PrimusGFS Audit

Food Safety Management Systems

(Module 1) Guidelines

Used in conjunction with the PrimusGFS v3.2 audit

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Index

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These guidelines help interpret/support the principles, requirements and expectations of the PrimusGFS v3.2 Modules 1, 2, 3, 4, 5, 6 and 7 as noted in the Scheme normative documents. These guidelines are neither exhaustive nor exclusive and detail minimum requirements only by means of statements related to audit questions and expectations. There will be variations in applicability to an operation based on the process(es) and commodities involved. Auditors and auditees should interpret the questions and criteria in different situations, with the food safety and risk minimization being the key concerns.

The operation's practices, policies and procedures should be pertinent to the situation at hand and be able to stand up to any challenge by an auditor or other relevant interested party (including law enforcement). Where laws, customer requirements and specifications, commodity specific guidelines and/or best practice recommendations exist and are derived from a reputable source, these practices and parameters should be followed if they present a higher level of compliance than those included in the audit scheme.

Website links shown in this document are there to aid understanding and provide assistance by way of example (link listings are not exhaustive). These links are not a sign of endorsement by Azzule. Furthermore, Azzule Systems accepts no liability for the content of these links.

Please be aware that there is additional information on the PrimusGFS website including the audit checklist templates. The PrimusGFS website also has access to the official PrimusGFS General Regulations, which explain the overall scheme scoring systems and other details of the scheme.

The following text is a modified excerpt from the PrimusGFS General Regulations v3.2. It is provided here as an introduction to the audit notes. For full and current text please refer to the most recent version of the PrimusGFS General Regulations at http://www.primusgfs.com/documents.aspx.

Audit Execution

The audit should be performed using the most recent version of the PrimusGFS normative documents. The PrimusGFS Standard is divided into seven Modules:

- Module 1 - Food Safety Management System
- Module 2 - Farm
- Module 3 – Indoor Agriculture
- Module 4 – Harvest Crew
- Module 5 – GMP
- Module 6 – HACCP
- Module 7 – Preventive Controls

Each Module is divided into sections, related to the specific Module and each section includes questions that detail the requirements for the specific section.

Scoring System

For all Modules, the amount of deficiencies and the associated risks have to be considered to assign the severity of the finding, which can be Minor Deficiency, Major Deficiency and Non-Compliance. When no

deficiencies are found, a Total Compliance is given. The possible points for the questions in each Module are listed in the following table:

Scoring System for Questions				
Possible answer	**Possible Points for the Question**			
Total compliance	15 points	10 points	5 points	3 points
Minor deficiency	10 points	7 points	3 points	2 points
Major deficiency	5 points	3 points	1 point	1 point
Non-compliance	0 points	0 points	0 points	0 points
Not applicable	0 points	0 points	0 points	0 points

Detailed compliance requirements are noted for each question throughout this document, but some general statements are described below. These statements are superseded by the specific question compliance criteria and users should be aware that some questions do not follow the general statements below (e.g., automatic failure questions).

Compliance for Questions	
Answer	**Criteria Used**
Total compliance	To meet the question and/or compliance criteria in full.
Minor deficiency	To have minor deficiencies against the question and/or compliance criteria. To have single or isolated non-severe deficiencies (usually up to three) against the question and/or compliance criteria. To have covered most of the question compliance criteria, but not all.
Major deficiency	To have major deficiencies against the question and/or compliance criteria. To have numerous non-severe deficiencies (usually more than three) against the question and/or compliance criteria. To have single or isolated severe deficiencies against the question and/or compliance criteria. To have covered some of the question compliance criteria, but not most of it.
Non-compliance	To have not met the question and/or compliance criteria requirements at all. Having fundamental deficiencies against the question and/or compliance criteria (severe or non-severe issues).
Not applicable	The requirement described in the question is not applicable for the operation being audited. Justification should be provided in the auditor's comments. Be aware that there are some questions that do not allow a non-applicable response.

Automatic Failure

There are some questions that if down scored will lead to an automatic failure and an overall score of 0% for the corresponding Module. On being immediately informed of the automatic failure by the auditor during the audit, the auditee has the option to have the auditor continue the audit or to have the audit halt at that point (all charges will apply). The auditor should explain the advantages of finishing the audit, including the

ability for the auditee to learn of other potential non-conformances and to show their buyers the status of their food safety system despite the automatic failure issue.

Special Circumstances for Not Certifying

Please also note, that under special circumstances and upon finding serious food safety risks, a "not certified" decision can be given. The auditee should be immediately informed of the automatic failure by the auditor during the audit. The auditee has the option to have the auditor continue the audit or to have the audit halt at that point (all charges will apply).

There are other Special Circumstance that are not technical in nature. Examples of these include detection of deliberate illegal activities, such as deliberate mislabeling, discovery of falsified records, attempting to bribe an auditor/CB personnel, threatening behavior towards an auditor/CB personnel, etc. Please refer to the General Regulations for further details.

Audit Termination

Once an audit has been started, should the auditee wish to stop the audit for any reason, the auditor will complete the report for as many questions as they were able to verify. PrimusGFS audits cannot be converted into a pre-assessment audit once the audit has been started. If an audit is terminated early, questions that the auditor was unable to verify will be marked as a non-compliance and will receive a score of zero. For questions unable to be verified, the auditor will indicate that the audit was terminated at the request of the auditee before the auditor could verify whether or not the audit conformed to the compliance criteria of the question. A report will be created on the database and issued, and all charges will apply.

Documentation Requirements

Organization's Food Safety Systems:

When an Organization and its associated Operations are being audited, the auditor is checking the systems (SOP's, policies, etc.) and the implementation of these systems throughout the visual inspection.

While auditees often create and implement their own systems, they can also use systems that have been created by other entities, for example, their customers' technical manager, their consultants, etc., or a combination of resources. The Organization can create their own SOPs, or in other instances, can utilize SOP templates provided by other entities. As long as the systems meet the requirements of the PrimusGFS questions and expectations and these systems are being implemented properly, the auditee should receive full points for their efforts. The auditee is responsible for ensuring that the systems they use are reviewed, maintained and up-to-date. If the auditor detects any inconsistency, it will result in a down score.

New PrimusGFS Auditees/First-Time PrimusGFS Auditees

- **In operations that operate for more than three consecutive months throughout the year** – auditee should have at least three months of documentation (i.e. records of monitoring, training, meetings, etc.) available for review. If the auditee has less than three months of most of their documentation available for review, a pre-assessment audit is strongly advised. If the auditee has less than three months of most of their documentation available for review and decides to have a regular scheduled audit, they should be aware that they **cannot receive full compliance for paperwork questions relating to monitoring and that the down score will be based on the amount of paperwork available**.
- **In short season operations that operate for less than three consecutive months throughout the year** - auditee should have at least three months of documentation (i.e. records of monitoring, training, meetings, etc.) available for review (this may include last season's documentation). Where an operation does not have three months of records available (e.g., they are in operation for one

month out of the year), the auditee should have at least the previous season's records available for review. If the auditee has less than three months of most of their documentation available for review and decides to have a regular scheduled audit, they should be aware that they **may not receive full conformance for paperwork questions relating to monitoring and that the down score will be based on the amount of paperwork available**.

Existing PrimusGFS Auditees

- **In operations that operate for more than three consecutive months throughout the year** – auditee should have documentation available from the date of the prior audit.
- **In short season operations that operate for less than three consecutive months throughout the year** – auditee should have at least three months of documentation and documentation at least since the last audit (which includes the last season). Where an operation does not have three months of records available (e.g. they are in operation for one month out of the year), the auditee should have at least the previous season's records available for review.

	Operates <three months/year	Operates >three months/year
New PrimusGFS Auditee	Three months of records (may include last season's records). Where an operation does not have three months of records available (e.g., they are in operation for one month out of the year), the auditee should have at least the previous season's records available for review.	Three months of records (may include last season's records).
Existing PrimusGFS Auditee	Records at least since the last audit (or longer) to meet the minimum requirement of three consecutive months of records.	Records since the last audit.

Visual versus Verbal Confirmation

Visual confirmation is the default method of auditing, whether on the visual inspection portion or the paperwork section. Scores and comments are assumed to have been visually confirmed, unless stated otherwise. Verbal confirmation should be the exception to the rule and, if auditing properly, these should be rarely used. If a verbal confirmation is accepted, the auditor should write this in the comments section of the report for that specific question.

