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Marketing and Regulatory Programs

Agricultural Marketing Service

Specialty Crops Program

Specialty Crops Inspection Division

AIM Inspection Series

Auditor Manual

Produce GAPs Harmonized Food Safety Audit Program

Policies and Procedures

February 2016

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Auditor Manual – Produce GAPs Harmonized Food Safety Audit Program
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INTRODUCTION

This manual is designed to help auditors interpret and apply the Produce Good Agricultural Practices (GAPs) Harmonized Food Safety Standards and the U.S. Department of Agriculture's (USDA) Produce GAPs Harmonized Food Safety 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 on an annual basis, to reflect current GAPs. Submit any recommended changes via email to the SCI Division's Audit Services Branch at FVAudits@ams.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: http://agnis/sites/FV/PPB/AIM/default.aspx.

When accessed electronically, AIM materials have hyperlinks and hypertext (visible as underlined blue text). Clicking on a hyperlink takes the reader to a website with information relating to the subject. Hypertext links take 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 your version of Adobe Reader. PDF documents are searchable for content within a document or within multiple documents. To learn about PDF search options:

- Click on the "Help" tab on the top of any page in Adobe Acrobat,
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- Type the word "Search" in the "Search" box, and click on the "Search" button,
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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 on site. 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 to 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 United Fresh Produce Association (United 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.

Any organization may use and link to the official versions of standards, which are freely accessible on the United Fresh website. The standards may only be used verbatim. 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 2012, USDA added an optional Global Markets Addendum to the USDA Produce GAPs checklists that may be assessed at the request of the auditee.

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 Audits 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 for the FPB 702 Unannounced Verification Review for GAP&GHP.

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 FPB 08-02 Instructions for the Corrective Action Process in the Good Agricultural Practices and Good Handling Practices (GAP&GHP) Audit Verification Program, 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

There are two standards used for Produce GAPs Harmonized Food Safety Standard Audits: the "Field Operations and Harvesting Harmonized Food Safety Standard" and the "Post-harvest Operations Harmonized Food Safety Standard." The official versions of these standards are posted on the United Fresh Produce GAPs Harmonization Initiative website at http://www.unitedfresh.org/food-safety/gap-harmonization-initiative. Before conducting an audit, auditors must check this website prior to conducting an audit to verify they have the most current version of, and are familiar with, the standards.

Each standard contains requirements and their corresponding procedures, verifications, and corrective actions. 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. The corrective action details the action that may be necessary to rectify when identified deficiencies.

CHECKLISTS

There are two USDA checklists for the Produce GAPs Harmonized Food Safety Standard Audits" the "Produce GAPs Harmonized Food Safety Standard Field Operations and Harvesting-USDA Checklist" and the "Produce GAPs Harmonized Food Safety Standard Post-harvest Operations-USDA Checklist." The official copies of the USDA checklists are posted on the USDA Good Agricultural Practices Audit Programs website at www.ams.usda.gov/gapghp. 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, Other Information, Additional Comments, Internal Use Only, Auditor Completion Instructions, Auditee Information, USDA Acceptance Criteria, Acceptance Criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment, the Audit Summary, the body of the checklist for each standard, the Global Markets Addendum, 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. 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?

Mark 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

Mark 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. Company Contact

List the person that 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.

E. Contact Title

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

F. 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).

G. Fax Number

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

H. 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.

I. 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.

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. Date and Time of the Audit

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.

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 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. Contractors used

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

D. Crops Covered by Audit

List all crops covered by the audit.

E. Crops Produced During Audit

List all crops that are covered by the audit and are in production at the time of the audit.

F. Send Certificate To

Indicate either (1) the inspection office and list the office to which the certificate should be mailed (this may or may not be the same office of the lead auditor) or (2) directly to auditee.

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 with the lead auditors name appearing first.

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 office of record. The lead auditor's signature should appear first on the file copy.

Other Information

This section of the audit report contains the following information that is pertinent to the audit.

A. Person(s) Interviewed

Record the first and last name of each person interviewed. As many workers go by a legal name and a "nickname," the auditor must use the name the employee uses on all operational paperwork. This will allow the auditor to make additional accurate verification of other documents, such as training records, during the audit.

B. Audit Report 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. The audit report can only be distributed to another person or company besides the auditee upon written request from the auditee to the auditor. The request must specify that the report can be released to the third party.

* It isn't 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 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

Mark 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 Global Markets Addendum or 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, but 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, and the presence or evidence of rodents and an excessive amount 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.

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. Use of the Global Markets Addendum

Assess the Global Markets Addendum only at the specific request of the auditee, as it is not an official part of the Produce GAPs Harmonized Food Safety Standard.

F. Submittal of the Audit Report for Review

Submit the Checklist (Excel file), the signed Agreement for Participation in Audit Verification Programs (FV-651), and the Request for Audit Services (FV-237A) to FVAudits@ams.usda.gov in accordance with the guidelines in the SCI Division Auditor Manual (In Development). Ensure the most recent FV-651 is on file before or during the opening meeting for the audit. The auditee can use the same FV-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), 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, or both.

A. Policies and Procedures

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

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 a deviation 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 proof of falsified records any time during the audit, contact your immediate supervisor for further instructions. Falsification of records is

considered an egregious offense and will lead to an Immediate Action Required for the audit.

Auditee Information

This section of the Audit Checklist is designed to provide information to the auditee about the Produce GAPs Harmonized Food Safety Standard 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, but you should verify them for accuracy upon completion of the audit to ensure that all questions were answered and recorded properly. List the number of any question 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 in the Field Operations and Harvesting, or the Post-Harvest Activities, audit checklists. This manual also includes example scenarios that provide guidance on how to interpret various situations you may encounter.

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 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.

If you may apply either the requirements in the standards or prevailing or applicable regulations, apply whichever guidance is more stringent. For example, Requirement 1.3.3 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.

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 III: 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.

FIELD OPERATIONS AND HARVESTING

USDA Acceptance Criteria

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	Questions 1.1.1; 1.1.2; 1.2.1; 1.6.1; 1.7.1; and 2.3.1 must be assessed as "compliant."
4	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.
5	Operation must have performed a risk assessment as addressed in Questions 2.1.1, 2.4.2.1, 2.5.1, 2.6.1, and 3.1.1 in the Harmonized Standard as well as Question 5.1.11 in the Global Markets section, if this section is covered by scope of audit.
6	In each major section (1 through 4) of the audit, at least 80% of the questions not answered as "N/A" must be answered as compliant.
7	If a major section has less than 5 questions, one "CAN" can be assessed and still meet the minimum acceptance criteria.

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 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 nonconformance 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 Criteria for Global Markets Primary Production Addendum

In addition to the USDA acceptance criteria, growers utilizing this audit to meet Global Markets Program for Primary Production Basic or Intermediate Level Assessment requirements must meet the following additional criteria, which are listed as major elements within the Global Markets Capacity Building Program for Primary Production. The auditor shall only assess the Global Markets addendum at the specific request of the auditee. This portion of the audit is not an official part of the Produce GAPs Harmonized Food Safety Standards.

The Global Markets Capacity Building Program for Primary Production has two levels, Basic and Intermediate. For the Basic level audit, only those questions identified as basic need to be answered (Intermediate questions should be marked N/A). For the Intermediate level audit both the basic AND intermediate questions must be answered.

Audit Element(s)	**Criteria**
1.3	Documentation and Recordkeeping (includes all 3 sub-questions)
1.4	Worker Training
2.1.1	Field History and Assessment (pre-planting)
2.2.1	Hygienic Procedure for All Activities Which Take Place on the Farm
2.2.2	Hygienic Practices are Effectively Implemented
2.2.4 & 2.2.5	Access to Clean Toilets and Handwashing Facilities
2.3.1	Agricultural Chemicals are Registered
2.3.2	If Exporting - Agriculture Chemicals Registered or Permitted for use in the Destination Country
2.3.4	Water Used for Plant Protection Products does not Present a Food Safety Risk.
2.3.5	Agricultural Chemical Disposal
2.4.3.1	No Untreated Sewage Water Used for Irrigation
2.4.3.1, 2.5.1, 2.6.1, 2.7.2	Where Food Safety Hazards have been Identified - Records to Demonstrate that They are Effectively Managed (water, animals, soil amendments, equipment)
2.5	Animal Control (includes all 3 sub-questions)
2.6	Soil Amendments (includes 2 sub-questions)
2.7.2	Documented Cleaning and Sanitation Procedures
3.2.2	Water Used on Harvested Crops is Potable
3.3	Containers, Bins & Packing Material (includes all 4 sub-questions)
3.5.3	Storage of Harvested Product
5.1.1 & 5.1.2	Awareness and Compliance to Customer Specific Food Safety Specifications
5.1.7	Food Safety Incidents Recorded and Assessed
5.3.1	No Untreated Human Sewage is Used
5.5.2	Operation Keeps List of Agricultural Chemicals Used on the Crops being Grown
5.5.6	Operations Demonstrate Knowledge of Calculating and Preparing Application Mix

FIELD OPERATIONS AND HARVESTING REQUIREMENTS

The Field Operations and Harvesting Checklist is taken verbatim from the Produce GAPs Harmonized Food Safety Standard. Use the checklist to report the verification of each requirement and comments that clearly communicate your observations. Have an accessible copy of the audit standard being assessed with you while performing all audit activities.

Section 1 - General Questions

The questions in this section assess the operation's Management Responsibility, Food Safety Plan, Documentation and Recordkeeping, Worker Education and Training, Sampling and Testing, Traceability, Recall Program, Corrective Actions, and Self Audits.

1.1 Management Responsibility

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

Requirement	**1.1.1. 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.**

Guidance
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 and food safety policy. 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.

Requirement 1.1.1 must be assessed as compliant to meet USDA acceptance criteria.

Requirement	1.1.2. 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.

Guidance
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. 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.

Requirement 1.1.2 must be assessed as compliant to meet USDA acceptance criteria. The comment for this question should include the name(s) of the individual(s) and their roles, responsibilities, and resources for food safety functions.

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.

Requirement	1.1.3. 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.

Guidance
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. Verify by interviews that employees are aware of and can explain the company's disciplinary policy for food safety violations.

1.2 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	1.2.1. There shall be a written food safety plan that covers the operation.
Procedure	The food safety plan shall identify all locations of the operation and products covered by the plan. The plan shall address potential physical, chemical, and biological hazards and hazard control procedures, including monitoring, verification and recordkeeping, for the following areas: water, soil amendments, field sanitation, production environment, and worker practices.
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.

Guidance
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. If hazards are not identified, controls will not necessarily be required. The plan must also include the operation's

recordkeeping requirements.

Requirement 1.2.1 must be assessed as compliant to meet USDA acceptance criteria. The comment should include the date or version of the current food safety plan being audited.

Example Scenarios
Scenario 1: The food safety plan is generic, and does not consider the operation's actual conditions and potential hazards.
Assessment: CAN for lack of a specific report; or IAR if the conditions and potential hazards for that operation are imminent food safety hazards.
Reason: The plan must consider the operation's actual conditions.

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.

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	**1.2.2. The food safety plan must 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.**

Guidance
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. Write a comment for this requirement that includes the date the food safety plan was last reviewed.

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 "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: The operation must have a food safety plan 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.

1.3 Documentation and Recordkeeping

Requirement	**1.3.1. Documentation shall be kept that demonstrates the food safety plan is being followed.**
Procedure	**Documents and records of procedures, standard operation procedures (SOPs) and policies shall be in place for meeting each of the food safety standards identified in the food safety plan.**
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.**

Guidance
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.

Requirement 1.3.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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 are no records for a particular food contact equipment.
Assessment: Corrective Action Needed unless there is an evident reason for the lack of records.
Reason: The operation's SOP states that records will be kept on the particular piece of equipment.

Scenario 4: One or more day's logs are not signed.
Assessment: Corrective Action Needed, unless there is a reasonable explanation.
Reason: The operation must follow its own food safety plan regarding documentation.

Scenario 5: 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.

Requirement	**1.3.2. Documentation shall be readily available for inspection.**
Procedure	**Documents and records may be maintained on-site or at an off-site location, or accessible electronically (e.g., MSDS), and shall be available for inspection in a reasonable timeframe or as required by prevailing regulation.**
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.**

Guidance
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 time frame 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, verify to the best of your 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 your office.

Requirement 1.3.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	1.3.3. 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	Records.

Guidance
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.

Requirement 1.3.3 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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: Corrective Action Needed.
Reason: Despite the unavoidable loss of records, the company is not meeting the record retention requirements. Assess the records present and explain the circumstances of the lack of records in the audit report.

1.4 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	**1.4.1. All personnel shall receive food safety training.**
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. 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.**

Guidance
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.

Look at the training records for each employee to assess training received when they 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. Your comment should include the title and topics covered by training and specify the records that show training is current as of the date of the audit.

Requirement 1.4.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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 "break room" 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.

Scenario 5: The sales team at an off-site office does not receive any food safety training. These employees are not normally onsite and are not involved in the growing operation.
Assessment: Compliant.
Reason: These employees are outside the scope of the audit. When onsite, they must be treated as "visitors" or "contractors" (see section 2.2.2).

Requirement	**1.4.2. Personnel with 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 formal food safety course/workshop or by job experience.**
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, or company training record. If the operation passes the food safety audit, the food safety individual's training is deemed adequate.**
Corrective Action	**Individual must obtain demonstrable food safety training.**
Documents Required	**N/A.**

Guidance
The individual designated 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.

If the food safety individual has documented education (e.g., a Master's degree in food safety), but the operation does not pass the audit, answer this question as compliant unless evidence indicates that the operation's failure to pass was due to inadequate training of the food safety individual. The food safety individual may receive food safety training at another company as

long as the training received is applicable to the responsibilities of the current operation. Include a comment on the training (this may include applicable on-the-job training) and/or certification.

Requirement 1.4.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Example Scenarios
Scenario 1: The designated food safety individual has no documentation of food safety training, but the operation "passes" the audit.
Assessment: Compliant.
Reason: According to the standard, "If the operation passes the food safety audit, the food safety individual's training is deemed adequate."

Scenario 2: 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.

Requirement	**1.4.3. Subcontractors are held to the relevant food safety standards as they would be as employees.**
Procedure	**Operations shall have procedures and/or records to demonstrate that subcontractors 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 the Field Operations and Harvesting standards.**
Verification	**Auditor reviews Operation's evidence that subcontractors are trained to the same food safety requirements as employees would be and, if practical during the audit, observes subcontractors for compliance.**
Corrective Action	**Operation obtains evidence, trains or discontinues using subcontractors.**
Documents Required	**Record.**

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

Requirement 1.4.3 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

1.5 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 1.5. 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	**1.5.1. 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.**

Guidance
Laboratory analysis required in a food safety plant must be performed by a laboratory that: 1) passed a 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 Organisation 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.

A laboratory also must use FDA's Bacteriological Analytical Manual (BAM), 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: http://www.aoac.org/iMIS15_Prod/AOAC/Home/AOAC_Member/Default.aspx?hkey=8fc2171a-6051-4e64-a928-5c47dfa25797.

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).

Include the type of testing required (e.g., soil, water, or Adenosine triphosphate (ATP) swabbing), identify the name of the lab, and indicate if the lab is accredited in the comment for this requirement.

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	1.5.2. Where microbiological analysis is required in the food safety plan, samples shall be collected in accordance with an established sampling procedure.
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.

Guidance
Verify that the operation has written sampling protocols for all testing required in the food safety plan. 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	1.5.3. Tests, their results and actions taken must be documented.
Procedure	All results for microbiological testing required in the Operation's food safety plan shall be recorded and the records maintained for two years.
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.

Guidance
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 has performed all microbiological tests required by its food safety plan for a minimum of 2 years. 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, you 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.

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.

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 receive results documents from the testing laboratory, only a pass/fail notification. The operation maintains the pass/fail records for 2 years, and says the laboratory maintains the full test records for at least 2 years, but has no documentation from the laboratory to confirm that claim.
Assessment: Compliant.
Reason: The operation maintains the documentation as required in its food safety plan.

Scenario 4: 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	1.5.4. 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.

Guidance

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 1.5.4 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.

1.6 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	**1.6.1. 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.**
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, Records**

Guidance
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. 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 operations records of where the product was sent to, to what is in the market place, how much is remaining, how much is for 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 sales, and you-pick operations. 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 what 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.

Requirement 1.6.1 must be assessed as compliant to meet USDA acceptance criteria.

Requirement	**1.6.2. 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.**

Guidance
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. 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. Include a comment on the date of last traceback and trace-

forward exercise.

This question may be answered as Not Applicable if the operation ships all of its product to only one customer.

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.

