tools that are used must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms. (d)(1) The operation must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in growing, harvesting, packing and holding activities as frequently as reasonably necessary to protect against contamination of produce. (2) The operation must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of produce. (e) If using equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact produce, you must do so in a manner that minimizes the potential for contamination of produce or food contact surfaces with known or reasonably foreseeable hazards.

P-10 Transportation (Packinghouse to Customer)

Requirement	**P-10.1. There is a written policy for transporters and conveyances to maintain a specified temperature(s) during transit.**
Procedure	**When refrigerated transport is required for food safety, transporters have written, predetermined temperature ranges for commodities being transported.**
Verification	**Auditor reviews documentation of predetermined temperature ranges.**
Corrective Action	**Operation develops, documents and implements temperature range requirements.**
Documents Required	**Written Policy.**
Mandatory	

Expectation

The operation must establish a written policy for transporters to maintain temperatures appropriate to the crop during transit. Transporters should be aware of the temperature requirements for produce being hauled and avoid delivery of mixed loads with incompatible refrigeration requirements.

Not all products require refrigeration during transport. In certain cases, shippers may require or specify a higher temperature for transportation than recommended for storage conditions. Shippers should recommend temperatures according to the product and conditions for transport. In general, manifests should be marked with the temperature range that the shipper requires the carrier to maintain.

Review auditee documentation to verify that there is an active policy in place addressing the ability of conveyances to maintain specified transport temperatures. If there are no transportation temperatures required by the auditee, or there is no indication of a required temperature this question can be answered Not Applicable. If refrigerated transport temperature control is required, the auditor will list the temperature range for each commodity in the comments.

Example Scenarios
Scenario 1: The operation transports totes of avocados in trailers with no temperature control or recording devices. The operation says that their customer has no temperature specifications for avocados.
Assessment: Not Applicable unless temperature control is required for food safety.
Reason: Temperature controls are not included in the company's food safety plan and are required for quality, not food safety purposes.

Scenario 2: A written procedure recommends that wrapped pallets of cartons of tomatoes, cucumbers and peppers be transported in trailers controlled and monitored at 38-41ºF, for quality. Other produce may also be shipped in the same trailer. No shipping records are available to demonstrate compliance.
Assessment: Not Applicable.
Reason: The standard only requires the operation to have a written specification for food safety.

Requirement	P-10.2. Prior to loading, the vehicle shall be pre-cooled.
Procedure	When refrigerated transport is required for food safety, the proper temperature for pre-cooling is appropriate to the type of produce and as specified by documented protocol.
Verification	Auditor reviews documented protocol, shipping checklist records, and observes vehicles during loading for compliance.
Corrective Action	Operation develops documents and implements vehicle cooling requirements.
Documents Required	Written Policy, Record.
Mandatory	

(Also See P-10.1)

Example Scenarios
Scenario 1: A written procedure recommends that trailers be pre-cooled, controlled and monitored at 38-41ºF, for quality. Loading records indicate that trailer temperature may occasionally be as high as 45ºF.
Assessment: Not Applicable.
Reason: Not Applicable unless temperature control is required for food safety.

Scenario 2: An operation that ships dry bulb onions in cartons, does not pre-cool or monitor shipping trailers.
Assessment: Not Applicable.
Reason: Not Applicable unless temperature control is required for food safety.

Scenario 3: An operation stores pears in a warehouse and ships bins as needed to a packinghouse 2 miles away. Bins are shipped on an open flatbed trailer.
Assessment: Not Applicable.
Reason: Not Applicable unless temperature control is required for food safety.

Requirement	**P-10.3. The refrigerated transport vehicles shall have properly maintained and fully functional refrigeration equipment.**
Procedure	**When refrigerated transport is required for food safety, operation has a written policy that refrigerated transportation equipment shall be controlled by a thermostatic device as necessary to maintain temperatures in the cargo area for the particular type of produce being transported and as specified by documented protocol.**
Verification	**Auditor reviews written policy and observes refrigerated transport vehicles in use at the time of the audit.**
Corrective Action	**Operation develops, documents and implements a policy. Retraining is performed and documented.**
Documents Required	**Written Policy.**
Mandatory	

Example Scenarios
Scenario 1: An operation has no temperature specifications for shipping cucumbers and uses only shipping trailers with no refrigeration equipment or temperature control devices.
Assessment: Not Applicable.
Reason: Not Applicable unless temperature control is required for food safety.

Scenario 2: An operation ships everything at 38-41ºF and maintains records of trailer temperatures at shipping, but policy and measurement protocol are not written.
Assessment: Not Applicable.
Reason: Temperature control is maintained for quality purposes and is not required by the operation for food safety.

Requirement	P-10.4. Where required, temperatures of product are taken and recorded prior to or upon loading.
Procedure	When refrigerated transport is required for food safety, operation has a written procedure for when and how to measure product temperatures prior to or during loading.
Verification	Auditor reviews written procedures and observes temperature monitoring procedures during loading.
Corrective Action	Operation develops, documents and implements a policy. Retraining is performed and documented.
Documents Required	Written Policy, Record.
Mandatory	

Example Scenarios
Scenario 1: A written procedure is not in place; however, the auditor observes the employees taking temperatures where required.
Assessment: Not Applicable.
Reason: Not Applicable unless temperature control is required for food safety.

Scenario 2: Temperatures are recorded on the bill of lading and not on a checklist.
Assessment: Not Applicable.
Reason: Not Applicable unless temperature control is required for food safety.

Requirement	P-10.5. The operation shall have a policy, written procedures, and a checklist to verify cleanliness and functionality of shipping units (e.g., trailer).
Procedure	Shipping units shall be clean, functional and free of objectionable odors before loading, in compliance with current industry practices or regulatory requirements for that commodity. Refrigeration units, if used, must be in working order. Procedures prohibit raw animal or animal product transport, or other materials that reasonably may be a source of contamination with biological, chemical (including allergens) or physical hazards, unless appropriate risk mitigation strategies are in place. Shipping units shall be washed between loads if prior transport included materials that reasonably may be a source of contamination. A responsible individual shall sign or initial the completed checklist or inspection report.
Verification	Auditor reviews cleaning procedures and inspection records and inspects produce transport vehicles for cleanliness.
Corrective Action	Operation develops the policy and written procedures. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Policy, Record.
Mandatory	●

(See requirement F-14.1)

Requirement	P-10.6. Loading/unloading procedures and equipment shall minimize damage to and prevent contamination of produce.
Procedure	Personnel responsible for the loading and unloading of produce shall take steps to minimize the potential of physical damage to produce, which can introduce and/or promote the growth of pathogens. Loading/unloading equipment shall be clean and well maintained and of suitable type to avoid contamination of the produce.
Verification	Auditor observes loading/unloading procedures for evidence of practices that result in excessive damage to produce. Auditor observes loading/unloading equipment for suitability and condition.
Corrective Action	Operation revises procedures. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.
Mandatory	

(See Requirement F-14.2)

USDA LOGO USE

This section is to be completed only for applicants who have applied and are in possession of an official Specialty Crops Inspection letter signed by the Director, approving them to use the GAP and GHP logo. The GAP & GHP logo is only permitted for use by participants that meet the GAP and GHP program logo use requirements.

The participant must have met the acceptance criteria for all audit scopes applicable to their operation. For example, a farming operation that grows, harvests, packs, and ships fruits and vegetables must be audited to the scope of the audit for each of those four activities. The checklist will be completed as part of the audit process on all subsequent audits as long as the participant continues to meet the USDA acceptance criteria of the GAP & GHP audit program.

L-1 Food Safety Plan or Quality Manual

Requirement	**L-1.1. The operation's food safety plan or quality manual contains procedures on how the USDA GAP & GHP logo will be used.**
Procedure	**The operation shall have a written policy describing proper use of the logo including having attained approved GAP & GHP program status by meeting the acceptance criteria for the audit being performed covering all scopes of the audit which are applicable to their operation. All commodities grown, handled or processed by the operation must be covered by the audit.**
Verification	**Auditor shall review the Food Safety Plan for detailed and complete procedures on logo use.**
Corrective Action	**The operation shall develop procedures on USDA GAP & GHP logo use.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
If a farming operation which grows, harvests, packs, and ships fruits and vegetables, they must be audited to the scope of the audit associated with those activities. For instance, if an operation has a farm and a separate packinghouse facility, but only requests to be audited against the Farm and Field Harvest Operation's scope, they would not be eligible to use the logo. In addition, any commodities grown on the farm, whether intended to be included on the audit or not, must be included and covered under the audit.

Requirement	L-1.2. There is a designated person to be responsible for the control of inventory bearing the logo.
Procedure	The operation shall designate, in their food safety plan or quality manual, an individual or individuals that are responsible for the control of inventory (any containers or labels) bearing the logo or language.
Verification	Auditor verifies there is a designated person responsible for control of inventory bearing the logo.
Corrective Action	Operation designates an individual, in their food safety plan or quality manual, to be responsible for the inventory bearing the USDA logo.
Documents Required	Written Policy.
Mandatory	●

L-2 Traceability and Recall Program

Requirement	L-2.1. The operation uses the USDA GAP & GHP logo only on packages, containers, or consumer units which are traceable.
Procedure	The operation shall have a policy that prohibits the use of the logo on any packages, containers or consumer units that are not part of the established traceability program.
Verification	Auditor reviews policy and observes packages labeled at the facility with the USDA GAP&GHP logo are traceable.
Corrective Action	Operation develops policy.
Documents Required	Written Policy.
Mandatory	●

L-3 Approved Suppliers

Requirement	L-3.1. The operation has supplied a list of approved suppliers to the local Federal or State auditor's office.
Procedure	Operation supplies the local Federal or State office who conduct the audits, with a current list of approved suppliers. The operation will notify the office of any additions to the suppliers list as well as if a supplier is no longer in compliance and must be removed from the list.
Verification	Auditor reviews record showing all names of suppliers and verifies dates of when their names were given to the local auditor's office.
Corrective Action	Operation supplies list to the local offices.
Documents Required	Record.
Mandatory	●

Requirement	L-3.2. All suppliers currently in use by the operation are listed on the supplied list of approved suppliers.
Procedure	Operation procures ingredients and materials only from approved suppliers.
Verification	Auditor reviews receipt records and compares suppliers of ingredients and materials against list of approved suppliers.
Corrective Action	Operation updates and or creates list of approved suppliers, and procures only from these suppliers.
Documents Required	Written Policy, Record.
Mandatory	●

L-4 GAP & GHP Logo Approved Use

Requirement	L-4.1. The logo is only used on products, processes, and packaging as approved on the SC-652.
Procedure	The operation shall have a copy of the approved SC-652 which lists the products, processes, and packaging types and any other way the logo is approved to be used, including websites, social media and banners. The logo is being used as approved.
Verification	Auditor verifies that the operation is only using the logo as approved on the SC-652.
Corrective Action	Operation discontinues use of packaging on unapproved products, processes, and/or packaging.
Documents Required	Record.
Mandatory	●

Expectation
Packaging type should be specified for each product on the SC-652 according to how the logo is approved to be used i.e. cartons, lugs, flats, master cartons, or bags. The operation shall only use the type of packaging that's specified on the form. The operation is restricted from using the logo beyond what is listed on the SC-652 and Specialty Crops Inspection Division approval letter. If only approved to use the logo on their website, social media and promotional material, the operation cannot use the logo in any other way.

Requirement	L-4.2. All packaging or labels, which bear the GAP & GHP logo, are accountable items.
Procedure	The operation shall have a policy stating all packaging or labels are accounted for.
Verification	Auditor reviews policy.
Corrective Action	Operation develops policy that ensures accountability of all packaging or labels bearing the logo.
Documents Required	Written Policy, Record.
Mandatory	●

Requirement	L-4.3. The operation's inventory list of these packaging or labels is maintained and current.
Procedure	The operation shall have an inventory list of any packaging or labels bearing the logo or language.
Verification	Auditor reviews records for accuracy and to ensure inventory list is up to date.
Corrective Action	Operation develops and maintains an inventory list of all packaging and labels.
Documents Required	Record.
Mandatory	●

Requirement	L-4.4. The logo is only used on packaging and labels that are clean and bright in appearance, without marks, stains, or other evidence of previous use.
Procedure	The operation is only using packaging and labels that are clean and bright in appearance without marks, stains, or other evidence of previous use.
Verification	Auditor verifies that packaging and labels are clean and bright in appearance.
Corrective Action	Operation updates their practices to use the logo on packaging and labels that are clean and bright in appearance.
Documents Required	Record.
Mandatory	●

TOMATO AUDIT PROTOCOL

In 2019, a Tomato Audit Protocol working group met to update the tomato metrics. As part of this update, it was decided that these tomato metrics would only include those requirements that were unique to tomatoes or were not in the Harmonized Standard and are intended to be used as an addendum to the Harmonized Standard, or other GAP Program. These metrics can be found on the Harmonization Initiative's Website: https://www.unitedfresh.org/food-safety/gap-harmonization-initiative/.

USDA has incorporated the Tomato Audit Protocol Addendum into the USDA Harmonized GAP and USDA Harmonized GAP Plus+ audit programs as an option to be requested by a tomato producer, packer, distributor, or repacker to verify additional tomato specific requirements are being met. There are four distinct addendums for the different segments of the tomato industry: Open-field Production and Harvesting, Packinghouse, Greenhouse, and Repacking and Distribution.

OPEN-FIELD PRODUCTION AND HARVESTING

The development of good agricultural practices for field tomato production must consider all the elements of the field production system: location of field site, prior land use, land preparation, adjacent land use, agricultural inputs (such as irrigation water, fertilizers, and crop protection materials), workers and production practices, single or multiple harvests. Microbial contamination can occur from several different sources; evaluation of these risks, and their management, are essential to proper food safety procedures in the production of fresh tomatoes.

TOF-1 Management Responsibility

Requirement	**TOF-1.1 Operation has current copies of the *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain, the relevant Harmonized Food Safety Standard, and additional food safety documents as required by state and/or federal regulation.**
Procedure	**Operation has a current copy of the Guidelines, this audit document and all other required documents.**
Verification	**Auditor observes the current copies at the operation.**
Corrective Action	**Operation obtains current copies.**
Documents Required	**Record.**
Mandatory	●

Expectation
Confirmation that the auditee has current copies of the *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain, and the relevant Harmonized Food Safety Standard shall be discussed with the auditee prior to the audit. If the auditee does not have the most recent version of these

documents, the auditor may provide an internet link or a pdf document for the auditee prior to the audit. Verification that copies of these documents are available to the auditee will be made during the audit.

Example Scenarios
Scenario 1: Operation has a current copy of *the Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, Programs and Auditing Protocol for the Fresh Tomato Supply Chain and additional food safety documents as required by state and/or federal regulation this audit document and all other required documents.
Assessment: Compliant
Reason: Operation has a current copy of the *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain* and additional food safety documents as required by state and/or federal regulation.

Scenario 2: Operation does not have a current copy of the *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, Programs and Auditing Protocol for the Fresh Tomato Supply Chain and additional food safety documents as required by state and/or federal regulation.
Assessment: Corrective Action Needed. The auditee will need to obtain the most current copy of the of the Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain.
Reason: Operation does not have a current copy of the *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, Programs and Auditing Protocol for the Fresh Tomato Supply Chain and additional food safety documents as required by state and/or federal regulation.

TOF-2 Self-Audits

Requirement	**TOF-2.1 Operation has procedures for conducting self-audits and conducts self-audits to verify compliance with established internal policies and procedures.**
Procedure	**In addition to the requirements of the Harmonized Standards, the operation's self-audit procedure ensures compliance with established internal policies and procedures, *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, these Tomato Metrics, and additional food safety documents as required by state and/or federal regulation.**
Verification	**Auditor reviews the self-audit procedures, and records of self-audits to verify compliance with the procedures.**
Corrective Action	**Operation obtains current copies. Operation develops and maintains self-audit program, with corrective actions preventive measures, documentation and follow-up.**
Documents Required	**Written Policy, Record.**
Mandatory	●

Expectation

Auditees must conduct self-audits to verify compliance with established internal policies and procedures. There is not a specified format for the self-audit. The self-audit must verify the requirements of the Harmonized Standard being utilized and Tomato Audit Protocol Open-Field Production Addendum requirements.

Example Scenarios
Scenario 1: The operation has procedures for conducting self-audits and conducts self-audits annually, but you find that the operation uses a self-made checklist for conducting self-audits.
Assessment: Compliant
Reason: As long as the self-audit performed addresses the requirements of the Harmonized Standards, ensures compliance with established internal policies and procedures, *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, the Tomato Metrics, and additional food safety documents as required by state and/or federal regulation.

Scenario 2: The operation maintains that they conduct self-audits but do not have a record of the self-audit.
Assessment: Corrective Action Needed.
Reason: The requirement requires a written policy and records. Records should document when the self-audit was started and completed.

Scenario 3: Operation develops and maintains a self-audit program, including a written record of required corrective actions and follow-up procedures but does not include preventive measures.
Assessment: Compliant or Corrective Action Needed.
Reason: If the operation has sufficiently satisfied the requirements of checklist questions G-8.1 and G-9.1, this checklist question shall be assessed as compliant.

TOF- 3 Field History and Pre-harvest Assessments

Adjacent land use must be assessed for conditions that may pose a risk to tomato production. These risks may include runoff from animal operations or other sources of contamination, domesticated animals, wildlife, chemical or sewage treatment plants, landfills or other conditions that pose a food safety risk. Appropriate measures must be taken to mitigate any identified food safety risks. These measures may include berms, fences, ditches, buffer zones or other strategies to mitigate any known risks.

Requirement	**TOF-3.1 If the field is subject to flooding, operation has an established decision tree or corrective action plan in the event of flooding in the production area. Procedures prohibit harvest of product that has come into contact with flood waters.**
Procedure	**Flooding is defined as the uncontrolled introduction of large amounts of water of unknown quality into the production area that is reasonably likely to come into contact with the edible portion of the crop, or otherwise cause adulteration of the crop. If the field is subject to flooding, procedure is established that includes a decision tree or corrective action to take in the event of flooding in a production area. Procedure specifies performance of a written risk assessment, which will consider whether there is an increased potential of contamination from the flood event. If warranted by the risk assessment, a no-harvest zone is positioned so that operations in the non-flooded zone are not compromised by the flooded zone; for example, 10 feet.**
Verification	**If the field is subject to flooding, auditor verifies that the operation has a policy/procedure regarding flooded fields. Auditor looks for evidence of flooding in the field. If the field has flooded since the last audit, the auditor observes the operation's risk assessment for current acceptability of the field and/or crop.**
Corrective Action	**Operation develops a written procedure for flooded fields. Operation must obtain/develop a written risk assessment for the relevant field.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
It is important to make the distinction between flooding versus standing water remaining from poor drainage after irrigation or substantial rain. Even though any standing water may pose a significant contamination risk to the crop, it's important not to report standing water remaining from poor drainage after irrigation or substantial rain as flooding, as the water would not be of unknown quality. Standing water that shows signs of algae or insect larva should still be documented and reported.

Example Scenarios
Scenario 1: The operation states that the production area has not flooded in the thirty years that they have been growing tomatoes on the land, so a written policy, corrective action plan or decision tree has not been established. During the walk through of the field, the auditor observes signs of flooding in rows of crops nearest the elevated road.
Assessment: Immediate Action Required
Reason: Substantial amounts of water that is of unknown quality contacting the edible portion of the crop would be considered an Immediate Action Required. Water that is clearly caused by run-off from a road should be considered a contaminant after heavy rainfall.

Scenario 2: In checklist question F-1.1, the operation has documented the risk associated with the land and adjacent land use history that includes equipment, structures, the possibility of physical, biological and chemical contamination with preventative controls, corrective actions and procedures that prohibit harvest of product that has come into contact with contaminates and the disposition of any possible contaminated product, but the written policy does not specifically state flooding as a possible contaminate.
Assessment: Compliant or Corrective Action Needed
Reason: If the field is not subject to flooding this would be compliant. If the field is subject to flooding this would be corrective action needed.

Scenario 3: The operation irrigates with furrows between the raised beds of crops. They do not have a written policy or decision tree for what to do in case of flooding because the field is above grade on all sides. The water used for irrigation is sourced from a well system and water test results show the water meets potable water standards. The auditor observes that several furrows still contain large amounts of water from the previous day's irrigation. The auditor can see that the water in the furrows has not been there long enough for algae growth or insect larva to form.
Assessment: N/A
Reason: If the field is not subject to flooding, a written policy or decision tree is not required.

Requirement	**TOF-3.2 Operation shall conduct the required Combined Harmonized Standard F-9.1 pre-harvest risk assessment no more than five (5) days from the first scheduled harvest date.**
Procedure	**The environmental assessment is reperformed, and documented, for environmental conditions that reasonably may have changed since the last assessment, including flooding, adequacy of water sources for their intended use, adjacent land uses, animal migrations, debris, worker health and hygiene, or other potential sources of fruit adulteration.**
Verification	**Auditor reviews the reassessment document, including corrective action documents for mitigations or deficiencies identified in the pre-production risk assessment, and confirms the assessment occurred within five (5) days of the first scheduled harvest date.**
Corrective Action	**Operation develops or modifies the document, or reviews, as needed. Perform training as needed.**
Documents Required	**Risk Assessment.**
Mandatory	●

Expectation
A documented pre-harvest risk assessment must be conducted prior to harvest, no more than five days from the first scheduled date. This assessment must include any environmental conditions that may have changed since the last assessment, the adequacy of the water source being used, adjacent land uses, animal migrations, debris, worker health and hygiene and any other potential sources of contamination.

Example Scenarios

Scenario 1: The operation has performed a pre-harvest assessment, and it includes an evaluation of conditions that may be reasonably likely to result in physical, chemical, or biological contamination of the produce. Results of the evaluation are documented but it does not depict when the assessment was performed.
Assessment: Corrective Action Needed,
Reason: The assessment must have been completed within five days of the expected harvest date.

Scenario 2: The operation completed a risk assessment dated seven days prior to the harvest date, the field manager states that they could not begin to harvest crew due to a shortage of personnel.
Assessment: Compliant or Corrective Action Needed
Reason: The auditor would need to determine if there were environmental conditions that reasonably may have changed since the last assessment.

Scenario 3: A second environmental assessment in the form of a review, based upon current conditions is conducted not more than five (5) days from the first scheduled harvest date, but the assessment is not signed by the field manager.
Assessment: Compliant
Reason: The requirement does not state that the assessment must be signed.

TOF- 4 Workers Health/Hygiene and Toilet/Handwashing Facilities

Requirement	**TOF-4.1 A response plan is in place in the event of a major spill or leak of field sanitation units.**
Procedure	**A written corrective response plan is developed and implemented in the event of a major leak or spill.**
Verification	**Auditor verifies existence of the plan and interviews the responsible person for knowledge.**
Corrective Action	**Operation prepares or edits the plan. Retrain or replace the responsible person.**
Documents Required	**Written Policy, Record.**
Mandatory	●

Expectation
(See requirement G-10.7)

Example Scenarios
Scenario 1: A response plan is in place in the event of a major spill or leak of field sanitation units but it is not a written policy in the operation's Food Safety Plan. The field manager states, we would call the company who services the units and flag off a ten-foot area around the unit.
Assessment: Corrective Action Needed.
Reason: A written corrective response plan must be part of the operation's Food Safety Plan and implemented in the event of a major leak or spill.

Scenario 2: The field supervisor states that the cleaning crew is responsible for any spills or leaks from the field sanitation units and shows you the written policy which states that the company who services the units should be contacted in case of a major spill or leak. The policy goes on to state that an eight-foot area around the spill should be flagged off to ensure that any affected produce will not be harvested. The auditor interviews the person in charge of the cleaning crew to verify that the responsible person is aware of the procedure. The cleaning crew lead states that it is the field supervisor's responsibility to contact the service company and flag the area.
Assessment: Corrective Action Needed.
Reason: If it is not clear that someone from the operation is going to accept responsibility, the written policy needs to be revised and retraining performed.

Scenario 3: During the inspection of the sanitation units, the auditor observes a wet area under the hand washing sink, upon further investigation, it is determined that the hand washing sink drainage is leaking.
Assessment: Corrective Action Needed.
Reason: Even if the leaking gray water is not directly affecting the production area, there is still a possibility that contaminants could runoff into the production area if left unchecked. The auditor should be able to determine by the amount of liquid, the size of the wet area and visual verification of the location of the leak as to if the leaking gray water would be reasonably likely to contaminate the crops.

Requirement	**TOF-4.2 If hand wash water tanks are used, they are cleaned and sanitized and the water is changed periodically.**
Procedure	**Water tanks used to provide hand wash water shall be maintained at a prescribed frequency in a clean and sanitary manner.**
Verification	**Auditor reviews cleaning and sanitizing protocol and service logs, and visually observes condition of water tanks for signs of noncompliance.**
Corrective Action	**Clean and sanitize the tank, replace water to compliance.**
Documents Required	**Record.**
Mandatory	●

Expectation
Water used for handwashing must be stored in a manner that maintains the quality of the water for no detectable generic *E. coli* in 100 mL of water. Part of this maintenance is to ensure that tanks used to store water are cleaned and sanitized at a prescribed frequency. Additionally, water stored in tanks must be changed periodically.

Example Scenarios
Scenario 1: Auditor reviews cleaning and service records for the operation's field sanitation units and confirms that the units are inspected every two hours and were serviced and cleaned the previous day, the service record does not specifically state that the hand wash water tank was cleaned and sanitized at the time of servicing. The auditor requests the service company SOP for

cleaning and sanitizing, the SOP states that the tanks are cleaned and sanitized at the beginning of each season and can produce records to confirm.
Assessment: Compliant
Reason: The Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain states that the hand wash water tanks are to be cleaned and sanitized and/or shall be maintained periodically or at a prescribed frequency.

Scenario 2: Auditor observes that the hand wash water tank at the field sanitation unit contains sediment of unknown origin, what appears to be green or black water marks around the inside perimeter of the tank and the tank lid is not secured. The auditor requests the most recent service records for the sanitation unit and finds that it was serviced and cleaned that morning by the operation's cleaning crew. The auditor requests the company SOP for cleaning and servicing of the unit and finds that it states that the hand wash water tanks will be cleaned, sanitized, and filled as needed.
Assessment: Immediate Action Required.
Reason: The company is not following its SOP regarding cleaning and sanitizing the hand wash water tanks.

Scenario 3: Upon inspection of the sanitation units the auditor observes that one sanitation station hand wash water tank is empty. The auditor notes that each sanitation station is comprised of four hand washing sinks, two water holding tanks each with four faucets, two toilets, four soap dispensers and four paper towel dispensers. The auditor also notes that it is nearing the end of the harvest crews' workday and all the other hand wash water tanks observed contain water. The sanitation stations are spaced one hundred yards apart to be within one quarter mile or a five-minute walk from where the eight harvest crews are working.
Assessment: Compliant
Reason: The operation has a sufficient number of sanitation stations and a sufficient amount of water in the second tank on that particular sanitation station.

Requirement	**TOF-4.3 Policies shall require hand washing with soap and potable water at the appropriate time, such as before starting work, after use of toilet facilities, after breaks and when hands may have become contaminated. Policy shall apply to employees, outside contractors, inspectors, and visitors. Compliance is emphasized by management.**
Procedure	**Operation shall have a written SOP regarding hand washing practices. Operation management reinforces importance of and compliance with handwashing policy. Sanitizers may not be used in lieu of soap and water hand washing, but may be used to supplement. If gloves are used when contacting tomatoes or food contact surfaces, policies will clearly communicate that gloves are not a replacement for good handwashing practices.**
Verification	**Auditor observes handwashing practices of employees and visitors for compliance. If handwashing practices are observed to be compliant, auditor will judge management emphasis to be sufficient. Affected product is evaluated for potential contamination and disposition.**
Corrective Action	**SOP is developed or revised. Retraining is performed. Management increases frequency of or approach to reinforcing hand washing policy.**
Documents Required	**Written Policy, Record.**
Mandatory	●

Expectation
The operation must have a written policy for hand washing with soap and potable water at the appropriate times, see requirement G-10.1 for additional guidance. When gloves are used by workers that will contact tomatoes or food contact surfaces, the policy must clearly communicate that gloves are not a replacement for good handwashing practices, see G-10.11 for additional guidance on glove use.

Example Scenarios
Scenario 1: While the auditor is observing handwashing practices for compliance, the auditor notes that some employees returning from lunch break are only spending five to ten seconds to soap, wash and dry their hands. The supervisor escorting the auditor does not think that it's an issue. The auditor notes that easily understandable hand washing signs are posted and specifically state that hands should be washed for a minimum of twenty seconds. The auditor recalls that the operation's written SOP states that proper hand washing procedure is to wet, soap and wash hands for a minimum of twenty seconds with hot water.
Assessment: Immediate Action Required.
Reason: The operation's management is not reinforcing the importance of proper hand washing.

Scenario 2: The auditor observes that a person exiting the sanitation station did not wash his hands. The person is determined by the auditor's escort to be from an outside company installing irrigation pipes in the field. The supervisor states that the person is not working in or around the production areas.

Assessment: Immediate Action Required.
Reason: The standard requires that all persons be compliant to the operation's hygiene policy.

Scenario 3: At a field sanitation station as the auditor is observing harvest crew hand washing practices, the auditor notes that most crew members are only wetting and drying their hands and then applying hand sanitizer. The field supervisor states that hand sanitizer is a sufficient substitute for soap and water because the crew are all required to use single use gloves while harvesting. The company SOP states the same.
Assessment: Immediate Action Required.
Reason: Sanitizers may not be used in lieu of soap and water hand washing but may be used to supplement. If gloves are used when contacting tomatoes or food contact surfaces, policies will clearly communicate that gloves are not a replacement for good handwashing practices.

Requirement	TOF-4.4 If gloves are used, there must be a written SOP regarding their use.
Procedure	**If gloves are used for product or food contact purposes, operation shall have a written policy and SOP regarding their use, maintenance and disposal, including cleaning of reusable gloves, not taking gloves into restrooms or eating areas, replacing gloves that may be damaged or have become a source of contamination. The SOP should also address limitations of use of non-sanitary gloves (i.e., work gloves). The SOP will require that reusable gloves shall not be taken home by workers for cleaning and sanitizing.**
Verification	**If gloves are used, auditor reviews the SOP, records of SOP performance, and visually verifies that glove use is consistent with the SOP; i.e., gloves at the beginning of tomato handling activities are clean and not damaged; workers are observed to not wear gloves into restrooms or eating areas; and that gloves are not taken into restrooms or eating areas.**
Corrective Action	**SOP is developed or revised. Non-compliances are corrected on site. Retraining is performed.**
Documents Required	**Written Policy, Record.**
Mandatory	●

Expectation
If gloves are used and will contact product or food contact surfaces, the operation must have a written policy regarding their use. This SOP should also address limitations on the use of non-sanitary gloves. The policy must also require that reusable gloves shall not be taken home by workers for cleaning and sanitizing. See G-10.11 for additional guidance on glove use.

Example Scenarios
Scenario 1: During the auditor's observation of harvesting activities, the auditor observes that the harvesters are all wearing different types of gloves. When the auditor asks the field manager about glove use, the field manager states that harvest crews are permitted to bring their own gloves from

home as long as they are maintained in an intact and sanitary condition at the start of the day and as long as they leave the gloves in the field during break or lunch. The auditor continues observation of harvest crews until it's time for the crew to take a break. After the break the auditor notes that the harvest crew members are washing their hands and putting on the same gloves that they had been using prior to their break, several of the gloves observed were dirty, torn or wet. The field manager does not consider the use of the same gloves as a problem. The company SOP states that gloves are to be cleaned and sanitized prior to use each day and should be changed if they become contaminated, torn or wet.
Assessment: Immediate Action Required
Reason: Gloves must be changed when they have become torn wet or contaminated, and at any time when hands would need to be washed. Appropriately cleaned and sanitized gloves shall be issued each day and at such times as needed during the day. Gloves shall not be permitted to be taken home by workers.

Scenario 2: The operation's SOP states that appropriately cleaned and sanitized gloves shall be issued to the harvest crews each day and at such times as needed during the day. The field manager keeps a log of to whom and when gloves are issued each day and collects the gloves at the end of each day. The gloves are then taken to the packinghouse where they are washed in a cloth washing machine and sanitized with the use of chlorine bleach for distribution and use the following day.
Assessment: Compliant
Reason: If gloves are utilized, a procedure for glove use must be documented and followed so that glove use does not become a source of contamination. Appropriately cleaned and sanitized gloves shall be issued each day and at such times as needed during the day.