How to Use Point Assignment Guidelines

The following sections of this guidance manual are designed to help auditors choose the right score for each question, thereby helping to ensure consistency. This document does not cover all situations and is intended to be a guideline, as opposed to a rule. Auditors are expected to follow the guidelines as much as possible, but it is understood that there will be situations where an auditor should use their discretion. If an auditor does have to make a judgment call and/or tackle a situation not covered by this manual, then the auditor should note the circumstances in the audit report with full justifications. (The auditor should also forward these details to their Certification Body and Azzule Systems, LLC in a separate note, so that this can be reviewed for future versions of the manual.)

In order to be consistent with the voluntary nature of requesting a third-party audit, and in order not to seem to be a legal document, the requirements within the questions are written as "should" and can be

scored against. In other questions that use the term “ideally”, these statements cannot be scored against, but give the auditee an opportunity for improvement.

Notes in “red” are where the questions and/or compliance criteria have changed significantly since the previous version. Many of the changes are to improve clarification, but some are changes to the actual requirements. Please read carefully to see if these changes impact your particular situation.

Module 1: FSMS
Management System

1.01.01: Is there a documented food safety policy detailing the company's commitment to food safety?
Total compliance (5 points): There should be a clear documented food safety policy statement and detailed objectives reflecting the company's ongoing commitment to meet the food safety needs of its products that is dated and signed (by senior management). The policy should include statements and objectives of the company's commitment to food safety, promoting a proactive and committed food safety culture, following food safety laws, adhering to industry food safety best practices and a process of continual improvement. Everyone in the company should understand the food safety policy and be aware of their role in ensuring that it is met (e.g. by training, communicating organizational chart, feedback to management, performance measurements related to food safety, etc.). The policy should be posted in a public area and in the language understood by the workers. The policy may take the form of a "mission statement" provided it meets the requirements detailed above.

Minor deficiency (3 points) if:
- Policy lacks an element listed above.
- Single/isolated instance(s) of errors or omissions in the policy.

Major deficiency (1 point) if:
- Policy lacks more than one element noted above.
- Numerous instances of errors or omissions in the policy.
- Failure to communicate the policy to workers.
- Policy is not posted in a public place.

Non-compliance (0 points) if:
- No policy exists.

1.01.02: Is there an organizational chart showing all management and workers who are involved in food safety related activities and documentation (job descriptions) detailing their food safety responsibilities?
Total compliance (10 points): There should be an organizational chart showing positions and reporting structure of workers whose activities affect food safety within the company. Chart is dated and signed by management to indicate it is correct and current. Job functions and responsibilities related to food safety should also be documented. Suitable alternates should be indicated or reference the document indicating this information. For very small companies, an individual worker may cover many jobs.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions on the organizational structure chart or responsibilities.
- A document is not dated and/or signed.

Major deficiency (3 points) if:
- Numerous instances of errors or omissions on the organizational structure chart or responsibilities.
- More than one document is not dated and/or signed.

Non-compliance (0 points) if:
- Fundamental errors on the organizational structure chart or responsibilities.
- No organizational structure chart or responsibilities.

1.01.03: Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?
Total compliance (5 points): There should be an active food safety committee, responsible for the strategic maintenance and development of the operation's food safety plan. If an operation has a

HACCP/PC plan, the HACCP/PC team may also look after the food safety issues. The company should be keeping logs and minutes/notes of meetings addressing food safety topics. In-person meetings should have names and signatures to indicate attendance; auditor discretion applies to signature recording of remote meeting attendance. These meetings might be dedicated to food safety or may be part of another regular meeting, e.g. a production meeting, HACCP meeting, etc. These records should demonstrate Senior Management involvement in the Food Safety program - for example show management attendance, minutes copied to management, and missing members are indicated on records. Meetings should occur at least quarterly during the season of operation. Where the operation has less than three months of records available (new, short season operations) there should still be at least one meeting available for review – score minor deficiency; if no records score non-compliance. Refer to "New PrimusGFS Auditees/First-Time PrimusGFS Auditees" section.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors and omissions in the meeting logs e.g. not noting who was attending the meeting (including Senior Management).
- Only three meetings have occurred in the last 12 months (for an all year-round operation).
- Signed attendance is not kept (attendee names only) for in-person meeting events.

Major deficiency (1 point) if:
- Numerous instances of errors and omissions in the meeting logs e.g. not noting who was attending the meeting (including Senior Management).
- Two or less meetings have occurred in the last 12 months (for an all year-round operation)

Non-compliance (0 points) if:
- Food safety committee has not been created.
- The company does not have logs of food safety meetings.

1.01.04: Is there a training management system in place that shows what types of trainings are required for various job roles of specific workers, including who has been trained, when they were trained, which trainings they still need to take, and a training schedule?
Total compliance (5 points). The company has a system in place (e.g. training matrix) that shows what types of trainings are required for various job roles that affect food safety, who has been trained, when they were trained, which trainings they still need to take, and a training schedule. This question is related to the organizational chart and job role descriptions. The training records required under specific questions will be reviewed in the applicable module(s).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of trainings for a job role being omitted from the system.

Major deficiency (1 point) if:
- Numerous instances of trainings for job roles being omitted from the system.

Non-compliance (0 points) if:
- There is no training management system.
- There is a training management system, but it does not reflect how workers are actually being trained.

1.01.05: Is there documented management verification review of the entire food safety management system at least every 12 months, including an evaluation of resources, and are there records of changes made?
Total compliance (15 points): There is documented verification of the entire food safety management system including the HACCP system and FDA FSMA Preventive Controls Systems (if applicable to the operation) at planned intervals (minimum 12 month intervals) and reviewed by senior management (e.g. signatures, meeting minutes) to ensure its continuing suitability, adequacy and effectiveness, and that they are continuing to support and invest in adequate food safety resources (e.g., equipment, services,

supplies, personnel training, worker staffing levels, customer requirements/specifications, etc.) and to building and maintaining a proactive and committed food safety culture. The documented review should meet any national or local legislative requirements. The review should include an analysis of the effectiveness of key food safety programs and that they are implemented correctly. Based on effectiveness, changes to the system are documented. The review should show if the system is being implemented correctly and determine the need for changes to the system. Where changes are required, this should be indicated on the verification paperwork along with corrective action details. If applicable, HACCP verification should be performed as well. Both activities can be performed together or separately. Changes made in programs should be reflected in the report. Records of all verification activities, reasons for amending documents, validations and changes should be available for review.

- Internal Audits
- External Audits (2nd Party and 3rd Party)
- Other food safety audits/visits (official)
- Analysis of feedback/complaints (from customers and workers) and recalls (where applicable)
- Review of incidents including unusual occurrences, foreign material issues, pest control issues, microbial testing results, food defense, food fraud, etc.
- Review and updates to operation's objectives
- Review of organizational chart
- Document control activities including updates, changes or new SOPs, customer specification issues
- HACCP/PC verification
- Sanitation
- Pest control
- Approved supplier/service provider program
- Worker training review
- Facility and equipment maintenance
- Recall program
- Other food safety managements system related activities

Minor deficiency (10 points) if:

- Single/isolated instance(s) of errors or omissions in the verification activities.
- Single/isolated instances of key programs not evaluated for effectiveness
- It has been more than 12 months since management verification but less than 18 months.

Major deficiency (5 points) if:

- Numerous instances of errors or omissions in the verification activities.
- Numerous key programs such as pest control, supplier control or sanitation operating procedures not evaluated for effectiveness
- It has been more than 18 months since management verification (but less than 24 months).
- No proof of senior management review.

Non-compliance (0 points) if:

- Widespread errors or omissions in the verification activities.
- Most key food safety programs not evaluated for effectiveness
- It has been more than 24 months since management verification.

1.01.06: Where specific industry guidelines or best practices exist for the crop and/or product, does the operation have a current copy of the document?

Total compliance (3 points). There is a current copy of any specific industry guidelines for the crop and/or product available for review (electronic copies are accepted). Some examples include the Produce Safety Rule, FSMA Seven Rules including Foreign Supplier Verification Programs, Sanitary Transportation of Human and Animal Food, the Leafy Green Marketing Agreement (LGMA), California Cantaloupe Program, Tomato Good Agricultural Practices (T-GAP), Commodity Specific Food Safety Guidelines for

the Production, Harvest, Post-Harvest, and Processing Unit Operations of Herbs, etc. Not applicable if no specific industry guidelines or best practices exist for the crop and/or product or activity.