1.7 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	**1.7.1. 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.**

Guidance
Verify that the operation has a recall program in place governed by written procedures, with documented records, has 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. Include the date of the last recall or mock recall.in the Comments section.

Requirement 1.7.1 must be assessed as compliant to meet USDA acceptance criteria.

Example Scenario
Scenario: 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.

1.8 Corrective Actions

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	**1.8.1. 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.**

Guidance
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 documented (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 Correct 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.

1.9 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	**1.9.1. 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.**

Guidance
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.

Section 2 - Field Production

2.1 Field History and Assessment

The following requirements address the evaluation and documentation field risks.

Requirement	**2.1.1. 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 for environmental conditions or risk awareness that has changed since the last assessment. The assessment 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	**Record.**

Guidance
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. 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. Verify that the risk assessment is accurate when visiting the fields.

Requirement 2.1.1 must be assessed as compliant to meet USDA acceptance criteria and the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment. Include the date of the last assessment in the Comment section.

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 adjacent land use.
Assessment: Corrective Action Needed.
Reason: The operation's assessment must include onsite risks and risks from adjacent land use.

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.

Scenario 4: A grower conducted a risk assessment. Upon visiting the farm site, the auditor sees that an adjacent hobby farm with two milk cows is not addressed in the risk assessment. Appropriate buffer distances and double fencing are in place.
Assessment: Corrective Action Needed.
Reason: The adjacent land use risk was not documented.

Scenario 5: A field located across the road from a cemetery is not mentioned in the risk assessment.
Assessment: Corrective Action Needed.
Reason: This is not compliant with requirement 2.1.1 because the cemetery should be mentioned in the risk assessment to demonstrate it has been considered. A well-maintained cemetery does not represent a food safety risk.

Requirement	2.1.2. For indoor growing and field storage facilities, facility shall be designed, constructed and maintained in a manner that prevents contamination of produce.
Procedure	Facility and equipment structures and surfaces (floors, walls, ceilings, doors, frames, hatches, etc.) shall be constructed in a manner that facilities 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 facility and equipment for evidence that the facility can be cleaned and maintained to prevent product contamination.
Corrective Action	Facility deficiencies are corrected. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.

Guidance

Observe that indoor facilities and equipment can be cleaned and maintained to prevent product contamination. A hoop house is not considered an indoor growing facility and should be evaluated for compliance when evaluating the field in requirement 2.1.1. Greenhouses with dirt floors that are not reasonably likely to result in contamination of the edible portion of the crop are compliant with requirement 2.1.2 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 facilities 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 of the crops that the operation wants audited. 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 2.1.2 unless the auditor observes that the facility poses a food safety risk to produce.

2.2 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. Federal regulations on worker health and hygiene, and toilet/handwashing facilities are found in Appendix I, Title 21 Part 110 for Good Manufacturing Practices and in Appendix II, Title 29 for Occupational Safety and Health.

Requirement	2.2.1. Operation shall have a policy for toilet, 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, hygiene and health exist.
Corrective Action	Operation develops written policies covering toilets, hygiene and health.
Documents Required	Written Policy.

Guidance
Verify the operations 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 and II of this document; familiarize yourself with state and local regulations related to worker health and hygiene.

Requirement 2.2.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	2.2.2. Employees and visitors shall 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.
Corrective Action	Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.

Guidance
All onsite employees and visitors at the operation must follow all personal hygiene practices required by the operation, including handwashing. Proper sanitation and hygiene practices for food processing establishments are described as GMPs under 21 CFR 110.10; not all of these GMPs 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.

Requirement 2.2.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	**2.2.3. Toilet facilities 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.**
Verification	**Auditor visually and by records 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.**

Guidance
Operations must comply with Federal regulations in the GMPs, 21 CFR 110.37, and in the Occupational Safety and Health Standards, 29 CFR, (see Appendix I and II). 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 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 are no more than ¼ mile away from farming and harvesting activities.

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 address any leaks likely to cause contamination of the produce immediately.

Handwashing facilities with soap and towels may be located within or outside the toilet facility. They must be near the toilet facility so food-handling employees 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 feces or 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.

Requirement	**2.2.4. Toilet facilities shall be of adequate number, easily accessible to employees 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.**

Guidance
The operation must have an adequate number of toilet facilities that are easily accessible by employees to promote good sanitary practices of employees in compliance with Federal regulations found in the Occupational Safety and Health Standards, 29 CFR (see Appendix II). Be aware of state and local regulations that apply to the operation being audited to determine if the operations adhere to these requirements.

Requirement 2.2.4 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	**2.2.5. 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 be located with the field sanitation units and 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.**
Verification	**Auditor observes toilet and handwashing facilities for compliance. Auditor observes checklist or other evidence of a documented system for tracking cleaning of toilets.**
Corrective Action	**Toilet or handwashing facility is replaced, repaired or maintained to be compliant.**
Documents Required	**Record.**

Guidance
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.

Requirement 2.2.5 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	**2.2.6. 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 and at any other time when their hands may have become a source of 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.**

Guidance
Thorough handwashing, including cleaning fingernails and cuticles, before working with produce and after using the toilet is critically important to preventing the spread of the many infectious diseases that are transmissible through food.

The operation must emphasize that handwashing with soap and/or other sanitizing agent(s) is required. Sanitizer use 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, 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 2.2.18. If a worker is observed with exposed cuts, sores or lesions this observation should be reported for requirement 2.2.19.

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.

Requirement	**2.2.7. 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.**

Guidance
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.

Requirement	**2.2.8. 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.**
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.**

Guidance

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.

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.

Requirement	2.2.9. 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. 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.

Guidance
An operation's glove use policy may be written or unwritten. Auditor's 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. The comment should include if gloves are used or optional and if there is a detailed policy on how to sanitarily/safely use the gloves.

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 operations must adhere to the glove use policy they have in place. If, for example, an operation's glove policy is that gloves are to be "clean and sanitary" and the harvest crew uses heavy leather gloves to protect them from injury, corrective action would be necessary because leather gloves can be kept clean but not made sanitary. 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: If 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: There is no glove use policy and workers are sorting cucumbers barehanded.
Assessment: Not Applicable.
Reason: No gloves are being used in the operation.

Scenario 3: An auditor observes, on a green pepper sorting line, that several workers' cloth gloves are water soaked and stained from working with peppers. Operation's glove policy requires gloves to be replaced when they become contaminated.
Assessment: Compliant.
Reason: Gloves are being used in accordance with the policy and no observation was made that the gloves are reasonably likely to contaminate the peppers.

Scenario 4: The operation's glove use policy is verbal (not documented). 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.

Requirement	**2.2.10. Protective clothing, when required, shall be maintained, stored, laundered and worn so as to protect product from risk of contamination.**
Procedure	**If protective clothing is used in proximity to product, the operation shall have a policy or procedures for how and when protective clothing are to be used, cleaned, replaced and stored. Policy shall be in compliance with current industry practices or regulatory requirements for that commodity.**
Verification	**If protective clothing is used, auditor observes use for compliance with the operation's policy and current industry practices or regulatory requirements.**
Corrective Action	**Operation develops or revises protective clothing policy or procedures. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**

Guidance
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.

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: Company policy is for employees to purchase and clean their own work aprons.
Assessment: Compliant.

Reason: Unless current industry practices or regulatory requirements for that crop prohibit, or unless auditor observes that the practice is creating a contamination risk the company has a policy on protective clothing that is being followed.

Scenario 4: 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.

Requirement	**2.2.11. 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 clothing, such as aprons and gloves, the Operation shall have a policy for how the clothing and tools shall be stored when not in use so as to avoid potential contamination.**
Verification	**If employees wear protective clothing, auditor observes whether storage areas are designated, available and used.**
Corrective Action	**Operation obtains and positions racks and storage containers as necessary. Retraining is performed and documented.**
Documents Required	**N/A.**

Guidance
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.

Requirement	2.2.12. 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.

Guidance
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 2.2.12. If workers are seen wearing jewelry, body piercings or carrying other personal effects (i.e., cell phones, mp3 players, etc.), observe whether they are wearing or using these items is in compliance with the company policy.

Requirement	2.2.13. 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.

Guidance
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. 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.

Requirement	2.2.14. 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.

Guidance
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.

Requirement	2.2.15. Smoking, chewing, eating, drinking (other than water), urinating, defecating or spitting is not permitted in any growing areas.
Procedure	Operation shall have policy prohibiting smoking, eating, chewing gum or tobacco, 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.

Guidance
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.

Requirement	2.2.16. 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.

Guidance
GMPs under 21 CFR, 110.10 state: "Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco." 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.

Requirement	2.2.17. Drinking water shall be available to all field 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 field trash receptacle shall be available to all field 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 field employees, in compliance with prevailing regulation.
Documents Required	Record.

Guidance
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.

Requirement	2.2.18. Workers and field personnel who show signs of illness shall be restricted from direct contact with produce or food-contact surfaces.
Procedure	Operation shall have a written policy that restricts personnel 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 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.

Guidance

GMPs under 21 CFR, 110.10 state: "(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors."

Supervisors should be familiar with the symptoms of infectious diseases so that if symptoms are evident, the supervisor can take appropriate steps. Several microbial diseases are able to readily invade and multiply in the human body and to produce severe disease. Any worker showing symptoms of an active case of illness that may be caused by such pathogens must be excluded from work assignments that involve direct or indirect contact with fresh produce. Workers with diarrheal disease and symptoms of other infectious diseases must not work directly with fresh produce or the sorting and packing equipment in the packing facility. Operators must instruct employees to report any active case of illness to their supervisor before beginning work.

Interview managers/supervisors to determine whether or not they show knowledge of known symptoms of the infectious diseases. Also, look for indications of worker illness, such as frequent trips to the toilet facilities by individual employees. Operations must have a written policy to follow when workers show signs of possible illness.

Question supervisory personnel in order to determine what would be done if a food handling worker showed signs of infectious disease or diarrhea. Such affected persons should not be handling food, food packages or be working around product flow zones. 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.

Requirement	2.2.19. 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.

Guidance
In addition to observation of field personnel, interview selected personnel for verification of their knowledge of the company's policy appropriate to their positions 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 2.2.9 for additional verification requirements if gloves are used to cover minor cuts or abrasions.

Requirement	2.2.20. 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.

Guidance
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.

Requirement	2.2.21. 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 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	N/A.

Guidance
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.

2.3 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 proves that 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	2.3.1. 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. Records of agricultural use are maintained.
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.

Guidance
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
- Preharvest 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 on labeling 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 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. 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: http://cfpub1.epa.gov/oppref/section18/search.cfm.

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

Requirement 2.3.1. must be assessed as compliant to meet USDA acceptance criteria and to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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 a closed container of fumigation concentrate staged in the produce sorting room, in an area that allows for unauthorized access. The container is not being supervised. The fumigation company is expected later that day.
Assessment: Corrective Action Needed.

Reason: Chemicals must be stored away from product handling areas and in a manner that inhibits unauthorized access. The staging area is not appropriate.

Scenario 3: 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 to clean the area according to label directions, and removes any potentially affected product.
Assessment: Compliant
Reason: The operation has a procedure and is following it.

Requirement	**2.3.2. 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.**

Guidance
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. If applicable to the operation, requirement 2.3.2 must be assessed as compliant to meet acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Example Scenarios
Scenario 1: The operation has evidence of training about MRLs. Chemical application records from growers which include 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	**2.3.3. 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.**

Guidance
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, review training documents to verify that the applicators have received training on the proper use of the materials. The comment should include the applicator licensed and/or personnel licensed.

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.

Requirement	2.3.4. Water used with agricultural chemicals shall not be a 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	N/A.

Guidance
All water used with agricultural chemicals must be microbially safe. For more information on the Water System Risk Assessment and Water Management Plan see requirements and guidance in sections 2.4.1 and 2.4.2 of this manual.

Requirement 2.3.4 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	2.3.5. 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.

Guidance
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. 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).

Requirement 2.3.5 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

2.4 Agricultural Water

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 edible 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.

2.4.1 Water System Description

Requirement	2.4.1.1. 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.
Verification	Auditor reviews water system description or map, and verifies accuracy during field inspection.
Corrective Action	Operation develops or corrects the water system description or map.
Documents Required	Written Policy.

Guidance
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.

Requirement	2.4.1.2. The water source shall be in compliance with prevailing regulations.
Procedure	Agricultural 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.

Guidance
The water source (municipal, well, or surface water) must be in compliance with prevailing regulations. You should be familiar with what source water is being used and any applicable 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, if a permit is needed to pull water from a canal or stream, testing regulations for quality of water appropriate for its intended use, etc.

Requirement	**2.4.1.3. Agricultural 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 agricultural 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.**

Guidance
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.

2.4.2 Water System Risk Assessment

Requirement	**2.4.2.1. 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	**Record.**

Guidance
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 source water in order to determine whether or not the product could become contaminated. Application methods include irrigation (overhead-sprinkler, flood-surface, furrow, drip-trickle, 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 where the water sprinkles or drenches the crop can be the most risky 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.

2.4.3 Water Management Plan

Requirement	**2.4.3.1. 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.**

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

Requirement 2.4.3.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	**2.4.3.2. 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 agricultural 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 for commodities being produced.**
Verification	**Auditor verifies that a water testing program is in compliance with the risk assessment and current industry standards 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 for the commodities being grown.**
Documents Required	**Written Policy.**

Guidance
It will be important 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 III of this manual.

This written plan 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 comment should include the water test dates and/or results for field operations.

Requirement	2.4.3.3. 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.

Guidance
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 1.5.2). Also, verify the operation's testing frequency and sampling frequency.

2.5 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 domestic animals from fresh produce fields, vineyards and orchards during the growing season. This would include pet dogs, goats, sheep, cows, horses, fowl, 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 or waterfowl in a field) or domestic 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 to 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	**2.5.1. 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	**Written Policy.**

Guidance
Verify that the operation has a written risk assessment on animal activity in and around the production area. The risk assessment must address domestic 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.).

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 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.

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.

Requirement 2.5.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	**2.5.2. 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.**

Guidance
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.

Requirement 2.5.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	**2.5.3. Based on the risk assessment, there shall be measures to prevent or minimize the potential for contamination from animals, including domestic 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 domestic 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	**Record.**

Guidance
Farming operations are never going to be able to completely exclude wild and/or domestic 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 domestic 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 water fowl, or fencing or other barriers to limit wildlife access. You should understand 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.

Requirement 2.5.3 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

2.6 Soil Amendments

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.

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 2.6 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 crops 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	**2.6.1. 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 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	**Record.**

Guidance
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.

If no soil amendments are used by the auditee, this requirement may be assessed as N/A.

If soil amendments are used, requirement 2.6.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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

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. Lawn litter is usually uncontrolled and can contain dead animals or animal manure.
Assessment: Corrective Action Needed.
Reason: 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.

Requirement	**2.6.2. 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.**
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.**

Guidance
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 or not raw manure is properly used, according to the recommendations. Review manure application records in order 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 at the facility must be stored in a way that ensures that it does not leach or runoff into adjacent crop production areas. 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.

Requirement 2.6.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Example Scenarios
Scenario 1: Leafy green operation applies animal-based compost to the field after harvest, works it into the ground and plants alfalfa between seasons. They have no records whether compost was sufficiently treated to destroy pathogens. Leafy Green Marketing Agreement Best Practices prohibits raw or non-fully composted animal manure within 12 months of leafy green production.
Assessment: Corrective Action Needed.
Reason: A minimum of one-year wait period supported by documentation is required for compliance with industry practices.

Scenario 2: 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: Unless the operation's food safety plan is based on LGMA, there are no industry or regulatory restrictions on application of fully composted manure.

2.7 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 2.7.

Requirement	2.7.1. 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.

Guidance
The operation must maintain a current and accurate list that has identified all vehicles, equipment, tools, and utensils used in the harvesting process. 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	2.7.2. 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. 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.

Guidance
Determine if the facility has procedures for cleaning equipment and harvesting aids. 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 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 should 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 in order to verify this factor.

The auditee's food safety manual should show the schedule for cleaning and disinfecting harvesting implements. It is understandable that these implements are going to get dirty from constant, repeated use during the course of a harvesting day and auditors should not answer this as a Corrective Action Needed just because a harvester is using a dirty knife. However, this should not be compliant if there is no documented procedure for a scheduled cleaning of the implements.

Requirement 2.7.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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 does 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.

Requirement	**2.7.3. 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.**

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	**2.7.4. 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.**

Guidance
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	**2.7.5. 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.**

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 spinach 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	2.7.6. 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.

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.

Section 3 - Harvesting

3.1 Preharvest Assessment

Requirement	**3.1.1. 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	**Written Policy, Record.**

Guidance
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 of 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.

3.2 Water/Ice

Requirement	**3.2.1. 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.**

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	3.2.2. 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.

