General Description of Changes to Module 1

1. Changes to question numbers
2. Expanded requirements in expectations

PrimusGFS v3.2 Summary of Changes

Section	Q #	v3.1 Question	v3.1 Expectations	v3.1 Interpretation Guideline	New #	v3.2 Question	v3.2 Expectation	v3.2 Interpretation Guideline
Management System	1.01.01	Is there a documented food safety policy detailing the company's commitment to food safety?	The documented policy should include a clear statement and detailed objectives of the company's commitment to meet the food safety needs of its products.	Total compliance (5 points): There should be a dated, signed (by senior management) documented food safety policy statement reflecting the organization's ongoing commitment to providing a safe product. The policy should include statements and objectives of the company's commitment to food safety, 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, 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.		No Change in v3.2	The documented policy should include a clear statement and detailed objectives of the company's commitment to food safety, promoting a proactive and committed food safety culture, food laws, best practices and continued 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 an area(s) visible to visitors and workers and in the language(s) understood by the workers.	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.
Management System	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?	The documented organizational chart should show positions and reporting structure of workers whose activities affect food safety within the company. This document should also detail job functions and responsibilities related to food safety. Suitable alternates should be indicated in case someone can not perform the assigned responsibilities at certain moment. Document should be current and accurate.	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 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 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. 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. Non-compliance (0 points) if: • Systematic errors on the organizational structure chart or responsibilities. • No process organizational structure chart or responsibilities.		No Change in v3.2	The organizational chart should show positions and reporting structure of workers whose activities affect food safety within the company. This document should also detail job functions and responsibilities related to food safety. Suitable alternates should be indicated in case someone can not perform the assigned responsibilities at certain moment. Document should be signed and dated by management to indicated it is current and accurate.	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 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.
Management System	1.01.03	Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?	Meetings that are either devoted to, or mention food safety issues, should be recorded as proof of company's ongoing commitment to food safety (minimum quarterly frequency). These meetings should detail Senior Management involvement in the Food Safety program.	Total compliance (5 points): There should be an active food safety committee, responsible for the strategic maintenance and development of the operations food safety plan. If an operation has a HACCP plan, the HACCP team may also look after the food safety issues. The company should be keeping logs and minutes/notes of meetings addressing food safety topics. 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 there should be at least one meeting available for review – score minor deficiency; if no records score non-compliance. 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 meeting have occurred in the last 12 months (for an all year-round operation) 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.		No Change in v3.2	Meetings that are either devoted to, or include food safety topics, should be recorded as proof of company's ongoing commitment to food safety (minimum quarterly frequency). These meetings should detail Senior Management involvement in the Food Safety program.	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.
Management System	1.01.04	Is there a training management system in place that shows what types of training 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?	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.	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 training program. The training records required under specific questions will be reviewed in the applicable module(s).		No Change in v3.2	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. The training records required under specific questions will be reviewed in the applicable module(s).	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).
Management System	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?	There should be written verification of the entire food safety management system at planned intervals (minimum every 12 months). There should be evidence that senior management is involved in the review 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.). The review should determine the need for changes and the changes made should be documented. The documented review should meet any national or local legislative requirements.	Total compliance (10 points): There is documented verification of the entire food safety management system at planned intervals (minimum 12 month intervals) and reviewed by senior management 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.). 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. Records of all verifications activities, reasons for amending documents, validations and changes should be available for review. • Internal Audits • External Audits (2nd Party and 3rd Party) • Analysis of feedback/complaints and recalls (where applicable) • Review and updates to operation's objectives • Review of organizational chart • Updates, changes or new SOPs • HACCP verification • Other food safety managements system related activities		No Change in v3.2 **Point change 10 to 15**	There should be written verification of the entire food safety management system at planned intervals (minimum every 12 months) and there should be evidence that senior management is involved in the review (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.	Total compliance (15 points): There is documented verification of the entire food safety management system 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, 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. 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