Reference:
FSMA: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm#guidance
FDA Produce & Plant Products Guidance Documents & Regulatory Information:
https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/default.htm
Center of Produce Safety Resources: https://www.centerforproducesafety.org/resources.php
Penn State Mushroom Resources: https://plantpath.psu.edu/facilities/mushroom/resources

Minor deficiency (2 points) if:
- Missing one copy of specific industry guidelines or best practices where more than one crop or product is handled.

Major deficiency (1 point) if:
- There is a copy of the best practices, but it is not the current version.
- Missing more than one copy of specific industry guidelines or best practices where more than one crop or product is handled.

Non-compliance (0 points) if:
- Specific industry guidelines or best practices exist for the crop/crop group being audited, but the operation does not have a copy.

Control of Documents and Records

1.02.01: Is there a written document control procedure (including document control register/record) describing how documents will be maintained, updated and replaced?
Total compliance (3 points): There should be a record of all documents used, when they were issued and updated with the current revision status to help avoid using obsolete documents. Document examples include pre-requisite programs, SSOPs, SOPs, forms (record templates), other work instructions, raw material and finished product specifications, etc.
The document control procedure should specify:
- Who is responsible for document control (i.e. making sure documents are updated and securely stored).
- How documents are to be written, coded and approved.
- How documents are updated, and amendments are approved (e.g. how paper versions are approved, computer records password protected, etc.).
- How changes are identified and recorded (e.g. date, issue number, different colored text or font, change history document etc.).
- How the inadvertent use of obsolete documents is prevented.
- Register/record listing all documents used, when issued, when updated and current revision status.

If using an electronic record keeping system, the procedure should cover the above, plus how electronic records are managed to control access, how changes to records are controlled, including who has edit rights and how electronic records are secured; i.e. back-up system.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in the procedure.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the procedure.

Non-compliance (0 points) if:
- There is no written procedure

1.02.02: Is there a documented and implemented procedure that requires all records to be stored for a minimum period of 24 months (or greater if legally required) or for at least the shelf life of the product if it is greater than 24 months?
Total compliance (5 points): There should be a written procedure in place requiring that all food safety related records (including any test results) be retained for a minimum of 24 months, regardless of the product(s) shelf-life. For Good Agricultural Practices (GAP) growing area records include all cultivation records; for GAP harvest crew records include harvesting related records. Food safety records for product(s) with a shelf-life beyond 24 months should be retained for at least the shelf-life of the product. Organizations are expected to follow any regulatory or legal requirements for food safety related record(s) retention beyond the 24 month minimum requirement stated here. Ideally (not part of the audit scoring), some records that might go to prove the long-term food safety performance of the operation should be retained for as long as possible, for example internal and third-party audit records and corrective actions.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of food safety related records not being required to be or retained for the required length of time (two years unless legally longer storage is required, or the product has a longer shelf life than 24 months).

Major deficiency (1 point) if:
- Numerous instances of food safety related control records not being required to be retained for the required length of time (two years unless legally longer storage is required, or the product has a longer shelf life than 24 months).

Non-compliance (0 points) if:
- Food safety related records are kept less than 24 months.
- Food safety related records are kept less than the required time mandated by law for a particular product.
- Food safety related records are kept for less than the shelf life of the product.

1.02.03: Are both paper and electronic food safety related documents and records created, edited, stored and handled in a secure manner?
Total compliance (5 points): Both paper and electronic food safety documentation that are part of the food safety program (e.g. procedures, policies, training records, testing results, monitoring records, etc.) should be created, edited and handled in a secure manner that deters theft and prevents tampering, when not in use. For example, the system might be the locking up of all manuals and recording logs at night in the QA Lab., when the operation is not running. There might also be rules for storing records in a secure archive room. Where computer systems are used to store SOP's, records, etc., there should also be security measures including access control (password protection). The electronic records and documents should also be "backed-up" in some way e.g. stored in two locations, so that if one location breakdowns or is damaged, the data is not lost. Paper files should be written in ink, not pencil and if changes are made to records after initial entry, changes should be clearly legible and tracked, and no use of correction fluid. When electronic records are amended, they should show what was amended, by whom and when (editing history). Electronic records should be storable in the database, available for immediate retrieval when needed (see 1.02.04) and have secure digital signature (including date and time (where appropriate)) capabilities. All records should be legible and accurate.
The system should include appropriate electronic security and comply with the relevant electronic regulatory record-keeping requirements, e.g. FDA (21CFR117.305, 21CFR11) and/or national equivalents.

FDA Electronic Records Guidance:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=117.305

Minor deficiency (3 points) if:
- Single/isolated instance(s) of hard copy documents and records not being created, edited, stored and handled securely.
- Single/isolated instance(s) of electronic documents and records not being created, edited, stored and handled securely.
- Single/isolated instance(s) of electronic documents lacking digital signature capabilities.

Major deficiency (1 point) if:
- Numerous instances of hard copy documents and records not being created, edited, stored and handled securely.
- Numerous instances of electronic documents and records not being created, edited, stored and handled securely.
- Numerous instances of electronic documents lacking digital signature capabilities.
- Electronic documents and records are not being backed-up.

Non-compliance (0 points) if:
- Hard copy documents and records are not stored securely.
- Computerized documents and records are not being stored securely.
- No control over creating or editing of hard copy and/or computerized records.
- Widespread failure to use electronic signatures and/or software lacks secure electronic signature capability.

1.02.04: Are records maintained in an organized and retrievable manner?
Total compliance (3 points): All food safety records and documents should be maintained in a designated area where they can be retrieved readily. These records should be well organized, and should be accessible, even if the operation is seasonal. This will aid in the detection of issues, the isolation of problems, and the identification of trends and retrieval of information. Binders or file system is acceptable. System might be by date or together in a single file for a particular record. It may be that data is kept on computer. Data on computers must be easily retrievable.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of records and/or documents not being organized and easy to retrieve.

Major deficiency (1 point) if:
- Numerous instances of records and/or documents not being organized and easy to retrieve.

Non-compliance (0 points) if:
- No organization of records and/or documents.
- Many missing records and/or documents.

1.02.05: Are all records and test results that can have an impact on the food safety program verified by a qualified person independent of the individual(s) completing the records?
Total compliance (5 points): Records and test results should be reviewed, signed off and dated by a qualified person within 7 days. The verifier is independent of the individual completing the record(s), understands the purpose of the verification and understands what they need to review on the record(s) before they sign (i.e. PCQI qualification, evidence of training, etc.). Examples of records may include composting records, pre-harvest records, pre-operational inspections, anti-microbial, water turbidity, cleaning and sanitation, etc. If any issues are detected, corrective actions should be recorded. Ideally (not a scoring issue), there is a summary document of records reviewed, who reviewed (position) and who verified the summary document (position). Pesticide application records are ideally reviewed and signed off on as above, however, individual situations including small farming operations and contract spray services may impact how records are being reviewed and signed.

Reference:

https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm#guidance
https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Records-Required-by-the-FSMA-PSR.pdf

Minor deficiency (3 points) if:
- Single/isolated instance(s) of records and/or test results not being reviewed and signed off by a qualified person within 7 days (second signatory).
- Single/isolated instance(s) of records and/or test results being signed off by a qualified person but there are issues with the records that have not been highlighted.

Major deficiency (1 point) if:
- Numerous instances of records and/or test results not being reviewed and signed off by a qualified person within 7 days (second signatory).
- Numerous instances of the records and/or test results being signed off by a qualified person but there are issues with the records that have not been highlighted.

Non-compliance (0 points) if:
- Fundamental failure for records and/or test results to be reviewed and signed off by a qualified person within 7 days (second signatory).
- Fundamental errors on the records and/or test results that are being signed off by a qualified person.
- The verifier is not independent of the individual(s) completing the records.

Procedures and Corrective Actions

1.03.01: Is there a written and standardized procedure for creating Standard Operating Procedures (SOPs) and their content?
Total compliance (5 points): There should be a written document that describes how to write Standard Operating Procedures (SOPs) for food safety activities related to good agricultural practices and/or good manufacturing practices that when followed, help prevent food safety hazards from occurring. SOPs should include a date and document number or reference code and detail:
- what is to be done,
- how it is done,
- how often,
- by whom,
- what recordings are required and
- any immediate corrective action procedures to implement when there are any deficiencies.