Guidance
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 good manufacturing practices to minimize the potential for the introduction or spread of pathogens via processing water.

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. Surface water should not be applied to the finished product. Review water tests in order to determine that the water is microbially safe.

The comment should include the water source for harvest operations and the water's initial potability. Requirement 3.2.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Example Scenarios
Scenario 1: A cherry operation soaks foam pads in water, and then places pads on top of cherries for transport. Operation uses uncontrolled water because they "don't have access to clean water."
Assessment: Corrective Action Needed or Immediate Action Required.

Reason: Corrective Action Needed to change the water source or treat the water to prevent product contamination. Immediate Action Required if the water being used may reasonably have contaminated cherries.

Scenario 2: An operation is using uncontrolled 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	**3.2.3. Water use SOPs address treatment of re-circulated water, if used.**
Procedure	**Operation's water use SOPs require re-circulated 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.**

Example Scenarios
Scenario 1: Water is used to flume tomatoes from harvest areas to packing facilities in greenhouse is treated with 100ppm total chlorine. The water treatment is not recorded or monitored during the day.
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-circulated 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-circulated 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	3.2.4. 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.

Guidance
Examples of water delivery systems include reservoirs, canals, ditches, pumps, hoses, and other facilities that move water.

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	3.2.5. 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	Records.

Guidance
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.

Example Scenarios
Scenario 1: A tomato operation maintains flume wash water temperature at least 10ºF warmer than the pulp temperature of tomatoes.
Assessment: Compliant.
Reason: This is compliant with current industry practice.

Scenario 2: Green onions are washed in the field by submerging in ambient temperature water where water temperature is not controlled.
Assessment: Compliant.
Reason: This is compliant with industry standards.

Scenario 3: The food safety plan requires cantaloupe to be washed in water at or higher than fruit temperature, but the temperature of the fruit or the water is not monitored or recorded during the day.
Assessment: Corrective Action Needed.
Reason: Monitoring records are required for produce susceptible to infiltration.

3.3 Containers, Bins and Packaging Materials

Requirement	**3.3.1. 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.**

Guidance
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.

Requirement 3.3.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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: Cucumber harvest bins are stored exposed to weather between seasonal uses and covered with vegetation and weed growth. The harvest bins are washed prior to delivery to the field, but some containers are still visibly soiled.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: Corrective Action Needed if the storage practice has led to contamination beyond the ability of washing to clean reliably. Immediate Action Required if the condition of the containers has already or may reasonably cause produce contamination.

Scenario 3: 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.

Requirement	**3.3.2. 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.**

Guidance
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.

Requirement 3.3.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Example Scenarios
Scenario 1: An 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 SOP regarding the inspection of stored bins prior to use.

Scenario 2: Reusable foam pads are placed on cherries during transport from orchards to packinghouse. The operation has not included foam pads in the container inspection SOP because "foam pads are not a container."
Assessment: Corrective Action Needed.
Reason: The foam pads are functionally a "packing material" and the standard requires packing materials to "be visually inspected, clean, intact and free of any foreign materials prior to use."

Scenario 3: 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 4: 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.

Requirement	3.3.3. 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.

Guidance
Requirement 3.3.3 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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."

Scenario 3: An operation has changed crops and uses existing harvest containers and packing materials in accordance with the operation's SOP to harvest and market "new" crop.
Assessment: Compliant.
Reason: The SOP is current/updated to allow the use of existing harvest containers and packing materials in the production of the "new" crop, and are suited for their intended purpose.

Requirement	3.3.4. 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.

Guidance
Requirement 3.3.4 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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.

3.4 Field Packaging Materials

Requirement	**3.4.1. Operation shall have a written policy that 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 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.**

The comment should include the type of growing method and if the product grown in contact with the ground (e.g., tomatoes staked or vine grown).

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."

Requirement	**3.4.2. 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). 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.**

Guidance
A written policy which explains whether or not drop product can be harvested is required. Employees must be trained on this policy. Interview employees to verify their understanding of the drop product policy.

Example Scenarios
Scenario 1: You observe 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: You observe strawberries being harvested that are in contact with the plastic mulch under the plants.
Assessment: Compliant.
Reason: Strawberries normally grow in contact with plastic mulch.

Scenario 3: You observe 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.

Scenario 4: You observe a tomato harvester picking non-staked tomatoes that are in contact with the ground (no plastic mulch).
Assessment: Compliant.
Reason: In this operation, tomato is harvested off the ground (not a drop, which may cause bruising or micro abrasion).

Requirement	**3.4.3. 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.**

Guidance
Harvest procedures for inspecting and removing physical hazards are not required to be written. Harvest employees who are responsible for the food safety procedures need to be trained on the procedures for inspecting and removing physical hazards appropriate to their job responsibilities (see requirement 1.4.1).

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	3.4.4. Cloths, towels, or other materials that pose a risk of cross-contamination shall not be used to wipe produce.
Procedure	Operations shall not use cloths or other cleaning materials to clean produce, unless there is a procedure to prevent 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.

The comment should include the type of cloth, towel, or other cleaning material and procedure for preventing cross contamination.

Example Scenarios
Scenario 1: You observe tomato harvesters cleaning surface dirt off of tomatoes with a dry cloth, prior to field-packing. The cloth is replaced several times a day, when it becomes too dirty to be useful.
Assessment: Immediate Action Required.
Reason: Using and then re-using a cloth to wipe surface dirt off the produce even if grown on the ground can increase the chances of contamination. This practice is prohibited by Tomato Metrics because of potential for cross-contamination.

Scenario 2: 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 the you observe evidence that the practice has resulted in product contamination, then it would be an Immediate Action Required.

Requirement	3.4.5. 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.

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.

Requirement	**3.4.6. 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.**

Guidance
Packing materials are product contact materials (bins, pads, cartons) used during harvest and products that will be further handled prior to shipping. Packaging materials are product contact materials (cartons, bags, clamshells, film) and products that are not likely to be further handled prior to shipping.

Packing containers and other packing 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.). Packing containers stored outside should be covered in some manner to protect against contamination. Observe where and how packing containers are stored. Containers which are stored in a manner that may lead to contamination by any reasonable means will result in Corrective Action Needed.

Example Scenarios
Scenario 1: 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.

Scenario 2: Same as Scenario 1, but the "designated area" is within a few feet of the area where cleaning and maintenance chemicals are stored in closed but unlocked cabinets.
Assessment: It depends.
Reason: You must determine if there is a reasonable likelihood that the chemicals are hazardous and could contaminate the packaging. If not, then compliant. If yes, then Corrective Action Needed (no evidence of actual contamination having occurred) or Immediate Action Required (auditor observes evidence that contamination likely has occurred).

Requirement	**3.4.7. 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 packing 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 packing 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.**

3.5 Postharvest Handling

Requirement	**3.5.1. 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, that may 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.**

Guidance
This policy does not have to be written. To determine if this question is compliant, observe if the actions practiced by the operation are compliant with company policies (including glove policy).

Example Scenarios
Scenario 1: You observe workers walking on stacks of potatoes in the on-farm storage building.
Assessment: Compliant.
Reason: This is compliant with industry standards.

Scenario 2: 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.

Requirement	**3.5.2. 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.**

Guidance
Review the condition of pallets and containers being used and those stored for future use. Interview the operator to determine what is done with broken or dirty pallets or containers.

Example Scenario
Scenario: You observe operators using dirty or broken pallets and containers.
Assessment: Corrective Action Needed.
Reason: These pallets and containers are not clean and in good repair.

Requirement	**3.5.3. Harvested produce shall be stored separately from chemicals which may pose a food safety hazard.**
Procedure	**Chemicals, including cleaning and maintenance compounds shall be stored in an area separate from harvested produce.**
Verification	**Auditor observes produce storage area for evidence of compliance.**
Corrective Action	**Operation designates a storage area and practices that reduce risk of contamination. Affected produce is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**

Guidance
The standard is silent on distance and what constitutes separation. 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.

Requirement 3.5.3 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Example Scenarios
Scenario 1: 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.

Scenario 2: Same as Scenario 1, but on a wrapped pallet of bagged salad.
Assessment: Corrective Action Needed.
Reason: Even though the likelihood of product contamination is less than Scenario 1, the cleaner is still stored on top of the produce, only separated because of the packaging.

Section 4 - Transportation (Field to Packinghouse)

4.1 Equipment Sanitation & Maintenance

Requirement	**4.1.1. 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.**

Guidance
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. You should not expect to see conveyances in like-new or sterilized condition; however, conveyances should be acceptably 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.

Requirement	**4.1.2. 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.**

All fresh produce should 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 Scenarios
Scenario 1: Peach harvesters empty harvest bags into large plastic bins, which are loaded onto flatbed trucks for transport to packing shed. You see juice leaking from several bins.

Assessment: Compliant.
Reason: Juice leaking may be caused by overripe fruit being harvested. You do not observe the equipment used to be the cause of the damage.

Scenario 2: 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.

Requirement	**4.1.3. Trash shall not come in contact with produce.**
Procedure	**The operation shall have a procedure describing how trash shall be handled and transported out of the field in a manner that does not pose a food safety risk.**
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.**

Example Scenarios
Scenario 1: A row crop operation has written procedure for workers to remove trash from field whenever found. You observe minor amounts of paper and two plastic bottles in field near road. The operation takes action to remove the trash when observed.
Assessment: Compliant.
Reason: The operation is following their policy to remove debris from the field when found.

Scenario 2: Same as Scenario 1 except, the paper and bottles are in a section of the field that has been harvested. The operation says the trash was not present before harvesting.
Assessment: Not Applicable.
Reason: The standard only applies to trash that is reasonably likely to come in contact with produce.

Scenario 3: Trash removed from field is placed in a designated, unlabeled harvest bin and transported from the field on the harvest truck.
Assessment: Corrective Action Needed.
Reason: Transport of trash on the harvest truck may contaminate the produce. Also, item 3.3.4 prohibits “use of harvest containers for non-harvest purposes.”

Section 5 - Global Markets Primary Production Addendum

5.1 Food Safety Plan and Documentation

Requirement	**5.1.1. If applicable, the food safety plan addresses customers' food safety specifications**
Level	**Basic Required Element Yes**
Procedure	**The producer shall be familiar with specifications concerning food safety (e.g. microbiological criteria, permitted chemical residues and limits) established by the buyer or, if exporting product, required by the country of destination. The producer has written copies of customer, country, and internal food safety specifications and is demonstrating compliance with these specifications.**
Verification	**Auditor reviews customers' food safety specifications and interviews appropriate personnel for familiarity of customer food safety specifications.**
Corrective Action	**Operation obtains customers' food safety specifications and/or trains appropriate personnel to become familiar with the customer' food safety specifications.**
Documents Required	**Record.**

Guidance
Ask the auditee if their customers have supplied them with any written food safety requirements they must adhere to. If the answer is yes, those requirements must be addressed in the auditee's food safety plan, and the operation must demonstrate they are adhering to those requirements. Verify if the auditee would or would not like the buyer names included on the audit report next to this requirement. Some auditees may not want specific buyer names listed in which case the comment should use generic language, for example, "Auditee stated they have incorporated buyer specific requirements from two buyers into food safety plan." Conversely, auditees may want to include names of buyers to show the buyer in the audit report they are meeting requirements they have requested.

If an auditee states that the customer expectation is that they must meet USDA Acceptance Criteria for the Harmonized audit, this question should be assessed and not answered as N/A. Comments for this requirement may state what customers' requirements are. Examples of food safety requirements could be specific microbiological testing requirements, acceptable water requirements, the use of gloves, etc.

If the auditee states none of their customers have any supplied them with any specific food safety requirements, then the question must be answered "N/A." The comment should include an explanation for the N/A, for example, "No customer has supplied auditee with any specific food safety requirements." or similar language.

Requirement 5.1.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	5.1.2. The operation can demonstrate compliance to customers' food safety specification (if applicable).		
Level	**Basic**	**Required Element**	**Yes**
Procedure	**The operation has implemented the food safety specifications of their customers.**		
Verification	**Auditor observes that food safety specifications verified in requirement 5.1.1 have been implemented in the operation.**		
Corrective Action	**Operation will implement food safety specifications in 5.1.1.**		
Documents Required	**Record.**		

Guidance
Requirement 5.1.2 requires that the operation demonstrate compliance to customers' food safety specifications. Observe the operation for implementation of customer's food safety specifications and review any associated records.

Requirement 5.1.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	5.1.3. A reference system for each field, orchard, greenhouse, plot and other production area has been established.		
Level	**Basic**	**Required Element**	**No**
Procedure	**The operation shall establish a reference system for each field, orchard, greenhouse, plot and/or production area.**		
Verification	**Auditor verifies an operation has a reference system in place and is able to demonstrate use of this reference system.**		
Corrective Action	**Operation shall establish a reference system.**		
Documents Required	**Record.**		

Guidance
Look for a map or other description of the operation which designates each production area. Ideally the descriptions are permanent identifiers, and do not change from year to year, although this is not an absolute requirement.

Requirement	**5.1.4. Documentation shall include records of all agronomic activities undertaken at each production unit.**
Level	**Basic** **Required Element** **Yes**
Procedure	**There shall be a description of the planned agronomic activities for each production unit/crop. Records shall be kept for each production unit/crop. There shall be a person responsible, accountable and trained to maintain the records in an accurate and timely manner. The record keeper shall make journal entries as soon as practicable after completing agricultural activities. These records shall include the date and type of agricultural activities, machines or equipment used, as well as the persons responsible for the agricultural activities.**
Verification	**Auditors shall verify records of all agronomic activity at each production unit.**
Corrective Action	**Operation shall implement record keeping for each production unit/crop and train personnel on this process.**
Documents Required	**Record.**

Guidance
An operation needs to have a system which documents agricultural activities undertaken for each production unit on the farm.

Requirement	**5.1.5. Corrective action procedures shall include a procedure to evaluate complaints.**
Level	**Basic** **Required Element** **Yes**
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 the 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	**Auditors 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.**

Guidance
The requirement 1.8.1 of the Harmonized Standard addresses corrective actions, but does not specifically require a procedure for addressing complaints. In order to meet the requirement of question 5.1.5 of the Global Markets Addendum, the operation must have a procedure for documenting, assessing, and addressing complaints.

Requirement	5.1.6. The operation shall record any food safety related non-conformances and complaints.		
Level	**Basic**	**Required Element**	**No**
Procedure	**Food safety related complaints and non-conformities shall be recorded and maintained.**		
Verification	**Auditors verifies records of any food safety related non-conformances and complaints.**		
Corrective Action	**Operation shall implement record keeping for food safety related non-conformances and complaints.**		
Documents Required	**Record.**		

Guidance
To have an effective corrective action program, the operation will need to have a method established for documenting any food safety related non-conformances and complaints. This method may be a log, individual corrective action reports, etc.

Requirement	5.1.7. Food safety incidents are recorded and assessed to determine its severity and risk and addressed accordingly.		
Level	**Intermediate Only**	**Required Element**	**No**
Procedure	**A food safety incident management mechanism 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 mechanism, 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.**		

Guidance
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.

Requirement 5.1.7 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Intermediate Level Assessment.

Requirement	**5.1.8. The incident management procedure is reviewed, tested and verified at least once a year.**
Level	**Intermediate Only Required Element No**
Procedure	**An annual review is conducted of the overall 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 firm 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 operations incident management procedure.**
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	**Record.**

Guidance
Each operation must have a food safety incident management procedure as specified in requirement 5.1.7. 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 comment should show the date of last incident management procedure reviewed, tested, and verified.

Requirement	**5.1.9. Operation has an approved supplier program for all inputs including contractors.**
Level	**Intermediate Only Required Element No**
Procedure	**The operation has an in-house documented approved supplier process covering the food safety related aspects in place for purchases of all agricultural inputs, chemicals, packaging and food safety related services.**
Verification	**Auditor verifies the in-house approved supplier program and the inputs monitored by this program.**
Corrective Action	**Operation establishes an approved supplier program for all agricultural inputs. Appropriate personnel are trained in tracking agricultural inputs and records are kept for these inputs.**
Documents Required	**Written Policy, Record.**

Guidance
Verify that the operation has a written approved supplier program for all agricultural inputs. Agricultural inputs may include agricultural chemicals, packaging, and other contracted food

safety related services. As there are many agricultural inputs in each operation it is expected that the auditor will review a sampling of the agricultural inputs for the operation being audited.

The comment should show the date of current list available.

Requirement	**5.1.10. Operation has performed and documented a risk assessment of the production area.**
Level	**Basic** **Required Element** **Yes**
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.**
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	**Record.**

Guidance
A risk assessment must be performed and documented by the operation for the production area, before planting. 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.