Management System	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?	There is a current copy of any specific industry guidelines for the crop and/or product available for review.	Total compliance (3 points). There is a current copy of any specific industry guidelines for the crop and/or product available for review. Some examples include 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.		No Change in v3.2	There is a current copy of any specific industry guidelines for the crop and/or product, best practice documents and required government regulations (e.g. US FDA FSMA, FSVP, etc.) available for review (electronic copies are accepted).	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.
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?	The document control procedure should show how controlled documents are to be written, coded, approved, issued and updated, and should also show how obsolete versions of documents are controlled. If using an electronic record keeping system, the procedure should cover this.	Total conformance (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.		No Change in v3.2	The document control procedure should show how controlled documents are to be written, coded, approved, issued and updated, and should also show how obsolete versions of documents are controlled. If using an electronic record keeping system, the procedure should also detail 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.	Total conformance (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.
Control of Documents and Records	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?	Food safety related records should be retained for auditing purposes and in case there are legal issues, customer queries, etc. There should be a procedure in place and all monitoring and process control records should be held for a minimum of 24 months regardless of the production item's shelf life. Any records required by law to be kept longer than 24 months should be kept for the legally mandated period. Any records pertaining to long life product should be kept at least for the duration of the shelf life of the product.	Minor deficiency (3 points) if: • Single/isolated instance(s) of process control records not being retained for the required length of time (one year unless legally longer storage is required, or the product has a longer shelf life than 12 months). Major deficiency (1 point) if: • Numerous instances of process control records not being retained for the required length of time (one year unless legally longer storage is required, or the product has a longer shelf life than 12 months). Non-compliance (0 points) if: • Process control records are kept less than 12 months. • Process control records are kept less than the required time mandated by law for a particular product. • Process control records are kept for less than the shelf life of the product.		No Change in v3.2	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. 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.	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 process food safety related records not being 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.
Control of Documents and Records	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 (3 points): Both paper and electronic food safety documentation e.g. SOP's, records, etc. including procedures, policies, programs, training records, testing results, monitoring records and tracebacks should be stored 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 computerized 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). Records should be legible and accurate. FDA Electronic Records Guidance: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11 Minor deficiency (2 points) if: • Single/isolated instance(s) of hard copy documents and records not being stored securely. • Single/isolated instance(s) of computerized documents and records not being stored securely. • Single/isolated instance(s) of hard copy and/or computerized records not being updated properly. Major deficiency (1 point) if: • Numerous instances of hard copy documents and records not being stored securely. • Numerous instances of computerized documents and records not being stored securely. • Computerized documents and records are not being backed-up. • Numerous instance(s) of hard copy and/or computerized records not being updated properly. Non-conformance (0 points) if:		No Change in v3.2 **Point change 3 to 5**	No Change in v3.2	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-conformance (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.
Control of Documents and Records	1.02.04	Are records maintained in an organized and retrievable manner?	All food safety records and documents should be stored in an organized manner, to allow for quick retrieval of records. This will aid in the detection of issues, the isolation of problems, and the identification of trends where attention is needed. Records should be accessible, even if the operation is seasonal.	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 where attention is needed. Records should be accessible, even if the operation is seasonal. 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.		No Change in v3.2	All food safety records and documents should be stored following an organized and consistent method, to allow for quick retrieval of records. This will aid in the detection of issues, the isolation of problems, and the identification of trends where attention is needed. Records should be accessible, even if the operation is seasonal. Data on computers must be easily retrievable.	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.