These SOPs can be used for training and as reference tools. There should be clear evidence that this system is being followed, based on SOPs reviewed. SOPs should follow the organizations document control systems, especially proper version management (see Control of Documents and Records).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of SOPs not having the required format.

Major deficiency (1 point) if:
- Numerous instances of errors and omissions within the document.
- Numerous instances of SOPs not having the required format.

Non-compliance (0 points) if:
- A document describing how to write standard operating procedures has not been created.
- Widespread evidence that SOPs are not written following the standardized procedure.

1.03.02: Are the written procedures available to relevant users and is a master copy maintained in a central file?

Total compliance (5 points): The written procedures (SOPs) should be available to the users and other interested parties involved in performing the activities described in the procedures. A master copy of all SOP's and associated recording forms should be assembled and stored as a reference. SOP's should be used by the relevant workers (e.g., QA workers, production, sanitation, etc.). SOPs can be used for training and for reference. The number of copies of SOPs depends on the size of the company and the types of processes involved. In the event of electronic SOP's, access should be allowed to all relevant workers, however, there should be controls in place to prevent unauthorized editing.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of SOP's not being made available to relevant workers.
- Single/isolated instance(s) of SOP's and recording forms being omitted from the Master SOP file (SOP Manual).

Major deficiency (1 point) if:
- Numerous instances of some SOP's not being made available to relevant workers.
- Numerous instances of SOP's and recording forms being omitted from the Master SOP file (SOP Manual).

Non-compliance (0 points) if:
- SOP's are not accessible to relevant workers.
- A master file (SOP Manual) containing the SOP's and recording forms that are being used, has not been created.

1.03.03: Is there a documented corrective action procedure that describes the basic requirements for handling all non-conformances affecting food safety?
Total compliance (5 points): There should be a documented corrective action procedure that outlines how the company manages corrective actions including preventative actions and follow-up validation to ensure corrective action taken has solved the problem. Specific corrective action procedures and records are assessed in each module. The procedure should require that records of the corrective action activities and their follow-up are completed using the same format with the required information (see below) detailed.
Corrective action procedure should include:
- the review of the non-conformance
- the determination of the cause(s)
- the establishment of an action plan to address such non-conformances and prevent future occurrences (preventive action plan)
- the implementation of corrective actions and preventive actions
- the follow-up validation to ensure actions taken have solved the problem (e.g. root cause summary, evidence of the solution)

Auditees may consider the option of using root cause analysis method when trying to determine the cause of a non-conformance or trend of non-conformances.

Minor deficiency (3 points) if:
- Single instance of an error or omission in the information within the corrective action procedure.
- Single instance of corrective action procedure missing a key element from list above.

Major deficiency (1 point) if:
- More than one instance of errors or omissions in the information within the corrective action procedure.
- More than one instance of corrective action procedure missing a key element from list above.

Non-compliance (0 points) if:
- Numerous errors or omissions in the corrective action procedure.
- Corrective action procedures have not been developed.

1.03.04: Is there an incident reporting system, also known as a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA)?
Total compliance (5 points): The company has a log or report for recording infrequent and/or unusual events that impact food safety such as deviations, incidents, process failures, unusual occurrences, etc., For example, foreign objects, chemical spills, rejected packaging, downtime, etc., that are not recorded on other logs. These should have corrective action records where relevant. This log, often called a NUOCA log (Notice(s) of Unusual Occurrence and Corrective Action Log), helps avoid creating multiple logs for events that do not occur very often. If product testing is performed (microbiological, heavy metal, pesticides, dioxins, aflatoxins, etc.), and there are out of specification results, there should be a NUOCA. Useful to consider recording issues that might or might not temporarily affect production e.g. loss of power, blocked drains, weather damage, earthquakes, flooding by heavy rainfall, evidence of human intrusion during non-working hours in or around the growing area, etc., since at a later date, if there are product issues, these events might be of significance.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (1 point)
- Numerous instances of omissions or incorrect data in the records.

Non-compliance (0 points)
- No records.
- Failure to maintain records.

Internal and External Inspections

1.04.01: Is there a documented procedure for how internal audits are to be performed at the operations, including frequency and covering all processes impacting food safety and the related documents and records?
Total compliance (10 points): Self-auditing (self-diagnostics) is a key part of an operation's food safety program. A written procedure for internal audits should be created for each operation (farm, indoor agriculture, harvest crew, or facility) in order to proactively ensure safe food production. The internal audits procedure should include the checklist used for the internal audits, cover the inspection of sites, the practices in place, the related documents required, the records generated, the frequency of the internal audits, and identification of the person(s) or position(s) responsible for conducting the internal audits. If the current PrimusGFS checklist is not utilized in the internal audit program the self-audit should still include the requirements applicable to the operation type from the PrimusGFS normative documents. Procedure should include the verification of the practices and the related documents and any corrective actions taken. If issues are found, there should be detailed corrective action records. Audit records should include the date, personnel involved, areas that were checked, findings and corrective actions (where necessary). Recording systems (documentation) for food safety related topics should be audited at least quarterly (frequency could increase or decrease depending on production seasonality) to ensure that they are being completed properly (e.g., using the correct log, correct frequencies, recording results correctly, recording corrective actions, etc.). This does not include the food safety management system every 12 months, see 1.01.05. The internal audit records are assessed in each module.
- Inspection frequency depends on type and size of operation but as a minimum:
  - Food safety management system: at least every 12 months.
  - Food safety documentation: at least quarterly.
  - Farm, Indoor Agriculture and Harvest Crew: at least a pre-season growing area assessment and a full GAP self-assessment during harvest season covering growing and harvesting operations should be on file. If growing and harvest activities are under the same organizational authority the self-assessment should be on file covering both growing and harvesting and conducted during the harvest season. A harvesting company not under the authority of a grower should have self-assessments on file during harvest season covering each type of harvest process utilized for the

crew(s), i.e. crew can harvest product in-field semi-processing and bulk/final packing in the growing area. A more frequent self-assessment frequency should be used depending on the crop type, farm or indoor agriculture location, any associated risk pressures, and/or if required by any national, local or importing country legal requirements, or customer requirements. These factors will also affect the need for pre-harvest inspections. Farm(s), indoor agriculture growing area(s), storage, harvesting, worker and visitor hygiene, agricultural water sources, training program, etc., and all associated paperwork should be included.

- Facility: Processing plants should have at least a monthly frequency. Packinghouses, coolers and storage operation ideally have a monthly frequency, but at least a quarterly frequency. Entire facility (inside and out) should be included.
- HACCP: self-audits of the HACCP program should have been done at least once within last 12 months to ensure that the process flow, hazard analysis and HACCP chart reflect reality and ensure that the program has captured any changes to the process. Whenever changes are made to the program i.e. new equipment added to the facility, new critical control points added to the plan, new limits added, new packaging is required, etc., then the plan needs to be re-evaluated by a self-audit to make sure it is working properly (6.02.03). HACCP program reviews should also take into account the latest guidelines, legal changes, issues arising from other audits and any other information gained about the production process. Self-audits help verify the effectiveness of the HACCP program, identify deficiencies and help improve the program.
- Preventive Controls: self-audit of the program at least every three years to ensure product descriptions, process flows, hazard analyses, preventative control decisions, preventative control recording and worker training reflect reality and ensure the program has captured any changes to the process. Whenever changes are made to the program and where emerging issues may be relevant to the product and processes, then the plan needs to be re-evaluated by a self-audit to make sure it is working properly.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of areas/issues missing on the inspection program.
- Single instance of self-audit not being required at least at the minimum frequency.

Major Deficiency (3 points) if:
- Inspection frequency is not adequate relative to the type of business and the number of issues that require monitoring.
- Numerous instances of areas/issues missing on the inspection program.
- More than one instance of a self-audit not being required at least at the minimum frequency.

Non-compliance (0 points) if:
- There is no procedure for how self-audits are to be performed.
- Numerous instances of self-audits not being required at least at the minimum frequency.

1.04.02: Are there written procedures for handling regulatory inspections?
Total compliance (3 points): Written procedures for handling food safety related regulatory inspections are available for workers to follow when regulatory agencies inspect the operation. Regulatory agencies could be Health Departments, State enforcement organizations, etc. (e.g., US: USDA/FDA, Canada: CFIA, Chile: Ministerio de Agricultura/SAG, Mexico: SAGARPA). The procedures should include at a minimum, rules for always accompanying inspections, identified meeting space, rules on taking samples and taking photographs, how to follow-up after the inspection, corrective action requirements, etc. This policy should be communicated to key personnel including the receptionists, field/plant workers and crew/line supervisors. Inspection policies must not contravene bio-terrorism laws or restrict access to documents that have been covered by these laws.

https://www.fda.gov/iceci/inspections/iom/default.htm

Minor deficiency (2 points) if:
- If one of the above elements of the policy is missing.