Requirement	**5.1.11. Operation has identified control measures to all significant hazards identified during risk assessment.**
Level	**Intermediate Only** **Required Element** **Yes**
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	**Record.**

Guidance
The Harmonized Standard requires risk assessments be performed in a number of sections, this question on the Global Markets Addendum just verifies they were completed, as it is a required element of the Global Markets Assessment. This question cannot be answered as N/A.

5.2 Propagation Material

Requirement	5.2.1. Operation keeps records of agricultural chemical applications used on nursery stock, transplants and other propagation material produced on site.		
Level	**Basic**	**Required Element**	**No**
Procedure	**Records shall be available of the use of plant protection products on propagation materials.**		
Verification	**Auditor shall verify operations records of agricultural chemical applications on propagation materials.**		
Corrective Action	**Operation keeps complete records of agricultural chemical applications on propagation materials.**		
Documents Required	**Record.**		

Guidance
If the auditee grows his/her own propagation material, it needs to keep records of all agricultural chemical applications used on the material. If the auditee does not grow his/her own material, this question can be answered as N/A.

Requirement	5.2.2. If nursery stock, transplants or other propagation material is purchased from an outside source, records of ag chemical use are obtained.		
Level	**Basic**	**Required Element**	**No**
Procedure	**In the case of propagation materials sourced from a third party, records from the supplier shall be available.**		
Verification	**Auditor shall verify records from the outside source of agricultural chemicals applications on purchased propagation materials.**		
Corrective Action	**Operation keeps complete records of agricultural chemical applications on propagation materials.**		
Documents Required	**Record.**		

Guidance
The auditee will need to show records of agricultural chemical applications on propagation materials obtained from outside sources. This question may be answered as N/A if no propagation materials are purchased from outside sources.

Requirement	5.2.3. The Operation has certificates/records showing the seed or other propagation material is free of injurious pests, diseases, viruses, etc.
Level	Basic Required Element No
Procedure	Records shall demonstrate that propagation material does not present a food safety risk.
Verification	Auditors shall verify the certificates/records showing the seed or other propagation material is free of injurious pests, diseases, viruses, etc.
Corrective Action	The operation will maintain certificates/records showing the seed or other propagation material is free of injurious pests, diseases, viruses, etc.
Documents Required	Record.

Guidance
The auditee will need to show records/certificates for seed or other propagation material is free of injurious pests, diseases, viruses, etc.

5.3 Fertilizers & Biosolids

Requirement	5.3.1. Operation does not use untreated human sewage.
Level	Basic Required Element Yes
Procedure	The operation shall have a written policy that it does not use untreated human sewage on its fields.
Verification	Auditor verifies operations written policy.
Corrective Action	Written policy will be established that untreated human sewage is not used.
Documents Required	Written Policy.

Guidance
This question was added because the Harmonized Standard did not specifically ban the use of untreated human sewage. The use of untreated human sewage is considered an “Immediate Action Required” by USDA/AMS and is reportable to local public health department/FDA.

Requirement 5.3.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	5.3.2. All applications of fertilizers, both organic and inorganic shall be recorded.		
Level	**Basic**	**Required Element**	**No**
Procedure	**All applications of organic and inorganic fertilizers shall be recorded together with the name/reference of the cultivated field, orchard, or greenhouse. Application date (day/month/year), trade name, composition (N, P, and K), application rate (weight or volume/ha), workers' name/s shall be recorded. Recommendations for application of fertilizers (organic or inorganic) shall be given by competent, qualified persons.**		
Verification	**Auditors shall verify that application records for fertilizers are recorded.**		
Corrective Action	**Operation will keep complete records of fertilizer applications.**		
Documents Required	**Record.**		

Guidance
Records of fertilizer application, for both organic and inorganic fertilizers must be recorded by the operation. The Global Markets Addendum requires that these records include the application date, the trade name, composition, application rate, and the name of the worker applying the fertilizer.

Requirement	5.3.3. Application equipment used to apply fertilizers are checked and calibrated on a scheduled basis.		
Level	**Intermediate Only**	**Required Element**	**No**
Procedure	**The equipment shall be checked for application rate accuracy at least once a growing season. Checks and calibrations shall be documented.**		
Verification	**Auditors shall verify records for annual (or more frequent) calibration of application equipment.**		
Corrective Action	**Operation will calibrate and keep records for annual (or more frequent) calibration of application equipment.**		
Documents Required	**Record.**		

Guidance
Many times the equipment manufacturer has specifications on how frequently and how to calibrate the equipment. Verify that calibration procedures are performed by the operation on a scheduled basis.

Requirement	5.3.4. Fertilizers are stored separately from agricultural chemicals.		
Level	Basic	Required Element	No
Procedure	Organic and inorganic fertilizers shall be stored separately from plant protection products in a manner that prevents cross contamination.		
Verification	Auditors will verify through observation that fertilizers are stored separately from agricultural chemicals.		
Corrective Action	Operation will store fertilizers separately from agricultural chemicals.		
Documents Required	N/A.		

Guidance
This requirement may be answered N/A when fertilizers and/or agricultural chemicals are not used by the operation. The standard is silent on distance and what constitutes separation.

5.4 Harvesting

Requirement	5.4.1. When product is field packed, collection, storage, and distribution points are maintained in a clean and hygienic condition.		
Level	Basic	Required Element	No
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.		

5.5 Agricultural Chemicals

Requirement	5.5.1. The operation shall have a documented crop protection policy.		
Level	Basic	Required Element	No
Procedure	A crop protection policy indicating the applications used for a target pest or disease that initiate applications shall be available.		
Verification	Auditor shall verify that the operation has a written crop protection policy.		
Corrective Action	A crop protection policy will be written.		
Documents Required	Written Policy.		

Guidance
Look for a written policy outlining the use of agricultural chemicals on the farm. Many operations participate in Integrated Pest Management (IPM) programs or have state regulations that require a policy outlining agricultural chemical use. For example; "ABC Farms is committed to the minimal use of pesticides, only applying chemicals that are targeted to the specific pests identified and causing economic damage to the crop." This is further backed up by the requirement in 5.5.3 documenting the target organism and the justification for the application. Examples of IPM used are service supplied pest management guides and packer pest management guides to establish their policy.

Requirement	**5.5.2. The operation has a current list of agricultural chemicals that are used and approved for the crops being grown.**
Level	**Intermediate Only. Required Element No**
Procedure	**A list is available for the commercial brand names of plant protection products (including their active ingredient composition or beneficial organisms) that are authorized on crops being grown within the scope of the audit for the last 12 months.**
Verification	**Auditor shall verify the operations 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.**

Guidance
The operation is responsible for keeping a list of agricultural chemicals that are used and approved for the crop being grown. Verify that the operation has this list of agricultural chemicals that have been used on crops used pre and post-harvest under the scope of the audit for at least a twelve month period prior to the audit.

Requirement 5.5.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Intermediate Level Assessment.

Requirement	**5.5.3. Agricultural chemical records include the target organism(s) and justification for application.**
Level	**Intermediate Only Required Element No**
Procedure	**The name of the pest(s), disease(s) and/or weed(s) treated and justification for application is documented in all plant protection product application records.**
Verification	**Auditors shall verify the operations 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.**

Guidance
This requirement is stricter than current federal or state EPA requirements for pesticide applications. To meet this requirement, the auditee needs to list the target pest (insect, disease, weed, etc.) and the justification for application. For example, IPM scouting reports show an insect exceeds the economic threshold level for that pest set by a state extension program. Records would show Target Pest Codling Moth; Justification exceeds threshold of 5 moths set by the Cooperative Extension IPM Program. Another example, herbicide used to prevent emergence of weeds.

Requirement	**5.5.4. Agricultural chemical records include the application equipment used to apply the chemicals.**
Level	**Intermediate Only Required Element No**
Procedure	**The application equipment type (e.g. knapsack, dusting, fogger, aerial, etc.), for all the plant protection products applied are detailed in all plant protection product application records. If there are various units, these are individually identified.**
Verification	**The auditor shall verify the operations records for agricultural chemicals include the application equipment used to apply the chemicals.**
Corrective Action	**The operation will keep records of the application equipment used to apply agricultural chemicals.**
Documents Required	**Record.**

Guidance
Current federal regulations do not require the documentation of the application equipment, so this requirement of the Global Markets assessment is above what most operations are documenting. If the operation only has one sprayer and its documented once on the front page of the spray records, that is acceptable, otherwise an entry of the equipment for each application is required.

Requirement	5.5.5. Equipment used to apply agricultural chemicals shall be kept in good condition and verified annually to ensure accurate application.
Level	Intermediate Only Required Element No
Procedure	The plant protection product 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 on site 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.

Guidance

The accuracy of agricultural chemical application is only as good as the equipment is calibrated to dispense and the operator is knowledgeable to use. Proper maintenance of chemical equipment is important to ensure accuracy of application rates of agricultural chemicals. A check that the equipment is working properly should be done before each chemical application by the trained and/or licensed applicator before each season to verify proper working condition of the equipment for use. To ensure good condition of all equipment the operation must annually test and maintain each piece of agricultural chemical application equipment and keep record of its maintenance. Verify records of at least annual maintenance for all equipment and should also observe equipment that is kept on site for evidence of good repair.

Requirement	5.5.6. Operator demonstrates knowledge of preparing and calculating agricultural chemical mixes.
Level	Intermediate Only Required Element Yes
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. A review of the mix records should be conducted to verify.
Verification	Auditors shall review mix records to verify agricultural chemicals are calculated properly. Responsible person(s) for applying agricultural chemicals should be interviewed.
Corrective Action	The operation will keep mix records. Retraining of responsible persons may be needed.
Documents Required	Record.

Guidance
Most commercial and private pesticide applicators are required to demonstrate knowledge of preparing and calculating chemical mixes in order to get their pesticide applicators license. Verify that the operator has knowledge of preparing and calculating chemical mixes. Interview on-site applicator's to verify their knowledge of preparing and calculating chemical mixes.

For example, insecticide "W" is applied at a rate of 2.5 lbs. per acre. The sprayer is calibrated at an application rate of 100 gallons per acre. Sprayer holds 500 gallons of water.

Question: How much water do you use to spray 4 acres?
Answer: 400 gallons.

Question: How much of "W" do you add to sprayer with 400 gallons of water to spray 4 acres?
Answer: 2.5lbs. x 4 = 10 lbs. of pesticide "W." Sprayer should have water in it and agitator running.

Requirement 5.5.6 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Intermediate Level Assessment.

Requirement	**5.5.7. The operation provides evidence of annual residue testing or participation in a third party plant protection product residue monitoring system.**
Level	**Intermediate Only Required Element No**
Procedure	**Current documented evidence or records are available either of annual plant protection product residue analysis results or of participation in a third party plant protection product residue monitoring system which is traceable to the farm.**
Verification	**Auditors shall verify records of annual (or more frequent) residue testing or participation in a third party plant protection product residue monitoring system.**
Corrective Action	**Operation shall keep records of their annual residue testing or third party plant protection product residue monitoring system.**
Documents Required	**Record.**

Guidance
The testing of annual residues and participation in a third party plant protection product residue monitoring system is not common in the U.S. unless the product is destined for export. To comply with this requirement, operations must have residue testing conducted on at least annual basis appropriate for the crops being grown. This residue monitoring system should be traceable to the farm.

The comment should show the date of most recent annual residue test.

Requirement	5.5.8. Agricultural chemicals approved for use on the crops being grown are stored separately from agricultural chemicals used for other purposes.		
Level	Intermediate Only	Required Element	No
Procedure	Only the plant protection products currently in the approved plant protection products list are kept in the storage area. Plant protection products 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 the crops being grown separated from agricultural chemicals used for other purposes.		
Documents Required	N/A.		

Requirement	5.5.9. 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.		
Level	Basic	Required Element	No
Procedure	Records of plant protection product 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.		

5.6 Waste Management

The operation should control waste and pollution to manage the risks they may pose to the safety of produce.

Requirement	5.6.1. Operation has implemented a waste management plan.
Level	Intermediate Only Required Element No
Procedure	There shall be visible actions and measures on the farm that confirm that the objectives of a comprehensive waste and pollution action plan are being carried out. These actions shall cover wastage reduction and pollution, if needed. Air, soil and water contamination must be considered.
Verification	The auditor shall verify the operation has implemented a waste management plan.
Corrective Action	The operation will implement a waste management plan.
Documents Required	Record.

Guidance
The operation must have a waste management plan that addresses sources of air, soil, and water contamination. This plan should address how the identified wastes and pollution are handled to minimize risk of contamination to produce.

Requirement	5.6.2. Operation has identified all sources of waste products and pollution created by the farm operation which pose a risk of food safety.
Level	Intermediate Only Required Element No
Procedure	All possible waste products (such as paper, cardboard, plastic, oil, etc.) and sources of pollution (e.g. fertilizer excess, exhaust smoke, oil, fuel, effluent, chemicals, etc.) produced by the farm processes shall be identified and listed.
Verification	Auditors shall verify the operation has identified sources of waste products and pollution which pose food safety risks.
Corrective Action	The operation will identify sources of waste products and pollution that may pose a risk to food safety.
Documents Required	Record.

Guidance
A large part of controlling risk is identifying the source of the risk. The operation must identify sources of waste products and pollution created by the farming operation which may pose risks to food safety.

5.7 Food Defense

After 9/11/01, protection of the nation's food supply from attacks became a national priority. The President has issued a series of directives - Homeland Security Presidential Directives (HSPDs) that cover outlining 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.

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.

The purpose of the following requirements for food defense is not to require that every farm in the United States build a fence around their property and hire security guards, but to take steps to protect their product from intentional contamination.

Requirement	**5.7.1. Have the threats to the produce as a result of intentional contamination been assessed?**
Level	**Intermediate Only Required Element No**
Procedure	**The risk assessment shall cover food defense and include the methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist like incident.**
Verification	**Auditors shall verify the operation has assessed risk for intentional contamination of produce.**
Corrective Action	**Operation shall assess risk of intentional contamination.**
Documents Required	**Record.**

Guidance
The operation must have a record of their assessment of food defense risks that could lead to intentional contamination.

Requirement	**5.7.2. Have those points in the process which are vulnerable to intentional contamination been identified and subjected to additional access control?**
Level	**Intermediate Only Required Element No**
Procedure	**Sensitive areas of the facility shall be identified as part of the food defense risk assessment. Access control measures shall be implemented in these areas.**
Verification	**Auditors shall verify that the operation has a written policy identifying food defense risks and records that show the operations control measures of these areas.**
Corrective Action	**A written policy for food defense risks will be written and implemented. Records shall be maintained for these areas.**
Documents Required	**Written Policy, Record.**

Guidance
Most food defense risk assessments will identify the production fields as a vulnerable point in the operation, however it is unlikely the operation will implement any additional access control for the fields as it is impractical to do so. For the purposes of this question, only assess whether or not vulnerable structures have been subjected to additional access control, and if the operation did implement access controls in the field, point out that fact on the audit report.

Requirement	**5.7.3. Are measures in place, if prohibited access took place and food may have been sabotaged?**
Level	**Intermediate Only Required Element No**
Procedure	**A documented procedure has been established addressing actions to be taken if food defense measures are in question or sabotage is suspected.**
Verification	**Auditors shall verify the operations written policy for measures taken if sabotage is suspected and that workers are knowledgeable of this policy appropriate to their responsibilities.**
Corrective Action	**The operation will develop a written policy for measures to be taken if sabotage is suspected. Workers will be trained on the operations policy.**
Documents Required	**Written Policy.**

Guidance
The operation must have a written policy addressing how it will react to sabotage if it is suspected. In addition to verifying the company's policy on sabotage, the auditor must interview employees for knowledge appropriate to their responsibilities of how they will handle food sabotage if it is suspected. Knowledge of who to report suspected sabotage to should be expected of all employees.

POST-HARVEST OPERATIONS

USDA Acceptance Criteria

The following criteria must be met in order for an operation 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	Questions 1.1.1; 1.1.2; 1.2.1; 1.6.1; 1.7.1; and 1.10.1 must be assessed as "compliant."
4	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.
5	Operation must have performed a risk assessment as addressed in the Harmonized Standard, as well as Question 4.1.2 in the Global Markets Addendum section, if this section is covered by scope of audit.
6	In each major section (1 through 3) of the audit, at least 80% of the questions not answered as "NA" must be answered as compliant.
7	If a major section has less than 5 questions, one "CAN" can be assessed and still meet the minimum acceptance criteria.

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 the Harmonized Standard as well as being posted to the USDA website. Corrective action reports will still be supplied to the auditee for all nonconformances.