Scenario 3: In a packinghouse that handles fresh tomatoes, the operation requires that anyone handling tomatoes or food contact surfaces wear single use gloves. New single use gloves are made available at entrances to the packing facility, hand washing stations and at each sorting line where tomatoes are handled. The operation's written SOP states that single use gloves are required when handling any product or food contact surfaces and must be removed before lunch breaks or using the restroom and replaced after hands are washed and before commencing work duties. The auditor observes and verifies that the employees and staff are following the written policy.
Assessment: Compliant.
Reason: The facility has a written procedure regarding glove use and it is being followed by the employees and staff.

TOF- 5 Pesticides

Requirement	**TOF-5.1 Pesticide Usage Water used to mix pesticides meets FDA *E. coli* standards for water in 21 CFR § 112.44(a); i.e., no detectable generic *E. coli* in 100 mL of agricultural water.**
Procedure	**Operation has a written policy requiring foliar-application pesticides to be diluted only with water that meets FDA microbial standards for post-harvest agricultural water. Operations will have documentation demonstrating compliance, such as test results for the water source used.**
Verification	**Auditor reviews the policy and inspects pesticide mixing and application records.**
Corrective Action	**Operation develops a written policy. Retraining of pesticide applicator as needed. If unknown or non-drinking quality water was used to prepare pesticides, then test the water source for compliance with FDA *E. coli* standards for post-harvest agricultural water. Do not harvest product unless water test results demonstrate compliance.**
Documents Required	**Record.**
Mandatory	●

Expectation
Records of testing for agricultural water must be maintained. It is not required that operations test agricultural water when water is provided by a public water supply (Municipal) that furnishes water meeting the microbial quality requirement, but results or certificates of compliance from the public water supplier that demonstrate the water meets the applicable standards are required. It is not required that operations test agricultural water when the water is treated by a method effective to make the water consistently safe and of adequate sanitary quality for its intended use and/or to meet the required standards. If treated, the treatment must be monitored at an adequate frequency to ensure that the water is consistently safe and of adequate sanitary quality for its intended use.

Example Scenarios
Scenario 1: The operation has a written policy requiring foliar-application pesticides to be diluted only with water that meets FDA microbial standards for drinking water. The operation contracts ABC Ag Air Services for application of all pesticides. The auditor reviews the water test records for the water used by ABC Ag Air Services for compliance and finds that the water is from a municipal source that meets EPA microbial standards for drinking water and annual testing is performed and documented by the municipality. The operation maintains the most recent records of the tests.
Assessment: Compliant
Reason: Water used to mix pesticides meets EPA microbial standards for drinking water; 21 CFR Part 112.44(a).

Scenario 2: Applications of pesticides are contracted through XYZ Ag Services. The contractor and the operation use the XYZ Ag Services electronic program as documentation for applications of pesticides. The XYZ electronic program includes the field serviced, the chemical and amount used, the target organism and justification for the application. The XYZ Ag Services website contains a

statement that all foliar chemical applications are applied with potable water. The operation does not keep records of the water tests performed for the water used by the contracted company nor are they posted on the XYZ Ag Services website.
Assessment: Corrective Action Needed.
Reason: Operations will have documentation demonstrating compliance, such as test results for the water source used.

TOF- 6 Water Used in Growing Activities

Requirement	**TOF-6.1 Non-Foliar The water test meets FDA *E. coli* standards for foliar application water as described in 21 CFR § 112.44(b).**
Procedure	**Written procedure requires a BAM or other testing procedure validated for generic *E. coli* quantitation in water.**
Verification	**Auditor reviews water test results and any corrective actions taken to bring the water source into compliance.**
Corrective Action	**Perform a sanitary survey for each affected water source, perform any remedial action as required and retest. If the retest also exceeds the standard, further evaluate potential corrective actions, such as treatment, retreatment, or discontinue use of source.**
Documents Required	**Record.**
Mandatory	●

Expectation
The *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain* specify that any water used for drip irrigation or non-contact uses shall meet the standard for *E. coli* levels of:

1. A geometric mean of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water, AND

2. A statistical threshold value (STV) of 410 or less CFU of generic *E. coli* per 100 mL of water.

Example Scenarios
Scenario 1: The tomato growing operation irrigates by use of furrows between the beds of crops. The operation has a written policy that states tomatoes which have been found in the furrows or in contact with the ground during harvesting operations are not to be harvested. When irrigating, the furrows are filled with water from an enclosed well. The most current water tests reviewed show <1 ppm/100 mL for generic *E. coli* and total coliforms.
Assessment: Compliant
Reason: Any non-foliar application of water to tomatoes (e.g., irrigation or crop protection sprays) shall meet the microbial standards contained in 21 CFR 112.44(b)

Scenario 2: The growing operation irrigates by use of furrows between the beds of tomatoes. The water is from an aqueduct system that is tested every month, the testing shows that over the last

twelve months the water never exceeded a geometric mean of 126 colony forming units of generic *E. coli* per 100 mL of water and a statistical threshold value of 410 or less CFU of generic *E. coli* per 100 mL of water.
Assessment: Compliant.
Reason: Any water used for drip irrigation or non-contact uses shall meet the standard for *E. coli* levels of (1) A geometric mean (GM) of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water and (2) a statistical threshold value (STV) of 410 or less CFU of generic *E. coli* per 100 mL of water.

Scenario 3: A tomato growing operation irrigates using drip tape embedded in the grow beds. The water is sourced from an aqueduct system. Prior to reaching the grow beds, the water passes through six filters and a system that adds a chlorinated liquid that the Auditee states is just to help keep the lines clear. Water samples are aseptically collected once each month from the water connection after the filters and chlorination system and before the grow beds. The water is tested by a GLP certified laboratory using the SM9223B method. All water tests are conducted for generic *E. coli* and total coliforms. The most recent water test results are 2.8 MPN/100 mL., 4.5 MPN/100 mL., 56 MPN/100 mL., 21 MPN/100 mL., 44 MPN/100 mL, 3.2 MPN/100 mL., 33.2 MPN/100 mL.
Assessment: Compliant.
Reason: Any water used for drip irrigation or non-contact uses shall meet the standard for *E. coli* levels of (1) A geometric mean (GM) of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water and (2) a statistical threshold value (STV) of 410 or less CFU of generic *E. coli* per 100 mL of water.

Requirement	**TOF-6.2 Foliar The water test meets FDA standards for water in 21 CFR § 112.44(a); i.e., no detectable generic *E. coli* in 100 milliliters (mL) of agricultural water.**
Procedure	**Written procedure requires a BAM or other testing procedure validated for generic *E. coli* quantitation in water.**
Verification	**Auditor reviews water test results and any corrective actions taken to bring the water source into compliance. If tomatoes have been contacted with noncompliant water, auditor reviews the risk assessment and disposition.**
Corrective Action	**Perform a sanitary survey for each affected water source, perform any remedial action as required and retest. If the retest also exceeds the standard, further evaluate potential corrective actions, such as treatment, retreatment, or discontinue use of source. Operation shall evaluate tomatoes that have been contacted with noncompliant water to assess food safety risk. The assessment is documented and tomatoes dispositioned accordingly.**
Documents Required	**Record.**
Mandatory	●

Expectation

The *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain* specify that any water used for foliar application of water (e.g. irrigation or crop protection sprays) shall have no detectable generic *E. coli* in 100 mL of agricultural water.

Example Scenarios
Scenario 1: The farm relies on rainwater for irrigating their crops, a private on site well is available for dry years if enough rain has not fallen. The operation has not had the well water tested in three years but uses the same well for the farmhouse and a barn that houses the farms animals. The farmer states that the water is safe enough for his wife and family because they never got sick from its use. The farmer goes on to say that he used the well for irrigation directly after planting the propagation materials received from the greenhouse down the road and again about three weeks ago for plant protection and fertigation and plans to use the well water again if necessary, just prior to harvesting. The farm applies the well water by overhead sprinkler.
Assessment: Immediate Action Required.
Reason: Records of testing of agricultural waters must be analyzed and maintained. Operations will have documentation demonstrating compliance, such as test results for the water source used.

Scenario 2: The operation applies water for irrigation and crop protection materials with a tractor sprayer. The water is sourced from the city where the operation resides. The operation does not perform microbial testing on the water but has the report from the city dated less than one year ago. The operation states that this is the most recent record available from the city.
Assessment: Compliant.
Reason: There is no requirement to test any agricultural water that is subject to the requirements of §112.44 when water is provided by a public water supply that furnishes water that meets the microbial quality requirement described in 21 CFR part 112.44(a). Results or certificates of compliance from the public water system are required that demonstrate that the water meets the required standards.

<u>TOF- 7 Soil Amendments</u>

Requirement	TOF-7.1 If fertilizers containing manures or composts are used, only properly treated (composted or heat treated) manures are allowed for use in fields. Biosolids are not permitted.
Procedure	Soil amendment use records are available, reviewed and current (conventional or organic). If treated manures are used, records of composition, dates of treatment, methods utilized, application dates and letter of guarantee, certificate of analysis (COA) or any test results or verification data demonstrating compliance with process or microbial standards must be documented. For non-composted animal by-products-containing soil amendments, the operations shall retain a certificate or letter showing the lethality of the process. Compost applications shall be no less than 45 days prior to harvest.
Verification	Auditor reviews the amendment use documents and records demonstrating compliance with prevailing national or local established composting or heat treatment standards or guidelines.
Corrective Action	Operations must obtain the necessary documents. If the documents cannot be obtained, field cannot be harvested for that crop cycle.
Documents Required	Record.
Mandatory	●

Expectation
The *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain* specify that compost applications shall be no less than 45 days prior to harvest. Only properly treated (composts or heat-treated manures) are allowed for use in tomato fields. These guidelines also specify that biosolids are not allowed for use in tomato fields. See F-7 for additional guidance on the use of soil amendments.

Example Scenarios
Scenario 1: The operation contracts the fertigation and plant protection material application to DEF Agriculture Services, Inc. The applications are requested by the operation through the DEF electronic system. The operation produces a letter of guarantee from DEF Services as confirmation that all materials applied by DEF contain no animal by-products.
Assessment: Compliant.
Reason: The letter of guarantee confirms that the applicator does not use biological soil amendments.

Scenario 2: The tomato growing operation applies treated animal-based soil amendments. The documentation confirms that the amendments are applied in October of each year. The operation plants the fields in April of each year. The operation produces a receipt for the purchase of the compost that confirms it was purchased from GES Farms in October. The receipt includes the composition of the soil amendment and the dates of treatment.
Assessment: Immediate Action Required
Reason: If treated manures are used, the following must be documented: composition, dates of treatment, methods utilized, application dates and test results or process verification data

demonstrating compliance with microbial standards. Evidence of processing adequate to eliminate pathogens of human concern, such as letter of guarantee, certificate of analysis (COA) or any test results or verification data (e.g., time and temperature) demonstrating compliance with process or microbial standards, shall be documented.

Scenario 3: The small family farm in the northeast growing tomatoes for a local retailer applies raw cow manure to his growing fields. The owner states that the manure is from his cow grazing fields and barn. The owner states that he applies the manure in October after completing the harvest and does not begin to plant new crops until May of the following year.
Assessment: Immediate Action Required
Reason: If fertilizers containing manures or composts are used, only properly treated (composted or heat treated) manures are allowed for use in fields. Biosolids are not allowed for use in tomato fields.

TOF- 8 Sanitizing Agents Used During Harvest

Requirement	**TOF-8.1 All compounds used to clean or sanitize food contact containers, tools, utensils, equipment or other food contact surfaces are approved for that use by the US EPA, FDA or other prevailing agency. Actual use conforms to label directions.**
Procedure	**Documentation is available to demonstrate that cleaning and sanitizing products are approved for their use and are used according to label directions. Sanitizing chemicals uses shall be documented.**
Verification	**Auditors review documentation and supplies to confirm approved use, and interview individuals responsible for their use for knowledge of approved use. Auditor reviews records of use, and visually observes use, to verify compliance with label directions.**
Corrective Action	**Non-compliances are corrected on site. Records are reviewed for potential product adulteration. Retraining is performed.**
Documents Required	**Record.**
Mandatory	●

Expectation
EPA considers any chemical making an antimicrobial claim, including those used to sanitize equipment and tomatoes, to be a pesticide. Sanitizing chemicals used must comply with all requirements of EPA registration and any federal, state or local regulations. Sanitizing chemicals must be appropriately registered for such use and must be used in accordance with label directions. Sanitizing chemicals uses shall be documented.

Any surfaces or equipment intended to touch fresh produce is a food contact surface and must be cleaned and sanitized at a frequency sufficient to prevent the surfaces from becoming a source of contamination.

Example Scenarios

Scenario 1: The operation uses a disinfecting bleach to clean and sanitize all food contact surfaces, containers, equipment and utensils. The facility manager states that the cleaning crew mixes the substance in accordance with the label instructions for food contact equipment. The mixing instructions are posted at the cleaning chemical mixing areas and records of where, when and what was cleaned and sanitized is documented with each use. The auditor reviews the use records, verifies that the substance is approved for cleaning and sanitizing and use on food contact equipment and interviews the cleaning crew for verification that the proper mixing procedure and use is being followed.
Assessment: Compliant.
Reason: Documentation is available to demonstrate that sanitizing products are approved for their intended use and are used according to label directions. The auditor verified that the substance is being mixed and used correctly and sanitizing chemical use is documented.

Scenario 2: The harvest crew lead supervisor cleans the plastic harvesting containers in a secluded area away from the field with a disinfectant. Records indicate that the substance is used every evening after harvesting for the day has been completed. The product is mixed in accordance with the label instructions. The auditor verifies that the product is approved for sanitizing food contact equipment, but notes that the label states surfaces need to be cleaned with a cleaning solution prior to disinfectant use. The auditee is unable to produce a record of cleaning prior to disinfecting.
Assessment: Corrective Action Needed.
Reason: Unless the label states that it cleans and disinfects, it's not a cleaning solution. The food contact containers need to be cleaned before they are sanitized. (according to the label instructions)

Scenario 3: For cleaning and sanitizing food contact surfaces and equipment, the operation's cleaning crew uses a concentrated chlorine solution used for swimming pools directly from the container, after use, the crew rinses the food contact surface with potable water. The auditor reviews the label instructions and finds that the chemical is not approved for use on food contact surfaces or equipment.
Assessment: Immediate Action Required.
Reason: The product is not approved for use of food contact surfaces or equipment.

TOF- 9 Product Containers

Requirement	TOF-9.1 Reusable product bins, trays and containers are made of impervious materials that can be cleaned and sanitized.
Procedure	Written SOP requires that all re-usable product containers are made of materials that can be sanitized, or clean and sanitary liners are used. Wood is not an appropriate food contact surface. Procedures require damaged containers that are no longer easily cleanable or sanitary shall be removed from service of food contact purposes.
Verification	Auditor reviews SOP, visually observes product bins, trays and containers and their use for evidence of noncompliance.
Corrective Action	Policy is developed or revised. Non-compliances are corrected. Operation makes a commitment for phasing out nonconforming product containers; e.g., wooden bins, in a reasonable timeline. Retraining is performed.
Documents Required	Written Policy.
Mandatory	●

Expectation
Equipment and tools must be used that are of adequate design, construction, and workmanship to enable them to be adequately cleaned, sanitized and properly maintained. They must be maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and stored and maintained to protect tomatoes from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests. The seams on food contact surfaces of equipment and tools used must be either smoothly bonded, or maintained to minimize accumulation of dirt, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.

Equipment and tools must be inspected, maintained, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of tomatoes. All non-food-contact surfaces of equipment and tools used during harvesting, packing, and holding must be cleaned and maintained as frequently as reasonably necessary to protect against contamination of tomatoes. If equipment such as pallets, forklifts, tractors, and vehicles are used so that they are intended to, or likely to, contact tomatoes, they must be used in a manner that minimizes the potential for contamination of the produce or food contact surfaces with known or reasonably foreseeable hazards.

(See F-8 for additional guidance for equipment and tools.)

Example Scenarios
Scenario 1: During the auditor's observation of harvesting, it is observed that one harvest employee has cardboard lining the bottom of his plastic harvest buckets. The auditor asks the supervisor if this is a common practice. The supervisor is not aware of the cardboard being used. When the supervisor asks the harvest employee about the cardboard, it is learned that the harvest employee thought that the cardboard would serve as protection for the tomatoes hitting the bottom

of the container. The supervisor immediately issues the employee new harvesting containers, and instructs him not to place anything but tomatoes in the containers.
Assessment: Corrective Action Needed.
Reason: Cardboard cannot be sanitized. Policy revised. Retraining is performed.

Scenario 2: The small farming operation is harvesting tomatoes into plastic buckets that are then collected in the field and dumped into wooden bins for transport to the packinghouse. The wooden bins are fitted with new clean plastic sheeting prior to each use. The owner states that plastic bins are just too expensive for him to purchase at this time but plans to replace the wood bins with plastic bins one or two at a time as the wood bins become unusable.
Assessment: Compliant.
Reason: The operation is taking precautions to protect the tomatoes from contamination and has a plan to replace the wood bins in a reasonable timeframe.

Requirement	**TOF-9.2 Operation has a policy that requires bins trays and boxes made of corrugated cardboard are for single use only.**
Procedure	**Written policy prohibits re-use of single-use bins, trays and boxes made of corrugated cardboard or fiberboard for product contact purposes.**
Verification	**Auditor reviews policy, observes practices related to corrugated cardboard or fiberboard bins, trays and boxes for evidence of noncompliance.**
Corrective Action	**Policy is developed or revised. Tomatoes that have been packed in a reused cardboard or fiberboard bin, tray or box shall be corrected, which may include tomatoes are segregated, washed and repacked in new containers, or discarded. Retraining is performed.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
The *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain* specifies that the reuse of single use containers (e.g., corrugated) for the field packing of tomatoes is prohibited.

Harvest containers, such as fiberboard boxes into which tomatoes are placed when harvested, could be the same containers in which the tomatoes are distributed (e.g., when tomatoes are field-packed). Food-packing materials also include "food-packaging materials," a term that has long been used to generally refer to a container that directly contacts the food. When a food-packing material is used, it must be adequate for its intended use, which includes being: Cleanable or designed for single use; and unlikely to support growth or transfer of bacteria.

Auditors should take the following steps to help determine whether food–packing material is adequate for its intended use: Identify the types of food-packing materials used and determine whether each type is reusable or for single use. Determine whether the food-packing materials are unlikely to support the growth or transfer of bacteria, taking into consideration the handling, maintenance, and storage practices; and determine whether reusable materials can be cleaned.

Example Scenarios
Scenario 1: The operation uses new fiberboard boxes to package fresh tomatoes, the operation's SOP states that fiberboard boxes are for single use only and the written policy prohibits re-use of single use boxes, trays and bins made of corrugated cardboard or fiberboard for product contact purposes.
Assessment: Compliant.
Reason: Operation has a policy that requires bins trays and boxes made of corrugated cardboard are for single use only and the written policy prohibits re-use of single use bins, trays and boxes made of corrugated cardboard or fiberboard for product contact purposes.

Scenario 2: The operation uses new fiberboard boxes to package fresh tomatoes but does not have a written policy prohibiting their use or re-use for any purpose.
Assessment: Corrective Action Needed.
Reason: The operation does not have a policy that requires bins, trays, and boxes made of corrugated cardboard are for single use only.

Scenario 3: The harvesting operation field packs fresh tomatoes into two-pound plastic clamshells, the plastic clamshells are then placed into fiberboard containers. The operation's SOP states that fiberboard containers are designated as single use only the auditor notes that the operation has no written policy for the plastic clamshells. The auditor does not observe any re-use of the fiberboard containers or plastic clamshells.
Assessment: Compliant.
Reason: The operation's SOP states that fiberboard containers are designated as single use only. No re-use of fiberboard containers was observed by the auditor.

Requirement	TOF-9.3 SOP specifies that workers do not remove harvest buckets from the field.
Procedure	Written SOP prohibits taking harvest buckets home.
Verification	Auditor reviews SOP and observes practices related to handling of harvest buckets.
Corrective Action	Policy is developed or revised. Retraining is performed.
Documents Required	Written Policy.
Mandatory	●

Expectation
The *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain* specifies that harvest containers should remain under the oversight of farm management. This requirement verifies that there is a written SOP that prohibits taking harvest buckets home.

Example Scenarios
Scenario 1: The auditee's SOP specifies that workers do not remove harvest buckets from the field until such time as the supervisor collects the harvest containers at the end of the shift. And that

harvest containers are not taken home by harvest employees. The auditor observes that at the end of the shift, the field supervisor instructs the harvest crew to place the used harvest containers into the back of his pick-up truck parked just off the field.
Assessment: Compliant
Reason: The auditee's SOP specifies that workers do not remove harvest buckets from the field until such time as the supervisor collects the harvest containers at the end of the shift, and that harvest containers are not taken home by harvest employees.

Scenario 2: The harvest operation does not have a written SOP that specifies workers do not remove harvest buckets from the field and that harvest containers are not taken home by harvest employees. The auditor observes harvest workers taking the harvest containers to the storage trailer before breaks or restroom use, and then being issued clean harvest containers prior to returning to the harvest activities.
Assessment: Corrective Action Needed.
Reason: The harvest operation does not have a written SOP that specifies workers are not to remove harvest containers from the field and that harvest containers are not taken home by harvest employees.

Scenario 3: The operation's SOP states that harvest containers shall not be taken home by harvest workers and shall remain in control of the field supervisor. The SOP also states that harvest containers be replaced and/or washed and sanitized each time the harvest crew re-enters the field. The auditor observes the harvest workers taking the harvest containers to the supervisor's truck prior to their lunch break and receiving new (clean) harvest containers after lunch break and prior to returning to the field. The auditor reviews cleaning records for the harvest containers, the operation's SOP regarding harvest containers and finds that the operation is following their SOP regarding product harvest containers.
Assessment: Compliant
Reason: The operation has a written procedure and is following their SOP regarding harvest containers.

TOF-10 Field Packing of Tomatoes

Requirement	**TOF-10.1 Packing containers shall be labeled as to their source, and to identify that the product has been field packed.**
Procedure	**Cartons or other primary packaging shall be labeled accurately and shall clearly communicate the tomatoes were packaged in the field.**
Verification	**Auditor observes packaging for accuracy and is clearly labeled as field packed.**
Corrective Action	**Operation ceases to use non-compliant packaging or labeling. Non-compliances are corrected on site.**
Documents Required	**Record.**
Mandatory	**●**

Expectation
The *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain* specifies that cartons or other primary packaging shall be labeled accurately and shall clearly communicate that the tomatoes were packaged in the field.

Example Scenarios
Scenario 1: Packing containers are labeled as to their source and identify that the product has been field packed.
Assessment: Compliant.
Reason: Packing containers are labeled as to their source and identify that the product has been field packed.

Scenario 2: Cartons and other primary packaging is labeled but does not clearly communicate the tomatoes were packaged in the field.
Assessment: Corrective Action Needed.
Reason: Cartons and other primary packaging is not labeled accurately and does not clearly communicate the tomatoes were packaged in the field.

Scenario 3: The operation's field packing containers contain a code number that links the container contents to the field and harvest date, commodity name, company name and address, grower, field location, date of harvest, harvester's name and address. According to the auditee the code also tells you if the product was field packed or packinghouse packed.
Assessment: Corrective Action Needed.
Reason: Cartons or other primary packaging shall be labeled accurately and shall clearly communicate the tomatoes were packaged in the field. Due to the operation using a code to label the product, the auditor cannot determine if the product was field packed.

PACKINGHOUSE

The development of good agricultural practices for the tomato packinghouse must address the unique needs of each packinghouse. These needs may vary due to location environment, the volume of tomatoes handled, local regulations and other components. The overall goal of the food safety program is to reduce physical, chemical and microbial risks.

<u>TPH-1 Management Responsibility</u>

Requirement	TPH-1.1 Operation has current copies of the *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain, the relevant Harmonized Food Safety Standard, and additional food safety documents as required by state and/or federal regulation.
Procedure	**Operation has a current copy of the Guidelines, this audit document and all other required documents.**
Verification	**Auditor observes the current copies at the operation.**
Corrective Action	**Operation obtains current copies.**
Documents Required	**Record.**
Mandatory	●

Expectation
(See requirement TOF-1.1)

Requirement	TPH-1.2 Operation has been registered or permitted as a food handling establishment as required by state or federal regulation.
Procedure	**Operation demonstrates knowledge of prevailing requirements and has a copy of required permit(s) or registration.**
Verification	**Auditor reviews copies at the operation to verify they are current and complete.**
Corrective Action	**Operation applies for or renews required permits or registration.**
Documents Required	**Record.**
Mandatory	●

Expectation
Operations that are required to register with the FDA as a food handling establishment as required by state or federal regulation, must provide the auditor records to verify that their registration is current and complete. For packinghouses not required to register with the FDA this requirement may be answered as N/A.

Example Scenarios
Scenario 1: Operation has been registered or permitted as a food handling establishment as required by state or federal regulation. Operation demonstrates knowledge of prevailing requirements and has a copy of required permit(s) or registration.
Assessment: Compliant.
Reason: Operation is registered or permitted as a food handling establishment as required by state or federal regulation. Operation demonstrates knowledge of prevailing requirements and has a copy of required permit(s) or registration.

Scenario 2: Operation has not been registered or permitted as a food handling establishment as required by state or federal regulation. Operation demonstrates knowledge of prevailing requirements but does not have a copy of required permit(s) or registration.
Assessment: Corrective Action Needed.
Reason: Operation has not been registered or permitted as a food handling establishment as required by state or federal regulation. Operation does not have a copy of required permit(s) or registration.

TPH-2 Raw Material Sourcing

Requirement	**TPH-2.1 The operation has a policy and takes affirmative steps to ensure that all fresh tomatoes that are packed or stored in the facility are grown following requirements in *Tomato Metrics Audit - Open Field Production, Harvest and Field Packing*.**
Procedure	**The packinghouse requires all raw product suppliers to provide evidence of food safety/GAP programs and compliance. Such evidence must include sufficient documentation to demonstrate that the supplier complies with the requirements in *Tomato Metrics Audit - Open Field Production, Harvest and Field Packing*.**
Verification	**Auditor reviews policy and verifies that operation's evidence of supplier compliance with food safety/GAP programs is in compliance with the operation's policy.**
Corrective Action	**Operation obtains required documentation. Operation ceases accepting or shipping product from non-approved suppliers, until sufficient documentation demonstrating compliance is received by the operation.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
Packinghouses must be able to demonstrate that fresh tomatoes that are packed or stored in the facility are grown following requirements in the *Tomato Metrics Audit – Open Field Production, Harvest and Field Packing*. There shall be a written policy on how this is done. Operations may demonstrate that tomatoes meet this requirement by a variety of methods. This may include an external audit, internal audit or self-assessment that can verify that the Tomato Metrics are being followed.

Example Scenarios
Scenario 1: The operation has a written policy and takes affirmative steps to ensure that all tomatoes that are packed or stored in the operation are grown following requirements in the *Tomato Metrics - Open Field Production, Harvest and Field Packing* Standard.
Assessment: Compliant.
Reason: The operation has a written policy and takes affirmative steps to ensure that all tomatoes that are packed or stored in the operation are grown following requirements in the *Tomato Metrics -*

Open Field Production, Harvest and Field Packing. The auditor reviews the policy and third-party audit certificates for the operation's raw product suppliers and finds all documents to be compliant.

Scenario 2: The operation does not have a written policy regarding taking affirmative steps to ensure that all tomatoes that are packed or stored in the operation are grown following requirements in the *Tomato Metrics - Open Field Production, Harvest and Field Packing* Standard.
Assessment: Corrective Action Needed.
Reason: The operation does not have a written policy regarding taking affirmative steps to ensure that all tomatoes that are packed or stored in the operation are grown following requirements in the *Tomato Metrics - Open Field Production, Harvest and Field Packing* Standard.

Scenario 3: The operation has a policy and takes affirmative steps to ensure that all tomatoes that are packed or stored in the operation are grown following requirements in the *Tomato Metrics - Open Field Production, Harvest and Field Packing* Standard. The policy is not written and the auditee is unable to furnish records of their supplier's third-party audits.
Assessment: Corrective Action Needed.
Reason: The policy is not written and the auditee is unable to furnish records of their operation's raw product suppliers third party audits.

Requirement	**TPH-2.2 Operation has procedures to ensure that the tomato staging area and staging practices do not pose a risk of tomato contamination.**
Procedure	**The packinghouse staging area is designed so that overhead areas do not pose a contamination risk of uncovered tomatoes, or that tomatoes are protected during staging to prevent contamination.**
Verification	**Auditor reviews procedures and inspects staging area for potential sources of contamination.**
Corrective Action	**Operation develops procedures and/or redesigns staging area or staging practices to prevent reasonably likely to occur opportunities for contamination. Tomatoes that have become contaminated are discarded.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
The tomato staging area and staging practices should not pose a risk of contamination for tomatoes. The written policy should address the assessment of the staging area that would minimize sources of contamination.

Example Scenarios
Scenario 1: Operation has written procedures to ensure that the tomato staging area and staging practices do not pose a risk of tomato contamination. The auditor confirms that the packinghouse staging area is designed so that overhead areas do not pose a contamination risk of uncovered tomatoes, and that tomatoes are protected during staging to prevent contamination.
Assessment: Compliant.

Reason: Operation has procedures and a written policy to ensure that the tomato staging area and staging practices do not pose a risk of tomato contamination.

Scenario 2: Operation has written procedures to ensure that the tomato staging area and staging practices do not pose a risk of tomato contamination. Upon the auditor's review of the staging area for potential sources of contamination he finds that the staging area is outside of the packinghouse and that the area is not covered and/or protected from possible contamination.
Assessment: Corrective Action Needed.
Reason: The operation redesigns the staging area or staging practices to prevent reasonably likely to occur opportunities for contamination. Tomatoes that have become contaminated are discarded.

Scenario 3: The operation covers the bins of tomatoes arriving from the field prior to storing them in the refrigerated area of the warehouse. The operation's written policy states that bins shall remain covered and refrigerated until such time as they can be washed and packed. The auditor confirms that the covered bins are protected from possible sources of contamination.
Assessment: Compliant.
Reason: The operation is following their written policy and tomatoes are protected from reasonably likely to occur possibilities for contamination.

TPH-3 Traceability

Requirement	**TPH-3.1 Lot identification shall be labeled on all cases and clearly legible.**
Procedure	**A product coding system is in place where product or raw material shall be labeled with grower and lot identification, and coded to enable access to date of harvest and/or packing, origin (name of farm, grower and/or packing location), and country of origin for traceback purposes.**
Verification	**Auditor reviews coding procedures, observes cases for appropriate coding, and verifies compliance by review of records.**
Corrective Action	**Boxes with missing, inaccurate or illegible coding are labeled with appropriate identification. Procedure is developed or revised. Retraining is performed.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
All levels of the tomato supply chain shall maintain adequate traceability to a minimum of one step forward (immediate next recipient) and one step back (immediate previous supplier) in compliance with FDA recordkeeping requirements. Documentation maintained by the packinghouse shall include sufficient information about the source (i.e., field packer firm name, identification of grower, field location, and date of harvest/field pack) as well as the customer receiving the product to allow for the appropriate tracing of product.

The packer must have established procedures to ensure that traceability information about the source is retained with tomatoes as they move through the packinghouse processes to shipping, including during resorting. Corrugated containers must be new and accurately labeled with commodity name, packinghouse firm name, and lot identification sufficient to allow for accurate traceability. Only containers able to be cleaned and sanitized (e.g., reusable plastic containers, "RPCs") may be reused. If using reusable containers, they shall be cleaned and sanitized before reuse. Labels that originate from a prior use or are inaccurate shall be removed or concealed prior to packing.

Example Scenarios
Scenario 1: The auditor confirms that a product coding system is in place where tomatoes shall be labeled with grower and lot identification, and coded to enable access to date of harvest and/or packing, origin (name of farm, grower and/or packing location), and country of origin for traceback purposes. Auditor verifies that coding systems are working as designed, that the carton labels are appropriate and verifies compliance by review of records.
Assessment: Compliant.
Reason: Auditor reviewed coding procedures, observed cases for appropriate coding, and verified compliance by review of records.