- If the receptionist(s) has/have not been briefed properly.

Major deficiency (1 point) if:
- If two or more elements of the policy are missing.

Non-compliance (0 points) if:
- A written procedure for handling regulatory inspections is not available for review.

1.04.03: Are there records of regulatory inspections and/or contracted inspections, company responses and corrective actions, if any?
Total compliance (5 points): Reports of previous food safety inspections are on file and any deficiencies noted have been responded to (date of response, action taken, and signature of responsible person (if applicable)). Inspections include regulatory (e.g., Federal and State) and third-party audits. This question is not applicable if there have been no regulatory or third-party inspections in the past year. Evidence of corrective actions (and their follow-up) is important, since there are legal implications if a company was warned of an issue and cannot prove that it has taken corrective actions and later has a serious incident which could have been prevented.

https://www.fda.gov/ICECI/Inspections/ucm256377.htm
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of corrective actions not being recorded.
- A single audit inspection report is missing in the last year.

Major Deficiency (1 point) if:
- Numerous instances of corrective actions not being recorded.
- More than one audit inspection report is missing in the last year.

Non-compliance (0 points) if:
- There are no records of previous inspections and corrective actions taken although there have been more than two inspections in the last year.
- If a previous inspection indicated an observation of contaminated ingredient, product or food contact packaging and there are no documented corrective actions.

1.04.04: Are there documented calibration and/or accuracy verification procedures for measuring and monitoring devices used in the operations that are related to the safety of the product?
Total compliance (10 points): The equipment used should be identified (i.e. catalog, roster, list) and there are documented procedures for the calibration for measuring and monitoring devices used in the operation. Regular calibration ensures correct and accurate operation. Scales/weight or volume measuring devices should have verification of accuracy and/or calibration regularly to ensure correct and accurate operation where relevant to food safety.

For GAP, this covers items such as fertilizer and pesticide application equipment, pesticide measuring equipment (e.g. scales), ORP and pH meters, and other equipment related to the safety of the product. Pesticide application equipment (e.g. sprayers), and corresponding measuring equipment (e.g. scales, cups) should be verified and when required calibrated (or replaced) regularly to ensure correct and accurate operation. Calibration and/or verification procedures should describe frequency, method and the acceptable range of variation (when applicable). Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency.

For GMP, this includes equipment used for measuring and monitoring processes (handheld and automated) related to food safety e.g. ATP testing systems, thermometers, scales for weighing

ingredients (e.g. in juice operations), metal detectors, ORP meters, flow meters and pH meters. Scales used to check final product weight are exempt (unless relevant to food safety).

Equipment is calibrated regularly to ensure correct and accurate operation. Calibration procedures should be traceable to a national or international standard or method, should describe the frequency of testing, the testing method, and the acceptable range of variation. Procedures should require that all test solutions/strips are within date code, appropriate for the concentrations used and stored correctly (especially light and temperature sensitive materials). Corrective actions should be detailed when applicable. Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency. Both internal (where the company checks the equipment for themselves) and external (where equipment is sent away, or an outside specialist company comes on site and checks the equipment in situ) calibrations should be documented and on file. Proof of calibration includes records, invoices and on machines labels. Where an external service is used, procedures, licenses and/or certifications are acceptable.

https://www.pubs.ext.vt.edu/content/dam/pubs_ext_vt_edu/424/424-100/PDF_part16.pdf
http://www.ugaurbanag.com/content/calibrating-your-spreader

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of omissions in the procedure(s).
- Single/isolated instance(s) of piece/set of equipment omitted from the procedure(s).

Major Deficiency (3 points) if:
- Numerous instances of omissions in the procedure(s).
- Numerous instances of pieces/sets of equipment omitted from the procedure(s).

Non-compliance (0 points) if:
- No procedure

1.04.05: Are calibration and/or accuracy verification records maintained and are they consistent with the requirements outlined in the SOP(s) for instruments and measuring devices requiring calibration?
Total compliance (5 points). Calibration and/or accuracy verification records should be available for all applicable equipment and should consider at least equipment identification, date, frequency of testing, testing method, result (variation), and corrective actions. Both internal (where the company checks the equipment for themselves) and external (where equipment is sent away, or an outside specialist company comes on site and checks the equipment in situ) calibrations should be documented and on file. Proof of calibration includes records, invoices and on machines labels. Where an external service is used, procedures, licenses and/or certifications are acceptable.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (1 point)
- Numerous instances of omissions or incorrect data in the records.

Non-compliance (0 points)
- No records.
- Failure to maintain records.

Release of Items/Product

1.05.01: Is there a documented product release procedure available?

Total compliance (5 points): Product release procedures are needed when the product is approved for shipment or harvest (they do not indicate the release of a product that has been placed on hold). Product release procedures assure that a lot is only released for shipment (sale) when the lot meets agreed standards, such as order requirements (e.g. specification) and/or meets agreed testing requirements (e.g. results confirmed negative or within limits results from testing, etc.). This includes crops approved for harvest and crop harvest where harvested product is directly packed in the final packaging unit during harvest (e.g., mushrooms, berries, individually wrapped lettuce) or there is in-field processing/semi-processing. Products should not be released for harvest or shipment without assuring that all food safety evaluations have been completed. Designated personnel are responsible for signing off. Sign off may be part of harvest record, bill of lading, etc. Procedures should be properly documented, implemented and pertinent records retained. Procedures should take into account any specific customer requirements, for example, testing requirements. N/A for organizations that only have authority over the growing activities and operation(s), and not the harvesting activities.

Minor deficiency (3 points) if:
- Single part of the procedure is omitted.
- Single/isolated instance(s) of the procedure not being applied in the field, production and/or storage areas.

Major deficiency (1 point) if:
- Procedure missing more than one part, but SOP exists.
- Numerous instances of the procedure not being applied in the field, production and/or storage areas.

Non-compliance (0 points) if:
- No procedure.
- Procedure created bears no resemblance to what is being applied in the field, production and/or storage areas.

1.05.02: Are there records of product releases kept on file?
Total compliance (5 points): Records showing product releases should be consistent with the Release Procedure (1.05.01) and available for review. Product release records are needed to document when the product is approved for shipment or harvest (they do not indicate the release of a product that has been placed on hold). Authorized personnel should sign a “release” for product. Sign off may be part of harvest record, bill of lading, etc. Records should be available demonstrating the sign off for the “release” of all product shipped. N/A for organizations that only have authority over the growing activities and operation(s), and not the harvesting activities.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major deficiency (1 point) if:
- Numerous instances of omissions or incorrect data in the records.

Non-compliance (0 points) if:
- No records.

1.05.03: Is there a documented procedure for handling on hold and rejected items?
Total compliance (5 points): A documented procedure exists that explains how products (including raw materials, packaging, work in progress, finished product, etc.) that have either been rejected or placed on hold should be handled, including the release of the on hold/rejected items. Procedure should explain how returned items and items for donation are handled (where relevant).

For harvested product in the field and the facility, the procedure should identify who (position/title) is authorized to determine the disposition of materials that are placed on hold and include details on how the affected item(s) is/are separated from other lots in terms of tagging systems (e.g., date showing when

the item was placed on hold/rejected, the reason for being on hold/rejected and the name of the person who put the item on hold (details may be recorded electronically as long as products are clearly tagged)) and any other physical separation needed to ensure that affected items are not commingled with other goods in such a way that their disposition is not clear.

For the pre-harvest materials, procedures should include how the affected product is indicated in the field (e.g., cordoned off, any buffer zones used, how these details are recorded, etc.).
Procedure requires authorized personnel should sign (with date and time) a "release" for any item placed on hold or rejected, detailing actions taken (e.g., disposition, re-work, food bank, tilled back into the ground, etc.).

Minor deficiency (3 points) if:
- Single part of the procedure is omitted.
- Single/isolated instance(s) of the procedure not being applied in the field, production and/or storage areas.

Major deficiency (1 point) if:
- Procedure missing more than one part, but SOP exists.
- Numerous instances of the procedure not being applied in the field, production and/or storage areas.