If an operation does not meet the acceptance criteria as outlined above, a corrective action report form will be issued for each nonconformance 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 Criteria for Global Markets Primary Production Addendum

In addition to the USDA acceptance criteria, growers utilizing this audit to meet the Global Markets Program for Primary Production Basic or Intermediate Level Assessment audit requirements must meet the following additional criteria, which are listed as major elements within the Global Markets Capacity Building Program for Primary Production. The auditor shall only assess the Global Markets addendum at the specific request of the auditee. This portion of the audit is not an official part of the Produce GAPs Harmonized Food Safety Standards.

The Global Markets Capacity Building Program for Primary Production has two levels, Basic

and Intermediate. For the Basic level audit, only those questions identified as basic need to be answered (Intermediate questions should be marked N/A). For the Intermediate level audit both the basic AND intermediate questions must be answered.

Audit Element (s)	**Criteria**
1.3.1	Raw Material Sourcing
1.4.1	Documentation & Recordkeeping
1.5.1	Worker Training
1.9.1	Self-Audits
1.10.2	Ag Chemicals, Biocides, Plant Protection Products
1.11.1	Water Use
1.11.3	Water System Assessment
1.13.2 & 1.13.5	Master Sanitation Schedule
1.14.1, 1.14.3 & 1.14.4	Storage Areas
1.18.1	Lubrication
1.21.1, 1.21.2	Toilet Facilities
1.21.7 & 1.21.8	Employee Hygienic Practices
1.24	Pest & Animal Control (includes all 3 sub-questions)
2.3, 2.4 & 2.5	Water Treatment Procedures
4.1.1	Customer Specifications
4.1.2	Risk Assessment of Packinghouse
4.1.3	Critical Control Points, HACCP Plan
4.1.6, 4.1.7 & 4.1.8	Record of Food Safety Non-conformances, Complaints, and Corrective Actions

POST-HARVEST OPERATIONS REQUIREMENTS

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.

Section 1 - General Questions

1.1 Management Responsibilities

Requirement	**1.1.1. A food safety plan 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.**

See Field and Harvest 1.1.1.

Requirement	**1.1.2. Management has designated individual(s) with roles and responsibilities 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. These roles and responsibilities shall be communicated within the organization.**
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.**
Corrective Action	**Operation identifies individual(s) for key food safety activities in the Food Safety Plan. Operation identifies actions to be taken when the identified individual(s) are not present.**
Documents Required	**Written Policy.**

See Field and Harvest 1.1.2.

Requirement	**1.1.3. 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.**

See Field and Harvest 1.1.3.

1.2 Food Safety Plan or Risk Assessment

Requirement	1.2.1. 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.

See Field and Harvest 1.2.1.

Requirement	1.2.2. 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.
Verification	Auditor reviews the last Food Safety Plan review.
Corrective Action	Operation reviews Food Safety Plan and documents review.
Documents Required	Record.

See Field and Harvest 1.2.2.

1.3 Raw Material Sourcing

Requirement	1.3.1. 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. 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.

Guidance
Incoming materials includes any materials purchased for use in production. This includes chemicals, produce, packaging material, labeling supplies, equipment used in the packing process, etc. Requirement 1.3.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Example Scenarios
Scenario 1: An operation has a program in place for approving suppliers, but the program is not written.
Assessment: Compliant.
Reason: Procedure for approving suppliers does not have to be written; only the supplier list must be written.

Scenario 2: An approved supplier program does not include food contact packaging material.
Assessment: Corrective Action Needed.
Reason: The approved supplier list must include packaging.

Scenario 3: An approved supplier program does not include equipment cleaning chemicals.
Assessment: Corrective Action Needed.
Reason: The approved supplier list must include all materials that may impact food safety.

Scenario 4: You review receiving records and finds ingredients from suppliers that are not on the approved supplier list.
Assessment: Corrective Action Needed.
Reason: All suppliers need to be on an approved list, unless there is evidence that the operation has followed its procedure for using an alternate supplier.

Scenario 5: Receiving personnel are not aware of the approved supplier list, but there is no evidence that the operation received product from suppliers that were not approved.

Assessment: Compliant.
Reason: The approved supplier list must be written and followed; whether receiving personnel are aware of the list is not required.

Scenario 6: 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 7: 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 8: 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	**1.3.2. The Operation has a policy and takes affirmative steps to ensure that all fresh produce that are packed or stored in the facility 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.**

Guidance
The operation needs to ensure that all fresh products that are packed or stored in the facility is 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: There is no written policy in place at the operation.

Assessment: Compliant.
Reason: The standard does not require the policy to be written, only that documentation is available to demonstrate compliance.

Scenario 2: 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 3: Same as Scenario 2, but the new grower supplies the results of an internal audit that demonstrates compliance with the requirements of the Harmonized Standards.
Assessment: Compliant.
Reason: This is consistent with the operation's supplier approval program and there is no indication that the grower is not in compliance.

Scenario 4: Same as Scenario 2, but the new grower demonstrates compliance with the Leafy Green Marketing Agreement metrics, which is recognized to cover the requirements of the Harmonized Standards.
Assessment: Compliant.
Reason: The grower is in compliance with the requirements of the harmonized standard.

Scenario 5: 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 6: 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.

1.4 Documentation & Recordkeeping

Requirement	1.4.1. 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.
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.

Guidance
Requirement 1.4.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See Field and Harvest 1.3.1.

Requirement	1.4.2. Documentation shall be readily available for inspection.
Procedure	Documents and records may be maintained on-site or at an off-site location, or accessible electronically (e.g., MSDS), and shall be available for inspection in a reasonable timeframe or as required by prevailing regulation.
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.

See Field and Harvest 1.3.2.

Requirement	1.4.3. 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 the 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	N/A.

See Field and Harvest 1.3.3.

1.5 Worker Education & Training

Requirement	1.5.1. All personnel shall receive food safety training.
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 prescribed frequencies. 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.

Guidance
Requirement 1.5.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See Field and Harvest 1.4.1.

Requirement	1.5.2. Personnel with 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 formal food safety course/workshop or by job experience.
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, or company training record. If the Operation passes the food safety audit, the food safety individual's training is deemed adequate.
Corrective Action	Individual must obtain demonstrable food safety training.
Documents Required	N/A.

See Field and Harvest 1.4.2.

1.6 Traceability

Requirement	1.6.1. 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 and other supplies and raw materials (one step backward). Records shall include the items and date of receipt, lot numbers, quantities, source of the produce, and transporter. Additional information may be included. Contents and retention of records shall be consistent with applicable regulations.
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.

See Field and Harvest 1.6.1.

Requirement	1.6.2. 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	N/A.

See Field and Harvest 1.6.2.

1.7 Recall Program

Requirement	1.7.1. 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 recall team and recall plan, and tests the plan for effectiveness.
Documents Required	Written Policy, Record.

See Field and Harvest 1.7.1.

1.8 Corrective Actions

Requirement	1.8.1. 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 timeliness 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 actions procedures.
Documents Required	Written Policy, Record.

See Field and Harvest 1.8.1.

1.9 Self Audits

Requirement	1.9.1. The Operation shall have documented self-audit procedures.
Procedure	Internal audits will be conducted at a minimum annually by an assigned individual who is knowledgeable in this standard, 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.

Guidance
Requirement 1.9.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See Field and Harvest 1.9.1.

1.10 Agricultural Chemicals/Plant Protection Products

Requirement	1.10.1. 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. Records of 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.

See Field and Harvest 2.3.1.

Requirement	1.10.2. 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.

Guidance
Requirement 1.10.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See Field and Harvest 2.3.2.

Requirement	1.10.3. 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.

See Field and Harvest 2.3.3.

1.11 Water/Ice

Requirement	1.11.1. 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.

Guidance
Requirement 1.11.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See Field and Harvest 3.2.2.

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	**1.11.2. 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	**Written Policy, Record.**

Guidance
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 water system description in the process of the review.

Example Scenarios
Scenario 1: An operation has a Google Earth map of the operation property with well and outside fixture locations marked in pen.
Assessment: Corrective Action Needed.
Reason: The map does not include permanent fixtures inside the facility.

Scenario 2: An operation has a diagram of all internal piping and fixtures, but only a verbal description that the water comes from an on-site well.
Assessment: Corrective Action Needed.
Reason: A water system documentation must include all water sources.

Scenario 3: The water system description is written in text, not on a map.
Assessment: Compliant.
Reason: A written description of the water system is acceptable.

Scenario 4: 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 5: The operation has no written description, but only uses municipal water.
Assessment: Corrective Action Needed.
Reason: A water system description is still required.

Requirement	**1.11.3. 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.**

Guidance
Review water system test and/or routine check documentation. It is not expected that an auditor test 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.

Requirement 1.11.3 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Example Scenarios
Scenario 1: 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.

Scenario 2: Records indicate that all backflow devices are checked every 6 months, and all were functioning at the last check. At the time of the audit, one device is not functional. The operation does not test its water supply because it comes from a municipal source.
Assessment: Corrective Action Needed or Immediate Action Required.
Reason: Corrective Action Needed because the backflow device is not working. Possible Immediate Action Required if there is a reason to believe that the lack of back flow prevention has or may result in contamination of the water system.

Requirement	**1.11.4. 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.**
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.**

Example Scenarios
Scenario 1: A hydrocooler waste line is plumbed in the same line with the operation's floor drains. On rare occasions, hydrocooler waste line becomes plugged and water backs up onto operation's floor. The operation's map does not show any cross-connections of water lines, but auditor observes cross-connection of gray water waste line with equipment clean area waste line. There is no backflow prevention.

Assessment: Immediate Action Required.
Reason: Either discontinue use of one or both of the waste lines, or install backflow prevention to prevent cross-contamination. A long term solution would be to remove the cross connection.

Scenario 2: You smell sewer gas from a floor drain.
Assessment: It depends.
Reason: The assessment would depend on operation's reaction to the observation. Operation should immediately investigate the cause. Potential impact on food safety (Corrective Action Needed or Immediate Action Required) would depend on the cause of the odor.

Requirement	**1.11.5. 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.**

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 commingling of product. 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.

Requirement	1.11.6. Re-circulated water that contacts product or food contact surfaces shall be treated using an approved antimicrobial process or chemical treatment.
Procedure	Re-circulated water shall be treated using an antimicrobial treatment sufficient to prevent cross-contamination. 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	Record.

Guidance
The comment should include the type of antimicrobial treatment used.

Example Scenarios
Scenario 1: Recirculated 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 (e.g., household Clorox).
Assessment: Immediate Action Required.
Reason: Treating with a chemical not approved for food use renders the food adulterated.

Scenario 4: An operation washes produce with a shower that uses single pass water that meets the microbial standards for drinking water. No antimicrobial is used.
Assessment: Not applicable.
Reason: This item only applies to water that is recirculated.

Requirement	1.11.7. 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.

Guidance
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 records are required. Possible Immediate Action Required if chlorine levels may have dropped or risen to unsafe levels.

Scenario 3: An operation's procedures require monitoring Oxidation-Reduction Potential (ORP). Operation measures free chlorine levels using test strips.
Assessment: Corrective Action Needed.
Reason: The operation is not following their SOP.

Requirement	1.11.8. 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.

Guidance
The comment should include the temperature specifications.

See Field and Harvest 3.2.5.

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.

1.12 Containers, Bins

Requirement	**1.12.1. 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.**

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: The practice is not in compliance with the written instructions.

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.

Requirement	**1.12.2. Operation has written policy regarding whether product-contact containers are permitted in direct contact with the ground.**
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 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.**

Example Scenarios
Scenario 1: The operation has a written procedure for keeping all bins off the ground. You observe two bins labeled to hold discarded product, on loading dock directly on the ground.
Assessment: Corrective Action Needed.
Reason: The requirement only applies to food-contact bins, 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	1.12.3. Operation has written policy regarding inspection of food contact containers and bins 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.

Guidance
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.

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: Reusable foam pads are placed on cherries during transport from orchards to packinghouse. The operation has not included foam pads in the container inspection SOP because "foam pads are not a container."
Assessment: Corrective Action Needed.
Reason: The foam pads are functionally a "packing material" and the standard requires packing materials to "be visually inspected, clean, intact and free of any foreign materials prior to use."

Scenario 3: The operation power washes plastic harvest bins prior to use. The operation's written policy considers the person who does the washing as being the "inspector."
Assessment: Compliant.
Reason: The operation has a written policy and is operating in accordance with it.

Scenario 4: The operation has an SOP requiring visual inspection of harvest containers prior to use. The 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.

Requirement	1.12.4. 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.

Example Scenarios
Scenario 1: A citrus 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.

Scenario 4: The operation sorts and reuses clean, dry, unlabeled cardboard cases from various incoming produce for packing produce, according to written procedures. Traceability records do not indicate the source of the cardboard cases.
Assessment: Immediate Action Required.
Reason: While repacking into boxes that were sourced from the same lot of produce is acceptable (compliant), it is not possible to make used cardboard cases sanitary sufficient to prevent cross-contamination from previous lots in the case. The use of sanitary, single-use liners would be acceptable (compliant).

Requirement	1.12.5. 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.

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	1.12.6. 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.

Guidance
Review the condition of pallets and containers being used and those stored for future use. Interview 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 Field and Harvest 3.5.2.

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 but could cause pieces of wood to fall in to produce if stored on top of or over other product.
Assessment: Corrective Action Needed.
Reason: Pallets shall be kept in good condition.

Scenario 2: Pallets are not reviewed before being used or upon receipt.
Assessment: Corrective Action Needed.
Reason: Operation is required to inspect pallets before use.

Scenario 3: 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.

1.13 Facility, Equipment, Tools

Requirement	1.13.1. Facility shall be designed, constructed and maintained in a manner that prevents contamination of produce during staging and cooling.
Procedure	Facility 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. 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 facility and equipment for evidence that the facility can be cleaned and maintained to prevent product contamination.
Corrective Action	Facility deficiencies are corrected. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.

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.

Scenario 3: Air intakes are located on the roof, which has recently been tarred.
Assessment: Compliant, unless there is evidence that fumes from the tar are contaminating the produce.
Reason: No evidence is present that fumes from the tar will contaminate the produce. Facility is constructed in a manner to not serve as a source of contamination to the produce.

Requirement	1.13.2. 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.
Verification	Auditor reviews Preventive Maintenance and/or Master Cleaning Schedule, observes facility and equipment for evidence that the facility is cleaned and maintained to prevent product contamination. Auditor reviews facility maintenance records for evidence of repairs.
Corrective Action	Operation develops a Preventive Maintenance and/or Master Cleaning Schedule, with related SOPs. Facility deficiencies are corrected. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Policy, Record.

Guidance
Requirement 1.13.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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 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 an appropriate for the operation.

Requirement	1.13.3. 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.

Guidance
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, making sanitization ineffective.

In order 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.

Example Scenarios
Scenario 1: The operation uses Formula 409 cleaner that was purchased at a local supply store to clean food contact surfaces. Surfaces are not rinsed before use.
Assessment: Immediate Action Required.
Reason: Cleaner was not meant to clean food contact surfaces. The local supply store will also need to be checked for compliance with Supplier Approval Program (See Post-harvest Operations Requirement 5.2.2).

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.
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.

Requirement	**1.13.4. 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.**

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.

Scenario 3: Cleaning mops for all areas are rinsed with potable water and left outside in open area to air/sun dry before being returned to their designated locations.
Assessment: Corrective Action Needed.
Reason: Corrective Action Needed so that mops are not spontaneously used in non-designated locations.

Requirement	1.13.5. 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. 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 procedures and observes food contact surfaces to verify compliance.
Corrective Action	Operation develops written cleaning and sanitizing procedures consistent with the Food Safety Plan. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.

Guidance
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 the you observe that cleaning and sanitizing is not sufficient this question must be answered as CAN or IAR depending on the severity.

Requirement 1.13.5 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Example Scenarios
Scenario 1: Open air packing facility utilizes Simple Green product and rags to wipe down white conveyor belts which transport fruit to sorters and packers.
Assessment: Compliant.
Reason: Compliant if the Simple Green 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 so that produce residues accumulate has 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.

Requirement	1.13.6. 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	Facility installs adequate, lighting.
Documents Required	N/A.

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 1.13.16 however corrective action needed for 1.17.1.
Reason: The lighting is adequate. The materials the lighting is made out of is potentially hazardous which does not comply with the requirement of 1.17.1.

Scenario 3: Lights are appropriately positioned and operate under motion detection system.
Assessment: Compliant.
Reason: As long as there is a master switch for the lights to remain on during the entire cleaning process, lights are adequate for their intended purpose.

Requirement	1.13.7. 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.

Guidance
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 Scenarios
Scenario 1: 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.