Scenario 2: The operation packs tomatoes in two-pound polyethylene bags. The bags are then placed into master cartons of twelve bags each. A product coding system is in place where master cartons are labeled with grower and lot identification and date of harvest and/or packing, origin (name of farm, grower and/or packing location), and country of origin for traceback purposes. But the polyethylene bags only depict a code number. The auditor asks the auditee how the code number is used to trace the product, the auditee explains the trace number. The auditor then verifies the coding system by review of records and finds the procedure to be in compliance with the standard.
Assessment: Compliant.
Reason: The auditor verified the coding system by review of records.

Scenario 3: A product coding system is in place where product or raw material shall be labeled with grower and lot identification, and coded to enable access to date of harvest and/or packing, origin (name of farm, grower and/or packing location), and country of origin for traceback purposes. Upon review by the auditor, it is observed that most of the product codes printed on the cartons are illegible.
Assessment: Corrective Action Needed.
Reason: Boxes with missing, inaccurate, or illegible coding are re-labeled with appropriate identification.

<u>TPH-4 Self-Audits</u>

Requirement	TPH-4.1 Operation has procedures for conducting self-audits and conducts self-audits to verify compliance with established internal policies and procedures.
Procedure	In addition to the requirements of the Harmonized Standards, the operation's self-audit procedure ensures compliance with established internal policies and procedures, the Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, these Tomato Metrics, and additional food safety documents as required by state and/or federal regulation.
Verification	Auditor reviews the self-audit procedures, and records of self-audits to verify compliance with the procedures.
Corrective Action	Operation develops and maintains self-audit program, with corrective actions preventive measures, documentation and follow-up.
Documents Required	Written Policy, Record.
Mandatory	●

Expectation
Auditees must conduct self-audits to verify compliance with established internal policies and procedures. There is not a specified format for the self-audit. The self-audit must verify the requirements of the Harmonized Standard being utilized and Tomato Audit Protocol addendum requirements.

Example Scenarios
Scenario 1: The operation has written procedures for conducting self-audits and conducts self-audits annually, but you find that the operation uses a self-made checklist for conducting self-audits.
Assessment: Compliant
Reason: As long as the self-audit performed addresses the requirements of the Harmonized Standards, ensures compliance with established internal policies and procedures, *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, the Tomato Metrics, and additional food safety documents as required by state and/or federal regulation.

Scenario 2: The operation maintains that they conduct self-audits but do not have a record of the self-audit.
Assessment: Corrective Action Needed,
Reason: The requirement requires a written policy and records. Records should document when the self-audit was started and completed.

TPH-5 Product Containers and Packaging Materials

Requirement	TPH-5.1 Tomato-contact bulk bins, gondolas, totes and trays shall not be constructed of wood.
Procedure	In accordance with the Post-Harvest Operations Harmonized Standard P-8.7 regarding acceptable product-contact containers, operation has eliminated or has a plan to eliminate the use of wooden product contact containers.
Verification	Auditor reviews SOP, visually observes product bins, trays and containers and their use for evidence of non-compliance.
Corrective Action	Policy is developed or revised. Non-compliances are corrected. Operation removes non-conforming product containers from food contact purposes. Retraining is performed. Operation develops a plan to phase out wooden bins, and demonstrates compliance with the plan.
Documents Required	Written Policy.
Mandatory	●

Example Scenarios

Scenario 1: In the packinghouse the auditor observes plastic and wooden bins containing tomatoes, the auditor asks the auditee about the observation. The auditee states that only cull tomatoes are placed in the wooden bins and only fresh tomatoes are placed in plastic bins. The operation's SOP confirms that wooden bins are only to be used for trash or tomatoes designated as not for human consumption.

Assessment: Compliant.

Reason: The operation has a written policy that clearly distinguishes the use of wooden bins as not for fresh tomatoes for human consumption.

Scenario 2: The small farming operation is harvesting tomatoes into plastic buckets that are then collected in the field and dumped into wooden bins for transport to the packinghouse. The wooden bins are fitted with new clean plastic sheeting prior to each use. Once in the packinghouse, the tomatoes are dumped into a bath of potable water treated with a chlorine-based sanitizing solution. The owner states that plastic bins are just too expensive for him to purchase at this time, but plans to replace the wood bins with plastic bins one or two at a time as the wood bins become too damaged for further use.

Assessment: Compliant.

Reason: The operation has a plan to replace the wood bins in a reasonable timeframe.

Scenario 3: The farming operation is harvesting tomatoes into wooden bins for transport to the packinghouse. At the packinghouse the wooden bins of tomatoes are lowered into a bath containing a chlorine-based sanitizer solution. The owner states that plastic bins are just too expensive for him to purchase. That's why he is using a sanitizer in his wash water.

Assessment: Corrective Action Needed.

Reason: The operation is not lining the wooden bins with any type of material that will protect the product from contamination. Wood cannot be sanitized. Auditee has no plan to eliminate the use of wooden bins.

Requirement	TPH-5.2 The operation has written procedures for cleaning and sanitizing of produce food contact containers, requiring that bulk bins, gondolas, totes and trays are cleaned and sanitized periodically and is documented.
Procedure	Written SOP is established to ensure that bulk bins, gondolas, totes, trays and other food contact containers and implements are adequately cleaned and sanitized at a frequency sufficient to maintain clean and sanitary food contact surfaces, and documentation of compliance is maintained.
Verification	Auditor reviews SOP, cleaning logs and records, interviews responsible individuals for knowledge of the SOP and observes containers, employees and records for evidence of compliance.
Corrective Action	Policy is developed or revised. Non-compliances are corrected on site. Retraining is performed.
Documents Required	Written Policy, Record.
Mandatory	●

Example Scenarios

Scenario 1: The operation has a written SOP for the cleaning and sanitizing of fresh produce food contact containers, requiring that bulk bins, gondolas, totes and trays are cleaned and sanitized periodically, the SOP states that bulk bins, totes, and trays are cleaned at the beginning of each season and as needed throughout the season with dish soap and a chlorine-based sanitizer solution. The gondola type trailers must be dedicated vehicles for the entire harvest season and are power washed with food safe cleaner and sanitized with the chlorine-based solution. The auditor reviews the cleaning logs for the bulk bins, totes and trays and finds that the logs are dated daily, monthly and annually and appear to be complete. The auditor then requests the cleaning logs for the gondola type trailers that transport the tomatoes from the field to the packinghouse. The logs list each trailer number, the date of the pre-season cleaning and sanitizing of the trailers and the trailer owner and company name. The auditor inquires if this is the only cleaning that has been done on the gondola type trailers, the auditee states that they are flushed out every day with the chlorine-based sanitizer when the trailers arrive at the packinghouse with a load of tomatoes. The auditor observes this process and reviews the associated logs during the walk through of the packinghouse.
Assessment: Compliant.
Reason: The operation has a written SOP and cleaning logs for all produce contact containers.

Scenario 2: The operation has a written SOP for the documentation and cleaning of food contact containers. The SOP states that food contact containers are cleaned and sanitized at the beginning of each harvest season and as needed throughout the season. The auditor reviews the SOP, cleaning logs and visually observes the food contact containers for evidence of compliance. The auditor finds that the packinghouse employees are using full strength chlorine bleach for cleaning and sanitizing the food contact containers. The auditor notes that the label instructions require the substance to be diluted with water at a 10 to 1 ratio for sanitizing food contact surfaces.
Assessment: Immediate Action Required.

Reason: The product that the employees are using is for sanitizing only, produce contact containers must be cleaned and sanitized. The packinghouse employees are not following the sanitizer label instructions for food contact surfaces.

Scenario 3: Upon review of the cleaning logs for food contact containers, the auditor observes that the most recent cleaning for the bulk bins is dated one year ago. The auditor recalls that the operation's SOP states that cleaning of food contact containers is completed and logged weekly. The auditor inquires as to why the most recent cleaning for the bins was not done in accordance with the operation's SOP. The auditee states that he is sure that the bins have been cleaned every week since the beginning of the season but cannot produce the most recent cleaning logs.
Assessment: Immediate Action Required or Corrective Action Needed.
Reason: The auditor should observe the food contact containers and make a determination based on the facts.

Requirement	TPH-5.3 Operation has a policy that requires bins trays and boxes made of corrugated cardboard are for single use only.
Procedure	Written policy prohibits re-use of single-use bins, trays and boxes made of corrugated cardboard or fiberboard for product contact purposes. Repacking of tomatoes into a corrugated cardboard container that contained the same lot of tomatoes is acceptable, provided the container is clean, sanitary and properly labeled.
Verification	Auditor reviews policy, observes practices related to corrugated cardboard or fiberboard bins, trays and boxes for evidence of non-compliance.
Corrective Action	Policy is developed or revised. Tomatoes that have been packed in a re-used cardboard or fiberboard bin, tray or box shall be corrected, which may include tomatoes are segregated, washed and repacked in new containers, or discarded. Retraining is performed.
Documents Required	Record.
Mandatory	●

Expectation
Packaging material should be inspected upon arrival to ensure that packaging material is free from contamination. Packaging materials must be stored in a manner as to prevent contamination. Containers must be protected from direct contact with the ground or floor. Finished product containers must be distinguished from those serving other purposes. The operation must have a policy prohibiting the re-use of single use bins, trays and boxes made of corrugated cardboard or fiberboard for product contact purpose unless used to pack the same lot of tomatoes. Resorting of tomatoes into a corrugated cardboard container that contained the same lot of tomatoes is acceptable, provided that the container is clean, sanitary, and properly labeled.

Example Scenarios

Scenario 1: The operation has a policy that requires corrugated cardboard food contact containers are for single use only. The auditor reviews the SOP and observes practices related to their use. The auditor does not observe any evidence of non-compliance.
Assessment: Compliant.
Reason: The auditor reviewed the policy and confirmed that corrugated cardboard food contact containers are being used in compliance with the operation's SOP and the TPH-5.3 standard requirements.

Scenario 2: Operation has an SOP that requires bins, trays and boxes made of corrugated cardboard are for single use only. The auditor reviews the SOP and observes practices related to their use. The auditor observes the packinghouse operation and finds that employees are packing product from corrugated cardboard containers into reusable plastic containers. The corrugated cardboard containers are being disassembled and disposed of away from the repacking operation.
Assessment: Compliant.
Reason: The standard is specifically regarding re-use of containers made of corrugated cardboard or fiberboard.

Scenario 3: The auditor reviewed the operation's policy for use of corrugated cardboard or fiberboard for product contact purposes. The policy states that corrugated cardboard and/or fiberboard produce contact containers are for single use only unless used to pack the same lot of tomatoes. During the walk-through of the packinghouse, the auditor observed employees repacking pallets of tomatoes that were damaged during transport from the packing line to the cooler. No product or product containers had touched the floor, the pallets had only shifted to one side. The undamaged corrugated containers were being used to repack the undamaged tomatoes.
Assessment: Compliant.
Reason: Repacking of tomatoes into a corrugated cardboard container that contained the same lot of tomatoes is acceptable, provided the container is clean, sanitary, and properly labeled.

TPH-6 Packinghouse Condition and Equipment

Requirement	**TPH-6.1 Facility is constructed/arranged to allow separation of incoming, in-process and finished products.**
Procedure	**Facilities or processes assure separation and positioning of incoming raw materials so as not to become a source of contamination of in-process and finished product.**
Verification	**Auditor observes placement of incoming raw materials, in-process and finished products for opportunities for cross-contamination.**
Corrective Action	**Procedures are developed or revised. Non-compliances are corrected on site. Retraining is performed.**
Documents Required	**Record.**
Mandatory	●

Expectation

Buildings, fixtures, food contact surfaces and other physical facilities of the packinghouse must be maintained in a clean and sanitary condition and must be kept in repair sufficient to prevent tomatoes from becoming adulterated. Storage ripening rooms and distribution facilities must be kept clean and sanitary, with debris minimized. All walls, floors, ceilings and other surfaces must be systematically and periodically cleaned and sanitized to avoid the build-up of mold or other potential contaminants. Proper precautions are to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur or by one or more of the following means: location, time, partition, enclosed systems, or other effective means.

Example Scenarios
Scenario 1: The auditor observes that the operation's facility is constructed and arranged to allow for separation of incoming, in-process, and finished products. The layout of the facility assures separation and positioning of incoming raw materials so as not to become a source of contamination of in-process and finished product.
Assessment: Compliant.
Reason: The operation's facility is constructed and arranged to allow for separation of incoming, in-process, and finished products. The layout of the facility assures separation and positioning of incoming raw materials so as not to become a source of contamination of in-process and finished product.

Scenario 2: The auditor observes that the operation's facility is not constructed and arranged to allow for separation of incoming, in-process, and finished products. The layout of the facility does not assure separation and positioning of incoming raw materials so as not to become a source of contamination of in-process and finished product. The auditor observes that the potential for contamination is reduced by effective timing because the operation only receives raw product in the evenings and runs/processes raw product in the morning and afternoon.
Assessment: Compliant.
Reason: The potential for contamination is reduced by effective timing because the operation receives raw product in the evenings and runs/processes raw product in the morning and afternoon.

Scenario 3: The auditor observes that the operation's facility is not constructed and arranged to allow for separation of incoming, in-process, and finished products. The layout of the facility does not assure separation and positioning of incoming raw materials so as not to become a source of contamination of in-process and finished product. The auditor observes the operation's procedure for receiving bins of incoming product and handling of in-process product and pallets of finished product and determines that reasonable opportunities for contamination are evident.
Assessment: Immediate Action Required.
Reason: The auditor observes that the operation's facility is not constructed and arranged to allow for separation of incoming, in-process, and finished products. The layout of the facility does not assure separation and positioning of incoming raw materials so as not to become a source of contamination of in-process and finished product. The auditor observes the operation's procedure for receiving bins of incoming product and handling of in-process product and pallets of finished product and determines that reasonable opportunities for contamination are evident.

Requirement	TPH-6.2 Operation has procedures that minimize the accumulation of standing water.
Procedure	If floor drains exist, they are adequate, functional, free of obstruction and are properly maintained and cleaned sufficient to prevent them from becoming sources of contamination. If standing water exists, it is removed from floors and floors cleaned in a manner and at a frequency sufficient to prevent creation of a source of contamination.
Verification	Auditor observes floor drains and evidence of standing water for compliance with procedures.
Corrective Action	Floor drains are installed, repaired or maintained, or procedures are modified, to prevent standing water from becoming a potential source of contamination.
Documents Required	Written Policy.
Mandatory	●

Example Scenarios

Scenario 1: The operation has a written policy that states the accumulation of standing water must be removed whenever it is present in the facility. Floor drains are cleaned prior to the beginning of the season, inspected daily as part of the pre-operation's procedure, and documented on the operation's master cleaning and maintenance checklist. The auditor observes small amounts of standing water around the facility's dump tanks and observes a packinghouse employee with a floor squeegee pushing the water toward the floor drains.
Assessment: Compliant.
Reason: The operation has a written policy that states the accumulation of standing water must be removed whenever it is present in the facility. Floor drains are cleaned prior to the beginning of the season, inspected daily as part of the pre-operation's procedure, and documented on the operation's master cleaning and maintenance checklist. The auditor observed only small amounts of water being effectively removed.

Scenario 2: The operation has a written policy that states the accumulation of standing water must be removed daily after equipment cleaning and prior to beginning of each day's operations. The auditor observes that the operation has no floor drains in or around the facility. The auditor also observes that several areas around the facility have large amounts of standing water and in some areas the water is discolored and contains debris.
Assessment: Corrective Action Needed.
Reason: The auditor observed that several areas around the facility have large amounts of standing water and in some areas the water is discolored and contains debris.

Scenario 3: The tomato packing operation does not have a written policy regarding the accumulation of standing water in or around the facility, the facility has floor drains under the dump tank where the tomatoes enter the wash process and in the refrigerated holding areas. The auditor determines that the drains are working as designed as the auditor has not observed any water accumulation.
Assessment: Corrective Action Needed.

Reason: The operation must have a written policy addressing the accumulation of standing water.

Requirement	TPH-6.3 All food contact surfaces are made of material and designed to be easily cleaned and sanitized, and are maintained in good condition.
Procedure	All tomato contact surfaces and equipment are made of materials, designed or constructed to be easily cleaned and sanitized, all food contact surfaces are free of rust or corrosion, and seams between food contact surfaces are smooth or accessible for cleaning.
Verification	Auditor observes product contact surfaces and equipment and their use for evidence of non-compliance.
Corrective Action	Non-compliances are corrected or replaced. Operation makes a commitment for phasing out non-conforming tomato contact surfaces and equipment, in a reasonable timeline. Retraining is performed.
Documents Required	
Mandatory	●

Example Scenarios
Scenario 1: The operation's food contact surfaces are made of material and designed to be easily cleaned and sanitized, and are maintained in good condition. The auditor reviews the operation's written policy and observes the food contact surfaces for evidence of compliance. The auditor determines that the food contact surfaces are adequate.
Assessment: Compliant.
Reason: The auditor reviewed the operation's written policy and observed the food contact surfaces for evidence of compliance. The auditor determined that the food contact surfaces are adequate.

Scenario 2: During the auditor's walk-through of the tomato packing facility, it is observed that some food contact surfaces are constructed with wood that is covered with vinyl, the vinyl covers have seams and cracks that can support the growth of bacteria. The auditor asks the operation's food safety coordinator if these food contact surfaces are ever in use, the food safety coordinator explains that the tables are used for repacking tomatoes. The auditor asks the auditee if they have a plan to phase out the use of these tables. The auditee states that they don't use them that much but no plans have been made to replace them.
Assessment: Immediate Action Required.
Reason: All food contact surfaces are not made of material that is designed to be easily cleaned and sanitized, and are maintained in good condition. The auditee stated that they have no plan to phase out the use of these tables.

Scenario 3: During the auditor's walk-through of the tomato packing facility, it is observed that some food contact surfaces are not able to be sanitized due to being constructed with wood. The applicant states that these surfaces have always been wood and nobody has ever been sick from his tomatoes. The auditor asks the auditee if he has plans to eliminate the wood food contact surfaces. The auditee states that he does not plan to replace something that has been working for ten years.
Assessment: Corrective Action Needed.

Reason: All food contact surfaces are not made of material that is designed to be easily cleaned and sanitized and the auditee has no plans to eliminate wood as a food contact surface.

Requirement	**TPH-6.4 Wood is not used as a food contact surface.**
Procedure	**Operation has eliminated, or has a plan to eliminate, use of wooden items as food contact surfaces.**
Verification	**Auditor inspects facility for evidence of wooden food contact surfaces.**
Corrective Action	**Operation that still utilizes wood as a food contact surface has a plan to phase out such surfaces, and is in compliance with the plan.**
Documents Required	
Mandatory	●

Example Scenarios

Scenario 1: During the auditor's walk-through of the tomato packing facility, it is observed that some food contact surfaces are not able to be sanitized due to being constructed with wood. The auditee states that the wood surfaces are covered with clean plastic sheeting each time they are used. The auditor observes one table with thick plastic sheeting covering the wood surface and a large roll of sheeting in close proximity to the area. The operation's manager states that he has ordered new tables made of stainless steel, but they won't arrive until the following week.
Assessment: Compliant.
Reason: The operation is taking positive steps to reduce the possibility of contamination by covering the tables with plastic and the operation has a plan to eliminate the use of wooden items as food contact surfaces.

Scenario 2: During the auditor's walk-through of the tomato packing facility, it is observed that some food contact surfaces are constructed with wood that is covered with vinyl, the vinyl covers have seams and cracks. The auditor asks the auditee if these food contact surfaces are ever in use, the auditee explains that the tables are used for repacking tomatoes. The auditor asks if they have a plan to replace the vinyl covered wood tables, the auditee states that they only use them occasionally, so there is no plan to replace them.
Assessment: Immediate Action Required.
Reason: All food contact surfaces are not made of material that is designed to be easily cleaned and sanitized, and are not maintained in good condition. The auditee has no plans to eliminate wood as a food contact surface.

Scenario 3: The operation's food contact surfaces are made of material and designed to be easily cleaned and sanitized and are maintained in good condition. The auditor observes the food contact surfaces for evidence of compliance. The auditor determines that the food contact surfaces are adequate.
Assessment: Compliant.
Reason: The auditor observed the food contact surfaces for evidence of compliance. The auditor determined that the food contact surfaces are adequate.

Requirement	TPH-6.5 SDS are on file for all chemicals used in the facility, and readily accessible.
Procedure	Operation maintains a list of all chemicals approved for use in facility and maintains SDS for all. SDS are in a location easily accessible by employees.
Verification	Auditor reviews SDS binder and observes chemicals in facility for evidence of compliance.
Corrective Action	Obtain missing SDS. Relocate SDS.
Documents Required	Records.
Mandatory	●

Example Scenarios
Scenario 1: The operation maintains a list of all chemicals approved for use in facility and maintains SDS for all. SDS are in a location easily accessible by employees.
Assessment: Compliant.
Reason: The operation maintains a list of all chemicals approved for use in the facility and maintains SDS for all. SDS are in a location easily accessible by employees.

Scenario 2: The operation maintains a list of all chemicals approved for use in the facility and maintains SDS for all chemicals used in the facility. SDS for chemicals used in the facility are not in a location accessible by employees.
Assessment: Corrective Action Needed.
Reason: The operation maintains a list of all chemicals approved for use in the facility and maintains SDS for all, but SDS are not in a location easily accessible by employees.

Scenario 3: SDS are on file for all chemicals used in the facility, and readily accessible. Upon review of the operation's SDS records, the auditor notes that there is no SDS for ABC Sanitizer said to be used in the operation's dump tanks and produce wash system. The auditor asks the operation's chemical specialist about the missing documentation. The employee states that they had just started using that chemical this season, prior to using this we used XYD Sanitizer.
Assessment: Corrective Action Needed.
Reason: SDS are not readily accessible or on file for all chemicals used in the facility.

<u>TPH-7 Worker Health/Hygiene and Toilet/Handwashing Facilities</u>

Requirement	TPH-7.1 If portable hand wash water tanks are used, they are cleaned and sanitized and the water is changed periodically.
Procedure	Water tanks used to provide hand wash water shall be maintained at a prescribed frequency in a clean and sanitary manner.
Verification	Auditor reviews cleaning and sanitizing protocol and service logs, and visually observes condition of water tanks for signs of non-compliance.
Corrective Action	Clean and sanitize the tank, replace water to compliance.
Documents Required	Records.
Mandatory	●

Expectation
(See requirement TOF-4.2)

Example Scenarios
Scenario 1: Auditor reviews cleaning and service records for the operation's portable sanitation units and confirms that the units are inspected every two hours and were serviced and cleaned the previous day, the service record does not specifically state that the hand wash water tank was cleaned and sanitized at the time of servicing. The auditor requests the service company SOP for cleaning and sanitizing, the SOP states that the tanks are cleaned and sanitized at the beginning of each season and can produce records to confirm.
Assessment: Compliant
Reason: The Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain states that the hand wash water tanks are to be cleaned and sanitized and/or shall be maintained periodically or at a prescribed frequency.

Scenario 2: Auditor observes that the hand wash water tank at the portable sanitation unit contains sediment of unknown origin, what appears to be green or black water marks around the inside perimeter of the tank and the tank lid is not secured. The auditor requests the most recent service records for the sanitation unit and finds that it was serviced and cleaned that morning by the operation's cleaning crew. The auditor requests the company SOP for cleaning and servicing of the unit and finds that it states that the hand wash water tanks will be cleaned, sanitized and filled as needed.
Assessment: Corrective Action Needed.
Reason: The company is not following its SOP regarding cleaning and sanitizing the hand wash water tanks.

Scenario 3: Upon inspection of the portable sanitation unit the auditor observes that the sanitation station hand wash water tank is empty. The auditor notes that this is the only portable sanitation station available to maintenance employees.
Assessment: Immediate Action Required
Reason: Water tanks used to provide hand wash water shall be maintained at a prescribed frequency in a clean and sanitary manner.

TPH-8 Product Wash Water Management

All water used in the packinghouse must meet the microbial requirements of no detectable generic *E. coli* in 100 mL of water.

Requirement	**TPH-8.1 In systems where tomatoes are submerged or dwell in water, water temperature is monitored and controlled. Water temperature should be at least 10°F above average pulp temperature of tomatoes when entering the water.**
Procedure	**Operation shall have methods for determining average pulp temperature of a minimum of 5 tomatoes, a procedure for control of water temperature, shall monitor temperature at a prescribed frequency sufficient to assure continuous compliance (minimum of hourly), and shall maintain records of water temperature. Operation shall have a procedure as to what corrective actions are taken if criteria are not met. Water spray or shower systems, wherein tomatoes are not submerged or dwell, do not require temperature control.**
Verification	**Auditor shall review the procedure and shall review records of temperature monitoring. Auditor observes process including the operation's sampling of pulp and water temperatures. Auditor reviews records for deviations and their disposition.**
Corrective Action	**Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at temperatures less than the average measured pulp temperature shall be discarded back to the last evidence of compliance.**
Documents Required	**Records.**
Mandatory	●

Expectation
The *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain* states:

"i. Internalization of bacteria into the fruit has been demonstrated with tomatoes submerged in water without a sanitizer. Water adequately treated with sanitizer is the most effective method of controlling internalization of pathogens due to cross contamination.

ii. Cold water immersion as a cooling technique shall not be done.

iii. While PS § 48 requires operations to maintain and monitor the temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce, studies indicate that the temperature differential between wash water and tomato pulp temperature may not be as influential as previously thought. Residence time and product depth

are influential and may be difficult to strictly control. Therefore, it is prudent for water temperature in dump tanks to be maintained at least 10°F warmer than the pulp temperature of the tomato.

1. Monitor water temperature and pulp temperature at least hourly.

2. Pulp temperature is the average of at least 5 tomatoes."

Example Scenarios
Scenario 1: Operation determines pulp temperature by checking one tomato per load. The procedure for control of water temperature is ensuring that the water temperature is at least ten degrees warmer than the tomato but averages twenty degrees warmer. The operation monitors temperature hourly to assure continuous compliance and maintains records of the lot number, trailer number, time of arrival and water and tomato temperatures. The operation has a procedure as to what corrective actions are taken if criteria are not met.
Assessment: Corrective Action Needed.
Reason: The operation shall have methods for determining the average pulp temperature by checking a minimum of five tomatoes.

Scenario 2: The operation has a method for determining average pulp temperature by checking a minimum of five tomatoes, a procedure for control of the water temperature, monitors temperatures hourly and maintains records of the water and tomato temperatures. The water temperature is continually twenty degrees higher than the tomato temperature. Operation has a procedure as to what corrective actions are taken if criteria are not met. The auditor reviews the records and verifies that the operation is following the SOP and is in compliance with the standard.
Assessment: Compliant
Reason: The auditor reviews the records and verifies that the operation is following the SOP and is in compliance with the standard.

Scenario 3: A small farming operation chooses to wash their tomatoes in a sanitized stainless steel farm sink directly following the harvesting of the crop. The operation's water is municipal, and they add a food grade chlorine-based sanitizer in accordance with the label instructions. They check the temperature of five tomatoes and determine the average, then the water temperature is set at twenty degrees above the average of the tomato temperatures to allow for cooling. The operation ensures that the water pH is between 6.5 and 7.5 and the free chlorine at 150 ppm with test strips. They log the temperatures of the water and the tomatoes, the pH, and the free chlorine. The tomatoes are placed in a single layer on a plastic submersible tray and lowered into the sink, the water just covers the tops of the tomatoes. The tomatoes are removed in eight to ten minutes then rinsed with the potable water and set aside to dry prior to packing. Auditor reviews the procedure and the records of temperature monitoring. Auditor observes process including the operation's sampling of pulp and water temperatures. Auditor reviews records for deviations and their disposition.
Assessment: Compliant.
Reason: Auditor reviewed the procedure and the records of temperature monitoring. Auditor observed process including the operation's sampling of pulp and water temperatures. Auditor reviewed records and found no deviations.

Requirement	TPH-8.2 Operations utilizing spray systems in place of whole tomato immersion shall design the line so that the entire tomato surface is rinsed.
Procedure	Spray systems shall be designed such that rinse water contacts all surfaces of the tomato.
Verification	Auditor observes spray system for compliance.
Corrective Action	Equipment or process is redesigned or retrofitted to ensure all surfaces of tomato are contacted.
Documents Required	
Mandatory	●

Example Scenarios

Scenario 1: The tomato packing operation utilizes a multiple bar spray system in place of a whole tomato immersion system. The line is designed to rotate the tomato so that the entire tomato surface is rinsed. The operation uses well water that they treat with an antimicrobial that is dosed electronically. The operation tests and logs the pH and free chlorine in the spray water every hour during operation. The facility does not check or log the wash water temperature.
Assessment: Compliant.
Reason: Temperature control of water, and the risk of internalization, does not apply to spray bar or other processes in which tomatoes are not submerged.

Scenario 2: The operation uses a spray bar system in place of a tomato emersion dump tank. The system has two spray bars, one on the top and one on the bottom of the tomatoes moving through the line to ensure that the entire surface of the tomatoes are rinsed. The operation's water is treated with chlorine dioxide electronically dosed at 3 ppm as a targeted operating level. The operation's SOP requires that the water be checked once every hour to ensure the ppm remains between 3 and 5 ppm. The SOP requires the water in the system to be changed daily. Upon the auditor's observation of the independent testing of the wash water of chlorine dioxide showed a level of 1 ppm. Upon review of the operation's hourly water test results the auditor finds that the ppm level has been testing at 1 ppm or below since the beginning of the day's run.
Assessment: Immediate Action Required.
Reason: The operation is not following the SOP regarding PPM levels of chlorine dioxide. The use of 1 ppm chlorine dioxide will not be adequate.

Scenario 3: The tomato packing operation utilizes a spray bar system in place of a whole tomato immersion system. The system sprays potable water treated with antimicrobials registered with the EPA and labeled for food use. Upon the auditor's walk-through of the facility, it is observed that some tomatoes passing under the far sides of the spray bar are not effectively being rinsed.
Assessment: Corrective Action Needed.
Reason: Spray systems shall be designed such that rinse water contacts all surfaces of the tomato.

Requirement	TPH-8.3 If a spray bar system is used, operation has a water use SOP that addresses treatment of that water.
Procedure	Operation's water use SOP requires spray bar water to be treated using an approved antimicrobial to maintain a microbially hostile environment on equipment.
Verification	Auditor shall review water use SOP for completeness, and observes water treatment records for adequacy and consistency of treatment.
Corrective Action	Operation discontinues using spray bar water that is not treated sufficiently to maintain a hostile environment on equipment. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Policy.
Mandatory	●

Expectation
The *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain* states:

> "Although the risk of cross contamination in a single pass spray bar system is lower than in a dump tank or flume, antimicrobial use (e.g., chlorine, PAA or chlorine dioxide is still required so that a hostile environment on equipment is maintained that limits cross contamination, biofilm formation, and the establishment of environmental pathogens."

Example Scenarios
Scenario 1: The operation uses a spray bar system for washing the tomatoes. The operation has a water use SOP that addresses treatment of that water. The auditor reviews the water use SOP for completeness, and observes water treatment records for adequacy and consistency of treatment. The auditor finds that the operation's SOP is adequate and they are following the policy as written.
Assessment: Compliant.
Reason: Auditor reviewed the operation's water use SOP for completeness and reviewed the water treatment records for adequacy and consistency of treatment. The auditor found no deviations from the written policy.

Scenario 2: The operation uses a spray bar system for washing the tomatoes the operation has a water use SOP that addresses treatment of that water. The auditor reviews the water use SOP for completeness, and observes water treatment records for adequacy and consistency of treatment. During the review of the records for the water treatment the auditor observes that the operation has not documented the change of water in the spray system for an entire week. The auditor reviews the operation's SOP regarding wash water and finds that it states the wash water in the spray system must be changed daily.
Assessment: Immediate Action Required.
Reason: Water used in post-harvest operations must be changed as necessary for the given operation. The operation's SOP states that the water in the system must be changed each week, the operation has not followed their SOP.

Scenario 3: The operation uses a spray bar system to rinse tomatoes exiting the dump tank, the water for the spray bar system is treated with peracetic acid at the same ppm level as the dump tank water. The records indicate that the pH, and ppm levels are checked and logged each hour for the dump tank and the spray bar water. The auditor finds no deviation from the operation's SOP.
Assessment: Compliant
Reason: The auditor reviewed logs and records for the water treatment and found no deviation from the operation's SOP.