Non-compliance (0 points) if:
- No procedure.
- Procedure created bears no resemblance to what is being applied in the field, production and/or storage areas.

1.05.04: Are there records of the handling of on hold and rejected items kept on file?
Total compliance (5 points): Records of items placed on hold or rejected (e.g. an on hold/disposition log) should be available for review and should be kept to provide information about any item (raw materials, packaging, work in progress, finished product, etc.) that is rejected or put on hold. Records should show date when the item was placed on hold/rejected, amount of product affected, the reason for being on hold/rejected, the name of the person who put the product on hold and any other actions taken to ensure that affected product is not commingled with other goods in such a way that their disposition is not clear. Authorized personnel should sign (with date and time) a "release" for any item placed on hold or rejected, detailing actions taken e.g. disposition, re-work, food bank, tilled back into the ground, etc. Disposition records for products placed on hold or rejected should be maintained and available for review where applicable. Where required by law, certificates of destruction should be kept for review.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major deficiency (1 point) if:
- Numerous instances of omissions or incorrect data in the records.

Non-compliance (0 points) if:
- There is no record of on hold or rejected materials.

1.05.05: Is there a documented procedure for dealing with customer and buyer food safety complaints/feedback, along with records and company responses, including corrective actions?
Total compliance (10 points): There is a documented procedure detailing how to handle food safety and food quality complaints and feedback. Food quality issues are relevant if they have the potential to also be food safety issues. It is important to keep the complaints and feedback related records on file to support company procedure. The procedure and records should include (where applicable):
- Date/Time of complaint/rejection,
- Who made the complaint/gave feedback,
- Contact information,

- Product description,
- Where the product was purchased,
- Amount of product,
- Product code/date,
- Nature of complaint/feedback,
- Corrective actions,
- Corrective actions taken to prevent reoccurrence.

Where appropriate (e.g. complaints of a repetitive nature), a trend analysis of food safety feedback should be performed to assist with the development of corrective actions.

Complaints and feedback information, along with any corrective actions that are taken or associated with the operation should be available for review. For example, a blue colored Band Aid in a product could have come from either a facility or a harvest crew so details of the issue(s) should be sent to both facility and harvesting company. Ideally (not part of the audit scoring) foreign material issues should include photographs of the issue found (where possible). Other examples of issues that are viewed as potentially food safety related include tainting, sickness and sometimes decay issues. Where there are many (e.g. more than 5 in a month) complaints, a degree of analysis and review is expected to determine if trends are present.

Where a corporate office/sales department or other parties handle the incoming food safety related complaints, the operation is still required to have a documented procedure including how complaints/feedback are communicated to the operation and how they are managed internally (e.g. investigation, root cause, corrective action, communication, etc.).
Where the auditee claims to have received no complaints/rejections, the auditor should verify that a complaint recording system is in place and has the necessary elements listed above.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of omissions and incorrect data in the records including corrective actions.
- More than 10 complaints/rejections received, but no trend analysis or review carried out.

Major Deficiency (3 points) if:
- Numerous instances of omissions and incorrect data in the records including corrective actions.

Non-compliance (0 points) if:
- There are no records of complaints/rejections and responses (complaints do occur).
- The company does not have a system for handling complaints/rejections

Supplier Monitoring/Control

1.06.01: Is there a written procedure detailing how suppliers and service providers are evaluated, approved, and include the ongoing verification activities including monitoring? *Note that supply chain preventive controls and supply-chain-applied controls are also mentioned in Preventive Controls Addendum.*
Total compliance (10 points): There is a written procedure detailing how suppliers and service providers (e.g. raw materials, propagation materials, fertilizers, crop protection products, ingredients, processing aids, primary packaging items) are evaluated, approved and monitored. The procedure for evaluation, approval and on-going verification, including monitoring of suppliers, on-site service providers and outsourced service providers should include the indicators to be considered for decision making (including food safety hazards), exceptions and the elements the providers should comply with to make sure they meet the defined specifications. This procedure should include monitoring requirements in order to remain approved, and methods for suspending and un-approving suppliers and service providers including product design and development (new products, changes to product or manufacturing processes). See also Modules 6 & 7 (where applicable). The procedure should also detail what is needed (minimum requirements) in the case of working with a supplier in an emergency situation (e.g. market

conditions, weather event) that has not yet been approved including ensuring approval from named management is justified and documented. U.S. Importers under the FDA's Rule Foreign Supplier Verification Programs rule should ensure requirements of rule are included in this procedure.
As a minimum, the procedure should detail the following where relevant:

- Agreed specifications
- Letters of guarantee
- Methods of evaluating approved suppliers and service providers (including second- and third-party food safety audits where relevant, at least for raw materials and primary packaging)
- Methods of approving approved suppliers and service providers
- Methods of approving "emergency" (temporary) suppliers and service providers.
- Methods and frequency of monitoring approved suppliers and service providers
- Methods of reviewing approved supplier and service providers performance and status (including removal of approved status)

Minor deficiency (7 points) if:

- If one of the above elements of the procedure is missing.

Major deficiency (3 points) if:

- If two or more elements of the procedure are missing.

Non-compliance (0 points) if:

- A written procedure detailing the selection, evaluation, approval and monitoring process of approved suppliers and/or service providers is not available for review.

1.06.02: Is there a list of approved suppliers and service providers including justification for use of any emergency (temporary) suppliers or providers?
Total compliance (10 points): There is a list of approved suppliers of materials and services. All incoming agricultural inputs, ingredients, products, materials (including primary packaging) and services that relate to food safety (e.g., contract crop protection sprayers, pest control, chemical suppliers, water and waste utilities, RPC rental, transport, laboratory testing, maintenance and sanitation services) are purchased from &/or provided by approved suppliers. Where exceptions are made (e.g., market conditions, emergency situations), approval from management is justified and documented as per procedure (1.06.01).

Minor deficiency (7 points) if:

- Single/isolated instance(s) of errors or omissions in the records.
- Single/isolated instance(s) of purchasing exceptions made (i.e. not from list of approved suppliers) without management approval.

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the records.
- Numerous instances of purchasing exceptions made (i.e. not from list of approved suppliers) without management approval.

Non-compliance (0 points) if:

- There is no list of approved suppliers.
- There is a list of approved suppliers but purchasing exceptions to it is the norm.

1.06.03: Are there current written food safety related specifications for all incoming products, ingredients, materials (including primary packaging), services provided on-site, and outsourced services?
Total compliance (10 points): A specification is an explicit set of food safety requirements or criteria to be met (e.g., indicating what an item is made of, contract details). Specifications are accurate, acceptable and ensure conformance with relevant customer and legislative requirements. There are written, detailed, up-to-date specifications for all incoming products, ingredients, materials (including primary packaging),

services provided on-site, and outsourced services (including when exceptions will be allowed) that have an effect on food safety, addressing the required Good Agricultural and/or Good Manufacturing Practices. Documented specifications are easily accessible to users and there is a documented procedure for review, amendment and approval of all specifications. Government registration and/or label information (e.g. EPA) for crop protection and processing aid products is acceptable in lieu of an actual specification provided there is evidence products are used according to label instructions. Specifications should be reviewed on at least an annual basis and there should be at least the following specifications available to review (where applicable):

- seeds (e.g. lettuce or leafy greens, sprouts, microgreens)
- transplants,
- fertilizer/crop protection materials/adjuvants,
- ingredients (e.g. product raw materials, ice),
- processing aids (e.g. anti-microbials, buffers, post-harvest fungicides),
- primary packaging materials (material/components manufactured with),
- other materials with potential for direct product contact based on risk assessment, for example labels in direct contact with product,
- on-site and outsourced services (e.g., contract crop protection sprayers, pest control, chemical suppliers, water and waste utilities, RPC rental, transport, laboratory testing, maintenance and sanitation services) provided.

Note that contracted auditee operations such as co-packers, harvest crews, etc., that use materials or services that are supplied and/or selected by their customers, i.e. not purchased by the auditee should still have copies of specifications for the item provided. For example, a harvest crew that has some or all of their primary packaging provided by their contracting customer should obtain a copy of the up-to-date specification(s) from the customer.

Minor Deficiency (7 points) if:

- Single/isolated instance(s) of errors or omissions in the records.

Major Deficiency (3 points) if:

- Numerous instances of errors or omissions in the records.

Non-compliance (0 points) if:

- No records.
- Failure to maintain records.