Scenario 2: All refrigeration units in the leafy greens receiving storage area are operating normally and temperature records are available for the past 7 days. There are no calibration records for the temperature sensor.
Assessment: Corrective Action Needed.
Reason: The calibration records are needed for the sensor to demonstrate proper ongoing calibration. Frequency of calibration should be per manufacturer recommendation or per Food Safety Plan.

Requirement	**1.13.8. 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	**N/A.**

Guidance
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.

Maintain temperatures that promote optimum produce quality.
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.

Maintain air cooling equipment and cooling areas.
Air cooling equipment and cooling areas should be periodically cleaned and inspected. Potential sources of contamination should not be located near air intakes.

Equipment should be clean and sanitary.
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.

Scenario 3: 10 evaporator units are in use in the facility, 8 units appear clean with no debris or soil visible on coils, fans, or adjacent surfaces, and 2 units have visible soils and lint build up. The operation's food safety manager explains that the two remaining units are next in line for service.
Assessment: Compliant.
Reason: Compliant if the cleaning schedule is according to written sanitation SOPs. Frequency of cleaning in SOPs may need Corrective Action if build-up on the two units is beyond reasonable for a plant in operation.

Requirement	1.13.9. 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	Records.

Guidance
Transporting equipment should be kept as clean as possible, and cleaned on a scheduled basis to assist in preventing unnecessary 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 in order 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.

Scenario 3: Same as Scenario 2, but one forklift is not on the maintenance and sanitation schedule. The forklift looks in good condition, but there are no records of service. The operation explains that the forklift is a rental.
Assessment: Depends on how long the forklift has been rented and who is responsible for servicing the rental.
Reason: Corrective Action Needed if forklift has been rented for more than the operation's usual service interval for their own forklifts.

Requirement	1.13.10. Outside garbage receptacles/dumpsters are closed and located away from facility 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. Facility deficiencies are corrected. Retraining is performed and documented.
Documents Required	N/A.

Guidance
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 facility entrances in order that pests will not be drawn to the facility. 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 facility. 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 is allowed to sit or accumulate or there is no action being taken to clean the spillage, this question must be answered Corrective Action Needed.

Example Scenarios
Scenario 1: You observe the waste storage containers to be full but covered and area is in relative good condition. There are minor amounts of insects present.
Assessment: Compliant.
Reason: Outside garbage receptacles are closed and the area around the waste containers is clean.

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 as long as 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.

Requirement	1.13.11. 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. 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.

Guidance

See Post-harvest Operations Requirement 1.14.

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 there 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.

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 operation has waist-high bushes adjacent to the back of the building (there are no doors or entryways on that side). A chipmunk scurries from the bushes as you approach.
Assessment: Corrective Action Needed.
Reason: The vegetation adjacent to the building is clearly a potential harborage, even if there

are no entrances on that side of the building.

1.14 Storage

Requirement	1.14.1. 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.

Guidance
Requirement 1.14.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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 operation's cleaning schedule requires produce storage room floor to be cleaned nightly. There are no records. There is dirt on the floor from today's forklift traffic.
Assessment: Compliant.
Reason: The standard does not require records of cleaning. The assessment might be different if auditor observes evidence of non-compliance with cleaning schedule, e.g., dirt on the floor first thing in the morning.

Scenario 3: 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.

Scenario 4: The product storage area has walls, floor, and ceiling that are sealed and cleanable. Lighting is sealed. Temperature is controlled and recorded. Condensate from cooling unit is plumbed to a drain outside the room.
Assessment: Compliant.
Reason: Product storage areas are appropriate for storage.

Requirement	1.14.2. 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. Facility deficiencies are corrected. Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Procedure.

Guidance
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.

Requirement	1.14.3. 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.

Guidance
Requirement 1.14.3 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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. Refer to 1.16.1.

Scenario 2: The operation is one big, enclosed room. Packaging material and chemicals are stored on separate, open racks attached to a wall at one end of the room, away from where produce is handled.
Assessment: Corrective Action Needed.
Reason: Chemicals must be securely stored in compliance with regulatory requirements.

Scenario 3: 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.

Requirement	1.14.4. 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. Facility deficiencies are corrected. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.

Guidance
Requirement 1.14.4 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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.

Scenario 4: Packaging film is covered in sealed plastic bags and is stored on a rack alongside cleaning and maintenance chemicals.
Assessment: Compliant as described, but corrective action needed per audit requirement 1.14.6.
Reason: Packaging film is stored to protect it from contamination but chemicals are not stored in a secured separate area.

Requirement	1.14.5. 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.

Currently FDA CGMP 21 CFR 110.20 (b) states: 1) "Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food." 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 follows the operation's food safety procedure.

Example Scenarios
Scenario 1: There are no written procedures, but incoming produce is stored in bins on pallets on the floor in a temperature controlled room. Lines are painted on the floor, large enough for four pallets in a square and providing 18 inch clearance between squares and between the pallets and the walls. No pallets are more than an inch over a line.
Assessment: Corrective Action Needed.
Reason: Written procedures are required by the standard.

Scenario 2: 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 3: 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.

Requirement	1.14.6. 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.

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.

1.15 Waste Materials

Requirement	1.15.1. 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. Facility deficiencies are corrected. Retraining is performed and documented.
Documents Required	N/A.

Example Scenarios
Scenario 1: You observe significant amount of trash, leaves and pieces of broken pallet boards in the produce handling area, within five yards from employees sorting and culling romaine lettuce.
Assessment: Immediate Action Required.
Reason: Waste materials are not managed to avoid contamination.

Scenario 2: 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 3: 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.

1.16 Outside Grounds

Requirement	1.16.1. Operation has procedures to prevent pest harborage in any equipment stored near the building.
Procedure	Equipment stored outside is stored away from the building perimeter. Equipment is not to accumulate near the building. Bone yards are located away from the building. Outside equipment storage areas are included in pest control programs.
Verification	Auditor observes outside equipment storage areas for evidence of compliance.
Corrective Action	Operation includes outside storage areas in pest control program. Equipment is moved to be in compliance.
Documents Required	N/A.

Guidance
"Bone yard" is a term used for old equipment and or supply storage/dumping grounds**.**

For additional guidance, see 1.24.1 and 1.24.2.

Example Scenarios
Scenario 1: 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.

Scenario 2: The facility has procedure for pest prevention which includes rodent traps. No pest activity is observed. However, old equipment is being stored next to the packing shed and hasn't been moved for a while.
Assessment: Corrective Action Needed.
Reason: The standard requires that equipment is stored away from the building perimeter.

Scenario 3: The facility has procedures for pest prevention, including rodent traps. You observe eight dead rodents in the traps near old equipment. The old equipment is being stored away from the building.
Assessment: Compliant, although corrective action may be needed for pest control.
Reason: The facility is following their procedures for pest prevention.

1.17 Glass Control

Requirement	**1.17.1. Only essential glass and brittle plastic shall be present in the facility.**
Procedure	**Light bulbs, fixtures, windows, mirrors, skylights and other glass and brittle plastic in the facility or in the product path entering or exiting the facility 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 facility, 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 facility.**
Documents Required	**Written Policy/Records.**

Guidance
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 or not 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. Product in exposed, open top boxes is being stored below the lights.
Assessment: Corrective Action Needed.
Reason: Lights are unshielded. This assessment could be an Immediate Action Required if there is a reasonable probability that the glass could break into the boxes.

Scenario 2: Lights in the storage building are unshielded glass and product 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 3: 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.

Scenario 4: The facility has a glass policy but no brittle plastic register. Brittle plastic is being used in the facility as overhead light covers in the storage areas where open top boxes are exposed.
Assessment: Corrective Action Needed.
Reason: The standard requires a brittle plastic register if brittle plastic must be used. This assessment could be an Immediate Action Required if there is a reasonable probability that the brittle plastic could break into the boxes.

1.18 Leaks/Lubricants

Requirement	1.18.1. 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.

Guidance
You will want to 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 so as to catch any leaking lubricant.

Requirement 1.18.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Example Scenarios
Scenario 1: A non-food grade lubricant is being used for a conveyor motor located underneath the trim waste conveyor. The supervisor explains that the motor is not in the product zone.
Assessment: Not Applicable.
Reason: The motor is located underneath the conveyor and is not over the product handling area. If the waste trim is going to a secondary food or feed use, or the auditor observes a reasonable opportunity for lubricant from the motor to be conveyed into a product handling area, then assessment (Corrective Action Needed or Immediate Action Required) would depend on whether the lubricant is reasonably likely to contact food or food contact surfaces in the product handling area.

Scenario 2: 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 is no indication that leaking lubrication has fallen onto Conveyor C.
Assessment: Immediate Action Required.

Reason: There is a reasonable probability that the lubricant will fall onto the conveyor and potentially exposed product.

Scenario 3: Same as Scenario 2, except that 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.

1.19 Equipment and Utensil Construction

Requirement	**1.19.1. 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.**
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 Procedure.**

Example Scenarios
Scenario 1: The operation's list of tools and utensils is complete but does not include manufacturer's data sheets.
Assessment: Not Applicable.
Reason: The standard has no requirement for manufacturer's data sheets.

Scenario 2: 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 3: 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 4: 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.

Requirement	**1.19.2. 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.**

Example Scenarios
Scenario 1: You observe that there is walk around space on all sides of food contact equipment but is not able 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.

Requirement	**1.19.3. 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.**

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.

1.20 Temporary Repairs

Requirement	**1.20.1. 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.**

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 cleanable/sanitizable, 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.

Scenario 3: Cardboard which was used for a temporary repair is new the day of the audit and a work order is available for the permanent fix. The cardboard is used in an area where it remains in good condition, and is replaced often enough to not become a source of contamination.
Assessment: Compliant.

1.21 Worker Health/Hygiene and Toilet/Handwashing Facilities

Requirement	**1.21.1. Restrooms shall be designed, constructed and located in a manner that minimizes the potential risk for product contamination.**
Procedure	**Restrooms shall be designed and constructed in a manner that minimizes the potential risk for product contamination, are located away from produce handling areas, and are directly accessible for servicing.**
Verification	**Auditor visually and by records verifies that toilet facilities are not positioned, leaking or serviced in a manner that poses a risk of produce contamination.**
Corrective Action	**Toilet facility is replaced, repaired or repositioned to be compliant.**
Documents Required	**N/A.**

Guidance
Requirement 1.21.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See Field and Harvest 2.2.3.

Example Scenarios
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.

Requirement	1.21.2. Toilet facilities shall be of adequate number, easily accessible to employees and in compliance with applicable regulation.
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.

Guidance
Requirement 1.21.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See Field and Harvest 2.2.4.

Example Scenarios
Scenario 1: A facility has 16 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: A facility 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: A facility 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.

Requirement	1.21.3. The practice of disposing of used toilet tissue on the floor, in trash receptacles, or in boxes is prohibited.
Procedure	Operation shall instruct employees that used toilet tissue shall only be disposed of in the toilet.
Verification	Auditor observes restrooms for evidence of compliance.
Corrective Action	Retraining is performed and documented.
Documents Required	N/A.

Example Scenarios
Scenario 1: You see toilet tissue in trash receptacles. A representative explains the tissue is just from employees cleaning their glasses and the mirror.
Assessment: Corrective Action Needed.
Reason: All toilet tissue must be disposed of in the toilet.

Scenario 2: 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.

Requirement	**1.21.4. Toilet and hand wash stations shall be maintained in a clean and sanitary condition.**
Procedure	**Toilet paper shall be available in toilet facility. 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.**
Corrective Action	**Toilet or handwashing facility is replaced, repaired or maintained to be compliant.**
Documents Required	**N/A.**

See Field and Harvest 2.2.5.

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: The toilet room is clean and compliant, but there is no cleaning log.
Assessment: Not Applicable.
Reason: The standard is silent on how to monitor.

Scenario 4: Gray water is plumbed, but auditor observes plumbing ends 30 feet away from the toilet room at an open ditch containing an open container for later disposal.
Assessment/Reason: Compliant with the requirement-procedure but a possible IAR for risk of

contamination and threat to food safety of public health consequences.

Requirement	1.21.5. 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.

See Field and Harvest 2.2.7.

Requirement	1.21.6. If protective clothing is required by the Operation in product handling areas, it 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 clothing, such as aprons and gloves, the Operation shall have a policy that the clothing not be left on product, work surfaces, equipment or packaging material but hung on apron and glove racks or in designated areas. 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 employees wear protective clothing, auditor reviews protective clothing policy and observes whether clothing rack and tool storage containers or designated storage areas are available and used.
Corrective Action	Operation develops or revises clothing policy. Operation obtains and positions racks and storage containers as necessary. Retraining is performed and documented.
Documents Required	N/A.

See Field and Harvest 2.2.10.

Example Scenarios
Scenario 1: The operation has racks for protective clothing immediately adjacent to toilets. The crew is observed to use the racks when using the toilets.
Assessment: Compliant, unless auditor observes a reasonable opportunity for rack placement to be a source of contamination.

Reason: Racks for protective clothing are provided.

Scenario 2: Racks are inadequate to properly hold clothing and/or 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 or train workers how to use the racks.

Requirement	**1.21.7. Employees and visitors shall 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 facility. The Operation shall designate competent supervisory personnel to ensure compliance with the requirements in this section.**
Verification	**Auditor observes personnel in operation for evidence of compliance.**
Corrective Action	**Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**

Guidance
Requirement 1.21.7 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See Field and Harvest 2.2.2.

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: An operation has designated competent supervisory personnel to ensure compliance. Through documentation/training records, the operation can demonstrate competency of designated supervisory personnel. However, designated personnel is not on-site/available on the day of the audit and harvest/agronomic activity is taking place.
Assessment: Compliant.
Reason: The standard does not require the person to be on-site the day of the audit.

Scenario 3: 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.

Requirement	1.21.8. Workers and visitors who show signs of illness shall be restricted 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 facility who show signs of illness (e.g., vomiting, jaundice, diarrhea) from contact with product or food contact surfaces.
Verification	Auditor reviews policy and observes 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	N/A.

Guidance
Requirement 1.21.8 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See Field and Harvest 2.2.18.

Example Scenarios
Scenario 1: You see a harvest worker sneeze or cough into her sleeve once. The operation takes no action.
Assessment: Compliant.
Reason: A single sneeze or cough is not a sign of illness.

Scenario 2: 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.

Scenario 3: An operation's policy allows workers to return to food contact jobs after 24 hr. of no symptoms.
Assessment: Immediate Action Required.
Reason: Ill workers can be shedders and spread infection for up to a month. Food Code recommends that "personnel should not return to these activities until a minimum of 48 hr. after the resolution of symptoms or longer as required by local health regulations." More information on restricting food handlers after resolution of illness is available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm189171.htm

Requirement	1.21.9. 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 for evidence of compliance.
Corrective Action	Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.

See Field and Harvest 2.2.19.

Example Scenario
Scenario: A worker on produce sorting line has 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."

Requirement	1.21.10. 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.

See Field and Harvest 2.2.20.

Requirement	1.21.11. First aid kits shall be accessible to all personnel.
Procedure	The kits shall be readily available in the facility and maintained in accordance with prevailing regulation. The kit materials shall be within shelf life and kept in a sanitary and usable condition.
Verification	Auditor observes that provisions exist for first aid kit to be readily available in facility 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 personnel.
Documents Required	N/A.

See Field and Harvest 2.2.21.

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.

Requirement	**1.21.12. Smoking, chewing, eating, drinking (other than water), chewing gum and using tobacco shall be prohibited except in clearly designated areas.**
Procedure	**Operation shall have policy prohibiting smoking, eating, chewing gum or tobacco, drinking other than water except in designated areas. Such areas shall be designated so as not to provide a source of contamination.**
Verification	**Auditor observes personnel for evidence of compliance.**
Corrective Action	**Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**

See Field and Harvest 2.2.15.

Example Scenarios
Scenario 1: 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.

Scenario 2: Two workers are observed drinking on the packing line; one is drinking water from a bottle, the other is drinking a carbonated soft drink from a can. There is no written policy.
Assessment: Corrective Action Needed.
Reason: The standard only allows for water outside of designated areas.

Scenario 3: 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.

Requirement	1.21.13. Personnel shall be required to wash their hands before beginning or returning to work, after each visit to the toilet and whenever their hands may have become 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 and at any other time when their hands may have become a source of contamination.
Verification	Auditor observes personnel for evidence of compliance.
Corrective Action	Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.

See Field and Harvest 2.2.6.

Requirement	1.21.14. 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 types of glove materials that are allowed, how and when gloves are to be used, cleaned, replaced and stored. 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.

See Field and Harvest 2.2.9.

Example Scenarios
Scenario 1: 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 2: 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.

Scenario 3: One person is seen wearing a glove to cover a bandage.
Assessment: Corrective Action Needed.

Reason: If gloves are used there needs to be a glove use policy.