Requirement	**TPH-8.4 If water quality is based upon a chlorine-based sanitizer, the process shall be targeted to be at least 100 ppm free available chlorine (FAC), measured at the exit of the product from the water system, unless validation data are available to demonstrate a lower FAC is effective under operating conditions.**
Procedure	**Operation shall have a procedure to manage FAC levels, shall establish process adjustments for when the FAC drops below 100 ppm, and shall maintain records to verify proper management of levels.**
Verification	**Auditor shall review the procedure and shall review records of FAC measurement and appropriate management. Auditor reviews records for deviations and their disposition.**
Corrective Action	**Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at FAC less than 100 ppm shall be discarded back to the last evidence of compliance.**
Documents Required	**Record.**
Mandatory	●

Expectation
When tomatoes are washed, the quality of post-harvest water that contacts fresh produce during post-harvest flume transport, cleaning, grading, and surface treatment application is widely recognized as an essential pathogen control point to limit cross contamination of fresh produce. While the use of antimicrobials in wash water does not constitute a "kill step", levels must be monitored so that the treated water adequately limits cross contamination. Because no point in the tomato supply chain applies a validated kill step, wash water is but one hurdle in the continuum of safe practices that needs to be implemented; it does not compensate for poor production and/or handling practices prior or subsequent to washing.

Oxidation reduction potential (ORP) is not directly correlated to free chlorine measurements in typical tomato dump tanks. Preliminary studies suggest that potential for cross contamination does not correlate well with ORP levels. Operations using free chlorine as the wash water antimicrobial should not rely solely on ORP readings to manage chlorine levels. Rather, free chlorine levels in such systems should be verified by a method such as chemical titration.

Example Scenarios

Scenario 1: The operation's water quality is based upon a chlorine-based sanitizer, the operation's SOP requires the targeted ppm to be not less than 150 ppm free chlorine and not more than 200 ppm. The operation's SOP states that the water be measured at the exit of the product from the water system. At the time of the audit, the independent test of the water in the system showed levels to be at 175 ppm. The auditor reviews the operation's records of hourly testing and finds that the ppm level has not been below 150 ppm or above 200 ppm. The auditor asks the operator what the procedure would be if the levels dropped below 150 ppm or was tested above 200 ppm. The operator quoted the operation's procedure to manage FAC levels.
Assessment: Compliant.
Reason: Operation is following their SOP and has a procedure to manage FAC levels and has established a process adjustment for when the FAC drops below 150 ppm and maintains records to verify proper management of levels.

Scenario 2: The tomato packing operation dump tank water quality is based upon a chlorine-based sanitizer, the operation's SOP requires the targeted ppm to be not less than 150 ppm free chlorine and not more than 200 ppm. The auditor reviews records of the ppm levels for the day and finds that the water ppm level dropped to less than 150 ppm just two hours prior to the auditor's arrival. The auditor inquired as to what was done to correct the drop in free chlorine. The system operator stated that he adjusted the level after consulting with the operation manager as per the operation's SOP. The documentation provided by the system operator showed that the system did not have tomatoes introduced until after the ppm levels were stabilized by the adjustment.
Assessment: Compliant.
Reason: The operation is following their SOP and the system is in compliance with the standard.

Scenario 3: The operation relies on electronic Oxidation Reduction Potential (ORP) for measuring the free chlorine in the wash system. The operation's SOP states that the operation's process targets at least 800 mV ORP levels and shall not be less than 650 mV. The operation's SOP does not have a procedure for action to be taken if levels drop below or exceed the targeted levels. At the time of the audit the electronic system is reading the ORP level to be at 600 mV. The auditor asks that an independent chemical titration be performed to test the free chlorine levels in the system. The system operator states that he is not able to perform the test and the person who can is not available today. Upon review of the day's logs, the auditor observes that the ORP levels have been below 600 mV since the beginning of the day.
Assessment: Immediate Action Required.
Reason: Oxidation reduction potential (ORP) is not directly correlated to free chlorine measurements in typical tomato dump tanks, free chlorine levels in such systems should be verified by a method such as chemical titration. The operation's SOP does not have a procedure for when ORP levels drop below the required 650 mV minimum.

Requirement	TPH-8.5 If water quality is based upon a peroxyacetic, peracetic or peracid system, levels shall be maintained in accordance with manufacturer's label directions.
Procedure	Operation shall have a procedure to manage peracid levels, shall establish process targets so as not to drop below the minimum ppm, shall establish adjustments for when the peracid level drops below the target ppm, and shall maintain records to verify proper management of levels.
Verification	Auditor shall review the procedure and shall review records of peracetic measurement and appropriate management. Auditor reviews records for deviations and their disposition.
Corrective Action	Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at less than manufacturer's recommendation shall be discarded back to the last evidence of compliance.
Documents Required	Record.
Mandatory	●

Expectation
Peroxyacetic, peracetic acid (PAA) or peracid must be used in accordance with the manufacturer's label directions. The *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain* states:

> "Although its efficacy is less pH dependent than chlorine, it should still be used in systems where the pH is maintained below 8.0 (because it dissociates to a less active form at pH levels above 8.2)."

The monitoring of wash systems using PAA is an important part of the management of these wash systems. Records shall be kept for all monitoring activities.

Example Scenarios
Scenario 1: The operation's wash water quality is based upon a peroxyacetic system, levels are maintained in accordance with manufacturer's label directions. Operation has a procedure to manage peracid levels and has established process targets so as not to drop below the minimum ppm. The operation has established adjustment procedures for when the peracid level drops below the target ppm and maintains records to verify proper management of levels. Peracetic acid is used according to manufacturer's label directions.
Assessment: Compliant.
Reason: The operation has established adjustments for when the peracid level drops below the target ppm, and maintains records to verify proper management of levels. Peracetic acid is used according to manufacturer's label directions.

Scenario 2: The operation's wash water quality is based upon a peroxyacetic system. The operation has not established adjustment procedures for when the peracid level drops below the

target ppm. The operation's records indicate that the level of peracetic acid has dropped below the acceptable level for affective use (based on the label instructions) several times in the last eight hours.
Assessment: Immediate Action Required
Reason: The operation has not established adjustment procedures for when the peracid level drops below the target ppm. The peracid has dropped below the acceptable levels without adjustments.

Scenario 3: The operation's wash water quality is based upon a peroxyacetic system, levels are maintained in accordance with manufacturer's label directions. The operation has not maintained records to verify proper management of the levels.
Assessment: Corrective Action Needed.
Reason: The operation has not maintained records to verify proper management of the peracetic acid levels.

TPH-9 Quarantine or On-hold Materials

Requirement	**TPH-9.1 Materials placed on hold, quarantined or rejected are clearly identified and segregated from other products and packaging materials.**
Procedure	**Operation has a written procedure to clearly identify and segregate on-hold, quarantined and rejected materials, to prevent commingling with other products or adulteration of products, production area or packaging materials.**
Verification	**Auditor reviews procedure, reviews logs and observes all currently on-hold, quarantined and rejected materials for compliance with procedure.**
Corrective Action	**Non-compliances are corrected on site. If on-hold, quarantined or rejected materials are not segregated according to procedure, operation shall assess potential for product adulteration. Procedures are developed or revised. Retraining is performed.**
Documents Required	**Record.**
Mandatory	●

Example Scenarios
Scenario 1: Operation has a written procedure to clearly identify and segregate on-hold, quarantined and rejected materials, to prevent commingling with other products or adulteration of products, production area or packaging materials. The auditor reviews the operation's written procedure, reviews logs and observes that all product currently on-hold, quarantined and rejected is in compliance with procedure.
Assessment: Compliant.
Reason: The auditor reviewed the operation's written procedure, reviewed logs and observed that all product currently on-hold, quarantined and rejected is in compliance with procedure.

Scenario 2: The operation has a written procedure to clearly identify and segregate on-hold, quarantined and rejected materials, to prevent commingling with other products or adulteration of

products, production area or packaging materials. During the observations of the packing line, the auditor notes that two pallets of tomatoes in the carton stacking area for tomatoes just coming off the packing line are tagged quarantined. The auditor inquires as to why the pallets are tagged with the quarantined tag. The operation manager was contacted and explained that the pallets were sent to the on-hold area just before lunch, and has no idea why the pallets are on the packing line. The manager instructs the lift operator to remove them to the on-hold area.
Assessment: Corrective Action Needed.
Reason: The operation is not following their written procedure to segregate on-hold, quarantined and rejected materials, to prevent commingling with other products or adulteration of products, production area or packaging materials.

TPH-10 Tomato Rerunning Processes

Requirement	**TPH-10.1 Tomato lots shall not be commingled in a rerunning process. Boxes shall not be reused if prohibited by prevailing regulation or law.**
Procedure	**Operation has a policy prohibiting commingling of tomato lots if lots are rerun.**
Verification	**Auditor reviews the policy, observes packing records and, if possible, example of rerunning process, for compliance.**
Corrective Action	**Operation ceases commingling lots. Boxes with commingled lots are labeled with component tomato sources and lot identification. Policy is developed or revised. Retraining is performed.**
Documents Required	**Record.**
Mandatory	●

Example Scenarios
Scenario 1: The operation has a policy prohibiting commingling of tomato lots if lots are rerun. Auditor reviews the policy, observes packing records and observes the rerunning process, for compliance. The auditor can clearly see that all of the pallets of tomatoes in the run are printed with the same lot ID.
Assessment: Compliant.
Reason: The operation has a policy prohibiting commingling of tomato lots and the auditor can clearly see that all of the pallets of tomatoes in the run are printed with the same lot ID.

Scenario 2: The operation has a policy prohibiting commingling of tomato lots if lots are rerun. Auditor reviews the policy, observes packing records and observes the rerunning process, for compliance. The auditor can clearly see that the pallets of tomatoes in the run are printed with three different lot numbers. The auditor asks the crew lead about the three different lot numbers. The crew lead states that as long as they are all the same size of tomato, it's acceptable to mix the lots.
Assessment: Corrective Action Needed.
Reason: Tomato lots shall not be commingled in a rerunning process. The operation is not following their policy prohibiting commingling of tomato lots if lots are rerun.

TPH-11 Food Defense Awareness

Requirement	TPH-11.1 The facility is registered with FDA as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
Procedure	If required by 21 CFR Part 1, Subpart H, facility is registered with FDA and registration is current.
Verification	Auditor asks whether facility is registered. Facility is not required to demonstrate registration to auditor.
Corrective Action	Facility registers with FDA as required.
Documents Required	Record.
Mandatory	●

Example Scenarios
Scenario 1: The facility is registered with FDA as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 as required by 21 CFR Part 1, Subpart H, facility is registered with FDA and registration is current.
Assessment: Compliant.
Reason: The facility is registered with FDA as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 as required.

Scenario 2: Operation has not been registered with the FDA or permitted as a food handling establishment as required by state or federal regulation. Operation demonstrates knowledge of prevailing requirements but does not have a copy of required permit(s) or registration.
Assessment: Corrective Action Needed.
Reason: Operation has not been registered or permitted as a food handling establishment as required by state or federal regulation. Operation does not have a copy of required permit(s) or registration.

Requirement	TPH-11.2 There are procedures in place that readily identify employees, and those with specific access privileges, e.g., to chemical storage, to the water system.
Procedure	Operation has a written procedure for identifying current employees. Procedure also indicates which employees have access to restricted areas or materials, and how access is restricted.
Verification	Auditor reviews procedure, verifies list of special access employees, observes restricted areas and materials for evidence of compliance and interviews employees for knowledge of procedure.
Corrective Action	Procedures are developed or revised. Retraining is performed.
Documents Required	Record.
Mandatory	●

Example Scenarios
Scenario 1: The operation has written procedures in place that readily identify employees, and those with specific access privileges to chemical storage and/or to the water system. Operation has a written procedure for identifying current employees. Procedure indicates which employees have access to restricted areas or materials, and how access is restricted. The auditor reviews the procedure, verifies that the operation has a list of special access employees, observes restricted areas and materials for evidence of compliance and interviews employees for knowledge of procedure.
Assessment: Compliant.
Reason: The auditor reviewed the procedure, verified that the operation has a list of special access employees, observed restricted areas and materials for evidence of compliance and interviewed employees for knowledge of procedure.

Scenario 2: The operation has written procedures in place that readily identify employees. The written procedure does not indicate which employees have access to restricted areas or materials, and how access is restricted.
Assessment: Corrective Action Needed.
Reason: The written procedure does not indicate which employees have access to restricted areas or materials, and how access is restricted.

Scenario 3: The auditor reviews the operation's procedure and notes that the restricted access is achieved by locking doors to sensitive areas and issuing keys only to qualified employees and keeping a file of who is issued keys to each door. During the auditor's walk-through of the packinghouse, the auditor observes that the door to the chemical room is unlocked.
Assessment: Immediate Action Required or Corrective Action Needed.
Reason: During the auditor's walk-through of the packinghouse, the auditor observes that the door to the chemical room is unlocked.

GREENHOUSE

TGH-1 Management Responsibility

Requirement	**TGH-1.1 Operation has current copies of the *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain, the relevant Harmonized Food Safety Standard, and additional food safety documents as required by state and/or federal regulation.**
Procedure	**Operation has a current copy of the Guidelines, this audit document and all other required documents.**
Verification	**Auditor observes the current copies at the operation.**
Corrective Action	**Operation obtains current copies.**
Documents Required	**Record.**
Mandatory	●

Expectation
(See requirement TOF-1.1)

TGH-2 Recordkeeping and Traceability

A. Greenhouse Packing

Requirement	**TGH-2.1 Containers shall be accurately labeled with commodity name, greenhouse firm name and information sufficient to allow for source and lot identification.**
Procedure	**A product coding system is in place where product shall be labeled with grower and lot identification, and coded to enable access to date of harvest and/or packing, origin (name of greenhouse, grower and/or packing location), and country of origin for traceback purposes. If using reusable containers, procedures ensure that labels are accurate prior to packing.**
Verification	**Auditor reviews coding procedures, observes cases for appropriate coding, and verifies compliance by review of records.**
Corrective Action	**Boxes with missing, inaccurate or illegible coding are labeled with appropriate identification Procedure is developed or revised. Retraining is performed.**
Documents Required	**Written Policy.**
Mandatory	●

Example Scenarios
Scenario 1: Containers are accurately labeled with commodity name, greenhouse firm name and information sufficient to allow for source and lot identification. A product coding system is in place where product is labeled with grower and lot identification and coded to enable access to date

of harvest and/or packing, origin (name of greenhouse, grower and/or packing location), and country of origin for traceback purposes. When using reusable containers, procedures ensure that labels are accurate prior to packing. Auditor reviews coding procedures observes cases for appropriate coding and verifies compliance by review of records.
Assessment: Compliant.
Reason: Auditor reviewed coding procedures observed cases for appropriate coding and verified compliance by review of records. Auditor verified that containers are accurately labeled.

Scenario 2: Containers are accurately labeled with commodity name, greenhouse firm name and information sufficient to allow for source and lot identification. A product coding system is in place where product is labeled with grower and lot identification and coded to enable access to date of harvest and/or packing, origin (name of greenhouse, grower and/or packing location), and country of origin for traceback purposes. During the auditor's review of the written policy, the auditor did not find procedures for using reusable containers, no written procedures exist to ensure that labels are accurate prior to packing.
Assessment: Corrective Action Needed.
Reason: During the auditor's review of the written policy, the auditor did not find procedures for using reusable containers, no written procedures exist to ensure that labels are accurate prior to packing.

Scenario 3: Containers are labeled with commodity name, greenhouse firm name and information to allow for source and lot identification. A product coding system is in place where product is labeled with grower and lot identification and coded to enable access to date of harvest and/or packing, origin (name of greenhouse, grower and/or packing location), and country of origin for traceback purposes. As the auditor was verifying the coding system used on the labels of product harvested during the audit, the auditor observed that the code used, as explained by the auditee, was dated for the next day. The auditor pointed it out to the auditee, the auditee stated that the code on the labels was incorrect, but the auditee stated that he did not know what happened, upon review of the containers harvested the previous day, the same coding error was discovered. The auditee stated that three pallets of that product was shipped out that morning.
Assessment: Corrective Action Needed.
Reason: The auditor observed that the code on the labels was incorrect, the auditee stated that he did not know what happened, upon review of the containers harvested the previous day, the same coding error was discovered. The auditee stated that three pallets of that product was shipped out that morning.

B. Packinghouse Packed Greenhouse Tomatoes

Requirement	TGH-2.2 The greenhouse shall maintain supply chain information available to the packinghouse to facilitate accurate traceability; i.e., quantity, greenhouse identification and date of harvest/pack.
Procedure	Operation has procedures to retain and provide to the packinghouse records of source of seed or transplants, soil inputs, irrigation water sources and test records, names of crews involved in greenhouse operations, and other crop history information relevant to product safety. Records are retained for at least two years or as required by prevailing regulation.
Verification	Auditor reviews policy and reviews records for compliance.
Corrective Action	Policy is developed or revised. Non-compliances are corrected on site. Retraining is performed.
Documents Required	Written Policy.
Mandatory	●

Example Scenarios

Scenario 1: The greenhouse operation has written procedures to retain and provide to the packinghouse records for source of seed or transplants, soil inputs, irrigation water sources and test records, names of crews involved in greenhouse operations, and other crop history information relevant to product safety. Records are retained for at least two years or as required by prevailing regulation. Auditor reviews policy and reviews records for compliance and finds no deviations from the written policy.
Assessment: Compliant.
Reason: Auditor reviewed the policy and records for compliance and found no deviations from the written policy.

Scenario 2: The greenhouse maintains supply chain information and makes it available to the packinghouse to facilitate accurate traceability; i.e., quantity, greenhouse identification and date of harvest and packing. The operation has written procedures to retain and provide to the packinghouse records for source of seed or transplants, soil inputs, irrigation water sources and test records. But does not keep records on the names of the employees involved in the daily greenhouse operations. When asked by the auditor, the owner states that he hires from a temp agency.
Assessment: Corrective Action Needed.
Reason: The operation does not keep records on the names of the employees involved in the daily greenhouse operations.

Scenario 3: The greenhouse maintains supply chain information and makes it available to the packinghouse to facilitate accurate traceability; i.e., quantity, greenhouse identification and date of harvest and packing. The operation has written procedures to retain and provide to the packinghouse records for source of seed or transplants, soil inputs, irrigation water sources and test records and names of crews involved in greenhouse operations. Upon the auditor's review of the facility's label, the auditor notes that the greenhouse address is different than the address where the audit is taking place. The auditor asks the auditee if he has another location, the auditee states that

the address on the cartons is the address of his old greenhouse and he just wanted to use up the old materials.
Assessment: Corrective Action Needed.
Reason: If cartons with the old address have been shipped from the new location it is assessed as IAR. If no containers have been shipped from the new location with the old address it would be assessed as Corrective Action Needed.

TGH-3 Self-Audit

Requirement	**TGH-3.1 Operation has procedures for conducting self-audits and conducts self-audits to verify compliance with established internal policies and procedures.**
Procedure	**In addition to the requirements of the Harmonized Standards, the operation's self-audit procedure ensures compliance with established internal policies and procedures, the *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, these Tomato Metrics and additional food safety documents as required by state and/or federal regulation.**
Verification	**Auditor reviews the self-audit procedures, and records of self-audits to verify compliance with the procedures.**
Corrective Action	**Operation develops and maintains self-audit program, with corrective actions preventive measures, documentation and follow-up.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
Auditees must conduct self-audits to verify compliance with established internal policies and procedures. There is not a specified format for the self-audit. The self-audit must verify the requirements of the Harmonized standard being utilized and Tomato Audit Protocol Open-Field Production Addendum requirements.

Example Scenarios
Scenario 1: The operation has procedures for conducting self-audits and conducts self-audits annually, but you find that the operation uses a self-made checklist for conducting self-audits.
Assessment: Compliant
Reason: As long as the self-audit performed addresses the requirements of the Harmonized Standards, ensures compliance with established internal policies and procedures, *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, the Tomato Metrics, and additional food safety documents as required by state and/or federal regulation.

Scenario 2: The operation maintains that they conduct self-audits but do not have a record of the self-audit.
Assessment: Corrective Action Needed. Explain to the auditee that at this point the operation does not meet USDA Acceptance Criteria. Any question marked with a ● in the MAN column is

considered Mandatory and must either be assessed as compliant (C) or not applicable (N/A) in order to meet USDA Acceptance Criteria.
Reason: The requirement requires a written policy and records. Records should document when the self-audit was started and completed.

Scenario 3: Operation develops and maintains a self-audit program, including a written record of required corrective actions and follow-up procedures but does not include preventive measures.
Assessment: Compliant or Corrective Action Needed.
Reason: If the operation has sufficiently satisfied the requirements of checklist questions G-8.1 and G-9.1, this checklist question shall be assessed as compliant.

TGH-4: Greenhouse

Requirement	TGH-4.1 The greenhouse shall be enclosed.
Procedure	The greenhouse shall be permanent or temporary structure, sufficiently enclosed to maintain a controlled environment. This does not apply to open structures such as shade or hoop houses, which should operate according to the auditing protocol for Open Field Production, Harvest and Field Packing.
Verification	The Auditor shall inspect the structure for compliance with this definition.
Corrective Action	If the structure is not in compliance, either the facility must be brought into compliance or different audit criteria (i.e., auditing protocol for Open Field Production, Harvest and Field Packing) should be used.
Documents Required	Written Policy, Record.
Mandatory	●

Example Scenarios
Scenario 1: The greenhouse is a permanent structure, sufficiently enclosed to maintain a controlled environment. The auditor inspects the structure for compliance with this definition and finds the structure to be in compliance.
Assessment: Compliant.
Reason: The auditor inspected the structure for compliance with this definition and finds the structure to be in compliance.

Scenario 2: The greenhouse is a temporary structure, sufficiently enclosed to maintain a controlled environment. The auditor inspects the structure for compliance with this definition and finds the structure to be in compliance.
Assessment: Compliant.
Reason: The auditor inspected the structure for compliance with this definition and finds the structure to be in compliance.

Scenario 3: The greenhouse is four posts covered with thick plastic sheeting. Three of the sides of the structure are open to the elements.

Assessment: Corrective Action Needed.
Reason: The structure is not sufficiently enclosed. If the structure is not in compliance, either the facility must be brought into compliance or different audit criteria (i.e., auditing protocol for Open Field Production, Harvest and Field Packing) should be used.

Requirement	**TGH-4.2 A foot dip station or other measure should be used to prevent the introduction of harmful microorganisms or agents and a written record of the sanitizer and maintenance kept.**
Procedure	**If the facility has determined that footborne contaminants are a risk to food safety, they shall have procedures that effectively prevent contaminants from being brought into the greenhouse on shoes. This could be by means of chemical disinfectants in foot dips, sprays or boot wash, or by means of a shoe change procedure. If chemical disinfectants are used, the chemical shall be used according to label instructions and monitored at a frequency sufficient to assure continual effectiveness, and records shall be maintained to demonstrate compliance.**
Verification	**If the facility is using footborne contamination controls, the auditor shall review the procedure, and will observe whether those procedures are being followed at the time of the audit. The auditor shall also review any associated records, including the label instructions for any chemical disinfectants used, for evidence of compliance with the facility's procedures.**
Corrective Action	**If the facility is using footborne contamination controls, they shall develop or implement the procedures to be effective, including training in their use.**
Documents Required	**Written Policy, Record.**
Mandatory	●

Example Scenarios
Scenario 1: The facility has determined that foot-borne contaminants are a risk to food safety. They have procedures that effectively prevent contaminants from being brought into the greenhouse on shoes. This is by means of chemical disinfectants in foot dips for visitors, and by means of a shoe change procedure for employees. The chemical disinfectants are used according to label instructions and monitored at a frequency sufficient to assure continual effectiveness, and records are maintained to demonstrate compliance. The auditor reviews the operation's written policy, the label instructions for the chemical used in the foot bath, and the logs associated with the foot-bath monitoring and finds that it is checked daily and changed as needed.
Assessment: Compliant.
Reason: The auditor reviewed the written policy, chemical label instructions, and the logs associated with the foot-bath monitoring and finds that it is checked daily and changed as needed.

Scenario 2: The facility has determined that foot-borne contaminants are not a risk to food safety as all of the growing tables are four feet off the ground and the operation does not harvest or pack

any product that contacts the ground. They have not introduced procedures that effectively prevent contaminants from being brought into the greenhouse on shoes.
Assessment: Compliant.
Reason: The facility has determined that foot-borne contaminants are not a risk to food safety.

Scenario 3: If the facility has determined that foot-borne contaminants are a risk to food safety, and they have developed written procedures that effectively prevent contaminants from being brought into the greenhouse on shoes. This is achieved by means of chemical disinfectants in foot dips, sprays, or boot wash, or by means of a shoe change procedure. Upon the auditor's review of the logs associated with boot safety, the auditor observes that a record for testing and changing the foot bath solution is not present. The auditor asks the auditee for the records and the auditee states that they do not keep records for the checking or changing of the foot-bath solution.
Assessment: Corrective Action Required.
Reason: If used, chemical disinfectants in footbaths should be monitored at a frequency sufficient to assure continual effectiveness, and records shall be maintained to demonstrate compliance.

TGH-5 Worker Health/Hygiene and Toilet/Handwashing Facilities

Requirement	**TGH-5.1 Restrooms should not open directly into greenhouse production areas.**
Procedure	**Restrooms that do open directly into greenhouse production areas shall be equipped with self-closing mechanisms or have a maze-type entrance/exit.**
Verification	**Auditor visually verifies that the toilet facilities are located and designed in a compliant manner.**
Corrective Action	**Operation retrofits or relocates the toilet facility.**
Documents Required	**N/A**
Mandatory	**●**

Example Scenarios
Scenario 1: The facility's restrooms open directly into greenhouse production area but are not equipped with a self-closing mechanism or have a maze-type entrance/exit.
Assessment: Corrective Action Needed.
Reason: Restrooms that open directly into greenhouse production areas shall be equipped with self-closing mechanisms or have a maze-type entrance/exit.

Scenario 2: The operation's restrooms do not open directly into greenhouse production area or are equipped with self-closing mechanisms or have a maze-type entrance/exit.
Assessment: Compliant.
Reason: The operation's restrooms do not open directly into greenhouse production area or are equipped with self-closing mechanisms or have a maze-type entrance/exit.

Scenario 3: The greenhouse operation utilizes portable sanitation stations positioned outside of the greenhouse fifty yards from the production area. The operation has proper documentation and records for cleaning and servicing of the units as well as an emergency response plan for any leaks of spills from the units.
Assessment: Compliant.
Reason: The portable sanitation stations are positioned outside of the greenhouse production area. The operation has proper documentation and records for cleaning and servicing of the units as well as an emergency response plan for any leaks of spills from the units.

Requirement	TGH-5.2 If portable hand wash water tanks are used, they are cleaned and sanitized and the water is changed periodically.
Procedure	Water tanks used to provide hand wash water shall be maintained at a prescribed frequency in a clean and sanitary manner.
Verification	Auditor reviews cleaning and sanitizing protocol and service logs, and visually observes condition of water tanks for signs of non-compliance.
Corrective Action	Clean and sanitize the tank, replace water to compliance.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TOF-4.2)

Requirement	TGH-5.3 Operation shall have a written policy regarding employees' outer garments.
Procedure	Policy includes that employees shall wear suitable outer garments, not reasonably likely to serve as a source of contamination of tomato or food contact surface, and, as appropriate to the operation, use of plastic aprons and sleeves, and empty pockets above the waist. Outer garments shall be changed after cleaning drains, restrooms or other activities that may result in contamination.
Verification	Auditor reviews the policy, observes employees for compliance and interviews employees for knowledge of the policy.
Corrective Action	Policy is developed or revised. Non-compliances are corrected on site. Retraining is performed.
Documents Required	Written Policy.
Mandatory	●

Example Scenarios
Scenario 1: Operation has a written policy regarding outer garments. The policy states, visitors and employees shall wear suitable outer garments, not reasonably likely to serve as a source of contamination of tomato or food contact surfaces, and, as appropriate to the operation. Use of

plastic aprons, sleeves and hairnets is required in production and packing areas at all times. Any pockets above the waist must be empty. Outer garments (aprons and sleeves) shall not be taken into restrooms, lunch or break areas and must be changed after cleaning drains, restrooms or other activities that may result in contamination. The auditor conducts interviews and observes that all employees and visitors are aware of and following the written policy.
Assessment: Compliant.
Reason: Operation has a written policy regarding outer garments. The auditor conducted interviews and made observations and determined that all employees and visitors are aware of and following the written policy.

Scenario 2: Operation has a written policy regarding outer garments. The policy states, employees shall wear suitable outer garments, not reasonably likely to serve as a source of contamination of tomato or food contact surfaces, and, as appropriate to the operation. Use of plastic aprons, sleeves and hairnets is required in the production and packing areas at all times. Any pockets above the waist must be empty. Outer garments (aprons and sleeves) shall not be taken into restrooms or break/lunch areas and must be changed after cleaning drains, restrooms or other activities that may result in contamination. The auditor observes a greenhouse employee enter and exit the restroom without removing or replacing the apron, sleeves and hairnet, the employee then enters the production and packing area of the greenhouse.
Assessment: Immediate Action Required
Reason: The operation is not following their SOP regarding outer garments.

Scenario 3: The operation does not have a written policy regarding outer garments.
Assessment: Corrective Action Needed.
Reason: The operation does not have a written policy regarding outer garments.

TGH-6 Pesticides

Requirement	**TGH-6.1 Water used to mix pesticides meets FDA *E. coli* standards for water in 21 CFR § 112.44(a); i.e., no detectable generic *E. coli* in 100 mL of agricultural water.**
Procedure	**Operation has a written policy requiring foliar-application pesticides to be diluted only with water that meets FDA microbial standards for post-harvest agricultural water. Operations will have documentation demonstrating compliance, such as test results for the water source used.**
Verification	**Auditor reviews the policy and inspects pesticide mixing and application records.**
Corrective Action	**Operation develops a written policy. Retraining of pesticide applicator as needed. If unknown or nondrinking quality water was used to prepare pesticides, then test the water source for compliance with drinking water *E. coli* standards. Do not harvest product unless test results demonstrate compliance.**
Documents Required	**Record.**
Mandatory	●

Expectation
(See requirement TOF-5.1)

Example Scenarios:
Scenario 1: The greenhouse operation has a written policy requiring foliar-application pesticides to be diluted only with water that meets FDA microbial standards for drinking water. The operation's chemical specialist conducts all applications of pesticides. The auditor reviews the water test records for the water used by the operation for compliance and finds that the water is from a municipal source that meets EPA microbial standards for drinking water and annual testing is performed and documented by the municipality.
Assessment: Compliant
Reason: Water used to mix pesticides meets EPA microbial standards for drinking water; 21 CFR Part 112.44(a).

Scenario 2: The operation conducts all foliar applications of pesticides. The operation has a policy requiring all application of pesticides to be mixed with the onsite well water. The auditor reviews the water test records for the water used by the operation for compliance and finds that the water used is tested three times annually. The most recent water tests all meet EPA recreational water standards for *E. coli* 21 CFR § 112.44(b)
Assessment: Immediate Action Required
Reason: Water used to mix pesticides must meet EPA microbial standards for drinking water; 21 CFR § 112.44(a) i.e., no detectable generic *E. coli* in 100 milliliters (mL) of agricultural water.

Scenario 3: The greenhouse operation uses municipal water for the application of pesticides, the municipal water is tested by the municipality annually, the operation does not do any additional testing of the water. The auditor requests the most recent water quality report from the water supplier. The auditee states that they do not have records of the water report from the city.
Assessment: Corrective Action Needed.
Reason: Operations will have documentation demonstrating compliance, such as test results for the water source used.

TGH-7 Water Used in Growing Activities

Requirement	TGH-7.1 Non-Foliar The water test meets FDA *E. coli* standards for foliar application of water as described in 21 CFR § 112.44(b).
Procedure	Written procedure requires a BAM or other testing procedure validated for generic *E. coli* quantitation in water.
Verification	Auditor reviews water test results and any corrective actions taken to bring the water source into compliance.
Corrective Action	Perform a sanitary survey for each affected water source, perform any remedial action as required and retest. If the retest also exceeds the standard, further evaluate potential corrective actions, such as treatment, retreatment, or discontinue use of source.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TOF 6.1)

Example Scenarios
Scenario 1: The greenhouse operation irrigates by channels molded into the specially constructed tables where the containers of produce are placed. The operation has a written policy that states tomatoes that have been found on the table or in contact with water during harvesting operations are not to be harvested. When irrigating, the table channels are filled with water from an enclosed well. The most current water tests reviewed show <1 ppm/100 mL for generic *E. coli* and total coliforms.
Assessment: Compliant
Reason: Any non-foliar application of water to tomatoes (e.g., irrigation or crop protection sprays) shall meet the microbial standards contained in 21 CFR 112.44(b)

Scenario 2: The growing operation irrigates by use of channels molded into the specially constructed tables where the containers of produce are placed. The operation has a written policy that states tomatoes that have been found on the table or in contact with water during harvesting operations are not to be harvested. The water is from an aqueduct system that is tested every month, the testing shows that over the last twelve months the water never exceeded a geometric mean of 126 colony forming units of generic *E. coli* per 100 mL of water and a statistical threshold value of 410 or less CFU of generic *E. coli* per 100 mL of water.
Assessment: Compliant.
Reason: While not required by the Produce Safety Rule, any water used for drip irrigation or non-contact uses shall meet the standard for *E. coli* levels in 21 CFR 112.44(b), i.e., (1) A geometric mean (GM) of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water and (2) a statistical threshold value (STV) of 410 or less CFU of generic *E. coli* per 100 mL of water.