1.06.04: Does the organization have documented evidence to ensure that all incoming products, ingredients, materials, services provided on-site, and outsourced service suppliers comply with the approval requirements and that all supplier verification activities (including monitoring) are being followed, as defined in the supplier approval procedure?

Total compliance (15 points): The organization has relevant information from approved suppliers/service providers to ensure that they are complying with the established supplier/service provider approval procedures, contracts, specifications, customer and regulatory requirements and best practice guidelines. This applies to agricultural inputs, raw material, primary packaging, processing aids and other ingredient suppliers, products and services suppliers. Supplier verification documents should demonstrate that the ongoing approval requirements detailed in 1.06.01 are being met (e.g., third party food safety audits, certificates of analysis, reviews of supplier records, etc.).

The evidence should include (as applicable):

- Current (within last 12 months) second and/or third-party food safety audit certificates that include the scope of certification (ideally GFSI standard or equivalent) for suppliers of product and ingredients including primary/food contact packaging. Ideally, a tests/analysis confirming no chemical migration to food contents if there is history of past occurrences.
- Letters of guarantee are acceptable from the actual manufacturer for agricultural inputs, processing aids, and other ingredients that are purchased, and service suppliers. Letters of guarantee (also certificate of conformance) should indicate that the items supplied meet any and

all legal standards and regulations (e.g., FDA, FIFRA, etc.), best practice guidelines and agreed specifications. Letters of guarantee should be current (within last 12 months) or indicate they are "on-going".
- U.S. Importers under the FDA's Rule Foreign Supplier Verification Programs should have documented evidence that foreign suppliers follow requirements to verify that imported food meets U.S. safety standards.

Note that contracted auditee operations such as co-packers, harvest crews, etc., that use materials or services that are supplied and/or selected by their customers, i.e. not purchased by the auditee should still have copies of the documents noted in this question, for example, third party audits. For example, in the case of a harvest crew company that has some or all of their packaging provided by their contracting customer, the harvest crew should obtain copies of the relevant packaging supplier documents such as third-party audits from their contracting customer

Minor Deficiency (10 points) if:
- Single/isolated instance(s) of errors or omissions in the records.

Major Deficiency (5 points) if:
- Numerous instances of errors or omissions in the records.

Non-compliance (0 points) if:
- No records.
- Failure to maintain records.

1.06.05: Where food safety related testing is being performed by laboratory service providers, are these licensed and/or accredited laboratories (e.g., ISO 17025 or equivalent, national and local regulations, etc.)?
Total compliance (5 points): All food safety relevant tests and/or analyses that are performed by laboratories (e.g., water, pesticide residue and microbial) should be done by laboratories with current licenses and/or accreditations for the methods used). These can be ISO 17025 or equivalent, National Regulations or State Department approvals in the country of production. Documented evidence of these licenses and/or accreditations should be available indicating the scope of the license/accreditation/what analyses the laboratory is accredited to perform, what standard/code it is accredited to, who accredited the laboratory and date of expiration. Auditor should confirm that the laboratory has the appropriate licenses and/or accreditations for the analyses being done i.e. product testing, water testing, pesticide residue testing, etc. Letters of guarantee from the laboratory are not acceptable and proficiency testing (while useful supporting information) does not replace the requirement for laboratory licensing and/or accreditation.

Minor Deficiency (3 points) if:
- Single instance of an omission or incorrect data in the documentation indicating the scope of the license/accreditation/what analyses the laboratory is accredited to perform, what standard/code it is accredited to, who accredited the laboratory and date of expiration.

Major Deficiency (1 point)
- More than one instance of omissions or incorrect data in the documentation indicating the scope of the license/accreditation/what analyses the laboratory is accredited to perform, what standard/code it is accredited to, who accredited the laboratory and date of expiration.

Non-compliance (0 points)
- No documentation.
- Using a non-licensed or unaccredited laboratory.
- License/accreditation of testing laboratory has expired.

Traceability and Recall

1.07.01: Is there a document that indicates how the company product tracking system works, thereby enabling trace back and trace forward to occur in the event of a potential recall issue?
Total compliance (10 points): The tracking system is shown in writing or in the form of a flow diagram and demonstrates the product tracking system that is used by the operation. The system should be able to show that it can trace back to the supplier(s) of materials, packaging, ingredients, processing aids, work-in-progress, etc., and show that the system can trace forward and indicate which customer(s) received products. This is usually accomplished by lot coding materials throughout a process and recording these lot codes at different points in the process. The traceability system should be in evidence when touring the operation and also when checking paperwork. The auditor should choose a finished product lot code to test the traceability system and have the auditee demonstrate how the code traces back to raw material supplier(s) and traces forward to the customer(s). The traceability system should include any product, ingredient, packaging and/or service related to the food safety that is outsourced.
The written traceability system should match the system that is being used in the field or production facility (as applicable). Recording batches of packaging is required for some products where packaging recalls might occur e.g. modified atmosphere packaging, juice bottles, etc. Recording packaging batches is not required for packaging that is not usually the cause of recall e.g. cardboard boxes. Cooling/Cold Storage & Storage and Distribution auditees that operate in a third-party capacity for their clients might have their own traceability system or have adopted their client(s'). Growers may have access to customer traceback system or create their own tracking seed/transplant to field/block code, input dates (water, fertilizer, pesticides) to harvest dates and onto facility. While either route is acceptable, if the individual client(s') traceability systems are used then the auditor will check each individual traceability system on site. Cooling/Cold Storage & Storage and Distribution operations should have a system that can traceback from outgoing lots back through their process to the incoming lots.

The tracking system must meet the requirements for "one step back, one step forward" as per the FDA requirements. Any national, local or importing country legal requirements should be considered.

https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list
https://www.fda.gov/food/new-era-smarter-food-safety/tracking-and-tracing-food

Minor deficiency (7 points) if:
- Single/isolated instance(s) of the written traceback system not reflecting what is happening in the production facility.
- Single/isolated instance(s) of clarity issue(s) in the traceability explanation (text or flow chart).
- Omitting packaging traceability (where packaging is sometimes the subject of a recall issue e.g. MAP packaging, juice bottles).

Major deficiency (3 points) if:
- Numerous instances of the written traceback system not reflecting what is happening in the production facility.
- Numerous instances of clarity issues in the traceability explanation (text or flow chart).
- Single/isolated instance(s) of either incorrect or missing elements of the traceability system that either limits or stops efficient tracing back or tracing forward of the production process. For example, not recording which lot codes are going to which customer thereby requiring that all customers are contacted in the case of a recall.

Non-compliance (0 points) if:
- Fundamental failure of the written traceback system to reflect what is happening in the production facility.
- Numerous instances of either incorrect or missing elements of the traceability system that either limits or stops efficient tracing back or tracing forward of the production process. For example, not recording which lot codes are going to which customer thereby requiring that all customers are

contacted in the case of a recall. The production step not properly recording what raw material lots are processed on a certain day.
- No written down traceability system.

1.07.02: Does the organization have a documented recall program including procedures, recall team roles and contact details, external contact listings, requirement for recall effectiveness checks, explanation of different recall classes and handling of recalled product?
Total compliance (15 points): To facilitate an efficient recall there should be a written procedure describing how to perform a product recall, recall team details (contact details, alternates, roles and responsibilities), referral to customer and supplier contact details, explanations of relevant laws e.g. product withdrawal, class of recalls (if USA is production or destination country), etc.
Documentation should include basic procedures and responsibilities, current facility contact listing with alternates and out of hour's numbers. Contact listings for customers and suppliers should also be part of the recall program, although these might be viewed as confidential (if so, then these listings must at least be referred to in the recall program). Listings should be reviewed regularly. An explanation of recall classes (Classes I, II, and III in the USA) should be in the recall program. Ideally contact details for the Certification Body, attorneys, media specialists (for getting the recall information to the various press outlets), local enforcement officials e.g. State and City Health Boards are a good idea (these are optional and should not cause a down score if missing).

Auditees that operate in a third-party capacity e.g. contract copacker, storage operations, etc. might not have supplier and customer contact details, but they should have their client(s) details as part of their recall program. Auditees that operate in a third-party capacity have the option of creating their own recall program or using those provided by their clients. If latter option is used, then the auditor will check each individual recall program on site. Growers may create their own recall program or be using their customer's recall system. If the latter option is used, then the auditor will check each individual recall program on site.

Potentially useful websites:
FDA Industry Guidance for Recalls: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls

Minor deficiency (10 points) if:
- One element of the written recall program is missing or is outdated

Major deficiency (5 points) if:
- Two or more elements of the written recall program are missing or are outdated

Non-compliance (0 points) if:
- The facility does not have a recall program.