Requirement	**1.21.15. Clothing, including footwear, shall be effectively maintained, stored, laundered and worn so as to protect product from risk of contamination.**
Procedure	**Operation shall have a policy that employee clothing shall be clean and appropriate for the operation.**
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.**

See Field and Harvest 2.2.8.

Requirement	**1.21.16. 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.**

Guidance
The operation's policy may be written or unwritten on how hair coverings must be used. If any employees are wearing hair coverings in the operation the operation must have a policy. Auditors must 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 no workers use hair coverings.

See Field and Harvest 2.2.13.

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 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.

Scenario 3: A packinghouse worker is profusely sweating, but is not wearing a protective head band.
Assessment: Not Applicable.
Reason: The standard is silent on the use of headbands.

Requirement	**1.21.17. 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 to minimize risk for jewelry or loose objects to be a source of product contamination. Policy shall be in compliance with current industry practices or regulatory requirements for that commodity.**
Verification	**Auditor observes personnel for evidence of compliance.**
Corrective Action	**Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.**
Documents Required	**N/A.**

Guidance
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 to determine if it is being followed.

See Field and Harvest 2.2.12.

Requirement	1.21.18. 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 produce handling areas and designated area for evidence of compliance.
Corrective Action	Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	N/A.

Guidance
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, or there may be lockers provided, if this is designated in the operation's policy and these storage areas are not observed to be reasonable sources of contamination in the operation.

See Field and Harvest 2.2.14.

Example Scenarios
Scenario 1: 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.

Scenario 2: Packinghouse workers are observed wearing a backpack, 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.

Requirement	1.21.19. Break areas shall be designated and located away from food contact/handling zones.
Procedure	Operation shall have a written policy that break areas are located so as not to be a source of product contamination.
Verification	Auditor observes break areas for evidence of compliance with Operation's policy.
Corrective Action	Retraining is performed and documented. Affected product is evaluated for potential contamination and disposition.
Documents Required	Written Policy.

Guidance
Facilities used by employees to take breaks, prepare to go to work, eat lunches, etc. must be clean and separate from the packing area. 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.

See Field and Harvest 2.2.16.

Example Scenarios
Scenario 1: 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 2: Cherry operation has written policy that workers can use designated areas of the receiving dock for breaks, if there is no produce present at the time. Workers are observed complying with the policy.
Assessment: Compliant.
Reason: Compliant, unless industry practices or regulation prohibit, or auditor observes reasonable potential for product contamination.

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."

1.22 Temperature Control

Requirement	**1.22.1. When produce is cooled, it is cooled to temperatures appropriate to 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 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.**

Example Scenarios

Scenario 1: An operation stores celery at 32 to 36°F. They say that the temperature range came from the UC Davis Postharvest 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.

Scenario 2: A packinghouse holds/stores whole tomatoes at less than 41ºF "because it's required by the Food Code."

Assessment: Corrective Action Needed.

Reason: Even though the policy does not create a food safety risk, operation should be trained that the holding temperature is inconsistent with industry guidance for tomatoes. The Food Code does not require temperature control of whole tomatoes. The Food Code does not apply to packinghouses.

1.23 Packing and Handling

Requirement	1.23.1. If applicable, Operation has a written Allergen Control Program.
Procedure	The Allergen Control Program lists the allergens in use or storage at the facility 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 facility.
Verification	Auditor reviews Allergen Control Program and inspects facility for evidence of allergen use and storage.
Corrective Action	Operation develops and implements an Allergen Control Program or eliminates allergens from the facility.
Documents Required	Written Policy.

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 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: 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 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: They operation needs an Allergen Control Program in case of accidental exposure.

Requirement	1.23.2. Specifications for all packaging materials that impact on finished product safety and quality 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	Written Policy.

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.

1.24 Pest and Animal Control

Requirement	1.24.1. Operation has procedures to manage pests to the extent appropriate to the facility.
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 facility. 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 facility for pest activity.
Corrective Action	Operation develops, documents and implements an effective pest control program.
Documents Required	Written Policy, Record.

Guidance
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.

Requirement 1.24.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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 on-site.
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.

Requirement	**1.24.2. Operation restricts animals from food handling facilities.**
Procedure	**Domestic 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.**
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.**

Guidance
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.

Requirement 1.24.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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 inspection, 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.
Assessment: Compliant.
Reason: The operation has policies and procedures to restrict animals from the food handling area.

Requirement	**1.24.3. 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 facility.**
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.**

Guidance
Requirement 1.24.3 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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: Traps must be relocated so as to pose no threat of contamination of the product or food handling surfaces.

Scenario 2: All trapping devices have non-toxic bait, are located along the perimeter walls at designated locations, away from produce handling operations.
Assessment: Compliant.
Reason: The trapping devices with non-toxic bait are located so as to not contaminate the produce or food handling surfaces.

Scenario 3: The operation uses toxic 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.

1.25 Sampling/Testing

This section must be answered for water.

Requirement	**1.25.1. 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 FDA's Bacteriological Analytical Manual (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.**

See Field and Harvest 1.5.1.

Requirement	1.25.2. Where microbiological analysis is required in Food Safety Plan, samples shall be in accordance with an established sampling procedure.
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.

See Field and Harvest 1.5.2.

Requirement	1.25.3. Tests, their results and actions taken must be documented.
Procedure	All results for microbiological testing required in the Operation's Food Safety Plan shall be recorded and the records maintained for two years.
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.

See Field and Harvest 1.5.3.

Requirement	1.25.4. 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 expectations of the Food Safety Plan.
Documents Required	Written Policy.

See Field and Harvest 1.5.4.

Section 2 - Packinghouse

Requirement	**2.1. 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	**Written Policy.**

See Field and Harvest 3.2.

Example Scenarios
Scenario 1: An immersion type product wash system for cucumbers is present. The water is chlorinated, monitored, and in compliance. The water temperature and product pulp temperature is not being recorded.
Assessment: Compliant unless there is an industry standard that a temperature differential is necessary for safety.
Reason: At this time, a temperature differential is only required for tomatoes.

Scenario 2: 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-circulated 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.
Reason: Test strips are beyond their expiration date.

Scenario 3: An overhead spray bar is used to wash incoming potatoes. The water is of drinkable quality, is not re- circulated, 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	2.2. Debris and damaged produce shall be removed from wash areas/dump tanks to the extent possible.
Procedure	Operation has procedures to determine how and when debris 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.

Example Scenarios
Scenario 1: There is a written procedure requiring the line to be stopped and cleaned when there is a significant buildup in the wash tank. You observe a significant buildup; the operation says it is not significant.
Assessment: Compliant, if in compliance with the operation's procedure and item 2.4 for antimicrobial levels.
Reason: The operation may want to revise the procedure to avoid the vagueness of "significant." If there is no written procedure, but the auditor does not observe an accumulation of debris in the wash tank this would also be compliant.

Scenario 2: The auditor observes a significant buildup in the wash tank. The operation says that the procedure is to remove the debris when the water is dumped at the end of the day.
Assessment: Compliant.
Reason: The operation is in compliance with their procedure and requirement 2.4 for antimicrobial levels.

Requirement	2.3. 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	Written Policy.

Guidance
Requirement 2.3 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See Field and Harvesting 3.2.

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: Immediate Action Required.
Reason: Inappropriate use of an unauthorized antimicrobial.

Scenario 3: A label for the sodium hypochlorite product used in the wash water is present, is approved for use by the proper authority, but the dose rate in use is not supported by the label.
Assessment: Immediate Action Required or Corrective Action Needed.
Reason: Immediate Action Required if the use rate in the wash water produces levels below the minimum acceptable range. Corrective Action Needed if the use rate in the wash water produced levels above the high end acceptable range, but was followed by an untreated drinkable quality water rinse, and was noted as a corrective action.

Requirement	**2.4. 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.**

Guidance
Requirement 2.4 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See also Field and Harvesting 3.2.2.

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. Same scenario. If ORP controller fails, corrective action is to "add more chlorine by hand." There are no corrective action records. Same response; also, corrective action procedures are incomplete.

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-recirculated (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	**2.5. All instruments used to measure temperature, pH, antimicrobial levels and/or other important devices used to monitor requirements in this section shall be 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 and sufficiently sensitive to their intended purpose.**
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.**

Guidance
Calibration is essential when using various equipment within Food Safety. Companies must calibrate when necessary or by defined date as may be required by the manufacture. Employees should be properly trained in how to calibrate their specific equipment. Training may consist of documentation provided by the manufacture or participation in class room environment. The comment should include the frequency of calibration.

Requirement 2.5 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

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: Corrective Action Needed.
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.

Requirement	**2.6. 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.**

Guidance
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 you have 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.

Example Scenarios
Scenario 1: You observe an employee operating a hand held metal detector at the end of the package processing line. Documentation shows the permanent metal detector is out of service for calibration issues.
Assessment: Compliant.
Reason: SOP documentation shows the hand held metal detector is a backup and it has been calibrated.

Scenario 2: 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 3: Same as Scenario 2 except the auditor observes that the wand used is 7 mm ferrous.
Assessment: Compliant or Corrective Action Needed.
Reason: Compliant, provided that the Food Safety Plan has concluded that ferrous metal is the only food safety risk, and that a 7 mm limit of detection is adequate to ensure safety. 7 mm has been established by FDA to be a maximum size for hard sharp objects (FDA citation: Compliance Policy Guide 555.425). Corrective Action Needed if you observe risks from metal beyond ferrous, e.g., use of stainless steel blades during harvest or post-harvest handling.

Scenario 4: 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 5: Same as Scenario 4 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.

Section 3 - Transportation (Packinghouse to Customer)

Audit requirements 3.1.1-3.1.4 only applies when temperature control is required for food safety. At this time, science has not identified any raw, intact produce items that require temperature control for food safety. Therefore, these items will be Not Applicable unless the operation's Food Safety Plan identifies temperature control during transit.

3.1 Temperature Control

Requirement	3.1.1. 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.

Guidance
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.

You should recognize that 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.

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	**3.1.2. 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.**

Also See 3.1.1.

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.

Scenario 4: The operation does not pre-cool the trailer when transporting in customer's trailers because "customer doesn't require it."
Assessment: Not Applicable.
Reason: Not Applicable unless temperature control is required for food safety.

Scenario 5: An operation does not monitor or record trailer temperature when transporting in customer's trailers because "customer doesn't require it."
Assessment: Not Applicable.
Reason: Not Applicable unless temperature control is required for food safety.

Requirement	3.1.3. 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.

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.

Scenario 3: An operation has written policy and maintains records only for produce that requires temperature control during shipping, including meeting customer specifications.
Assessment: Not Applicable.
Reason: Not Applicable unless temperature control is required for food safety.

Requirement	3.1.4. 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.

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: The operation does not record the temperatures however, the auditor observed the employees taking temperatures where required.
Assessment: Not Applicable.
Reason: Not Applicable unless temperature control is required for food safety.

Scenario 3: 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.

Scenario 4: Temperatures that do not meet specifications are recorded and no corrective actions are taken.
Assessment: Not Applicable.
Reason: 1.8.1 requires corrective action procedures and records for non-conformance with food safety requirements. If temperature requirements are not for food safety, the standard is silent on corrective actions, but product temperature records must be maintained.

Scenario 5: You observe product that required a temperature check but the temperature was not taken.
Assessment: Not Applicable.
Reason: Not Applicable unless temperature control is required for food safety.

Scenario 6: The procedure does not include product that requires a temperature check.
Assessment: Not Applicable.
Reason: Not Applicable unless temperature control is required for food safety.

3.2 Equipment Sanitation and Maintenance

Requirement	3.2.1. 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. Procedures include prohibition of raw animal or animal product transport, or other materials that reasonably may be a source of contamination with biological, chemical or physical hazards. 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.

See Field and Harvest 4.1.1.

Requirement	3.2.2. 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 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.

See Field and Harvest 4.1.2.

Requirement	3.2.3. 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 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.

See Field and Harvest 4.1.3.

Section 4 - Global Markets Addendum4.1 Food Safety Plan & Documentation

Requirement	4.1.1. If applicable, the food safety plan addresses customers' food safety specifications.		
Level	Basic	Required Element	No
Procedure	The producer shall be familiar with specifications concerning food safety (e.g. microbiological criteria, permitted chemical residues and limits) established by the buyer or, if exporting product, required by the country of destination. The producer has written copies of customer, country, and internal food safety specifications and is demonstrating compliance with these specifications.		
Verification	Auditor reviews customers' food safety specifications and interviews appropriate personnel for familiarity of customer food safety specifications.		
Corrective Action	Operation obtains customers' food safety specifications and/or trains appropriate personnel to become familiar with the customer' food safety specifications.		
Documents Required	Record.		

Guidance
Requirement 4.1.1 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See Field and Harvest 5.1.1.

Requirement	4.1.2. Operation has performed and documented a risk assessment of the packinghouse.
Level	**Basic** **Required Element** **Yes**
Procedure	**Records shall be available to demonstrate that the packinghouse has been evaluated with regards to potential food safety hazards.**
Verification	**Auditors verify the operation has performed and documented a risk assessment of the packinghouse.**
Corrective Action	**The operation shall perform and document a risk assessment for the packinghouse. Training of appropriate personnel may need to take place to on conducting and recording this assessment.**
Documents Required	**Record.**

Guidance
A risk assessment must be performed and documented by the operation for the packinghouse. 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. Observation will be important for you to verify the accuracy of this requirement.

The auditor comment should include the date that the last risk assessment of the packinghouse was performed. Requirement 4.1.2 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	**4.1.3. If the risk assessment shows the need for a critical control point(s) in the packinghouse, a documented HACCP plan or additional procedures addressing monitoring of control points and disposition of non-conforming products must be in place. The HACCP plan or additional policies must be documented and implemented.**
Level	**Intermediate Only Required Element Yes**
Procedure	**The Operation shall have a HACCP plan or documented detailed procedures which cover monitoring, documentation, product testing etc. This should include instructions to follow when there is a loss of control of a CCP so that adjustments can be made in a timely manner as well as withholding of product that is out of compliance, if necessary. If changes are made to the process, equipment, etc., all HACCP systems or procedures should be reviewed and the food safety coordinator should inform all employees involved.**
Verification	**Auditors shall review records to verify procedures are being followed correctly. Employees should have a basic understanding of what HACCP is in general and also how it applies to their operations. Employees should also have a good understanding of the details of the CCPs that they have been assigned to monitor.**
Corrective Action	**Detailed procedures are developed and re-training or educational sessions may be necessary.**
Documents Required	**Record.**

Guidance
Requirement 4.1.3 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Intermediate Level Assessment.

See the information presented here for guidance on HACCP plans: National Advisory Committee Guidance for HACCP Principles and Application.

Requirement	4.1.4. A documented hold and release program has been implemented for all non-conforming product and packaging.		
Level	**Basic**	**Required Element**	**No**
Procedure	**There should be a documented procedure that explains how product that has either been rejected or placed on hold should be handled. Rejected or on hold product should be kept separate and identified from other product to avoid accidental use or shipping. Pallets or rejected product is properly marked e.g. date item was placed on hold, reason and name of the person placing the item on hold. A separate area also helps ensure that there are no accidental uses or shipping of on hold product. Product release procedures assure that a lot is only released for shipment (sale) when lot meets agreed standards (e.g. specification) or meets agreed testing requirements (e.g. results confirmed negative or within limits results from testing, etc.). Products should not be released for shipment without assuring that necessary evaluations have been performed.**		
Verification	**Auditors shall observe product that is on hold and release to verify proper identification and distance from non-segregated product.**		
Corrective Action	**Procedure shall be developed and any hold and release product is segregated and identified.**		
Documents Required	**N/A.**		

Guidance
A hold and release program is where all finished product produced will be placed on automatic quarantine, to prevent it from shipping to a customer, until they receive verification from a 3rd party lab regarding micro results.

Requirement	4.1.5. Corrective action procedures shall include a procedure to evaluate complaints.		
Level	**Basic**	**Required Element**	**No**
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 the 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	**Auditors 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.**		

Guidance
The requirement 1.8.1 addresses corrective actions, but does not specifically require a procedure for addressing complaints. In order to meet the requirement of question 4.1.5 of the Global

Markets Addendum, the operation must have a procedure for documenting, assessing and addressing complaints.

Requirement	**4.1.6. The operation shall record any food safety related non-conformances and complaints.**		
Level	**Basic**	**Required Element**	**No**
Procedure	**Food safety related complaints and non-conformities shall be recorded and maintained.**		
Verification	**Auditor verifies records of any food safety related non-conformances and complaints.**		
Corrective Action	**Operation shall implement record keeping for food safety related non-conformances and complaints.**		
Documents Required	**Written Policy, Record.**		

Guidance
To have an effective corrective action program the operation will need to have a method established for documenting any food safety related non-conformances and complaints. This method may be a log, individual corrective action reports, etc.