Requirement	TGH-7.2 Foliar The water test meets FDA standards for water in 21 CFR § 112.44(a); i.e., no detectable generic *E. coli* in 100 milliliters (mL) of agricultural water.
Procedure	Written procedure requires a BAM or other testing procedure validated for generic *E. coli* quantitation in water.
Verification	Auditor reviews water test results and any corrective actions taken to bring the water source into compliance. If tomatoes have been contacted with non-compliant water, auditor reviews the risk assessment and disposition.
Corrective Action	Perform a sanitary survey for each affected water source, perform any remedial action as required and retest. If the retest also exceeds the standard, further evaluate potential corrective actions, such as treatment, retreatment, or discontinue use of source. Operation shall evaluate tomatoes that have been contacted with noncompliant water to assess food safety risk. The assessment is documented and tomatoes dispositioned accordingly.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TOF 6.2)

Example Scenarios
Scenario 1: The greenhouse relies on an onsite, private well for irrigation. The operation has not had the well water tested in three years but uses the same well for the house where he lives. The auditee states that the water is safe enough for his wife and family because they never got sick from its use. The auditee goes on to say that he used the well for irrigation all season. The operation applies the well water by use of an overhead sprinkler system.
Assessment: Immediate Action Required
Reason: Records of testing of agricultural waters must be analyzed and maintained. Operations will have documentation demonstrating compliance, such as test results for the water source used.

Scenario 2: The operation applies water for irrigation and crop protection materials with a hand sprayer. The water is sourced from the city where the operation resides. The operation does not perform microbial testing on the water but has the report from the city dated over one year ago. The operation states that this is the most recent record available from the city.
Assessment: Compliant.
Reason: There is no requirement to test any agricultural water that is subject to the requirements of §112.44 when water is provided by a public water supply that furnishes water that meets the microbial quality requirement described in 21 CFR part 112.44(a). Results or certificates of compliance from the public water system are required that demonstrate that the water meets the required standards.

TGH-8 Soil and Soil Amendments

Requirement	TGH-8.1 Soil or other growth medium shall be stored in a manner that minimizes opportunities for contamination.
Procedure	If soil or growth medium is stored onsite, it is held in a sanitary manner to ensure it is not a source of contamination. Procedures for storage of growth media shall comply with prevailing laws or regulations in the location of the greenhouse.
Verification	The auditor shall observe storage location and procedures for evidence of compliance.
Corrective Action	Operation develops a written procedure and provides training. If there is evidence of contamination of public health significance, the medium shall not be used.
Documents Required	N/A
Mandatory	●

Example Scenarios

Scenario 1: The greenhouse purchases its organic potting soil from an approved supplier, records of purchases and letters of guarantee are available and reviewed by the auditor. The product is stored in the operation's enclosed, sealed and locked storage shed and the area is included in the operation's pest management program.
Assessment: Compliant.
Reason: The product is stored in the operation's enclosed, sealed and locked storage shed and the area is included in the operation's pest management program.

Scenario 2: The greenhouse uses growth medium that is comprised of shredded coconut shells, the product is stored in accordance with the label instructions.
Assessment: Compliant.
Reason: The product is stored in accordance with the label instructions.

Scenario 3: The operation uses soil obtained from the farming operation that was onsite previous to the greenhouse construction. The soil is not stored, it is left in the ground until such time as the operation needs more soil inside the greenhouse. A soil assessment and soil testing were done prior to purchasing the land and is done annually, the testing provided no evidence of contamination of public health significance.
Assessment: Compliant.
Reason: A soil assessment and soil testing was done prior to purchasing the land and is performed annually, the testing provided no evidence of contamination of public health significance.

Requirement	TGH-8.2 Fertilizer manufacturer's instructions for usage and storage shall be followed.
Procedure	Non-organic fertilizers must be used and stored in compliance with label instructions and any prevailing federal, state or local regulations. Fertilizer uses shall be documented.
Verification	Auditor reviews non-organic fertilizers used, storage location and application records.
Corrective Action	Perform training on fertilizer handling and recordkeeping procedures, as needed.
Documents Required	Record.
Mandatory	●

Example Scenarios

Scenario 1: The operation uses and stores non-organic fertilizers in compliance with label instructions and any prevailing federal, state or local regulations. Fertilizer use is documented. Auditor reviews non-organic fertilizers used, storage location and application records and finds that use, storage, and documentation are in compliance with the label instructions and federal, state and local regulations.

Assessment: Compliant.

Reason: The auditor reviewed non-organic fertilizers used, storage location and application records and found that use, storage and documentation is in compliance with the label instructions and federal, state and local regulations.

Scenario 2: The operation uses and stores non-organic fertilizers. Fertilizer use is documented. Auditor reviews non-organic fertilizers used, storage location and application records and finds that use, storage, and documentation are not in compliance with the label instructions and/or federal, state and local regulations.

Assessment: Corrective Action Needed.

Reason: Auditor reviewed non-organic fertilizer use, storage location and application records and finds that use, storage, and documentation are not in compliance with the label instructions and/or federal, state and local regulations.

Requirement	TGH-8.3 If fertilizers containing manures or composts are used, only properly treated (composted or heat treated) manures are allowed for use in greenhouses. Biosolids are not permitted.
Procedure	Soil amendment use records are available, reviewed and current (conventional or organic). If treated manures are used, records of composition, dates of treatment, methods utilized, application dates and letter of guarantee, certificate of analysis (COA) or any test results or verification data demonstrating compliance with process or microbial standards must be documented. For non-composted animal by-products containing soil amendments, the operations shall retain a certificate or letter showing the lethality of the process. Compost applications shall be no less than 45 days prior to harvest.
Verification	Auditor reviews the amendment use documents and records demonstrating compliance with prevailing national or local established composting or heat treatment standards or guidelines.
Corrective Action	Operations must obtain the necessary documents. If the documents cannot be obtained, crop cannot be harvested for that crop cycle.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TOF 7.1)

Example Scenarios
Scenario 1: The operation purchases the liquid soil amendments from DEF Agriculture Services, Inc. The fertilizer application date and use are documented. The operation produces a letter of guarantee from DEF Services as confirmation that all materials applied by DEF contain no untreated manure or animal by-products.
Assessment: Compliant.
Reason: The letter of guarantee confirms that the applicator does not use soil amendments containing raw or untreated manure.

Scenario 2: The tomato growing operation applies treated animal-based soil amendments. The documentation confirms that the amendments are applied forty-five days prior to the expected harvest date. The operation produces a receipt for the purchase of the compost that confirms it was purchased from GES Farms in October. The receipt includes the composition of the soil amendment and the dates of treatment.
Assessment: Immediate Action Required
Reason: If treated manures are used, the following must be documented: composition, dates of treatment, methods utilized, application dates and test results or process verification data demonstrating compliance with microbial standards. Evidence of processing adequate to eliminate pathogens of human concern, such as letter of guarantee, certificate of analysis (COA) or any test

results or verification data (e.g., time and temperature) demonstrating compliance with process or microbial standards, shall be documented.

Scenario 3: The small family greenhouse in the northeast growing tomatoes for a local retailer, applies raw cow manure to his growing fields. The owner states that the manure is from his cow grazing fields and barn. The owner states that he applies the manure in October after completing the harvest and does not begin to plant new crops until May of the following year.
Assessment: Immediate Action Required
Reason: If fertilizers containing manures or composts are used, only properly treated (composted or heat treated) manures are allowed for use. While permitted by the Produce Safety Rule under specific conditions, biosolids are not allowed for use in tomato production.

TGH-9 Sanitizing Agents Used During Harvest

Requirement	**TGH-9.1 All compounds used to clean or sanitize food contact containers, tools, utensils, equipment or other food contact surfaces are approved for that use by the US EPA, FDA or other prevailing agency. Actual use conforms to label directions.**
Procedure	**Documentation is available to demonstrate that cleaning and sanitizing products are approved for their use, and are used according to label directions. Sanitizing chemicals uses shall be documented.**
Verification	**Auditors review documentation and supplies to confirm approved use, and interview individuals responsible for their use for knowledge of approved use. Auditor reviews records of use, and visually observes use, to verify compliance with label directions.**
Corrective Action	**Non-compliances are corrected on site. Records are reviewed for potential product adulteration. Retraining is performed.**
Documents Required	**Record.**
Mandatory	●

Expectation
(See requirement TOF 8.1)

Example Scenarios
Scenario 1: Documentation is available to demonstrate that cleaning and sanitizing products are approved for their use and are used according to label directions. Sanitizing chemical use is documented daily. The auditor reviews the documentation and supplies to confirm approved use, and interviews individuals responsible for their knowledge of approved use. Auditor reviews records of use and visually observes use to verify compliance with label directions.
Assessment: Compliant.
Reason: The auditor reviewed the documentation and supplies to confirm approved use and interviewed individuals responsible for their knowledge of approved use. Auditor reviewed records of use and visually observed use to verify compliance with label directions.

Scenario 2: Documentation is available to demonstrate that cleaning and sanitizing products are approved for their use. Sanitizing chemical use is documented. The auditor reviews the documentation and supplies to confirm approved use, and interviews individuals responsible for their knowledge of approved use. While the auditor is visually observing use to verify compliance with label directions, it is observed that the chemical is not being mixed in accordance with the label instructions. The head cleaning employee was asked why he mixed the product at a stronger concentration. The employee's reply was if a little is good, then more must be better.
Assessment: Immediate Action Required.
Reason: While the auditor was observing chemical use to verify compliance with label directions, it was observed that the chemical is not being mixed in accordance with the label instructions.

Scenario 3: The auditor reviews the documentation and supplies to confirm approved use, and interviews individuals responsible for their knowledge of approved use. The auditor then asks the auditee for the records of use, the most recent use log is dated three months ago. The auditee states that the head cleaning person retired around that time, and he did not realize until just now that the new cleaning crew was not logging chemical use.
Assessment: Corrective Action Needed.
Reason: Sanitizing chemicals uses shall be documented.

Requirement	**TGH-9.2 Chemicals used on product that are not registered pesticides may be permitted for food contact use if allowed under regulations of the FDA or prevailing agency.**
Procedure	**Any product contact chemicals not specifically approved as registered pesticides shall be identified, the authority permitting their use identified and their uses documented.**
Verification	**Auditors review documentation and supplies to confirm approved use, and interview individuals responsible for their use for knowledge of approved use. Auditor reviews records of use, and visually observes use, to verify compliance with label directions.**
Corrective Action	**Non-compliances are corrected on site. Records are reviewed for potential product adulteration. Retraining is performed.**
Documents Required	**Record.**
Mandatory	●

Expectation
EPA considers any chemical making an antimicrobial claim, including those used to sanitize equipment and tomatoes, to be a pesticide. Sanitizing chemicals used must comply with all requirements of EPA registration and any federal, state or local regulations. Sanitizing chemicals must be appropriately registered for such use and must be used in accordance with label directions. Sanitizing chemicals uses shall be documented.

Any surfaces or equipment intended to touch fresh produce is a food contact surface and must be cleaned and sanitized at a frequency sufficient to prevent the surfaces from becoming a source of contamination.

Example Scenarios

Scenario 1: The operation uses a disinfecting bleach to clean and sanitize all food contact surfaces, containers, equipment and utensils. The facility manager states that the cleaning crew mixes the substance in accordance with the label instructions for food contact equipment. The mixing instructions are posted at the cleaning chemical mixing areas and records of where, when and what was cleaned and sanitized are documented with each use. The auditor reviews the use records, verifies that the substance is approved for cleaning on food contact equipment, and interviews the cleaning crew to verify that the proper mixing procedure and use are being followed.
Assessment: Compliant.
Reason: Documentation is available to demonstrate that sanitizing products are approved for their intended use and are used according to label directions. The auditor verified that the substance is being mixed and used correctly and sanitizing chemical use is documented.

Scenario 2: The supervisor oversees the sanitizing of the food contact containers and surfaces. Records indicate that the substance used for cleaning is mixed every evening after packing for the day has been completed. The product is mixed in accordance with the label instructions. The auditor verifies that the product is approved for sanitizing food contact equipment, but notes that the label states surfaces need to be cleaned with a cleaning solution prior to sanitizer use. The auditee is unable to produce a record of cleaning prior to sanitizing.
Assessment: Corrective Action Needed.
Reason: Unless the label states that it cleans and sanitizes, it's not a cleaning solution. The food contact containers need to be cleaned before they are sanitized (according to the label instructions).

Scenario 3: For cleaning and sanitizing food contact surfaces and equipment, the operation's cleaning crew uses a concentrated chlorine used for swimming pools directly from the container. After use, the crew rinses the food contact surface with potable water. The auditor reviews the label instructions and finds that the chemical is not approved for use on food contact surfaces or equipment.
Assessment: Immediate Action Required.
Reason: The product is not approved for use of food contact surfaces or equipment.

TGH-10 Product Wash Water Management

Requirement	TGH-10.1 In systems where tomatoes are submerged or dwell in water, water temperature is monitored and controlled. Water temperature should be at least 10ºF above average pulp temperature of tomatoes when entering the water.
Procedure	Operation shall have methods for determining average pulp temperature of a minimum of 5 tomatoes, a procedure for control of water temperature, shall monitor temperature at a prescribed frequency sufficient to assure continuous compliance (minimum of hourly) and shall maintain records of water temperature. Operation shall have a procedure as to what corrective actions are taken if criteria are not met. Water spray or shower systems, wherein tomatoes are not submerged or dwell, do not require temperature control.
Verification	Auditor shall review the procedure and shall review records of temperature monitoring. Auditor observes process including the operation's sampling of pulp and water temperatures. Auditor reviews records for deviations and their disposition.
Corrective Action	Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at temperatures less than the average measured pulp temperature shall be discarded back to the last evidence of compliance.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TOF 8.1)

Requirement	TGH-10.2 Operations utilizing spray systems in place of whole tomato immersion shall design the line so that the entire tomato surface is rinsed.
Procedure	Spray systems shall be designed such that rinse water contacts all surfaces of the tomato.
Verification	Auditor observes spray system for compliance.
Corrective Action	Equipment or process is redesigned or retrofitted to ensure all surfaces of tomato are contacted.
Documents Required	N/A
Mandatory	●

Expectation
(See requirement TPH-8.2)

Requirement	TGH-10.3 If a spray bar system is used, operation has a water use SOP that addresses treatment of that water.
Procedure	Operation's water use SOP requires spray bar water to be treated using an approved antimicrobial to maintain a microbially hostile environment on equipment.
Verification	Auditor shall review water use SOP for completeness, and observes water treatment records for adequacy and consistency of treatment.
Corrective Action	Operation discontinues using spray bar water that is not treated sufficiently to maintain a hostile environment on equipment. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Policy.
Mandatory	●

Expectation
(See requirement TPH 8.3)

Requirement	TGH-10.4 If water quality is based upon a chlorine-based sanitizer, the process shall be targeted to be at least 100 ppm free available chlorine (FAC), measured at the exit of the product from the water system, unless validation data are available to demonstrate a lower FAC is effective under operating conditions.
Procedure	Operation shall have a procedure to manage FAC levels, shall establish process adjustments for when the FAC drops below 100 ppm, and shall maintain records to verify proper management of levels.
Verification	Auditor shall review the procedure and shall review records of FAC measurement and appropriate management. Auditor reviews records for deviations and their disposition.
Corrective Action	Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at FAC less than 100 ppm shall be discarded back to the last evidence of compliance.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TPH-8.4)

Requirement	TGH-10.5 If water quality is based upon a peroxyacetic, peracetic or peracid system, levels shall be maintained in accordance with manufacturer's label directions.
Procedure	Operation shall have a procedure to manage peracid levels, shall establish process targets so as not to drop below the minimum ppm, shall establish adjustments for when the peracid level drops below the target ppm, and shall maintain records to verify proper management of levels.
Verification	Auditor shall review the procedure and shall review records of peracetic measurement and appropriate management. Auditor reviews records for deviations and their disposition.
Corrective Action	Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at less than manufacturer's recommendation shall be discarded back to the last evidence of compliance.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TPH-8.5)

TGH-11 Product Containers and Packaging Materials

Requirement	TGH-11.1 Operation has a written procedure for inspecting incoming packaging material.
Procedure	All packaging materials are inspected for evidence of contamination upon arrival. Results are recorded.
Verification	Auditor reviews procedure and examples of packaging and receiving records for compliance.
Corrective Action	Operation creates or revises policy. Contaminated or adulterated packaging material is rejected or discarded. Retraining is performed.
Documents Required	Record.
Mandatory	●

Example Scenarios
Scenario 1: The operation has a written procedure for inspecting incoming packaging material. The SOP states that all packaging materials are inspected for evidence of contamination upon arrival. Results are logged on the incoming product receiving log. Auditor reviews procedure and examples of packaging and receiving records for compliance.
Assessment: Compliant.
Reason: The auditor reviewed the written procedure and examples of packaging. The auditor reviewed receiving records for compliance.

Scenario 2: The operation has a written procedure for inspecting incoming packaging material. The auditor reviews the written procedure. The SOP states that all packaging materials are inspected for evidence of contamination upon arrival and that the receiver will note any damage to product, pallet wrapping, or pallets on the incoming product receiving log. The auditor reviews packaging and receiving records for compliance. The auditor observes that several pallets of packaging materials received the previous day had torn, damaged or no wrapping. The auditor observes that the receiver did not note the damaged wrapping on the product receiving log.
Assessment: Corrective Action Needed.
Reason: The employee has not followed the operation's SOP regarding documenting damage to incoming products.

Scenario 3: The operation has a written procedure for inspecting incoming packaging material. The auditor reviews the written procedure. The SOP states that all packaging materials are inspected for evidence of contamination upon arrival and that the receiver will note any damage or possible contamination to product, pallet wrapping, or pallets on the incoming product receiving log. The auditor reviews packaging and receiving records for compliance. The auditor observes that several pallets of packaging materials received the previous day had torn, damaged or no wrapping and some packaging was discolored, dirty and torn. One pallet with torn wrapping contained evidence of bird droppings. The auditor observes that the receiver noted the damaged wrapping on the product receiving log, but did not observe any notes about the discolored, dirty, torn packaging or evidence of bird droppings.
Assessment: Corrective Action Needed.
Reason: The auditor observes that the receiver noted the damaged wrapping on the product receiving log, but did not observe any notes about the discolored, dirty, torn packaging or evidence of bird droppings. The operation is not following the SOP.

Requirement	**TGH-11.2 Reusable containers and food contact equipment and utensils shall be constructed of impervious materials that can be easily cleaned and sanitized.**
Procedure	**Written SOP requires that all reusable product containers are made of materials that can be sanitized, or clean and sanitary liners are used. Wood is not an appropriate food contact surface. Procedures require damaged containers that are no longer easily cleanable or sanitary shall be removed from service of food contact purposes.**
Verification	**Auditor reviews SOP, visually observes product bins, trays and containers and their use for evidence of non-compliance.**
Corrective Action	**Policy is developed or revised. Non-compliances are corrected. Operation makes a commitment for phasing out non-conforming product containers; e.g., wooden bins, in a reasonable timeline. Retraining is performed.**
Documents Required	**Record.**
Mandatory	●

Expectation

(See requirement TOF-9.1)

Example Scenarios
Scenario 1: During the auditor's observation of the greenhouse operations, the auditor observes several plastic harvesting containers are broken or cracked and held together with duct tape. The facility manager states that they ordered new harvest containers, but the order has not yet arrived.
Assessment: Immediate Action Required.
Reason: Using harvest containers that have duct tape may result in contamination of harvested product as duct tape cannot be sanitized.

Scenario 2: The greenhouse operation is harvesting tomatoes into wooden crates. The wooden crates are fitted with new clean plastic sheeting prior to each use. The owner states that plastic crates are just too expensive for him to purchase at this time, but plans to replace the wood crates with plastic crates one or two at a time as the wood crates become no longer usable.
Assessment: Compliant.
Reason: The operation has a plan to replace the wood crates in a reasonable timeframe.

Scenario 3: The greenhouse operation is using wood tables for packing consumer units of tomatoes. The consumer units are then placed in master cartons for shipping. The wood tables are stained, discolored, some splintering in areas and clearly not suitable for food contact use. The auditee states that the product never touches the table.
Assessment: Immediate Action Required.
Reason: Even though the tomatoes may not contact the table, the consumer units do contact the table as do the master cartons into which the consumer units are packed.

Requirement	**TGH-11.3 Finished product containers are prohibited from direct contact with the floor, and pallets, slip sheets, and supports used to keep product containers off the floor are clean and in good condition.**
Procedure	**Operation has a policy prohibiting finished product containers in direct contact with the floor, and that pallets, slip sheets, and supports used to keep product containers off the floor are maintained so as not to be a source of contamination.**
Verification	**Auditor reviews policy and examines finished product staging and storage areas and pallets, slip sheets, and supports for compliance with the policy.**
Corrective Action	**Operation creates or revises policy. Non-compliances are corrected on site. Retraining is performed.**
Documents Required	**Written Policy.**
Mandatory	●

Example Scenarios
Scenario 1: The operation has a written policy prohibiting finished product containers in direct contact with the floor. The SOP also states that all pallets, slip sheets, and supports used to keep product containers off the floor are maintained so as not to be a source of contamination. Auditor

reviews the policy and examines finished product staging and storage areas and pallets, slip sheets, and supports for compliance with the policy. The auditor finds that the facility is following the SOP and is in compliance with the standard.
Assessment: Compliant.
Reason: The auditor finds that the facility is following the SOP and is in compliance with the standard.

Scenario 2: The operation has a written policy prohibiting finished product containers in direct contact with the floor. The SOP also states that all pallets, slip sheets, and supports used to keep product containers off the floor are maintained so as not to be a source of contamination. As the auditor reviews the policy and examines finished product staging and storage areas, the auditor observes pallets, slip sheets, and supports that are not in compliance with the written policy.
Assessment: Corrective Action Needed.
Reason: The auditor observed pallets, slip sheets, and supports that are not in compliance with the written policy in the finished product staging and storage areas.

Scenario 3: The auditee states that the operation has a policy prohibiting finished product containers in direct contact with the floor. The SOP is not written in the operation's food safety plan.
Assessment: Corrective Action Needed.
Reason: The policy must be written.

REPACKING AND DISTRIBUTION

TPD-1 Management Responsibility

Requirement	**TPD-1.1 Operation has current copies of the *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain, the relevant Harmonized Food Safety Standard, and additional food safety documents as required by state and/or federal regulation.**
Procedure	**Operation has a current copy of the Guidelines, this audit document and all other required documents.**
Verification	**Auditor observes the current copies at the operation.**
Corrective Action	**Operation obtains current copies.**
Documents Required	**Record.**
Mandatory	●

Expectation
(See requirement TOF-1.1)

Requirement	TPD-1.2 Operation has been registered or permitted as a food handling establishment as required by state or federal regulation.
Procedure	Operation demonstrates knowledge of prevailing requirements and has a copy of required permit(s) or registration.
Verification	Auditor reviews copies at the operation to verify they are current and complete.
Corrective Action	Operation applies for or renews required permits or registration.
Documents Required	Written Policy.
Mandatory	●

Expectation
(See requirement TPH-1.2)

Example Scenarios
Scenario 1: Operation has been registered or permitted as a food handling establishment as required by state or federal regulation. Operation demonstrates knowledge of prevailing requirements and has a copy of required permit(s) or registration.
Assessment: Compliant.
Reason: Operation is registered or permitted as a food handling establishment as required by state or federal regulation. Operation demonstrates knowledge of prevailing requirements and has a copy of required permit(s) or registration.

Scenario 2: Operation has not been registered or permitted as a food handling establishment as required by state or federal regulation. Operation demonstrates knowledge of prevailing requirements but does not have a copy of required permit(s) or registration.
Assessment: Corrective Action Needed.
Reason: Operation has not been registered or permitted as a food handling establishment as required by state or federal regulation. Operation does not have a copy of required permit(s) or registration.

TPD-2 Raw Material Sourcing

Requirement	**TPD-2.1 The operation has a policy and takes affirmative steps to ensure that all fresh tomatoes that are packed or stored in the facility are grown following requirements in *Tomato Metrics Audit - Open Field Production, Harvest and Field Packing*.**
Procedure	**The packinghouse requires all raw product suppliers to provide evidence of food safety/GAP programs and compliance. Such evidence must include sufficient documentation to demonstrate that the supplier complies with the requirements in *Tomato Metrics Audit - Open Field Production, Harvest and Field Packing*.**
Verification	**Auditor reviews policy and verifies that operation's evidence of supplier compliance with food safety/GAP programs is in compliance with the operation's policy.**
Corrective Action	**Operation obtains required documentation. Operation ceases accepting or shipping product from nonapproved suppliers, until sufficient documentation demonstrating compliance is received by the operation.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
(See requirement TPH-2.1)

Example Scenarios
Scenario 1: The operation has a written policy and takes affirmative steps to ensure that all Tomatoes that are packed or stored in the Operation are grown following requirements in the *Tomato Metrics - Open Field Production, Harvest and Field Packing* Standard.
Assessment: Compliant.
Reason: The operation has a written policy and takes affirmative steps to ensure that all tomatoes that are packed or stored in the operation are grown following requirements in the *Tomato Metrics - Open Field Production, Harvest and Field* Packing. The auditor reviews the policy and third-party audit certificates for the operation's raw product suppliers and finds all documents to be compliant.

Scenario 2: The operation does not have a written policy regarding taking affirmative steps to ensure that all tomatoes that are packed or stored in the operation are grown following requirements in the *Tomato Metrics - Open Field Production, Harvest and Field Packing* Standard.
Assessment: Corrective Action Needed.
Reason: The operation does not have a written policy regarding taking affirmative steps to ensure that all tomatoes that are packed or stored in the operation are grown following requirements in the *Tomato Metrics - Open Field Production, Harvest and Field Packing* Standard.

Scenario 3: The operation has a policy and takes affirmative steps to ensure that all tomatoes that are packed or stored in the operation are grown following requirements in the *Tomato Metrics - Open Field Production, Harvest and Field Packing* Standard. The policy is not written and the auditee is unable to furnish records of their suppliers' third-party audits.

Assessment: Corrective Action Needed.
Reason: The policy is not written and the auditee is unable to furnish records of their operation's raw product suppliers' third-party audits.

Requirement	TPD-2.2 Operation has procedures to ensure that the tomato staging area and staging practices do not pose a risk of tomato contamination.
Procedure	The packinghouse staging area is designed so that overhead areas do not pose a contamination risk of uncovered tomatoes, or that tomatoes are protected during staging to prevent contamination.
Verification	Auditor reviews procedures and inspects staging area for potential sources of contamination.
Corrective Action	Operation develops procedures and/or redesigns staging area or staging practices to prevent reasonably likely to occur opportunities for contamination. Tomatoes that have become contaminated are discarded.
Documents Required	Written Policy.
Mandatory	●

Expectation
(See requirement TPH-2.2)

Example Scenarios
Scenario 1: Operation has written procedures to ensure that the tomato staging area and staging practices do not pose a risk of tomato contamination. The auditor confirms that the packinghouse staging area is designed so that overhead areas do not pose a contamination risk of uncovered tomatoes, and that tomatoes are protected during staging to prevent contamination.
Assessment: Compliant.
Reason: Operation has procedures and a written policy to ensure that the tomato staging area and staging practices do not pose a risk of tomato contamination.

Scenario 2: Operation has written procedures to ensure that the tomato staging area and staging practices do not pose a risk of tomato contamination. Upon the auditor's review of the staging area for potential sources of contamination he finds that the staging area is outside of the packinghouse and that the area is not covered and/or protected from possible contamination.
Assessment: Corrective Action Needed.
Reason: The operation redesigns the staging area or staging practices to prevent reasonably likely to occur opportunities for contamination. Tomatoes that have become contaminated are discarded.

Scenario 3: The operation covers the bins of tomatoes arriving from the field prior to storing them in the refrigerated area of the warehouse. The operation's written policy states that bins shall remain covered and refrigerated until such time as they can be washed and packed. The auditor confirms that the covered bins are protected from possible sources of contamination.
Assessment: Compliant.
Reason: The operation is following their written policy and tomatoes are protected from reasonably likely to occur possibilities for contamination.

TPD-3 Traceability

Requirement	TPD-3.1 All levels of the tomato supply chain shall maintain adequate traceability to a minimum of immediate next recipient and immediate previous supplier.
Procedure	Operation shall have a procedure to identify the sources of incoming product and recipients of outgoing product (including trash).
Verification	Auditor shall review procedure.
Corrective Action	Procedure is developed or revised.
Documents Required	Written Policy.
Mandatory	●

Expectation
All levels of the tomato supply chain must maintain adequate traceability to a minimum of one step forward (immediate next recipient) and one step back (immediate previous supplier) in compliance with FDA recordkeeping requirements. Documentation maintained by the packinghouse must include sufficient information about the source (i.e., field packer firm name, identification of grower, field location, and date of harvest/field pack) as well as the customer receiving the product to allow for the appropriate tracing of product. The packer must have established procedures to ensure that traceability information about the source is retained with tomatoes as they move through the packinghouse processes to shipping, including during resorting. Corrugated containers must be new and accurately labeled with commodity name, packinghouse firm name, and lot identification sufficient to allow for accurate traceability. Only containers able to be cleaned and sanitized (e.g., reusable plastic containers, "RPCs") may be reused. If using reusable containers, they must be cleaned and sanitized before reuse. Labels that originate from a prior use or are inaccurate must be removed or concealed prior to packing.

Example Scenarios
Scenario 1: The auditor confirms that a product coding system is in place where tomatoes shall be labeled with grower and lot identification, and coded to enable access to date of harvest and/or packing, origin (name of farm, grower and/or packing location), and country of origin for traceback purposes. Auditor verifies that coding systems are working as designed, that the carton labels are appropriate and verifies compliance by review of records.
Assessment: Compliant.
Reason: Auditor reviewed coding procedures, observed cases for appropriate coding, and verified compliance by review of records.

Scenario 2: The operation packs tomatoes in two-pound polyethylene bags. The bags are then placed into master cartons of twelve bags each. A product coding system is in place where master cartons are labeled with grower and lot identification and date of harvest and/or packing, origin (name of farm, grower and/or packing location), and country of origin for traceback purposes. But the polyethylene bags only depict a code number. The auditor asks the auditee how the code

number is used to trace the product, the auditee explains the trace number. The auditor then verifies the coding system by review of records and finds the procedure to be in compliance with the standard.
Assessment: Compliant.
Reason: The auditor verified the coding system by review of records.

Scenario 3: A product coding system is in place where product or raw material shall be labeled with grower and lot identification, and coded to enable access to date of harvest and/or packing, origin (name of farm, grower and/or packing location), and country of origin for traceback purposes. Upon review by the auditor, it is observed that most of the product codes printed on the cartons are illegible.
Assessment: Corrective Action Needed.
Reason: Boxes with missing, inaccurate, or illegible coding are re-labeled with appropriate identification.

Requirement	**TPD-3.2 Establish procedures to maintain lot identity of tomatoes, including setbacks and primary containers, throughout the repacking process.**
Procedure	**Operation shall have a procedure and maintain records to identify all outgoing product lots and shipments with all component tomato lots and prior lots in reused primary boxes, in both traceback and trace forward directions.**
Verification	**Auditor shall review procedure and review batch records for compliance. Auditor shall ask operation to traceback one, auditor selected product lot to all supplier lots and primary boxes, and trace forward one supplier lot to all product lots and shipments.**
Corrective Action	**Procedure is developed or revised. Retraining is performed.**
Documents Required	**Written Policy.**
Mandatory	●

Example Scenarios
Scenario 1: The operation has a written procedure and maintains records to identify all outgoing product lots and shipments with all component tomato lots and prior lots in reused primary boxes, in both traceback and trace forward directions. Auditor reviews the procedure and reviews batch records for compliance. The auditor asks the operation to traceback one product lot to all supplier lots and primary boxes, and trace forward one supplier lot to all product lots and shipments. The operation can complete the trace exercise in a reasonable timeframe.
Assessment: Compliant.
Reason: The operation's written procedure and documentation is adequate and is able to complete the trace exercise.