1.07.03: Is testing of recall procedures (including trace back) performed and documented at least every six months and the company can demonstrate the ability to trace materials (one step forward, one step back) effectively?
Total compliance (10 points): Testing of recall procedures should be performed at least every six months. (For short season crops where the operation runs 6 months or less throughout the year, only one mock recall is required and should include primary packaging (where applicable)). Where two mock recalls per year are required, one of the mock recalls should include the primary packaging as part of the exercise (not required for operations not using or handling primary packaging). The steps taken to conduct the mock recall, as well as the records utilized to demonstrate the program are effective and should be consistent with the scenario identified. Documentation should indicate the date and time the mock recall was initiated, the product or material chosen, the scenario, amount of product produced, affected lot ID's (date code(s), lot code(s), etc.), amount located, percent located, time product was located and time mock recall was completed. Scenario should be varied to provide experience in a range of conditions that are likely to occur; some examples include customer complaints for foreign materials, test results (buyer, government, in-house) detecting issues such as pathogens, pesticide residues, etc. Mock recall

documentation should include copies of documentation that support the traceback scenario from the affected finished good lot through to the production run(s) affected and therefore showing if other lots are affected and which other customers might have received affected lot(s). Checks should be carried out to ensure that contact details exist for the affected customers. Documentation should also include any "lessons learned" from the mock recall process. GAP related organizations (for example (farm and crew)) operations may create a mock scenario where they receive information from a client indicating there is a problem that warrants a recall. An alternate GAP mock scenario is that the grower is informed of a problem with an input that may warrant a recall e.g. some form of crop contamination. They should show how they know which lots were affected and the associated records of agricultural inputs, they should also be able to show who the field was harvested by and where the harvested crops were sent to. If an Organization (for example, a grower) opts to use a customer's recall program to meet the requirements of this question then the Organization can also use a valid mock recall from the customer that shows that the recall system has been properly tested. This mock recall would only cover the relationship between the Organization and the customer who has provided the mock recall example.

Documentation should state "Mock Recall", especially the document that shows the scenario, so that at a later date, no one is confused as to whether this was a mock or a real recall. Auditors should remember that mock traceback and recall will vary considerably depending on the scenario chosen. Recalls should be completed within two hours with 100% of chosen product located. Mock recalls might note that product had been culled and rejected in some situations. Auditees are not expected to call or otherwise contact any suppliers or customers when carrying out mock recalls. If a live (real) recall has occurred in the last year, then this can be used to meet the requirements of this question, but the documentation details noted above should be in place.

Minor deficiency (7 points) if:
- Three or less elements of the mock recall are missing (e.g., supporting documentation, packaging material)
- Five percent or less of product or packaging was not located.
- A few gaps noted in the logic of the traceback documentation
- Not noting "lessons learned" from mock recall exercise (if there are any)
- Total time to complete mock recall took longer than 2 hours but not more than 3 hours.

Major deficiency (3 points) if:
- Four or more elements of the mock recall are missing (e.g., supporting documentation, packaging material)
- Mock recall scenario is not varied to provide experience in a range of conditions
- More than five percent of product or packaging was not located.
- Lacking documentation that proves how the traceback and recall system identified all affected items and customers.
- Total time to complete mock recall took more than 3 hours.
- Only one mock recall was performed in the prior 12 months.

Non-compliance (0 points) if:
- Mock recall has not been performed within the prior 12 months.
- Mock recall was initiated, but could not be completed

Food Defense

1.08.01: Is there a written food fraud vulnerability assessment (FFVA) and protection plan for all types of fraud, including all incoming and outgoing products?
Total compliance (5 points). There should be a vulnerability (risk) assessment and comprehensive protection plan for all types of food fraud. This includes economically motivated hazards, economically motivated food safety hazards, adulterant substances, mislabeling, theft, tampering, simulation, diversion or gray market, intellectual property rights and counterfeiting.

An example of a food fraud scenario that may occur at an operation is when suppliers provide products/materials that do not match their required specifications (e.g. unapproved chemicals, non-food grade packaging material, product substitution).

Additional resources:
https://www.federalregister.gov/documents/2015/09/17/2015-21920/current-good-manufacturing-practicehazard-analysis-and-risk-based-preventive-controls-for-human
https://mygfsi.com/press_releases/gfsi-position-paper-on-mitigating-the-public-health-risk-of-food-fraud/
https://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2018/is-that-a-beet-or-a-banana-unwrapping-food-fraud-in-the-produce-industry/
https://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2017/food-fraud-vulnerability-assessment-and-prefilter-for-fsma-gfsi-and-sox-requirements/

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors or omissions in the vulnerability assessment.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the vulnerability assessment.

Non-compliance (0 points) if:
- There is no vulnerability assessment.
- Fundamental failure to review food fraud types for the assessment.

1.08.02: Is there a written food defense vulnerability assessment and food defense plan based on the risks associated with the operation?
Total compliance (5 points): The operation should have a documented food defense plan that outlines the organization's security controls based on a written food defense vulnerability assessment of risks associated with the operations. This plan should include Good Agricultural Practices and/or Good Manufacturing Practices, as well as a written risk/vulnerability assessment, and controls for the identified risks.

The document should include relevant food defense risks such as site/building access, personnel, visitors, contractors, computers, raw material receipt (raw materials, product and packaging), trucks (incoming and outbound), water sources, storage areas for product, materials, chemicals, production areas, shipping areas, etc. There may also be a requirement to ensure that suppliers have proper food defense programs. The food defense plan creation should also meet any national or local regulations (including management oversight and approval). Documented operational risk management (ORM) systems are acceptable if they show the controls that have been implemented for the food defense risks that have been identified. The plan should be reviewed at least once every 12 months e.g. as part of management verification review process.

Additional resources:
https://www.fsis.usda.gov/wps/wcm/connect/9fb1c725-4aae-4e06-b56e-217e0fc08f43/Self_Assessment_Checklist_Food_Security.pdf?MOD=AJPERES
https://www.fda.gov/food/food-defense-tools-educational-materials/food-defense-plan-builder

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors or omissions in the risk assessment or food defense plan.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the risk assessment or food defense plan.

Non-compliance (0 points) if:
- Food defense plan has not been documented.
- There is no risk assessment.

1.08.03: Are records associated with the food defense plan and its procedures being maintained, including monitoring, corrective action and verification records (where appropriate)?
Total compliance (5 points). The records required in the food defense plan should be maintained, in accordance with the details of the plan (see 1.08.02) and its associated procedures. These records are also subject to the document control and records requirements of this module.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors or omissions in the records.
- Single/isolated instance(s) of records not being maintained as per plan.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the records.
- Numerous instances of records not being maintained as per plan.

Non-compliance (0 points) if:
- There are no available records.
- Fundamental failure to maintain records as per plan.

1.08.04: Is there a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies?
Total compliance (3 points): The operation should have a current list of emergency contact phone numbers available for management, law enforcement and appropriate regulatory agencies. This information may be found as part of the recall plan.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in the list.
- The list has not been updated in more than a year (less than two years).

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the list.
- The list has not been updated in more than two years.

Non-compliance (0 points) if:
- A list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies has not been documented.

1.08.05: Are visitors and contractors to the company operations required to adhere to food defense procedures?
Total compliance (3 points): All visitors and contractors should be required to abide by the operation's food defense policies, including wearing appropriate identification. The rules and policies should be clearly stated in relevant languages. This requirement may be evidenced by signing a log on arrival at the operation, where the requirements are available for review, where they are agreeing to meet the company visitor and contractor food defense requirements.

Minor deficiency (2 points) if:
- Single/isolated instance(s) that visitor(s) and contractor(s) are not being required to comply with the operations' food defense policies.

Major deficiency (1 point) if:
- Numerous instances of visitors and contractors not being required to comply with the operations' food defense policies.
- Policy is not in the relevant language(s) of the visitors/contractors.

Non-compliance (0 points) if:

- The company does not have evidence of a requirement for visitors and contractors to comply with the operations' food defense policies.
- Fundamental failure of visitors and contractors not being required to comply with the operations' food defense policies.

Document Revision History		
Date	Rev.#	Description
2/18/21	0	Initial
10/8/21	1	Changes to questions 1.01.05, 1.04.04, 1.06.01 & 1.06.05