Requirement 4.1.6 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

Requirement	**4.1.7. Corrective action procedures shall include a procedure to evaluate complaints.**		
Level	**Basic**	**Required Element**	**No**
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 the demonstration of the evidence of effectiveness.**		
Verification	**The time frame necessary for corrective action shall be documented. Objective evidence shall demonstrate that the procedure is effective.**		
Corrective Action	**Auditors shall verify the operation has a procedure to evaluate complaints.**		
Documents Required	**Written Policy.**		

Guidance
Requirement 4.1.7 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Basic or Intermediate Level Assessment.

See 4.1.5 for guidance.

Requirement	4.1.8. Food safety incidents are recorded and assessed to determine its severity and risk and addressed accordingly.		
Level	Intermediate Only	Required Element	No
Procedure	An effective incident management procedure shall be implemented that covers incident reporting, product withdrawal, and recall procedure for the product.		
Verification	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 Action	Operation shall implement an incident management procedure.		
Documents Required	Record.		

Guidance
The operation needs to have a policy in which 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, you should document this on the audit report.

Requirement 4.1.8 must be assessed as compliant to meet the acceptance criteria for the Global Markets Program for Primary Production Intermediate Level Assessment.

Requirement	4.1.9. The incident management procedure is reviewed, tested and verified at least once a year.		
Level	Intermediate Only	Required Element	No
Procedure	An annual review shall be conducted of the overall incident management procedure, including a review of records and corrective actions related to any food safety incidents that occurred.		
Verification	Records are reviewed. If there has been no food safety incident in the previous year, a mock incident management exercise has been conducted by the firm to test the existing system.		
Corrective Action	Any identified deficiencies in the incident management system have been corrected.		
Documents Required	Record.		

Guidance
Each operation must have a food safety incident management procedure as specified in requirement 4.1.8. 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 comment should show the date that the last incident management procedure was reviewed, tested and/or verified.

Requirement	**4.1.10. The operation has an approved supplier program for all agricultural inputs, chemicals, packaging and food safety related services.**
Level	**Intermediate Only** **Required Element** **No**
Procedure	**An in-house documented approval supplier process covering the food safety related aspects shall be in place for purchases of all agricultural inputs, chemicals, packaging and food safety related services.**
Verification	**Auditor shall verify purchased covering materials, services and outsourced processes are conducted only from approved suppliers.**
Corrective Action	**The organization identifies, documents, and monitors outsourced processes related to food safety.**
Documents Required	**Record.**

Guidance
Auditors must verify that the operation has a written approved supplier program for all agricultural inputs. Agricultural inputs may include agricultural chemicals, packaging and other contracted food safety related services. As there are many agricultural inputs in each operations it is expected that the auditor will review a sampling of the agricultural inputs for the operation being audited.

The auditor comment should show the date of the current list available.

Requirement	**4.1.11. 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.**
Level	**Intermediate Only** **Required Element** **No**
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 schedule to ensure frequency is according to established food safety plan.**
Corrective Action	**Procedure is developed at an established frequency. Training is implemented.**
Documents Required	**Record.**

Guidance
The auditor comment should show the frequency for scheduled check of metal detection equipment.

4.2 Food Defense

Requirement	4.2.1. Threats to the produce as a result of intentional contamination been assessed and documented.		
Level	Intermediate Only	Required Element	No
Procedure	The risk assessment shall cover food defense and include the methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist like incident.		
Verification	Auditor reviews risk assessment.		
Corrective Action	Operation shall assess and document intentional threats to the produce and perform a risk assessment.		
Documents Required	Record.		

Guidance
The operation must have a record of their assessment of food defense risks that could lead to intentional contamination.

Requirement	4.2.2. Those points in the process which are vulnerable to intentional contamination been identified and subjected to additional access control.		
Level	Intermediate Only	Required Element	No
Procedure	Sensitive areas of the facility shall be identified as part of the food defense risk assessment. Access control measures shall be implemented in these areas.		
Verification	Auditor reviews policy		
Corrective Action	Policy is written identifying sensitive areas.		
Documents Required	Written Policy, Record.		

Guidance
Most food defense risk assessments will identify the vulnerable points in the operation and will implement any additional access controls that are necessary. Verify whether the identified vulnerable points in the facility have access control and point out that fact on the audit report.

Requirement	4.2.3. If access to prohibited areas took place, are measures in place to evaluate food for evidence of sabotage/intentional contamination?		
Level	Intermediate Only	Required Element	No
Procedure	A documented procedure has been established addressing actions to be taken if food defense measures are in question or sabotage is suspected.		
Verification	Auditor reviews policy for detailed actions and defense measures.		
Corrective Action	Operation establishes policy.		
Documents Required	Written Policy.		

Guidance
The operation must have a written policy addressing how it will react to sabotage if it is suspected. In addition to verifying the company's policy on sabotage, interview employees for knowledge appropriate to their responsibilities of how they will handle food sabotage if it is suspected. Knowledge of who to report suspected sabotage should be expected of all employees.

Section 5 - USDA Logo Use Addendum
5.1 Active and Effective Traceability and Recall Program

Requirement	**5.1.1. Questions in Section 1.6 and 1.7 have been marked Compliant.**
Procedure	**An active traceability and recall program shall be in place. The logo may only be displayed on package, containers or consumer units which are traceable.**
Verification	**Auditor reviews answers to questions in Sections 1.6 and 1.7. If all are compliant, this requirement has been satisfied.**
Corrective Action	**Operation establishes an effective traceability program and a recall plan, and is compliant on all questions in Sections 1.6 and 1.7.**
Documents Required	**Written Policy, Record.**

Requirement	**5.1.2. 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.**

5.2 Approved Suppliers

Requirement	5.2.1. 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.

Requirement	5.2.2. 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.

Requirement	5.2.3. All suppliers have successfully completed and met the requirements of a USDA approved GAP & GHP audit (USDA GAP&GHP audit, commodity specific audit, or Produce GAPs Harmonized audit performed by USDA).
Procedure	The Operation requires the packinghouses, distribution centers and other post-farm gate operations who wish to utilize the logo, to have an approved supplier program, which at a minimum verifies that all suppliers of fresh produce have successfully completed and met the requirements of a USDA approved GAP&GHP audit. All audits must be conducted by a licensed USDA auditor under federal oversight.
Verification	Auditor reviews evidence of suppliers having met the requirements of a USDA GAP and GHP audit.
Corrective Action	Operation ceases to use non-compliant suppliers. Non-compliant suppliers must discontinue use of the logo immediately.
Documents Required	Record.

5.3 Food Safety Plan or Quality Manual

Requirement	5.3.1. 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.

Guidance
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.

5.4 Containers or Labels with GAP&GHP logo

Requirement	5.4.1. All containers or labels, which bear the GAP&GHP logo, are accountable items.
Procedure	The Operation shall have a policy stating all containers or labels are accounted for.
Verification	Auditor reviews policy.
Corrective Action	Operation develops policy that ensures accountability of all containers or labels bearing the logo.
Documents Required	Written Policy, Record.

Requirement	5.4.2. The operation's inventory list of these containers or labels is maintained and current.
Procedure	The Operation shall have an inventory list of any containers 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 containers and labels.
Documents Required	Record.

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 market place.
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)**

☐ **FDA's Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables:** _____

http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM169112.pdf

☐ **FV-237A Request for Audit Services Form:** _____
http://eforms.ams.usda.gov/metastormpdf/fv237a/

☐ **FV-651 Agreement for Participation in Audit Verification Programs Form:** _____
http://eforms.ams.usda.gov/metastormpdf/FV651/

☐ **Unannounced Verification Review for GAP&GHP:** _____
http://www.ams.usda.gov/publications/content/fpb-702-unannounced-verification-review-gap-ghp-audit-verification-program

☐ **Produce GAPs Harmonized Standard- Field Operations and Harvesting:** _____
http://www.ams.usda.gov/sites/default/files/media/GAP-GHP-FieldHarvesting-Harmonized-Food-Safety.pdf

☐ **Produce GAPs Harmonized Standard- Post-harvest Operations:** _____
http://www.ams.usda.gov/sites/default/files/media/GAP-GHP-Post-Harvest-Harmonized-Food-Safety.pdf

☐ **USDA Harmonized Checklist- Field Operations and Harvesting:** _____
http://www.ams.usda.gov/services/auditing/gap-ghp/harmonized

☐ **USDA Harmonized Checklist- Post-harvest Operations:** _____
http://www.ams.usda.gov/services/auditing/gap-ghp/harmonized

Checked Materials have been printed from the links in this manual and included for reference.

APPENDIX I – FOOD AND DRUG ADMINISTRATION- TITLE 21

TITLE 21—FOOD & DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 110--CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

Subpart A--General Provisions

Sec. 110.3 Definitions.
The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:
(a) Acid foods or acidified foods mean foods that have an equilibrium pH of 4.6 or below.
(b) Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.
(c) Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
(d) Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
(e) Critical control point means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
(f) Food means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.
(h) Lot means the food produced during a period of time indicated by a specific code.
(i) Microorganisms mean yeasts, molds, bacteria, and viruses and include, but are not limited to, 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 within the meaning of the act. Occasionally in these regulations, FDA used the adjective "microbial" instead of using an adjectival phrase containing the word microorganism.
(j) Pest refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.
(k) Plant means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.
(l) Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.
(m) Rework means clean, unadulterated food that has been removed from processing for reasons other than unsanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.
(n) Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (aw). An aw will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable microorganisms.
(o) Sanitize means to adequately treat food-contact 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.
(p) Shall is used to state mandatory requirements.
(q) Should is used to state recommended or advisory procedures or identify recommended equipment.
(r) Water activity (aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Sec. 110.5 Current good manufacturing practice.
(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).
(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

Sec. 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

Sec. 110.19 Exclusions.
(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.
(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B--Buildings and Facilities

Sec. 110.20 Plant and grounds.
(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:
(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.
(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:
(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or 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, air flow, enclosed systems, or other effective means.
(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:
(i) Using protective coverings.
(ii) Controlling areas over and around the vessels to eliminate harborages for pests.
(iii) Checking on a regular basis for pests and pest infestation.
(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.
(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.
(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.
(7) Provide, where necessary, adequate screening or other protection against pests.

Sec. 110.35 Sanitary operations.
(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
(b) Substances used in cleaning and sanitizing; storage of toxic materials. (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:
(i) Those required to maintain clean and sanitary conditions;
(ii) Those necessary for use in laboratory testing procedures;
(iii) Those necessary for plant and equipment maintenance and operation; and
(iv) Those necessary for use in the plant's operations.
(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.
(c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.
(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.
(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.
(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.
(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.
(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.
(e) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.
[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

Sec. 110.37 Sanitary facilities and controls.
Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:
(a) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.
(b) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to:
(1) Carry sufficient quantities of water to required locations throughout the plant.
(2) Properly convey sewage and liquid disposable waste from the plant.
(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.
(c) Sewage disposal. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:
(1) Maintaining the facilities in a sanitary condition.
(2) Keeping the facilities in good repair at all times.
(3) Providing self-closing doors.
(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).
(e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:
(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
(2) Effective hand-cleaning and sanitizing preparations.
(3) Sanitary towel service or suitable drying devices.
(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of 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 may 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.
(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.
(f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Subpart C--Equipment

Sec. 110.40 Equipment and utensils.
(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.
(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.
(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.
(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.
(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.
(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Subpart D [Reserved]

Subpart E--Production and Process Controls

Sec. 110.80 Processes and controls.
All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.
(a) Raw materials and other ingredients.
(1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.
(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this

requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.
(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.
(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.
Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.
(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.
(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.
(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.
(b) Manufacturing operations.
(1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.
(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.
(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:
(i) Maintaining refrigerated foods at 45 deg. F (7.2 deg. C) or below as appropriate for the particular food involved.
(ii) Maintaining frozen foods in a frozen state.
(iii) Maintaining hot foods at 140 deg. F (60 deg. C) or above.
(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.
(5) Work-in-process shall be handled in a manner that protects against contamination.
(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.
(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.
(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.
(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.
(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.
(11) Heat blanching, when required in the preparation of food, should be affected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.
(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:
(i) Using ingredients free of contamination.
(ii) Employing adequate heat processes where applicable.
(iii) Using adequate time and temperature controls.
(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.
(v) Cooling to an adequate temperature during manufacturing.
(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:
(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.
(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.
(iii) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in Sec. 130.3(d) of this chapter.
(iv) Providing physical protection from contamination, particularly airborne contamination.
(v) Using sanitary handling procedures.
(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of aw for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:
(i) Monitoring the aw of food.
(ii) Controlling the soluble solids-water ratio in finished food.
(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the aw of the food does not increase to an unsafe level.
(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:
(i) Monitoring the pH of raw materials, food in process, and finished food.
(ii) Controlling the amount of acid or acidified food added to low-acid food.
(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.
(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.
[51 FR 24475, June 19, 1986, as amended at 65 FR 56479, Sept. 19, 2000]

Sec. 110.93 Warehousing and distribution.
Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F [Reserved]

Subpart G--Defect Action Levels

Sec. 110.110 Natural or unavoidable defects in food for human use that present no health hazard.
(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current

good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.
(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.
(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.
(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.
(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition (HFS-565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.
[51 FR 24475, June 19, 1986, as amended at 61 FR 14480, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

FDA Defect Action Levels - Nuts

NUTS, TREE	Multiple Defects (MPM-V81)	Reject nuts (insect-infested, rancid, moldy, gummy, and shriveled or empty shells) as determined by macroscopic examination at or in excess of the following levels:

NUT TYPE	**UNSHELLED %**	**SHELLED %**
Almonds	5	5
Brazils	10	5
Cashew	--	5
Green Chestnuts	15	--
Baked Chestnuts	10	--
Dried Chestnuts	--	5
Filberts	10	5
Lichee Nuts	5	--
Pecans	10	5
Pili Nuts	15	10
Pistachios	10	5
Walnuts	10	5

DEFECT SOURCE: *Insect infested - preharvest and/or post-harvest and/or processing, Mold - preharvest and/or post-harvest and/or processing infection, Gummy & shriveled - preharvest physiological condition, Rancidity - post harvest*
SIGNIFICANCE: *Aesthetic, Potential health hazard - may contain mycotoxin producing fungi*

PEANUTS, SHELLED	Multiple defects (MPM-V89)	Average of 5% or more kernels by count are rejects (insect-infested, moldy, rancid, otherwise decomposed, and dirty)
	Insects (MPM-V89)	Average of 20 or more whole insects or equivalent in 100-pound bag siftings

DEFECT SOURCE: *Insect infested - post harvest and/or processing infestation, Moldy - preharvest and/or post-harvest and/or processing infection, Rancid & decomposed - post harvest abuse, Dirty - harvest contamination.*
SIGNIFICANCE: *Aesthetic, Potential health hazard - may contain mycotoxin producing fungi*

PEANUTS, UNSHELLED	Multiple defects (MPM-V89)	Average of 10% or more peanuts by count are rejects (insect- infested, moldy, rancid, otherwise decomposed, and dirty)

DEFECT SOURCE: *Insect infested - post harvest and/or processing infestation, Mold - preharvest and/or post-harvest and/or processing infection, Rancid & decomposed - post harvest abuse*
SIGNIFICANCE: *Aesthetic, Potential health hazard - may contain mycotoxin producing fungi*

APPENDIX II: 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 III: FDA & INDUSTRY GUIDANCE DOCUMENTS

FDA Guidance Documents

- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (October 26, 1998)
- Reducing Microbial Food Safety Hazards For Sprouted Seeds (October 1999)
- 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

- Guide to Minimize Microbial Food Safety Hazards of Tomatoes (July 2009)
- Guide to Minimize Microbial Food Safety Hazards of Melons (July 2009)
- Guide to Minimize Microbial Food Safety Hazards of Leafy Greens (July 2009)

Industry Guidance in Collaboration with FDA

- Commodity Specific Food Safety Guidelines for the Production, Harvest, Storage, and Packing of Potatoes (June 17, 2013) (PDF - 7325KB)
- Commodity-Specific Food Safety Guidelines for Cantaloupes and Netted Melons (March 29, 2013) (PDF - 4.77MB)
- Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Processing Unit Operations of Fresh Culinary Herbs (January 24, 2013) (PDF - 7.34MB)
- Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Valued-Added Unit Operations of Green Onions February 26, 2010
- Commodity Specific Food Safety Guidelines for the Melon Supply Chain, 1st Edition November 7, 2005
- Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, 2nd Edition July 2008
- Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain, 1st Edition April 25, 2006

APPENDIX IV: REFERENCES USED FOR MANUAL DEVELOPMENT

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