Scenario 2: The operation has a written procedure and maintains records to identify all outgoing product lots and shipments with all component tomato lots and prior lots in reused primary boxes,

in both traceback and trace forward directions. Auditor reviews the procedure and reviews batch records for compliance. The auditor asks the operation to traceback one product lot to all supplier lots and primary boxes, and trace forward one supplier lot to all product lots and shipments. The operation does not complete the trace exercise in the timeframe allotted.
Assessment: Corrective Action Needed.
Reason: The operation's written procedure and documentation appears adequate but is not able to complete the trace exercise.

Scenario 3: The operation has a written procedure and maintains records to identify all outgoing product shipments with all component tomato lots and prior lots in reused primary boxes, in both traceback and trace forward directions. Auditor reviews the procedure and batch records for compliance. The auditor observes that the batch records are incomplete. The auditor asks the operation to traceback one product lot to all supplier lots and primary boxes, and trace forward one supplier lot to all product lots and shipments. The operation is unable to complete the trace exercise.
Assessment: Corrective Action Needed.
Reason: The operation's written procedure and documentation is inadequate and is not able to complete the trace exercise.

Requirement	TPD-3.3 Establish procedures for reconciliation of incoming tomato lots to usage.
Procedure	Operation shall have a procedure and maintain records of tomato use and shrink to allow 100% reconciliation of tomato lots within 4 hrs.
Verification	Auditor reviews reconciliation procedure and asks operation to provide records to support one, auditor-selected reconciliation.
Corrective Action	Procedure is developed or revised. Retraining is performed.
Documents Required	Written Policy.
Mandatory	●

Example Scenarios
Scenario 1: The repacking operation has established procedures for reconciliation of incoming tomato lots to usage. The operation has a written procedure and maintains records of tomato use and shrink to allow 100% reconciliation of tomato lots within four hours. The auditor reviews reconciliation procedure and asks for records to support one reconciliation on a specific lot. The auditor finds that the operation has correctly documented and reconciled the lot to 100% in four hours.
Assessment: Compliant.
Reason: The auditor found that the operation had correctly documented and reconciled the lot to 100% in four hours.

Scenario 2: The repacking operation has established procedures for reconciliation of incoming tomato lots to usage. The operation has a written procedure and maintains records of tomato use and shrink to allow 100% reconciliation of tomato lots within four hours. The auditor reviews

reconciliation procedure and asks for records to support one reconciliation on a specific lot. The auditor finds that the tomato lot reconciliation does not account for the entire lot of tomatoes.
Assessment: Corrective Action Needed.
Reason: The auditor found that the tomato lot reconciliation did not account for the entire lot of tomatoes.

Scenario 3: The repacking operation has procedures for reconciliation of incoming tomato lots to usage. The operation does not have a written procedure to document shrink or allow for 100% reconciliation of tomato lots within 4 hours.
Assessment: Corrective Action Needed.
Reason: The operation does not have a written procedure to document shrink or allow for 100% reconciliation of tomato lots within 4 hours.

TPD-4 Self-Audits

Requirement	**TPD-4.1 Operation has procedures for conducting self-audits, and conducts self-audits to verify compliance with established internal policies and procedures.**
Procedure	**In addition to the requirements of the Harmonized Standards, the operation's self-audit procedure ensures compliance with established internal policies and procedures, the *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, these Tomato Metrics and additional food safety documents as required by state and/or federal regulation.**
Verification	**Auditor reviews the self-audit procedures, and records of self-audits to verify compliance with the procedures.**
Corrective Action	**Operation develops and maintains self-audit program, with corrective actions preventive measures, documentation and follow-up.**
Documents Required	**Written Policy, Record.**
Mandatory	●

Expectation
(See requirements TPH-4.1)

Example Scenarios
Scenario 1: The operation has written procedures for conducting self-audits and conducts self-audits annually, but you find that the operation uses a self-made checklist for conducting self-audits.
Assessment: Compliant
Reason: As long as the self-audit performed addresses the requirements of the Harmonized Standards, ensures compliance with established internal policies and procedures, *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, the Tomato Metrics, and additional food safety documents as required by state and/or federal regulation.

Scenario 2: The operation maintains that they conduct self-audits but do not have a record of the self-audit.
Assessment: Corrective Action Needed,
Reason: The requirement requires a written policy and records. Records should document when the self-audit was started and completed.

Scenario 3: Operation develops and maintains a self-audit program, including a written record of required corrective actions and follow-up procedures but does not include preventive measures.
Assessment: Compliant or Corrective Action Needed.
Reason: If the operation has sufficiently satisfied the requirements of checklist questions G-8.1, G-9.1, and TOF 2.1 this checklist question shall be assessed as compliant.

TPD-5 Product Containers and Packaging Materials

A. Bins, Gondolas, Totes

Requirement	**TPD-5.1 Tomato-contact bulk bins, gondolas, totes and trays shall not be constructed of wood.**
Procedure	**In accordance with the Post- Harvest Operations Harmonized Standard P-8.7 regarding acceptable product-contact containers, operation has eliminated or has a plan to eliminate the use of wooden product contact containers.**
Verification	**Auditor reviews SOP, visually observes product bins, trays and containers and their use for evidence of noncompliance.**
Corrective Action	**Policy is developed or revised. Non-compliances are corrected. Operation removes non-conforming product containers from food contact purposes. Retraining is performed. Operation develops a plan to phase out wooden bins, and demonstrates compliance with the plan.**
Documents Required	**Written Policy.**
Mandatory	●

Expectation
(See requirement TPH-5.1)

Requirement	TPD-5.2 The operation has written procedures for cleaning and sanitizing of produce food contact containers, requiring that bulk bins, gondolas, totes and trays are cleaned and sanitized periodically and is documented.
Procedure	Written SOP is established to ensure that bulk bins, gondolas, totes, trays and other food contact containers and implements are adequately cleaned and sanitized at a frequency sufficient to maintain clean and sanitary food contact surfaces, and documentation of compliance is maintained.
Verification	Auditor reviews SOP, cleaning logs and records, interviews responsible individuals for knowledge of the SOP and observes containers, employees and records for evidence of compliance.
Corrective Action	Policy is developed or revised. Non-compliances are corrected on site. Retraining is performed.
Documents Required	Written Policy, Record.
Mandatory	●

Expectation
(See requirement TPH-5.2)

B. Primary Packing Boxes

Requirement	TPD-5.3 The repacker must label the container as being repacked. The box contains information on the commodity, repacker identification and provides lot identification.
Procedure	Operation shall ensure that all product containers containing repacked tomatoes are labeled as repacked. The container shall also include the commodity, repacker identification, and repacker lot identification.
Verification	Auditor observes repacked product boxes for compliance.
Corrective Action	Procedure is developed or revised. Retraining is performed.
Documents Required	Record.
Mandatory	●

Example Scenarios
Scenario 1: Operation ensures that all product containers containing repacked tomatoes are labeled as repacked. The containers also include the commodity name, packer identification, and packer lot identification. Auditor observes repacked product boxes and finds them to be in compliance.
Assessment: Compliant.
Reason: Auditor observed repacked product boxes and found them to be in compliance.

Scenario 2: The repacker labels the containers with product information, the packer information and lot ID but does not identify as repacked product.
Assessment: Corrective Action Needed.
Reason: Auditor observes that the repacked containers do not indicate that the product is repacked.

Scenario 3: The box contains information on the commodity, repacker identification and multiple lot identification markings and is clearly printed as repacked. The auditor observes repacked product boxes for compliance.
Assessment: Compliant.
Reason: If tomato lots are commingled, then tomatoes should be repacked into new or used containers where the original label matches at least one tomato in the commingled lot. Reused containers shall be clean and sanitary, and accurately labeled with the repacker's information and lot identification that maintains the integrity of traceability information to all the included lots. In the event of a recall, all lots in the commingled lot are affected.

Requirement	**TPD-5.4 Operation has a process to ensure that inaccurate information on previously used boxes is obliterated, or otherwise made clear that original information no longer applies, to prevent misidentification.**
Procedure	**Boxes shall not be reused if prohibited by prevailing regulation or law.**
Verification	**Auditor observes one or more repacked lots and repacking documentation for those lots using reused cartons to verify that only the cartons from the original lot(s) are used to repack reworked tomatoes and a positive effort has been made to obliterate (mark out by any means) inaccurate information; OR a label that clearly states the information on the box is no longer valid has been affixed and has the proper lot information on the label.**
Corrective Action	**Operation ceases using boxes inappropriately. Procedure is developed or revised. Retraining is performed.**
Documents Required	**Written Policy.**
Mandatory	●

Example Scenarios
Scenario 1: The operation has a written policy and a process to ensure that inaccurate information on previously used boxes is obliterated, or otherwise made clear that original information no longer applies. Auditor observes one or more repacked lots and repacking documentation for those lots using reused cartons to verify that only the cartons from the original lot(s) are used to pack reworked tomatoes and a positive effort has been made to obliterate (mark out by any means) inaccurate information; OR a label that clearly states the information on the box is no longer valid has been affixed and has the proper lot information on the label.
Assessment: Compliant.
Reason: The operation has a written policy and a process to ensure that inaccurate information on previously used boxes is obliterated and the auditor has reviewed the policy, procedure and observed repacked lots for compliance.

Scenario 2: The operation has a written policy and a process to ensure that inaccurate information on previously used boxes is obliterated. The auditor observes that on several pallets of containers, only the outside facing carton label has been obliterated. The inside facing carton label contains the previous lot information.
Assessment: Corrective Action Needed.
Reason: The auditor observed that on several pallets of containers, only the outside facing carton label had been obliterated. The inside facing carton label contained the previous lot information.

Requirement	**TPD-5.5 Used boxes may be used as secondary shipping containers, provided that the original identification information on the box has been obliterated or otherwise made clear that it is no longer accurate.**
Procedure	**Operation may reuse tomato boxes as secondary (no product contact) shipping containers. Operation has a process to ensure that inaccurate information is obliterated, or otherwise made clear that original information no longer applies, to prevent misidentification.**
Verification	**If used boxes are used as secondary shipping containers, auditor observes one or more repacked lots and repacking documentation for those lots using reused cartons to verify that a positive effort has been made to obliterate (mark out by any means) inaccurate information; OR a label that clearly states the information on the box is no longer valid has been affixed and has the proper lot information on the label.**
Corrective Action	**Operation relabels mislabeled boxes. Procedure is developed or revised. Retraining is performed.**
Documents Required	**N/A**
Mandatory	**●**

Example Scenarios
Scenario 1: The operation has a written policy and a process to ensure that inaccurate information on previously used boxes is obliterated, or otherwise made clear that original information no longer applies. Auditor observes one or more repacked lots and repacking documentation for those lots using reused cartons to verify that only the cartons from the original lot(s) are used to pack reworked tomatoes and a positive effort has been made to obliterate (mark out by any means) inaccurate information; OR a label that clearly states the information on the box is no longer valid has been affixed and has the proper lot information on the label.
Assessment: Compliant.
Reason: The operation has a written policy and a process to ensure that inaccurate information on previously used boxes is obliterated and the auditor has reviewed the policy, procedure and observed re-packed lots for compliance.

Scenario 2: The operation has a written policy and a process to ensure that inaccurate information on previously used boxes is obliterated. The auditor observes that on several pallets of containers, only the outside facing carton label has been obliterated. The inside facing carton label contains the previous lot information.
Assessment: Corrective Action Needed.

Reason: The auditor observed that on several pallets of containers, only the outside facing carton label had been obliterated. The inside facing carton label contained the previous lot information.

Scenario 3: The auditor observes pallets of tomato lots that have been commingled during the repacking process, each of the three lots of tomatoes are repacked into the original containers that they came from, the containers all include the original lot ID numbers and also an additional label that indicates the tomatoes have been repacked.
Assessment: Compliant.
Reason: The information on the repacked containers is accurate as long as each lot has been repacked into the original containers.

TPD-6 Packinghouse Condition and Equipment

A. General Building

Requirement	TPD-6.1 Facility is constructed/arranged to allow separation of incoming, in-process and finished products.
Procedure	Facilities or processes assure separation and positioning of incoming raw materials so as not to become a source of contamination of in-process and finished product.
Verification	Auditor observes placement of incoming raw materials, in-process and finished products for opportunities for cross-contamination.
Corrective Action	Procedures are developed or revised. Non-compliances are corrected on site. Retraining is performed.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TPH-6.1)

Requirement	TPD-6.2 Operation has procedures that minimize the accumulation of standing water.
Procedure	If floor drains exist, they are adequate, functional, free of obstruction and are properly maintained and cleaned sufficient to prevent them from becoming sources of contamination. If standing water exists, it is removed from floors and floors cleaned in a manner and at a frequency sufficient to prevent creation of a source of contamination.
Verification	Auditor observes floor drains and evidence of standing water for compliance with procedures.
Corrective Action	Floor drains are installed, repaired or maintained, or procedures are modified, to prevent standing water from becoming a potential source of contamination.
Documents Required	Written Policy.

Mandatory	●

Expectation
(See requirement TPH-6.2)

B. Facility and Equipment

Requirement	**TPD-6.3 All food contact surfaces are made of material and designed to be easily cleaned and sanitized, and are maintained in good condition.**
Procedure	**All tomato contact surfaces and equipment are made of materials, designed or constructed to be easily cleaned and sanitized, all food contact surfaces are free of rust or corrosion, and seams between food contact surfaces are smooth or accessible for cleaning.**
Verification	**Auditor observes product contact surfaces and equipment and their use for evidence of non-compliance.**
Corrective Action	**Non-compliances are corrected or replaced. Operation makes a commitment for phasing out non-conforming tomato contact surfaces and equipment, in a reasonable timeline. Retraining is performed.**
Documents Required	**N/A**
Mandatory	●

Expectation
(See requirement TPH-6.3)

Requirement	**TPD-6.4 Wood is not used as a food contact surface.**
Procedure	**Operation has eliminated, or has a plan to eliminate, use of wooden items as food contact surfaces.**
Verification	**Auditor inspects facility for evidence of wooden food contact surfaces.**
Corrective Action	**Operation that still utilizes wood as a food contact surface has a plan to phase out such surfaces, and is in compliance with the plan.**
Documents Required	**N/A**
Mandatory	●

Expectation
(See requirement TPH-6.4)

Requirement	TPD-6.5 SDS are on file for all chemicals used in the facility, and readily.
Procedure	Operation maintains a list of all chemicals approved for use in facility, and maintains SDS for all. SDS are in a location easily accessible by employees.
Verification	Auditor reviews SDS binder and observes chemicals in facility for evidence of compliance.
Corrective Action	Obtain missing SDS. Relocate SDS.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TPH-6.5)

TPD-7 Worker Health/Hygiene and Toilet/Handwashing Facilities

Requirement	TPD-7.1 If portable hand wash water tanks are used, they are cleaned and sanitized and the water is changed periodically.
Procedure	Water tanks used to provide hand wash water shall be maintained at a prescribed frequency in a clean and sanitary manner.
Verification	Auditor reviews cleaning and sanitizing protocol and service logs, and visually observes condition of water tanks for signs of noncompliance.
Corrective Action	Clean and sanitize the tank, replace water to compliance.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TOF-4.2)

TPD-8 Product Wash Water Management

Requirement	TPD-8.1 In systems where tomatoes are submerged or dwell in water, water temperature is monitored and controlled. Water temperature should be at least 10ºF above average pulp temperature of tomatoes when entering the water.
Procedure	Operation shall have methods for determining average pulp temperature of a minimum of 5 tomatoes, a procedure for control of water temperature, shall monitor temperature at a prescribed frequency sufficient to assure continuous compliance (minimum of hourly), and shall maintain records of water temperature. Operation shall have a procedure as to what corrective actions are taken if criteria are not met. Water spray or shower systems, wherein tomatoes are not submerged or dwell do not require temperature control.
Verification	Auditor shall review the procedure and shall review records of temperature monitoring. Auditor observes process including the operation's sampling of pulp and water temperatures. Auditor reviews records for deviations and their disposition.
Corrective Action	Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at temperatures less than the average measured pulp temperature shall be discarded back to the last evidence of compliance.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TPH-8.1)

Requirement	TPD-8.2 Operations utilizing spray systems in place of whole tomato immersion shall design the line so that the entire tomato surface is rinsed.
Procedure	Spray systems shall be designed such that rinse water contacts all surfaces of the tomato.
Verification	Auditor observes spray system for compliance.
Corrective Action	Equipment or process is redesigned or retrofitted to ensure all surfaces of tomato are contacted.
Documents Required	N/A
Mandatory	●

Expectation
(See requirement TPH-8.2)

Requirement	TPD-8.3 If a spray bar system is used, operation has a water use SOP that addresses treatment of that water.
Procedure	Operation's water use SOP requires spray bar water to be treated using an approved antimicrobial to maintain a microbially hostile environment on equipment.
Verification	Auditor shall review water use SOP for completeness, and observes water treatment records for adequacy and consistency of treatment.
Corrective Action	Operation discontinues using spray bar water that is not treated sufficiently to maintain a hostile environment on equipment. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Policy.
Mandatory	●

Expectation
(See requirement TPH-8.3)

Requirement	TPD-8.4 If water quality is based upon a chlorine-based sanitizer, the process shall be targeted to be at least 100 ppm free available chlorine (FAC), measured at the exit of the product from the water system, unless validation data are available to demonstrate a lower FAC is effective under operating conditions.
Procedure	Operation shall have a procedure to manage FAC levels, shall establish process adjustments for when the FAC drops below 100 ppm, and shall maintain records to verify proper management of levels.
Verification	Auditor shall review the procedure and shall review records of FAC measurement and appropriate management. Auditor reviews records for deviations and their disposition.
Corrective Action	Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at FAC less than 100 ppm shall be discarded back to the last evidence of compliance.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TPH-8.4)

Requirement	TPD-8.5 If water quality is based upon a peroxyacetic, peracetic or peracid system, levels shall be maintained in accordance with manufacturer's label directions.
Procedure	Operation shall have a procedure to manage peracid levels, shall establish process targets so as not to drop below the minimum ppm, shall establish adjustments for when the peracid level drops below the target ppm, and shall maintain records to verify proper management of levels.
Verification	Auditor shall review the procedure and shall review records of peracetic measurement and appropriate management. Auditor reviews records for deviations and their disposition.
Corrective Action	Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at less than manufacturer's recommendation shall be discarded back to the last evidence of compliance.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TPH-8.5)

TPD-9 Quarantine or On-hold Materials

Requirement	TPD-9.1 Materials placed on hold, quarantined or rejected are clearly identified and segregated from other products and packaging materials.
Procedure	Operation has a written procedure to clearly identify and segregate on-hold, quarantined and rejected materials, to prevent commingling with other products or adulteration of products, production area or packaging materials.
Verification	Auditor reviews procedure, reviews logs and observes all currently on-hold, quarantined and rejected materials for compliance with procedure.
Corrective Action	Non-compliances are corrected on site. If on-hold, quarantined or rejected materials are not segregated according to procedure, operation shall assess potential for product adulteration. Procedures are developed or revised. Retraining is performed.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TPH-9.1)

TPD-10 Food Defense Awareness

Requirement	TPD-10.1 The facility is registered with FDA as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
Procedure	If required by 21 CFR Part 1, Subpart H, facility is registered with FDA and registration is current.
Verification	Auditor asks whether facility is registered. Facility is not required to demonstrate registration to auditor.
Corrective Action	Facility registers with FDA as required.
Documents Required	Record.
Mandatory	●

Expectation
(See requirement TPH-11.1)

Requirement	TPD-10.2 There are procedures in place that readily identify employees, and those with specific access privileges, e.g., to chemical storage, to the water system.
Procedure	Operation has a written procedure for identifying current employees. Procedure also indicates which employees have access to restricted areas or materials, and how access is restricted.
Verification	Auditor reviews procedure, verifies list of special access employees, observes restricted areas and materials for evidence of compliance and interviews employees for knowledge of procedure.
Corrective Action	Procedures are developed or revised. Retraining is performed.
Documents Required	Written Policy.
Mandatory	●

Expectation
(See requirement TPH-11.2)

GLOSSARY

Agricultural Water	Refers to water used in the growing environment (for example, field, vineyard, or orchard) for agronomic reasons. It includes water used for irrigation, transpiration control (cooling), frost protection, or as a carrier for fertilizers and pesticides. Typical sources of agricultural water include flowing surface waters from rivers, streams, irrigation ditches, open canals, impoundments (such as ponds, reservoirs, and lakes), wells, and municipal supplies.[1]
Adequate	Means that which is needed to accomplish the intended purpose in keeping with good practice. [1]
Clean	Means that food and food-contact surfaces are washed and rinsed and are visually free of dust, dirt, food residues, and other debris. [1]
Composting	Refers to a managed process in which organic materials, including animal manure and other wastes, are digested aerobically or anaerobically by microbial action. [1]
Control	Means (a) to manage the conditions of an operation in order to be consistent with established criteria, and (b) to follow correct procedures and meet established criteria. [1]
Control measure	Any action or activity that can be used to prevent, reduce, or eliminate a microbiological hazard. [1]
Facility	The buildings and other physical structures used for or in connection with the harvesting, washing, sorting, storage, packaging, labeling, holding, or transport of fresh produce. [1]
Food-contact surfaces	Are those surfaces that contact fresh produce and those surfaces from which drainage onto the produce or onto surfaces that contact the produce may occur during the normal course of operations. "Food contact surfaces" includes equipment, such as containers and conveyor belts, that contact fresh produce, whether used in harvesting, post-harvesting, and packing operations. It would not include tractors, forklifts, hand trucks, pallets, etc. that are used for handling or storing large quantities of contained or packed fresh produce and that do not come into actual contact with the food. [1]
Fresh fruits and vegetables	Refers to fresh produce that is likely to be sold to consumers in an unprocessed or minimally processed (e.g., raw) form. Fresh produce may be intact, such as strawberries, whole carrots, radishes, and fresh market tomatoes, or cut during harvesting, such as celery, broccoli, and cauliflower. The guidance in this document is also applicable to "fresh cut" produce, such as pre-cut, packaged, ready-to-eat salad mixes. However, some fresh produce specialty items, such as fresh cut produce, may be subject to additional processing steps and/or handling that may warrant consideration of specific good manufacturing practices in addition to the good agricultural and management practices covered in this guidance document. [1]

Good management practices	General practices to reduce microbial food safety hazards. The term may include both "good agricultural practices" used in growing harvesting, sorting, packing and storage operations and "good manufacturing practices" used in sorting, packing, storage, and transportation operations. [1]
Microorganisms	Yeasts, molds, bacteria, protozoa, helminthes (worms), and viruses. Occasionally, the term "microbe" or "microbial" is used instead of the term "microorganisms." [1]
Microbial hazard	Occurrence of a microorganism that has the potential to cause illness or injury. [1]
Mock Recall	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.
Municipal biosolids (Biosolids)	Are the by-product of human waste treatment by local government that may be used as fertilizer or as a soil amendment. [1]
Operator	The person or persons who have day-to-day responsibility for the production, harvesting, washing, sorting, cooling, packaging, shipping, or transportation of fresh fruits and vegetables, and responsibility for management of all employees who are involved in each of these activities. [1]
Oxidation-Reduction Potential (ORP)	A measurement to oxidize contaminants, a practical method to electronically monitor sanitizer effectiveness.
Parts Per Million (PPM)	A measurement expressing very dilute concentrations of substances. Just as percent means out of a hundred, so parts per million or ppm means out of a million.
Pathogen	A microorganism capable of causing disease or injury. [1]
Pest	Any animal or insect of public health importance including, but not limited to, birds, rodents, cockroaches, flies, and larvae, that may carry pathogens that can contaminate food. [1]
Processing water	Water used for post-harvest treatment of produce, such as washing, cooling, waxing, and product transport. [1]
Reasonably	Agreeable to reason and sound judgment; logical; rational; fair; not excessive or extreme.
Recall	A means to return marketed product to its origin; to remove it from the marketplace.
Sanitize	To treat clean produce by a process that is effective in destroying or substantially reducing the number of microorganisms of public health concern, as well as other undesirable microorganisms, without adversely affecting the quality of the product or its safety for the consumer. [1]
Sanitize (food contact surfaces)	To treat clean produce by a process that is effective in destroying or substantially reducing the number of microorganisms of public health concern, as well as other undesirable microorganisms, without adversely affecting the quality of the involved product or its safety for the consumer. It means the application of cumulative heat or

	chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to reduce populations of representative microorganisms by 5 log or 99.999%.[1]
Shall	Used to state a mandatory requirement.
Should	Used to state recommended or advisory procedures or identify recommended equipment.
Traceback	The ability to trace a fruit or vegetable back to its field of origin. A common practice used by health officials to investigate foodborne illness outbreaks.
Transporter	The operator of a conveyance such as a truck, railcar, vessel, or aircraft used to transport fresh produce from grower to market. [1]

[1] "Guidance for Industry-Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables", U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN). October 1998.

REFERENCE LINKS **Version Date (Printed for distribution)**

☐ **FPB 703 Fresh Products Branch Good Agricultural Practices and Good Handling Practices (GAP&GHP) Audit Appeals, Complaints and Dispute Process:** _____
https://www.ams.usda.gov/sites/default/files/media/FPB-703%20%E2%80%93%20Fresh%20Products%20Branch%20GAP-GHP%20Audit%20Procedures.pdf

☐ **GAP Audit Program Scope:** _____
https://www.ams.usda.gov/sites/default/files/media/GAPProgramScope.pdf

☐ **SC-237A Request for Audit Service Form:** _____
https://www.ams.usda.gov/sites/default/files/media/SC237A.pdf

☐ **SC-651 Agreement for Participation in Audit Services form:** _____
https://www.ams.usda.gov/sites/default/files/media/SC651.pdf

☐ **Harmonized GAP Standard** _____
https://www.ams.usda.gov/sites/default/files/media/Harmonized_GAP_Standard_Version2.pdf

☐ **Harmonized GAP Checklist:** _____
https://www.ams.usda.gov/sites/default/files/media/HarmonizedGAPsChecklist5.pdf

☐ **Harmonized GAP Plus Standard** _____
https://www.ams.usda.gov/sites/default/files/media/HarmonizedGAPPlus%2BStandardVersion4.0_0.pdf

☐ **Harmonized GAP Plus Checklist:** _____
https://www.ams.usda.gov/sites/default/files/media/HarmonizedGAPPlusChecklist4.0.pdf

☐ **Aquaponic Operation Good Agricultural Practices:** _____
https://www.ams.usda.gov/sites/default/files/media/AquaponicOperationGAP.pdf

☐ **USDA GAP Program Water FAQs:** _____
https://www.ams.usda.gov/sites/default/files/media/GAPWATERFAQS.pdf

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APPENDIX I – PRODUCE SAFETY RULE (PSR)

Subpart A: General Provisions

§ 112.1 What food is covered by this part?

(a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:

(1) Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel- Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and

(2) Mixes of intact fruits and vegetables (such as fruit baskets).

§ 112.2 What produce is not covered by this part?

(a) The following produce is not covered by this part:

(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list -- asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

(2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and

(3) Produce that is not a raw agricultural commodity.

(b) Produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (2), and (3) of this section) under the following conditions:
(1) The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of parts 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products; and
(2) You must disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is "not processed to adequately reduce the presence of microorganisms of public health significance;" and
(3) You must either:
(i) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from the customer that performs the commercial processing described in paragraph (b)(1) of this section that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or
(ii) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in paragraph (b)(1) of this section and that the customer:
(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to adequately reduce the presence of microorganisms of public health significance"; and
(B) Will only sell to another entity that agrees, in writing, it will either:
(1) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance; or
(2) Obtain a similar written assurance from its customer that the produce will receive commercial processing described in paragraph (b)(1) of this section, and that there will be disclosure in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to adequately reduce the presence of microorganisms of public health significance"; and
(4) You must establish and maintain documentation of your compliance with applicable requirements in paragraphs (b)(2) and (3) in accordance with the requirements of subpart O of this part, including:
(i) Documents containing disclosures required under paragraph (b)(2) of this section; and
(ii) Annual written assurances obtained from customers required under paragraph (b)(3) of this section; and
(5) The requirements of this subpart and subpart Q of this part apply to such produce; and
(6) An entity that provides a written assurance under § 112.2(b)(3)(i) or (b)(3)(ii) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 112.3 What definitions apply to this part?

(a) The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part.

(b) For the purpose of this part, the following definitions of very small business and small business also apply:

(1) Very small business. For the purpose of this part, your farm is a very small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $250,000.

(2) Small business. For the purpose of this part, your farm is a small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.

(c) For the purpose of this part, the following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Adequately reduce microorganisms of public health significance means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

Agricultural tea means a water extract of biological materials (such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase.

Agricultural teas are held for longer than one hour before application. Agricultural teas are soil amendments for the purposes of this rule.

Agricultural tea additive means a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

Animal excreta means solid or liquid animal waste.

Application interval means the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied.

Biological soil amendment means any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

Biological soil amendment of animal origin means a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term “biological soil amendment of animal origin” does not include any form of human waste.

Composting means a process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of "farm" as defined in this chapter. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term "covered produce" refers to the harvestable or harvested part of the crop.

Curing means the final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation, depending on environmental conditions.

Direct water application method means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.

Farm means:

(1) Primary Production Farm. A Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:
   (i) Pack or hold raw agricultural commodities;
   (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and
   (iii) Manufacture/process food, provided that:
      (A) All food used in such activities is consumed on that farm or another farm under the same management; or
      (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:
         (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);
         (2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and
         (3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary Activities Farm. A Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm in paragraph (1)(ii) and (iii) of this definition.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.

Food contact surfaces means those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food contact surfaces" includes food contact surfaces of equipment and tools used during harvest, packing and holding.

Ground water means the supply of fresh water found beneath the Earth's surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.

Growth media means material that acts as a substrate during the growth of covered produce (such as mushrooms and some sprouts) that contains, may contain, or consists of components that may include any animal waste (such as stabilized compost, manure, non-fecal animal byproducts or table waste).

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological agent that has the potential to cause illness or injury in the absence of its control.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological hazard that is known to be, or has the potential to be, associated with the farm or the food.
Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.
Manure means animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.
Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.
Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but that also conducts activities outside the farm definition that require the establishment to be registered.
Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement.
Non-fecal animal byproduct means solid waste (other than manure) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.
Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act
Pest means any objectionable animals or insects, including birds, rodents, flies, and larvae.
Pre-consumer vegetative waste means solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with an end user (consumer). Pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Production batch of sprouts means all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).

Qualified end-user with respect to a food means the consumer of the food; or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located:

(i) In the same State or the same Indian reservation as the farm that produced the food; or

(ii) Not more than 275 miles from such farm.

The term "consumer" does not include a business.

Raw agricultural commodity (RAC) means "raw agricultural commodity" as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Sewage sludge biosolids means the solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of "sewage sludge" in 40 CFR 503.9(w).

Soil amendment means any chemical, biological, or physical material (such as elemental fertilizers, stabilized compost, manure, non-fecal animal byproducts, peat moss, perlite, pre- consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).

Spent sprout irrigation water means water that has been used in the growing of sprouts.

Stabilized compost means a stabilized (i.e., finished) biological soil amendment produced through a controlled composting process.

Static composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile (or row) that may or may not be covered with insulating material, or in an enclosed vessel) by a mechanism that does not include turning. Examples of structural features

for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots. Examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting material or blow air into the composting material using positive pressure).
Surface water means all water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.
Table waste means any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer.
Turned composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections.
Visitor means any person (other than personnel) who enters your covered farm with your permission.
Water distribution system means a system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings.
We means the U.S. Food and Drug Administration (FDA).
Yard trimmings means purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils.
You, for purposes of this part, means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of this part.

§ 112.4 Which farms are subject to the requirements of this part?

(a) Except as provided in paragraph (b) of this section, a farm or farm mixed-type facility with an average annual monetary value of produce (as "produce" is defined in § 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, is a "covered farm" subject to this part. Covered farms subject to this part must comply with all applicable requirements of this part when conducting a covered activity on covered produce.
(b) A farm is not a covered farm if it satisfies the requirements in § 112.5 and we have not withdrawn the farm's exemption in accordance with the requirements of subpart R of this part.

112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

(a) A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:
(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3(c)) the farm sold directly to

qualified end-users (as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in § 112.3(c)) the farm sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

(b) For the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

§ 112.6 What modified requirements apply to me if my farm is eligible for a qualified exemption in accordance with § 112.5?

(a) If your farm is eligible for a qualified exemption in accordance with § 112.5, you are subject to the requirements of:
(1) This subpart A (General Provisions);
(2) Subpart O of this part (Records);
(3) Subpart Q of this part (Compliance and Enforcement); and
(4) Subpart R of this part (Withdrawal of Qualified Exemption).

(b) In addition, you are subject to the following modified requirements:
(1) When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act or its implementing regulations, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.
(2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.
(3) The complete business address that you must include in accordance with the requirements of paragraph (b)(1) or (b)(2) of this section must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

§ 112.7 What records must I establish and keep if my farm is eligible for a qualified exemption in accordance with § 112.5?

If your farm is eligible for a qualified exemption in accordance with § 112.5:

(a) You must establish and keep records required under this provision in accordance with the requirements of subpart O of this part, except that the requirement in § 112.161(a)(4) for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. Such receipts must be dated as required under § 112.161(a)(4).

(b) You must establish and keep adequate records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption that are described in § 112.5, including a

written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption.

Subpart B: General Requirements

§ 112.11 What general requirements apply to persons who are subject to this part?

You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act on account of such hazards.

§ 112.12 Are there any alternatives to the requirements established in this part?

(a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in § 112.49, provided that you satisfy the requirements of paragraphs (b) and (c) of this section.

(b) You may establish and use an alternative to any of the requirements specified in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part, and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions.

(c) Scientific data and information used to support an alternative to a requirement specified in paragraph (a) of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in accordance with the requirements of subpart O of this part. You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.

Subpart C: Personnel Qualifications and Training

§ 112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?

All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces:

(a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.

(b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with this part.

(c) Training must be conducted in a manner that is easily understood by personnel being trained.

(d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of this part.

§ 112.22 What minimum requirements apply for training personnel who conduct a covered activity?

(a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:
  (1) Principles of food hygiene and food safety;
  (2) The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food contact surfaces with microorganisms of public health significance; and
  (3) The standards established by FDA in subparts C through O of this part that are applicable to the employee's job responsibilities.

(b) Persons who conduct harvest activities for covered produce must also receive training that includes all of the following:
  (1) Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;
  (2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and
  (3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.

(c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.

§ 112.23 What requirements apply regarding supervisors?

You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of this part.

§ 112.30 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.

Subpart D: Health and Hygiene

§ 112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?

(a) You must take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).

(b) The measures you must take to satisfy the requirements of paragraph (a) of this section must include all of the following measures:

(1) Excluding any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health; and

(2) Instructing personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.

§ 112.32 What hygienic practices must personnel use?

(a) Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination.

(b) The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food contact surfaces during a covered activity must include all of the following practices:

(1) Maintaining adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;

(2) Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;

(3) Washing hands thoroughly, including scrubbing with soap (or other effective surfactant) and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices:

(i) Before starting work;

(ii) Before putting on gloves;

(iii)After using the toilet;

(iv)Upon return to the work station after any break or other absence from the work station;

(v) As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and

(vi)At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards;

(4) If you choose to use gloves in handling covered produce or food contact surfaces, maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so;

(5) Removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand; and
(6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas).

§ 112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?

(a) You must make visitors aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures.
(b) You must make toilet and hand-washing facilities accessible to visitors.

Subpart E: Agricultural Water

§ 112.41 What requirements apply to the quality of agricultural water?
All agricultural water must be safe and of adequate sanitary quality for its intended use.

§ 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?

(a) At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:
(1) The nature of each agricultural water source (for example, ground water or surface water);
(2) The extent of your control over each agricultural water source;
(3) The degree of protection of each agricultural water source;
(4) Use of adjacent and nearby land; and
(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.
(b) You must adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.
(c) You must adequately maintain all agricultural water sources to the extent they are under your control (such as wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of

debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

(d) As necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of contact of covered produce with pooled water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.

§ 112.43 What requirements apply to treating agricultural water?

(a) When agricultural water is treated in accordance with § 112.45:
  (1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable.
  (2) You must deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.

(b) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.

§ 112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?

(a) When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:
  (1) Used as sprout irrigation water;
  (2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;
  (3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and
  (4) Used for washing hands during and after harvest activities.

(b) When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with § 112.49):
  (1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and

(2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic *E. coli* per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).

§ 112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?

(a) If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 and/or if your agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44(a), you must immediately discontinue that use(s), and before you may use the water source and/or distribution system again for the intended use(s), you must either:

(1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and, as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or

(2) Treat the water in accordance with the requirements of § 112.43.

(b) If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44(b), as soon as practicable and no later than the following year, you must discontinue that use, unless you either:

(1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by:

(i) Applying a time interval between last irrigation and harvest using either:

(A) A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your geometric mean (GM) and statistical threshold value (STV) to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of 4 consecutive days; or

(B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or

(ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate supporting scientific data and information;

(2) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable); or

(3) Treat the water in accordance with the requirements of § 112.43.

§ 112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?

(a) There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:
  (1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (as defined in 40 CFR 141.2) approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;
  (2) You receive water from a public water supply that furnishes water that meets the microbial quality requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or
  (3) You treat water in accordance with the requirements of § 112.43.

(b) Except as provided in paragraph (a) of this section, you must take the following steps for each source of water used for purposes that are subject to the requirements of § 112.44(b):
  (1) Conduct an initial survey to develop a microbial water quality profile of the agricultural water source.
    (i) The initial survey must be conducted:
      (A) For an untreated surface water source, by taking a minimum total of 20 samples of agricultural water (or an alternative testing frequency that you establish and use, in accordance with § 112.49) over a minimum period of 2 years, but not greater than 4 years.
      (B) For an untreated ground water source, by taking a minimum total of four samples of agricultural water during the growing season or over a period of 1 year.
    (ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. The microbial water quality profile initially consists of the geometric mean (GM) and the statistical threshold value (STV) of generic *Escherichia coli* (*E. coli*) (colony forming units (CFU) per 100 milliliter (mL)) calculated using this data set. You must determine the appropriate way(s) in which the water may be used based on your microbial water quality profile in accordance with § 112.45(b).
    (iii) You must update the microbial water quality profile annually as required under paragraph (b)(2) of this section, and otherwise required under paragraph (b)(3) of this section.
  (2) Conduct an annual survey to update the microbial water quality profile of your agricultural water.
    (i) After the initial survey described in paragraph (b)(1)(i) of this section, you must test the water annually to update your existing microbial water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze:

(A) For an untreated surface water source, a minimum number of five samples per year (or an alternative testing frequency that you establish and use, in accordance with § 112.49).
(B) For an untreated ground water source, a minimum of one sample per year.

(ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest.

(iii) To update the microbial water quality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual survey data from within the previous 4 years, to make up a rolling data set of:
(A) At least 20 samples for untreated surface water sources; and
(B) At least 4 samples for untreated ground water sources.

(iv) You must modify your water use, as appropriate, based on the revised GM and STV values in your updated microbial water quality profile in accordance with § 112.45(b).

(3) If you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of your water source), you must develop a new microbial water quality profile reflective of the time period at which you believe your microbial water quality profile changed.

(i) To develop a new microbial water quality profile, you must calculate new GM and STV values using your current annual survey data (if taken after the time of the change), combined with new data, to make up a data set of:
(A) At least 20 samples for untreated surface water sources; and
(B) At least 4 samples for untreated ground water sources.

(ii) You must modify your water use based on the new GM and STV values in your new microbial water quality profile in accordance with § 112.45(b).

(c) If you use untreated ground water for the purposes that are subject to the requirements of § 112.44(a), you must initially test the microbial quality of each source of the untreated ground water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected to be representative of the intended use(s). Based on these results, you must determine whether the water can be used for that purpose, in accordance with § 112.45(a). If your four initial sample results meet the microbial quality criteria of § 112.44(a), you may test once annually thereafter, using a minimum of one sample collected to be representative of the intended use(s). You must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criteria in § 112.44(a).

§ 112.47 Who must perform the tests required under § 112.46 and what methods must be used?

(a) You may meet the requirements related to agricultural water testing required under § 112.46 using:

(1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or

(2) Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of this part are met.

(b) Agricultural water samples must be aseptically collected and tested using a method as set forth in § 112.151.

§ 112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

(a) You must manage the water as necessary, including by establishing and following water-change schedules for re-circulated water, to maintain its safety and adequate sanitary quality and minimize the potential for contamination of covered produce and food contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce);

(b) You must visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for buildup of organic material (such as soil and plant debris).

(c) You must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

§ 112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?

Provided you satisfy the requirements of § 112.12, you may establish and use one or more of the following alternatives:

(a) An alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b);

(b) An alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i);

(c) An alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A); and

(d) An alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(2)(i)(A).

§ 112.50 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep the following records:

(1) The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a);

(2) Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance with this subpart;

(3) Scientific data or information you rely on to support the adequacy of a method used to satisfy the requirements of § 112.43(a)(1) and (2);
(4) Documentation of the results of water treatment monitoring under § 112.43(b);
(5) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that you used to determine the time interval (in days) between harvest and end of storage, including other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic Escherichia coli (*E. coli*), in accordance with § 112.45(b)(1)(ii);
(6) Documentation of actions you take in accordance with § 112.45. With respect to any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (b)(1)(ii), such documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing);
(7) Annual documentation of the results or certificates of compliance from a public water system required under § 112.46(a)(1) or (a)(2), if applicable;
(8) Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49; and
(9) Any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a).

Subpart F--Biological Soil Amendments of Animal Origin and Human Waste

§ 112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

(a) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water.
(b) A biological soil amendment of animal origin is untreated if it:
(1) Has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials of animal origin used to make the tea have not been so processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic *E. coli* in 100 mL of water;
(2) Has become contaminated after treatment;
(3) Has been recombined with an untreated biological soil amendment of animal origin;
(4) Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or
(5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.

§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?

(a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.

(b) You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.

(c) You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated.

§ 112.53 What prohibitions apply regarding use of human waste?

You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.

§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 112.56:

(a) A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting), or a combination of scientifically valid controlled physical, chemical and/or biological processes that has been validated to satisfy the microbial standard in § 112.55(a) for *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella* species, and *E. coli* O157:H7; or

(b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for *Salmonella* species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) include:

(1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and

(2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

§ 112.55 What microbial standards apply to the treatment processes in § 112.54?

The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.

(a) For *L. monocytogenes*, *Salmonella species*, and *E. coli* O157:H7, the relevant standards in the table in this paragraph; or

For the microorganism	The microbial standard is
(1) *L. monocytogenes*	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.
(2) *Salmonella* species	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.
(3) *E. coli* O157:H7	Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.

(b) *Salmonella* species are not detected using a method that can detect three MPN *Salmonella* species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).

§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

(a) You must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph in accordance with the application requirements specified in the second column of the table in this paragraph and the minimum application intervals specified in the third column of the table in this paragraph.

If the biological soil amendment of animal origin is	Then the biological soil amendment of animal origin must be applied	And then the minimum application interval is
(1)(i) Untreated	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application	[Reserved]
(ii) Untreated	In a manner that does not contact covered produce during or after application	0 days

(2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b).	In a manner that minimizes the potential for contact with covered produce during and after application	0 days
(3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or biological processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a).	In any manner (i.e., no restrictions)	0 days

112.60 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:

(1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that:

(i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and

(ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and

(2) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.

Subpart G--[Reserved]

Subpart H--[Reserved]

Subpart I--Domesticated and Wild Animals

§ 112.81 How do the requirements of this subpart apply to areas where covered activities take place?

(a) The requirements of this subpart apply when a covered activity takes place in an outdoor area or a partially- enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.
(b) The requirements of this subpart do not apply:
  (1) When a covered activity takes place in a fully- enclosed building; or
  (2) To fish used in aquaculture operations.

§ 112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?

(a) You must take the steps set forth in paragraph (b) of this section if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce.
(b) You must:
  (1) Assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and
  (2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.

§ 112.84 Does this regulation require covered farms to take actions that would constitute a "taking" of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?

No. Nothing in this regulation authorizes the "taking" of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531-1544) (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Subpart J--[Reserved]

Subpart K--Growing, Harvesting, Packing, and Holding Activities

§ 112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?

If you grow, harvest, pack or hold produce that is not covered in this part (i.e., excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to:

(a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and

(b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.

§ 112.112 What measures must I take immediately prior to and during harvest activities?

You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used.

§ 112.113 How must I handle harvested covered produce during covered activities?

You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards--for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil.

§ 112.114 What requirements apply to dropped covered produce?

You must not distribute dropped covered produce. Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).

§ 112.115 What measures must I take when packaging covered produce?

You must package covered produce in a manner that prevents the formation of *Clostridium botulinum* toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).

§ 112.116 What measures must I take when using food-packing (including food packaging) material?

(a) You must use food-packing material that is adequate for its intended use, which includes being:

(1) Cleanable or designed for single use; and

(2) Unlikely to support growth or transfer of bacteria.

(b) If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

Subpart L--Equipment, Tools, Buildings, and Sanitation

§ 112.121 What equipment and tools are subject to the requirements of this subpart?
Equipment and tools subject to the requirements of this subpart are those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance. Examples include knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).

§ 112.122 What buildings are subject to the requirements of this subpart?
Buildings subject to the requirements of this subpart include:

(a) Any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls; and
(b) Storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials).

§ 112.123 What general requirements apply regarding equipment and tools subject to this subpart?
All of the following requirements apply regarding equipment and tools subject to this subpart:

(a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and
(b) Equipment and tools must be:
  (1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces, and
  (2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.
(c) Seams on food contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.
(d) (1) You must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.
  (2) You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.
(e) If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you must do so in a manner that minimizes the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards.

§ 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?

Instruments or controls you use to measure, regulate, or record temperatures, hydrogen- ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be:

(a) Accurate and precise as necessary and appropriate in keeping with their purpose;
(b) Adequately maintained; and
(c) Adequate in number for their designated uses.

§ 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?

Equipment that is subject to this subpart that you use to transport covered produce must be:

(a) Adequately clean before use in transporting covered produce; and
(b) Adequate for use in transporting covered produce.

§ 112.126 What requirements apply to my buildings?

(a) All of the following requirements apply regarding buildings:
  (1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must:
    (i) Provide sufficient space for placement of equipment and storage of materials;
    (ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and
  (2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.
(b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in your buildings, as appropriate, considering the potential for such contamination through:
  (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and
  (2) Drip or condensate.

§ 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?

(a) You must take reasonable precautions to prevent contamination of covered produce, food contact surfaces, and food-packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:
  (1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food contact surfaces, or food-packing material is exposed; or
  (2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition.

(b) Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food contact surfaces, or food-packing materials.

§ 112.128 What requirements apply regarding pest control in buildings?

(a) You must take those measures reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.
(b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings.
(c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established in your buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).

§ 112.129 What requirements apply to toilet facilities?

All of the following requirements apply to toilet facilities:

(a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.
(b) Your toilet facilities must be designed, located, and maintained to:
  (1) Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;
  (2) Be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use, and be kept supplied with toilet paper; and
  (3) Provide for the sanitary disposal of waste and toilet paper.
(c) During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.

§ 112.130 What requirements apply for hand-washing facilities?

All of the following requirements apply to hand-washing facilities:

(a) You must provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities.
(b) Your hand-washing facilities must be furnished with:
  (1) Soap (or other effective surfactant);
  (2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and
  (3) Adequate drying devices (such as single service towels, sanitary towel service, or electric hand dryers).
(c) You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(d) You may not use antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water.

§ 112.131 What must I do to control and dispose of sewage?

All of the following requirements apply for the control and disposal of sewage:

(a) You must dispose of sewage into an adequate sewage or septic system or through other adequate means.

(b) You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(c) You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

(d) After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

§ 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?

All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for covered activities:

(a) You must convey, store, and dispose of trash, litter and waste to:

(1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and

(2) Protect against contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(b) You must adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity.

§ 112.133 What requirements apply to plumbing?

The plumbing must be of an adequate size and design and be adequately installed and maintained to:

(a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for hand-washing and toilet facilities.

(b) Properly convey sewage and liquid disposable waste;

(c) Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources; and

(d) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.

§ 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?

(a) If you have domesticated animals, to prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you must:
  (1) Adequately control their excreta and litter; and
  (2) Maintain a system for control of animal excreta and litter.

(b) [Reserved]

§ 112.140 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in:
  (1) Growing operations for sprouts; and
  (2) Covered harvesting, packing, or holding activities.

Subpart M--Sprouts

§ 112.141 What commodities are subject to this subpart?

The requirements of this subpart apply to growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots.

§ 112.142 What requirements apply to seeds or beans used to grow sprouts?

In addition to the requirements of this part, all of the following requirements apply to seeds or beans used to grow sprouts.

(a) You must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting.

(b) Except as provided in paragraph (c) of this section, if you know or have reason to believe that a lot of seeds or beans may be contaminated with a pathogen (either because it has been associated with foodborne illness; or based on microbial test results, including a positive finding of a pathogen in tests required under § 112.144(b)), you must:
  (1) Discontinue use of all seeds or beans from that lot for sprout production and ensure that sprouts grown from that lot of seeds or beans do not enter commerce; and
  (2) Report the information (association with illness and/or findings of microbial testing) to the seed grower, distributor, supplier, or other entity from whom you received the seeds or beans.

(c) If your reason to believe that a lot of seeds or beans may be contaminated was based only on microbial test results:
  (1) You are not required to take the steps set forth in paragraph (b)(1) of this section if you treat your lot of seeds or beans with a process that is reasonably certain to achieve destruction or elimination in the seeds or beans of the most resistant microorganisms of public health significance that are likely to occur in the seeds or beans; or
  (2) You are not required to take the steps set forth in paragraph (b)(1) and (2) of this section if you later reasonably determine, through appropriate followup actions, that the lot of

seeds or beans is not the source of contamination (e.g., the lot of seeds or beans is not the source of a pathogen found in spent sprout irrigation water or sprouts).

(d) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards.

(e) You must either:

(1) Treat seeds or beans that will be used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance; or

(2) Rely on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of the seeds or beans (whether to fulfill this requirement completely or for the purpose of considering such prior treatment when applying appropriate additional treatment of the seeds or beans at the covered farm immediately before sprouting), provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that:

(i) The prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and

(ii) The treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination.

§ 112.143 What measures must I take for growing, harvesting, packing, and holding sprouts?

You must take all of the following measures for growing, harvesting, packing, and holding sprouts:

(a) You must grow, harvest, pack, and hold sprouts in a fully-enclosed building.

(b) Any food contact surfaces you use to grow, harvest, pack, or hold sprouts must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts.

(c) You must conduct testing during growing, harvesting, packing, and holding sprouts, as specified in § 112.144.

(d) You must establish and implement a written environmental monitoring plan as specified in § 112.145.

(e) You must take certain actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment, as specified in § 112.146.

(f) You must establish and implement a written sampling plan to test spent sprout irrigation water or sprouts for pathogens as specified in § 112.147.

(g) You must take certain actions if the samples of spent sprout irrigation water or sprouts test positive for a pathogen as specified in § 112.148.

§ 112.144 What testing must I do during growing, harvesting, packing, and holding sprouts?

All of the following testing must be done during growing, harvesting, packing, and holding sprouts:

(a) You must test the growing, harvesting, packing, and holding environment for Listeria species or L. monocytogenes in accordance with the requirements of § 112.145.

(b) You must either:

(1) Test spent sprout irrigation water from each production batch of sprouts for *E. coli* O157:H7, Salmonella species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147; or

(2) If testing spent sprout irrigation water is not practicable (for example, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water), test each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing) for

E. coli O157:H7, *Salmonella* species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147.

(c) In addition to *E. coli* O157:H7 and *Salmonella* species, you must conduct tests as provided in paragraph (b) of this section for additional pathogens when the following conditions are met:
   (1) Testing for the pathogen is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts; and
   (2) A scientifically valid test method for the pathogen is available to detect the pathogen in spent sprout irrigation water (or sprouts).

§ 112.145 What requirements apply to testing the environment for Listeria species or L. monocytogenes?

All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes*.

(a) You must establish and implement a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing, or holding environment.
(b) Your written environmental monitoring plan must be directed to sampling and testing for either *Listeria* species or *L. monocytogenes*.
(c) Your written environmental monitoring plan must include a sampling plan that specifies:
   (1) What you will test collected samples for (i.e., Listeria species or L. monocytogenes);
   (2) How often you will collect environmental samples, which must be no less than monthly, and at what point during production you will collect the samples; and
   (3) Sample collection sites; the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment.
(d) You must aseptically collect environmental samples and test them for *Listeria* species or *L. monocytogenes* using a method as set forth in § 112.152.
(e) Your written environmental monitoring plan must include a corrective action plan that, at a minimum, requires you to take the actions in § 112.146, and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*.

§ 112.146 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for Listeria species or L. monocytogenes?

You must, at a minimum, take the following actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment:

(a) Conduct additional testing of surfaces and areas surrounding the area where *Listeria* species or *L. monocytogenes* was detected to evaluate the extent of the problem, including the potential for *Listeria* species or *L. monocytogenes* to have become established in a niche;
(b) Clean and sanitize the affected surfaces and surrounding areas;
(c) Conduct additional sampling and testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated;
(d) Conduct finished product testing when appropriate;

(e) Perform any other actions necessary to prevent recurrence of the contamination; and
(f) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce.

§ 112.147 What must I do to collect and test samples of spent sprout irrigation water or sprouts for pathogens?

All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts for pathogens as required in § 112.144(b):

(a) You must establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination.
(b) In accordance with the written sampling plan required under paragraph (a) of this section, you must aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for pathogens using a method as set forth in § 112.153. You must not allow the production batch of sprouts to enter into commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for *E. coli* O157:H7, *Salmonella* species, and, if applicable, a pathogen meeting the criteria in § 112.144(c).
(c) Your written sampling plan must include a corrective action plan that at a minimum, requires you to take the actions in § 112.148, and details when and how you will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in § 112.144(c).

§ 112.148 What actions must I take if the samples of spent sprout irrigation water or sprouts test positive for a pathogen?

You must, at a minimum, take the following actions if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in § 112.144(c):

(a) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce;
(b) Take the steps required in § 112.142(b) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under § 112.142(c));
(c) Clean and sanitize the affected surfaces and surrounding areas; and
(d) Perform any other actions necessary to prevent reoccurrence of the contamination.

§ 112.150 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart M in accordance with the requirements of subpart O of this part.
(b) You must establish and keep the following records:
  (1) Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment, in accordance with the requirements of § 112.142(e);

(2) Your written environmental monitoring plan in accordance with the requirements of § 112.145;
(3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of § 112.147(a) and (c);
(4) Documentation of the results of all analytical tests conducted for purposes of compliance with this subpart;
(5) Any analytical methods you use in lieu of the methods that are incorporated by reference in §§ 112.152 and 112.153; and
(6) Documentation of actions you take in accordance with §§ 112.142(b) and (c), 112.146, and 112.148.

Subpart N--Analytical Methods

§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.46?

You must test the quality of water using:

(a) The method of analysis published by the U.S. Environmental Protection Agency (EPA), "Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC), EPA-821-R-09- 007)," December, 2009. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from EPA, Office of Water (4303T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. You may inspect a copy at FDA's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202- 741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html; or

(b) (1) A scientifically valid method that is at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity; or
(2) For any other indicator of fecal contamination you may test for pursuant to § 112.49(a), a scientifically valid method.

§ 112.152 What methods must I use to test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* to satisfy the requirements of § 112.144(a)?

You must test the growing, harvesting, packing, and holding environment for Listeria species or L. monocytogenes using:

(a) The method of analysis described in "Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples," Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; FDA's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039;

http://www.fda.gov/fsma; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

(b) A scientifically valid method that is at least equivalent to the method of analysis in § 112.152(a) in accuracy, precision, and sensitivity.

§ 112.153 What methods must I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of § 112.144(b) and (c)?

You must test spent sprout irrigation water (or sprouts) from each production batch for pathogens using:

(a) For *E. coli* O157:H7, *Salmonella* species:

(1) The method of analysis described in "Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water (or Sprouts)," Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; FDA's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039; http://www.fda.gov/fsma; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

(2) A scientifically valid method that is at least equivalent to the method of analysis in § 112.153(a)(1) in accuracy, precision, and sensitivity; and

(b) For any other pathogen(s) meeting the criteria in § 112.144(c), a scientifically valid method.

Subpart O--Records

§ 112.161 What general requirements apply to records required under this part?

(a) Except as otherwise specified, all records required under this part must:

(1) Include, as applicable:

(i) The name and location of your farm;

(ii) Actual values and observations obtained during monitoring;

(iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;

(iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and

(v) The date and time of the activity documented;

(2) Be created at the time an activity is performed or observed;

(3) Be accurate, legible, and indelible; and

(4) Be dated, and signed or initialed by the person who performed the activity documented.

(b) Records required under §§ 112.7(b), 112.30(b)(2), 112.50(b)(2), 112.50(b)(4), 112.50(b)(6), 112.60(b)(2), 112.140(b)(1), 112.140(b)(2), 112.150(b)(1), 112.150(b)(4), and 112.150(b)(6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

§ 112.162 Where must I store records?

(a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.

(b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.

§ 112.163 May I use existing records to satisfy the requirements of this part?

(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

§ 112.164 How long must I keep records?

(a) (1) You must keep records required by this part for at least 2 years past the date the record was created.

(2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year.

(b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.

§ 112.165 What formats are acceptable for the records I keep?

You must keep records as:

(a) Original records;

(b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or

(c) Electronic records. Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 112.166 What requirements apply for making records available and accessible to FDA?

(a) You must have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.
(b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible.
(c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.

§ 112.167 Can records that I provide to FDA be disclosed to persons outside of FDA?

Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

Subpart P--Variances

§ 112.171 Who may request a variance from the requirements of this part?

A State, Federally- recognized tribe (or "tribe"), or a foreign country from which food is imported into the United States may request a variance from one or more requirements of this part, where the State, tribe, or foreign country determines that:

(a) The variance is necessary in light of local growing conditions; and
(b) The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.172 How may a State, tribe, or foreign country request a variance from one or more requirements of this part?

To request a variance from one or more requirements of this part, the competent authority (i.e., the regulatory authority for food safety) for a State, tribe, or a foreign country must submit a petition under § 10.30 of this chapter.

§ 112.173 What must be included in the Statement of Grounds in a petition requesting a variance?

In addition to the requirements set forth in § 10.30 of this chapter, the Statement of Grounds in a petition requesting a variance must:

(a) Provide a statement that the applicable State, tribe, or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act and to provide the same level of public health protection as the requirements of this part;

(b) Describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of this part to which the variance would apply;
(c) Present information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part.

§ 112.174 What information submitted in a petition requesting a variance or submitted in comments on such a petition are publicly available?
We will presume that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with this request.

§ 112.175 Who responds to a petition requesting a variance?
The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director, Office of Compliance, CFSAN, responds to a request for a variance.

§ 112.176 What process applies to a petition requesting a variance?
(a) In general, the procedures set forth in § 10.30 of this chapter govern our response to a petition requesting a variance.
(b) Under § 10.30(h)(3) of this chapter, we will publish a notice in the Federal Register, requesting information and views on a filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (e.g., because their farm is covered by the petition or as a person similarly situated to persons covered by the petition).
(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing and will also make public a notice on FDA's Web site announcing our decision to either grant or deny the petition.
    (1) If we grant the petition, either in whole or in part, we will specify the persons to whom the variance applies and the provision(s) of this part to which the variance applies.
    (2) If we deny the petition (including partial denials), our written response to the petitioner and our public notice announcing our decision to deny the petition will explain the reason(s) for the denial.
(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied).

§ 112.177 Can an approved variance apply to any person other than those identified in the petition requesting that variance?
A State, tribe, or a foreign country that believes that a variance requested by a petition submitted by another State, tribe, or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with § 10.30 of this chapter. These comments must include the information required in § 112.173. If FDA determines that these comments should instead be

treated as a separate request for a variance, FDA will notify the State, tribe, or foreign country that submitted these comments that a separate request must be submitted in accordance with §§ 112.172 and 112.173.

(a) If we grant a petition requesting a variance, in whole or in part, we may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition.

(b) If we specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, we will inform the applicable State, tribe, or foreign country where the similarly situated persons are located of our decision in writing and will publish a notice on our Web site announcing our decision to apply the variance to similarly situated persons in that particular location.

§ 112.178 Under what circumstances may FDA deny a petition requesting a variance?

We may deny a variance request if it does not provide the information required under § 112.173 (including the requirements of § 10.30 of this chapter), or if we determine that the variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.179 When does a variance approved by FDA become effective?

A variance approved by FDA becomes effective on the date of our written decision on the petition.

§ 112.180 Under what circumstances may FDA modify or revoke an approved variance?

We may modify or revoke a variance if we determine that such variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.181 What procedures apply if FDA determines that an approved variance should be modified or revoked?

(a) We will provide the following notifications:

(1) We will notify a State, tribe, or a foreign country directly, in writing at the address identified in its petition, if we determine that a variance granted in response to its petition should be modified or revoked. Our direct, written notification will provide the State, tribe, or foreign country with an opportunity to request an informal hearing under part 16 of this chapter.

(2) We will publish a notice of our determination that a variance should be modified or revoked in the Federal Register. This notice will establish a public docket so that interested parties may submit written comments on our determination.

(3) When applicable, we will:

(i) Notify in writing any States, tribes, or foreign countries where a variance applies to similarly situated persons of our determination that the variance should be modified or revoked;

(ii) Provide those States, tribes, or foreign countries with an opportunity to request an informal hearing under part 16 of this chapter; and

(iii)Include in the Federal Register notice described in paragraph (a)(2) of this section public notification of our decision to modify or revoke the variance granted to States, tribes, or foreign countries in which similarly situated persons are located.

(b) We will consider submissions from affected States, tribes, or foreign countries and from other interested parties as follows:
  (1) We will consider requests for hearings by affected States, tribes, or foreign countries under part 16 of this chapter.
    (i) If FDA grants a hearing, we will provide the State, tribe, or foreign country with an opportunity to make an oral submission. We will provide notice on our Web site of the hearing, including the time, date, and place of the hearing.
    (ii) If more than one State, tribe, or foreign country requests an informal hearing under part 16 of this chapter about our determination that a particular variance should be modified or revoked, we may consolidate such requests (for example, into a single hearing).
  (2) We will consider written submissions submitted to the public docket from interested parties.

(c) We will provide notice of our final decision as follows:
  (1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter.
  (2) We will publish a notice of our decision in the Federal Register. The effective date of the decision will be the date of publication of the notice.

§ 112.182 What are the permissible types of variances that may be granted?

A variance(s) may be requested for one or more requirements in subparts A through O in this part. Examples of permissible types of variances include:

(a) Variance from the microbial quality criteria when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, established in § 112.44(b);

(b) Variance from the microbial die-off rate that is used to determine the time interval between last irrigation and harvest, and/or the accompanying maximum time interval, established in § 112.45(b)(1)(i); and

(c) Variance from the approach or frequency for testing water used for purposes that are subject to the requirements of § 112.44(b), established in § 112.46(b).

Subpart Q--Compliance and Enforcement

§ 112.192 What is the applicability and status of this part?

(a) The failure to comply with the requirements of this part, issued under section 419 of the Federal Food, Drug, and Cosmetic Act, is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act.

(b) The criteria and definitions in this part apply in determining whether a food is:
  (1) Adulterated within the meaning of:
    (i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or

(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

§ 112.193 What are the provisions for coordination of education and enforcement?

Under section 419(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act, FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials by helping develop education, training, and enforcement approaches.

Subpart R--Withdrawal of Qualified Exemption

§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

(a) We may withdraw your qualified exemption under § 112.5:
  (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or
  (2) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.

(b) Before FDA issues an order to withdraw your qualified exemption, FDA:
  (1) May consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction;
  (2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and
  (3) Must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption.

§ 112.202 What procedure will FDA use to withdraw an exemption?

(a) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 112.203 What information must FDA include in an order to withdraw a qualified exemption?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 must include the following information:

(a) The date of the order;
(b) The name, address and location of the farm;
(c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order:
  (1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or
  (2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm.
(d) A statement that the farm must either:
  (1) Comply with subparts B through O of this part on the date that is 120 calendar days from the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or
  (2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 112.206.
(e) A statement that a farm may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 112.213.
(f) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act and of this subpart;
(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 112.208;
(h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and
(i) The name and the title of the FDA representative who approved the order.

§ 112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?

The owner, operator, or agent in charge of a farm that receives an order to withdraw a qualified exemption applicable to that farm under § 112.5 must either:

(a) Comply with applicable requirements of this part within 120 calendar days of the date from receipt of the order or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or
(b) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 112.206.

§ 112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?

(a) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(b) If the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order:

(1) The owner, operator, or agent in charge of the farm must comply with applicable requirements of this part within 120 calendar days from the date of receipt of the order, or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and

(2) The owner, operator, or agent in charge of the farm is no longer subject to the modified requirements in §§ 112.6 and 112.7.

§ 112.206 What is the procedure for submitting an appeal?

(a) To appeal an order to withdraw a qualified exemption applicable to a farm under § 112.5, the owner, operator, or agent in charge of the farm must:

(1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of the order; and

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in § 112.207.

§ 112.207 What is the procedure for requesting an informal hearing?

(a) If the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within 15 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, a written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial.

§ 112.208 What requirements are applicable to an informal hearing?

If the owner, operator, or agent in charge of the farm requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a) of this chapter, provides notice of the opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 112.209, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.208(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (2), (3), and (5), and § 112.208(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 112.209 Who is the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 112.210 What is the timeframe for issuing a decision on an appeal?

(a) If the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 is revoked if:

(a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

(d) Confirmation of a withdrawal order by the presiding officer is considered a final Agency action for purposes of 5 U.S.C. 702.

§ 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

(a) If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that the farm has adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or at the request of a farm, reinstate the qualified exemption.

(b) You may ask FDA to reinstate a qualified exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and
(2) Present, in writing, data and information to demonstrate that you have adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

(c) If your qualified exemption was withdrawn under § 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under § 112.5, and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your qualified exemption was withdrawn under § 112.201(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of paragraph (b) of this section.

APPENDIX II – REQUIRED RECORDS FOR THE PRODUCE SAFETY RULE

Subpart	Section	Description	Required records	112.161(b) Review, date, sign?
A	112.2(b)(2)	Processing Exemption - disclosure	Disclosure (“ not processed..)	NO
A	112.2(b)(3)	Processing exemption	Written assurances	NO
A	112.7(b)	Qualified Exemption	Records demonstrating criteria	YES, except signature
A	112.7(b)	Qualified Exemption	Written annual review/verification	YES
B	112.12(c)	Alternatives	Scientific data and information relied on	NO
C	112.30(b)(2)	Personnel Training	Date, topic, persons trained	YES
E	112.50(b)(1)	Water system inspection	Inspection findings	NO
E	112.50(b)(2)	Ag water analyses	Analysis reports	YES
E	112.50(b)(3)	Water treatment	Scientific support of adequacy of method	NO
E	112.50(b)(4)	Water treatment	Monitoring records	YES
E	112.50(b)(5)	Time interval / removal rate	Scientific support	NO
E	112.50(b)(6)	Time interval / removal rate	Monitoring records	YES

E	112.50(b)(7)	Public water system	Annual certificate	NO
E	112.50(b)(8)	Alternatives	Scientific support	NO
E	112.50(b)(9)	Water Analysis Method	Non-PSR analytical methods	NO
F	112.60(b)(1)	Treated BSA from 3rd party	Documentation that process is scientifically valid and monitored; and BSAOA was handled to minimize contamination	NO
F	112.60(b)(2)	Treatment of BSA on farm	Process monitoring (time, temperature, turn)	YES
L	112.140(b)(2)	Equipment cleaning and sanitize	Date and method of cleaning and sanitizing equipment used for harvest, pack, hold	YES

APPENDIX III: DEPARTMENT OF LABOR- TITLE 29

29 CFR 1910 - Occupational Safety and Health Standards

1910 Subpart J – General Environmental Controls
1910.141 - SANITATION

1910.141(a)
General --

1910.141(a)(1)
Scope. This section applies to permanent places of employment.

1910.141(a)(2)
Definitions applicable to this section.

Nonwater carriage toilet facility, means a toilet facility not connected to a sewer.

Number of employees, means unless otherwise specified, the maximum number of employees present at any one time on a regular shift.

Personal service room, means a room used for activities not directly connected with the production or service function performed by the establishment. Such activities include, but are not limited to, first-aid, medical services, dressing, showering, toilet use, washing, and eating.

Potable water means water that meets the standards for drinking purposes of the State or local authority having jurisdiction, or water that meets the quality standards prescribed by the U.S. Environmental Protection Agency's National Primary Drinking Water Regulations (40 CFR 141).

Toilet facility, means a fixture maintained within a toilet room for the purpose of defecation or urination, or both.

Toilet room, means a room maintained within or on the premises of any place of employment, containing toilet facilities for use by employees.

Toxic material, means a material in concentration or amount which exceeds the applicable limit established by a standard, such as 1910.1000 and 1910.1001 or, in the absence of an applicable standard, which is of such toxicity so as to constitute a recognized hazard that is causing or is likely to cause death or serious physical harm.

Urinal, means a toilet facility maintained within a toilet room for the sole purpose of urination.

Water closet, means a toilet facility maintained within a toilet room for the purpose of both defecation and urination and which is flushed with water.

Wet process, means any process or operation in a workroom which normally results in surfaces upon which employees may walk or stand becoming wet.

1910.141(a)(3)
Housekeeping.

1910.141(a)(3)(i)
All places of employment shall be kept clean to the extent that the nature of the work allows.

1910.141(a)(3)(ii)
The floor of every workroom shall be maintained, so far as practicable, in a dry condition. Where wet processes are used, drainage shall be maintained and false floors, platforms, mats, or other dry standing places shall be provided, where practicable, or appropriate waterproof footgear shall be provided.

1910.141(a)(3)(iii)
To facilitate cleaning, every floor, working place, and passageway shall be kept free from protruding nails, splinters, loose boards, and unnecessary holes and openings.

1910.141(a)(4)
Waste disposal.

1910.141(a)(4)(i)
Any receptacle used for putrescible solid or liquid waste or refuse shall be so constructed that it does not leak and may be thoroughly cleaned and maintained in a sanitary condition. Such a receptacle shall be equipped with a solid tight-fitting cover, unless it can be maintained in a sanitary condition without a cover. This requirement does not prohibit the use of receptacles which are designed to permit the maintenance of a sanitary condition without regard to the aforementioned requirements.

1910.141(a)(4)(ii)
All sweepings, solid or liquid wastes, refuse, and garbage shall be removed in such a manner as to avoid creating a menace to health and as often as necessary or appropriate to maintain the place of employment in a sanitary condition.

1910.141(a)(5)
Vermin control. Every enclosed workplace shall be so constructed, equipped, and maintained, so far as reasonably practicable, as to prevent the entrance or harborage of rodents, insects, and other vermin. A continuing and effective extermination program shall be instituted where their presence is detected.

1910.141(b)

Water supply.

1910.141(b)(1)
Potable water.

1910.141(b)(1)(i)
Potable water shall be provided in all places of employment, for drinking, washing of the person, cooking, washing of foods, washing of cooking or eating utensils, washing of food preparation or processing premises, and personal service rooms.

1910.141(b)(1)(ii)
[Reserved]

1910.141(b)(1)(iii)
Portable drinking water dispensers shall be designed, constructed, and serviced so that sanitary conditions are maintained, shall be capable of being closed, and shall be equipped with a tap.

1910.141(b)(1)(iv)
[Reserved]

1910.141(b)(1)(v)
Open containers such as barrels, pails, or tanks for drinking water from which the water must be dipped or poured, whether or not they are fitted with a cover, are prohibited.

1910.141(b)(1)(vi)
A common drinking cup and other common utensils are prohibited.

1910.141(b)(2)
Nonpotable water.

1910.141(b)(2)(i)
Outlets for nonpotable water, such as water for industrial or firefighting purposes, shall be posted or otherwise marked in a manner that will indicate clearly that the water is unsafe and is not to be used for drinking, washing of the person, cooking, washing of food, washing of cooking or eating utensils, washing of food preparation or processing premises, or personal service rooms, or for washing clothes.

1910.141(b)(2)(ii)
Construction of nonpotable water systems or systems carrying any other nonpotable substance shall be such as to prevent backflow or backsiphonage into a potable water system.

1910.141(b)(2)(iii)
Nonpotable water shall not be used for washing any portion of the person, cooking or eating utensils, or clothing. Nonpotable water may be used for cleaning work premises, other than food processing and preparation premises and personal service rooms: Provided, That this

nonpotable water does not contain concentrations of chemicals, fecal coliform, or other substances which could create unsanitary conditions or be harmful to employees.

1910.141(c)
Toilet facilities.

1910.141(c)(1)
General.

1910.141(c)(1)(i)
Except as otherwise indicated in this paragraph (c)(1)(i), toilet facilities, in toilet rooms separate for each sex, shall be provided in all places of employment in accordance with table J-1 of this section. The number of facilities to be provided for each sex shall be based on the number of employees of that sex for whom the facilities are furnished. Where toilet rooms will be occupied by no more than one person at a time, can be locked from the inside, and contain at least one water closet, separate toilet rooms for each sex need not be provided. Where such single-occupancy rooms have more than one toilet facility, only one such facility in each toilet room shall be counted for the purpose of table J-1.

Number of employees	Minimum number of water closets[1]
1 to 15	1
16 to 35	2
36 to 55	3
56 to 80	4
81 to 110	5
111 to 150	6
Over 150	([2])

[1]Where toilet facilities will not be used by women, urinals may be provided instead of water closets, except that the number of water closets in such cases shall not be reduced to less than 2/3 of the minimum specified.
[2]1 additional fixture for each additional 40 employees.

1910.141(c)(1)(ii)
The requirements of paragraph (c)(1)(i) of this section do not apply to mobile crews or to normally unattended work locations so long as employees working at these locations have transportation immediately available to nearby toilet facilities which meet the other requirements of this subparagraph.

1910.141(c)(1)(iii)
The sewage disposal method shall not endanger the health of employees.

1910.141(c)(2)
Construction of toilet rooms.
1910.141(c)(2)(i)

Each water closet shall occupy a separate compartment with a door and walls or partitions between fixtures sufficiently high to assure privacy.

1910.141(d)
Washing facilities.

1910.141(d)(1)
General. Washing facilities shall be maintained in a sanitary condition.

1910.141(d)(2)
Lavatories.

1910.141(d)(2)(i)
Lavatories shall be made available in all places of employment. The requirements of this subdivision do not apply to mobile crews or to normally unattended work locations if employees working at these locations have transportation readily available to nearby washing facilities which meet the other requirements of this paragraph.

1910.141(d)(2)(ii)
Each lavatory shall be provided with hot and cold running water, or tepid running water.

1910.141(d)(2)(iii)
Hand soap or similar cleansing agents shall be provided.

1910.141(d)(2)(iv)
Individual hand towels or sections thereof, of cloth or paper, air blowers or clean individual sections of continuous cloth toweling, convenient to the lavatories, shall be provided.

1910.141(d)(3)
Showers.

1910.141(d)(3)(i)
Whenever showers are required by a particular standard, the showers shall be provided in accordance with paragraphs (d)(3)(ii) through (v) of this section.

1910.141(d)(3)(ii)
One shower shall be provided for each 10 employees of each sex, or numerical fraction thereof, who are required to shower during the same shift.

1910.141(d)(3)(iii)
Body soap or other appropriate cleansing agents convenient to the showers shall be provided as specified in paragraph (d)(2)(iii) of this section.

1910.141(d)(3)(iv)
Showers shall be provided with hot and cold water feeding a common discharge line.

1910.141(d)(3)(v)
Employees who use showers shall be provided with individual clean towels.

1910.141(e)
Change rooms. Whenever employees are required by a particular standard to wear protective clothing because of the possibility of contamination with toxic materials, change rooms equipped with storage facilities for street clothes and separate storage facilities for the protective clothing shall be provided.

1910.141(f)
Clothes drying facilities. Where working clothes are provided by the employer and become wet or are washed between shifts, provision shall be made to insure that such clothing is dry before reuse.

1910.141(g)
Consumption of food and beverages on the premises.

1910.141(g)(1)
Application. This paragraph shall apply only where employees are permitted to consume food or beverages, or both, on the premises.

1910.141(g)(2)
Eating and drinking areas. No employee shall be allowed to consume food or beverages in a toilet room nor in any area exposed to a toxic material.

1910.141(g)(3)
Waste disposal containers. Receptacles constructed of smooth, corrosion resistant, easily cleanable, or disposable materials, shall be provided and used for the disposal of waste food. The number, size, and location of such receptacles shall encourage their use and not result in overfilling. They shall be emptied not less frequently than once each working day, unless unused, and shall be maintained in a clean and sanitary condition. Receptacles shall be provided with a solid tight-fitting cover unless sanitary conditions can be maintained without use of a cover.

1910.141(g)(4)
Sanitary storage. No food or beverages shall be stored in toilet rooms or in an area exposed to a toxic material.

1910.141(h)
Food handling. All employee food service facilities and operations shall be carried out in accordance with sound hygienic principles. In all places of employment where all or part of the food service is provided, the food dispensed shall be wholesome, free from spoilage, and shall be processed, prepared, handled, and stored in such a manner as to be protected against contamination.

[39 FR 23502, June 27, 1974, as amended at 40 FR 18446, April 28, 1975; 40 FR 23073, May 28, 1975; 43 FR 49748, Oct. 24, 1978; 63 FR 33450, June 18, 1998; 76 FR 33607, June 8, 2011]

1910 Subpart K – Medical and First Aid

1910.151 Medical Services and first aid

1910.151(a)

The employer shall ensure the ready availability of medical personnel for advice and consultation on matters of plant health.

1910.151(b)

In the absence of an infirmary, clinic, or hospital in near proximity to the workplace which is used for the treatment of all injured employees, a person or persons shall be adequately trained to render first aid. Adequate first aid supplies shall be readily available.

1910.151(c)

Where the eyes or body of any person may be exposed to injurious corrosive materials, suitable facilities for quick drenching or flushing of the eyes and body shall be provided within the work area for immediate emergency use.

[63 FR 33450, June 18, 1998]

Appendix A to Sec. 1910.151--First aid kits (Non-Mandatory)

First aid supplies are required to be readily available under paragraph § 1910.151(b). An example of the minimal contents of a generic first aid kit is described in American National Standard (ANSI) Z308.1-1998 "Minimum Requirements for Workplace First-aid Kits." The contents of the kit listed in the ANSI standard should be adequate for small worksites. When larger operations or multiple operations are being conducted at the same location, employers should determine the need for additional first aid kits at the worksite, additional types of first aid equipment and supplies and additional quantities and types of supplies and equipment in the first aid kits.

In a similar fashion, employers who have unique or changing first-aid needs in their workplace may need to enhance their first-aid kits. The employer can use the OSHA 300 log, OSHA 301 log, or other reports to identify these unique problems. Consultation from the local fire/rescue department, appropriate medical professional, or local emergency room may be helpful to employers in these circumstances. By assessing the specific needs of their workplace, employers can ensure that reasonably anticipated supplies are available. Employers should assess the specific needs of their worksite periodically and augment the first aid kit appropriately.

If it is reasonably anticipated that employees will be exposed to blood or other potentially infectious materials while using first aid supplies, employers are required to provide appropriate personal protective equipment (PPE) in compliance with the provisions of the Occupational Exposure to

Blood borne Pathogens standard, § 1910.1030(d)(3) (56 FR 64175). This standard lists appropriate PPE for this type of exposure, such as gloves, gowns, face shields, masks, and eye protection.

[63 FR 33450, June 18, 1998; 70 FR 1141, Jan. 5, 2005; 76 FR 80739, Dec. 27, 2011]

29 CFR 1928 Occupational Safety and Health Standards for Agriculture

1928 Subpart I – General Environmental Controls

1928.110 – FIELD SANITATION

1928.110(a)

Scope. This section shall apply to any agricultural establishment where eleven (11) or more employees are engaged on any given day in hand-labor operations in the field.

1928.110(b)

Definitions.

Agricultural employer means any person, corporation, association, or other legal entity that:

[i] Owns or operates an agricultural establishment;

[ii] Contracts with the owner or operator of an agricultural establishment in advance of production for the purchase of a crop and exercises substantial control over production; or

[iii] Recruits and supervises employees or is responsible for the management an condition of an agricultural establishment.

Agricultural establishment is a business operation that uses paid employees in the production of food, fiber, or other materials such as seed, seedlings, plants, or parts of plants.

Hand-labor operations means agricultural activities or agricultural operations performed by hand or with hand tools. Except for purposes of paragraph (c)(2)(iii) of this section, "hand labor operations" also include other activities or operations performed in conjunction with hand labor in the field. Some examples of "hand labor operations" are the hand-cultivation, hand-weeding, hand-planting and hand-harvesting of vegetables, nuts, fruits, seedlings or other crops, including mushrooms, and the hand packing of produce into containers, whether done on the ground, on a moving machine or in a temporary packing shed located in the field. "Hand-labor" does not include such activities as logging operations, the care or feeding of livestock, or hand-labor operations in permanent structures (e.g., canning facilities or packing houses).

Handwashing facility means a facility providing either a basin, container, or outlet with an adequate supply of potable water, soap and single-use towels.

Potable water means water that meets the standards for drinking purposes of the State or local authority having jurisdiction, or water that meets the quality standards prescribed by the U.S.

Environmental Protection Agency's National Primary Drinking Water Regulations (40 CFR part 141).

Toilet facility means a fixed or portable facility designed for the purpose of adequate collection and containment of the products of both defecation and urination which is applied with toilet paper adequate to employee needs. Toilet facility includes biological, chemical, flush and combustion toilets and sanitary privies.

1928.110(c)
Requirements. Agricultural employers shall provide the following for employees engaged in hand-labor operations in the field, without cost to the employee:

1928.110(c)(1)
Potable drinking water.

1928.110(c)(1)(i)
Potable water shall be provided and placed in locations readily accessible to all employees.

1928.110(c)(1)(ii)
The water shall be suitably cool and in sufficient amounts, taking into account the air temperature, humidity and the nature of the work performed, to meet the needs of all employees.

1928.110(c)(1)(iii)
The water shall be dispensed in single-use drinking cups or by fountains. The use of common drinking cups or dippers is prohibited.

1928.110(c)(2)
Toilet and handwashing facilities.

1928.110(c)(2)(i)
One toilet facility and one handwashing facility shall be provided for each (20) employees or fraction thereof, except as stated in paragraph (c)(2)(v) of this section.

1928.110(c)(2)(ii)
Toilet facilities shall be adequately ventilated, appropriately screened, have self-closing doors that can be closed and latched from the inside and shall be constructed to insure privacy.

1928.110(c)(2)(iii)
Toilet and handwashing facilities shall be accessibly located an in close proximity to each other. The facilities shall be located within a one-quarter-mile walk of each hand laborer's place of work in the field.

1928.110(c)(2)(iv)
Where due to terrain it is not feasible to locate facilities as required above, the facilities shall be located at the point closest vehicular access.

1928.110(c)(2)(v)

Toilet and handwashing facilities are not required for employees who perform field work for a period of three (3) hours or less (including transportation time to and from the field) during the day.

1928.110(c)(3)
Maintenance. Potable drinking water and toilet and handwashing facilities shall be maintained in accordance with appropriate public health sanitation practices, including the following:

1928.110(c)(3)(i)
Drinking water containers shall be constructed of materials that maintain water quality, shall be refilled daily or more often as necessary, shall be kept covered and shall be regularly cleaned.

1928.110(c)(3)(ii)
Toilet facilities shall be operational and maintained in clean and sanitary condition.

1928.110(c)(3)(iii)
Handwashing facilities shall be refilled with potable water as necessary to ensure an adequate supply and shall be maintained in a clean and sanitary condition; and

1928.110(c)(3)(iv)
Disposal of wastes from facilities shall not cause unsanitary conditions.

1928.110(c)(4)
Reasonable use. The employer shall notify each employee of the location of the sanitation facilities and water and shall allow each employee reasonable opportunities during the workday to use them. The employer also shall inform each employee of the importance of each of the following good hygiene practices to minimize exposure to the hazards in the field of heat, communicable diseases, retention of urine and agrichemical residues.

1928.110(c)(4)(i)
Use the water and facilities provided for drinking, handwashing and elimination.

1928.110(c)(4)(ii)
Drink water frequently and especially on hot days;

1928.110(c)(4)(iii)
Urinate as frequently as necessary;

1928.110(c)(4)(iv)
Wash hands both before and after using the toilet; and

1928.110(c)(4)(v)
Wash hands before eating and smoking.

1928.110(d)
Dates -

1928.110(d)(1)
Effective Date. This standard shall take effect on May 30, 1987.

1928.110(d)(2)
Startup Dates. Employers must comply with the requirements of paragraphs:

1928.110(d)(2)(i)
Paragraph (c)(1), to provide potable drinking water, by May 30, 1987;

1928.110(d)(2)(ii)
Paragraph (c)(2), to provide handwashing and toilet facilities, by July 30, 1987;

1928.110(d)(2)(iii)
Paragraph (c)(3), to provide maintenance for toilet and handwashing facilities, by July 30, 1987; and

1928.110(d)(2)(iv)
Paragraph (c)(4), to assure reasonable use, by July 30, 1987.

[52 FR 16095, May 1, 1987; 76 FR 33612, June 8, 2011]

APPENDIX IV: FDA & INDUSTRY GUIDANCE DOCUMENTS

FDA Guidance Documents

- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (February 2008)
- Reducing Microbial Food Safety Hazards For Sprouted Seeds (June 2019)
- Sampling And Microbial Testing Of Spent Irrigation Water During Sprout Production (October 1999)
- Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Pistachio-Derived Product As An Ingredient (June 2009)
- Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Peanut-Derived Product as an Ingredient (March 2009)

FDA Draft Guidance Documents

- Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (October 2018)
- Draft Guidance for Industry: Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations (January 2017)

Industry Guidance in Collaboration with FDA

- Commodity Specific Food Safety Guidelines for the Production, Harvest, Storage, and Packing of Potatoes (June 2013)
- Commodity-Specific Food Safety Guidelines for Cantaloupes and Netted Melons (March 2013)
- Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Processing Unit Operations of Fresh Culinary Herbs (January 2013)
- Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Valued-Added Unit Operations of Green Onions (February 2010)
- Commodity Specific Food Safety Guidelines for the Melon Supply Chain, 1st Edition (November 2005)
- Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, 3rd Edition (September 2018)
- Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain, 1st Edition (April 2006)

APPENDIX V: REQUIRED COMMENTS FOR AUDIT REPORTS

Auditors are required to include comments in the audit report to give a clear understanding of what is observed at the time of the audit. All findings related to any question answered CAN or IAR must be documented in the comment section of the checklist. Auditors may document observations associated with any question on the checklist regardless of whether it is a non-conformity to clarify why a question was answered compliant. Write a comment for each question answered N/A explaining the rationale for that answer.

The following table is a minimum requirement to ensure that auditors provide uniform baseline information on the following requirements. Each audit is a unique situation. Auditors must include additional relevant information as it pertains to any of the requirements to increase the understanding of what is observed at the time of the audit.

Req. #	Complete comments are required. Address the following in your comments.
G-1.1	
G-1.1.a	
G-1.2	Include the name(s) of the individual(s) responsible for the Food Safety Plan with their roles/responsibilities.
G-1.2.a	
G-1.3	
G-2.1	Include the date and/or version of the current Food Safety Plan being audited.
G-2.2	Include the date the Food Safety Plan was last reviewed. If Not Applicable is selected, include that the plan is less than a year old.
G-2.2.a	
G-2.3	Include the date of current approved supplier list.
G-2.3.a	
G-2.3.b	
G-2.3.c	
G-3.1	
G-3.2	
G-3.3	If Not Applicable is selected, include that the business or Food Safety Plan has been in operation for less than two years.
G-3.3.a	
G-4.1	Include the title and topics covered by training and specify the records that show training is current as of the date of the audit.
G-4.2	Include training and/or certifications received which are applicable.
G-4.3	
G-5.1	Include the name of the lab. If the lab is accredited, include the type of accreditation.
G-5.2	
G-5.3	Include the type of testing required (e.g., soil, water, or Adenosine triphosphate (ATP) swabbing) and the testing method.
G-5.4	If thresholds are exceeded, state the operation's threshold criteria, the test results, and what actions are taken based on the results.

Req. #	Complete comments are required. Address the following in your comments.
G-6.1	
G-6.1.a	
G-6.1.b	
G-6.2	Include the date and product(s) of last traceback and trace-forward exercise, and the effectiveness of the reconciliation within the four hours or as required.
G-7.1	Include the date of the last actual recall or mock recall.
G-8.1	
G-8.1.a	
G-8.1.b	Include there are no incidences to document if the auditee states this during the audit.
G-8.1.c	Include the date of the annual review and the date of the actual incident or mock incident exercise.
G-8.2	
G-9.1	Include the date and the role/title of the person who performed the annual self-audit.
G-10.1	
G-10.2	
G-10.3	
G-10.4	
G-10.5	If operation is disposing of used toilet tissue in trash receptacles describe the reason and state mitigation measures taken to include monitoring and cleaning frequencies.
G-10.6	
G-10.7	
G-10.8	
G-10.9	
G-10.10	
G-10.11	Include if gloves are used, are optional, or not used. If gloves are used include the type of gloves and confirm the operation has a policy to sanitarily/safely use gloves.
G-10.12	
G-10.13	
G-10.14	
G-10.15	
G-10.16	
G-10.17	
G-10.18	Include the drinking water source (i.e., municipal, bottled, well).
G-10.19	
G-10.20	
G-10.21	
G-10.22	
G-11.1	
G-11.2	

Req. #	Complete comments are required. Address the following in your comments.
G-12.1	
G-12.2	
G-12.3.a	Include the date the food defense assessment was conducted.
G-12.3.b	
G-13.1.a	Include the date the food fraud assessment was conducted.
G-13.1.b	
F-1.1	Include the date and the role/title of the person who conducted the last assessment.
F-1.1.a	Include the date and the role/title of the person who conducted the last assessment.
F-1.1.b	
F-1.2	
F-1.3	
F-2.a	
F-2.1	
F-2.1.a	
F-2.1.b	
F-2.1.c	
F-2.1.d	
F-2.2	
F-2.3	Include the applicator and/or personnel name, license number and expiration date.
F-2.3.a	
F-2.4	Include water source used for agricultural chemical sprays. If applicable, include mitigation methods.
F-2.4.a	
F-2.5	
F-2.5.a	
F-3.1	
F-3.2	
F-3.3	
F-4.1	Include the date and the role/title of the person who conducted the last assessment.
F-5.1	
F-5.2	Include frequency of testing and threshold criteria for water test results.
F-5.3	Include the water test dates, water application method (i.e., drip, overhead, furrow) and source (i.e., well, surface, municipal). Include target organism and present/absent or quantified number from most recent water test results.
F-5.4	If water is treated, include treatment method, for chemical include chemical name with EPA Reg. No.
F-5.5	If post-harvest handling is used, include the die-off or removal rate, time interval, log reduction and dates relevant to these activities.
F-5.6	
F-6.1	Include the date and the role/title of the person who conducted the last assessment.
F-6.2	
F-6.3	
F-7.1	Include the date and the role/title of the person who conducted the last assessment.

Req. #	Complete comments are required. Address the following in your comments.
F-7.2	
F-8.1	
F-8.2	
F-8.2.a	
F-8.2.b	Include the recognized standards used for calibration.
F-8.2.c	
F-8.3	
F-8.4	
F-8.5	
F-8.6	
F-8.7	
F-9.1	Include the date and the role/title of the person who conducted the pre-harvest risk assessment.
F-10.1	
F-10.2	Include the water source for harvest operation and the water's test results.
F-10.3	Include the type of antimicrobial treatment used and the parameters of use (i.e., ranges of pH, ppm free chlorine).
F-10.4	
F-10.5	If the commodity is susceptible to microbial infiltration, include the required temperature differential.
F-11.1	
F-11.2	
F-11.3	
F-11.4	
F-12.1	
F-12.2	Include the type of growing method and if the product grown in contact with the ground (e.g., tomatoes staked or vine grown).
F-12.3	
F-12.4	If used, include the type of cloth, towel, or other cleaning material and procedure for preventing cross contamination.
F-12.5	
F-12.6	
F-12.7	
F-12.8.a	
F-13.1	
F-13.1.a	
F-13.2	
F-14.1	
F-14.2	
P-1.1	
P-2.1	
P-2.2	
P-2.3	

Req. #	Complete comments are required. Address the following in your comments.
P-3.1	Include the date and the role/title of the person who conducted the most recent hazard analysis.
P-3.1.a	
P-3.2	
P-3.3	
P-3.4	
P-3.5	
P-3.6	
P-4.1	Include who manages the pest/animal control program.
P-4.2	
P-4.3	
P-5.1	
P-5.2	
P-5.3	
P-5.4	Include the instruments/equipment being calibrated, the method of calibration and the frequency of calibration.
P-5.4.a	Include the recognized standards used for calibration.
P-5.5	
P-5.5.a	If metal detection equipment is used, include the frequency the equipment is being checked.
P-6.1	
P-6.2	
P-6.3	
P-6.4	
P-6.5	
P-6.5.a	
P-6.6	
P-6.7	
P-6.8	
P-6.9	
P-6.10	
P-6.11	
P-7.1	
P-7.2	Include frequency of water delivery system assessment.
P-7.3	Include the water source for post-harvest operation and the water's test results.
P-7.4	Include a description of the washing process identifying the type of wash system and type of sanitizer used for each product.
P-7.5	Include the frequency of microbial, physical, or chemical testing monitoring.
P-7.6	
P-7.7	
P-7.8	Include the type of antimicrobial treatment used and the concentration/critical limits.

Req. #	Complete comments are required. Address the following in your comments.
P-7.9	If the commodity is susceptible to microbial infiltration, include the required temperature differential.
P-7.10	Include the frequency of the re-used water change schedule for each commodity.
P-7.11	
P-8.1	
P-8.2	
P-8.3	
P-8.4	
P-8.5	
P-8.6	
P-8.7	
P-8.8	
P-8.9	
P-9.1	
P-9.2	
P-9.3	
P-9.4	
P-9.4.a	
P-9.5	
P-9.6	
P-9.7	If temperature control is required, list the temperature range for each commodity.
P-9.8	
P-9.9	Include the date last maintenance or cleaning was conducted on the cooling equipment.
P-10.1	If refrigerated transport temperature control is required, list the temperature range for each commodity.
P-10.2	
P-10.3	
P-10.4	
P-10.5	
P-10.6	

APPENDIX VI: REFERENCES USED FOR MANUAL DEVELOPMENT

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APPENDIX VII: SUMMARY OF REFERENCE LINKS IN PROGRAM MANUAL

21 CFR 58:
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-58

40 CFR 160:
https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-160

40 CFR 792:
https://www.ecfr.gov/current/title-40/chapter-I/subchapter-R/part-792

Bacteriological Analytical Manual (BAM):
http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm

AOAC International:
https://www.aoac.org/

Emergency Exemption Database:
https://iaspub.epa.gov/apex/pesticides/f?p=124:2::::::

FDA Bioresearch Monitoring Information:
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-bioresearch-monitoring-information

FDA Food Allergies:
https://www.fda.gov/food/food-labeling-nutrition/food-allergies

Good Laboratory Practices Standards Compliance Monitoring Program:
https://www.epa.gov/compliance/good-laboratory-practices-standards-compliance-monitoring-program

Mushroom Good Agricultural Practices Program Guidelines:
https://www.americanmushroom.org/clientuploads/Food_Safety/MGAP_All_Species_2016.pdf

Organization for Economic Co-operation and Development (OECD):
http://www.oecd.org/

Produce Safety Alliance General Resource Listing:
https://producesafetyalliance.cornell.edu/resources/general-resource-listing/

International Fresh Produce GAPs Harmonization Initiative website:
https://www.freshproduce.com/resources/food-safety/produce-gaps-harmonized-audit-standard/

USDA GAP & GHP website:
https://www.ams.usda.gov/services/auditing/gap-ghp

Guidance on Environmental Monitoring and Control of Listeria for the Fresh Produce Industry:
https://www.freshproduce.com/siteassets/files/reports/food-safety/guidance-on-environmental-monitoring-and-control-of-listeria.pdf