Control of Documents and Records	1.02.05	Are all records and test results that can have an impact on the food safety program reviewed and signed off by a person responsible for the food safety program?	Records and test results should be reviewed and signed off by a designated person(s) responsible for the food safety program within a reasonable timeframe. The sign off should not be done by the same person who carried out the monitoring activities. If any issues are detected, corrective actions should be recorded.	Total compliance (3points): Records and test results should be reviewed and signed off by a designated person(s) responsible for the food safety program within a reasonable timeframe. The sign off should not be done by the same person who carried out the monitoring activities. The review should include that the records are complete as applicable to the monitoring activity performed, and if any issues were detected the corrective actions were addressed in a reasonable timeframe and recorded. Examples of monitoring records may include composting records, CCPs, sanitizer, pH, water turbidity cleaning and sanitation, etc. Reference: https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM623178.pdf#page=132 https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Records-Required-by-the-FSMA-PSR.pdf Minor deficiency (2 points) if: • Single/isolated instance(s) of records and/or test results not being reviewed and signed off by the responsible person. • Single/isolated instance(s) of records and/or test results being signed off by the responsible 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 the responsible person. • Numerous instances of the records and/or test results being signed off by the responsible person but there are issues with the records that have not been highlighted. Non-conformance (0 points) if: • Systematic failure for records and/or test results to be reviewed and signed off. • Systematic errors on the records and/or test results that are being signed off by the responsible person.		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?	Records and test results should be reviewed and signed off 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. evidence of training). If any issues are detected, corrective actions should be recorded.	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 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-conformance (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?	There should be a written document that describes how to create SOPs when required to cover any food safety related activities. SOPs should include a date and document number or reference code and require detailing what is to be done, how it is done, how often, by whom, what recordings are required and any immediate corrective action to perform when deficiencies occur. There should be clear evidence that this system is being followed, based on SOPs reviewed.	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 require detailing: • what is to be done, • how it is done, • how often, • by whom, • what recordings are required and • any corrective action procedures to perform 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-conformance (0 points) if: • A document describing how to write standard operating procedures has not been created. • Systematic evidence that SOPs are not written following the standardized procedure.		No Change in v3.2	There should be a written document that describes how to create SOPs when required to cover any food safety related activities. 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 to implement when deficiencies occur. There should be clear evidence that this system is being followed, based on SOPs reviewed.	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-conformance (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.
Procedures and Corrective Actions	1.03.02	Are the written procedures available to relevant users and is a master copy maintained in a central file?		Total conformance (5 points): The written procedures (SOPs) should be available to the users and other interested parties. A master copy of all SOP's and associated recording forms should be collated in order to create (an) SOP Manual(s), sometimes called a Quality Manual. 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. A master copy of all SOPs and associated recording forms should be assembled and stored as a reference.		No Change in v3.2	No Change in v3.2	Total conformance (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.
Procedures and Corrective Actions	1.03.03	Is there a documented corrective action procedure that describes the required processes for handling non-conformances affecting food safety?	The corrective action procedure should outline how the operation manages corrective actions. Specifically, the determination of cause, establishment of an action plan(s) to address immediate issue(s) regarding non-conformance(s) (including any actions taken regarding affected product), corrective actions taken and the development of preventive actions to help avoid future occurrences. Records of the corrective action activities and their follow-up should be kept on file.	Total compliance (5 points): The corrective action procedure should outline how the operation manages corrective actions including preventative actions and follow-up validation to ensure corrective action taken has solved the problem. Records of the corrective action activities and their follow-up should be kept on file (omission of corrective actions is scored under specific questions in later modules). 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 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.		Is there a documented corrective action procedure that describes the basic requirements for handling all non-conformances affecting food safety?	The corrective action procedure should outline how the operation manages corrective actions. Specifically, requiring the determination of cause, establishment of an action plan(s) to address immediate issue(s) regarding non-conformance(s) (including any actions taken regarding affected product), corrective actions taken, the development of preventive actions to help avoid future occurrences and validation of corrective action. Procedure should require that records of the corrective action activities and their follow-up are completed using the same format with the required information detailed. Specific corrective action procedures and records are assessed in each module.	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 actoin 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.

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. Self-audits should be fully documented even if No Change in v3.1a are located. 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 for food safety related topics should be audited at least quarterly (frequency could increase or decrease depending in 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 should include: • Inspection frequency depends on type and size of operation but as a minimum: • Food safety management system: at least every 12 months. • 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 field. 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. • Who conducted the inspection • Documented findings • Corrective actions (items (including completion date) • Preventative 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 follow up/corrective actions not noted. • Single/isolated instance(s) of incomplete or missing records. • 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: • Numerous instances of follow up/corrective actions not noted. • Numerous instances of incomplete or missing records. • Inspection frequency is not adequate relative to the type of business and the number of issues that require monitoring. • Changes to the HACCP plan have been made but the self-audit had not been conducted. • 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-conformance (0 points) if: • Systematic failure to record self-audits properly.		No Change in v3.2	No Change in v3.2	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. Self-audits should be fully documented. 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. • Preventative 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.
Internal and external inspections	1.04.02	Are there written procedures for handling regulatory inspections?	Written procedures for handling regulatory inspections allow workers to be aware of how to handle the inspection appropriately. For example, documenting the inspector's credentials, contact information to facilitate open actions after the inspection, ensuring that the inspector is always accompanied, identified meeting space, rules on taking samples and photographs, how to follow-up after the inspection, etc.	Total compliance (3 points): Written procedures for handling 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, rules on taking samples and taking photographs, how to follow-up after the inspection, corrective actions requirements, etc. This policy should be communicated to key personnel including the receptionists, field staff and crew supervisors. Inspection policies must not		No Change in v3.2	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 and restrict access to documents that have been covered by these laws.	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 and restrict access to documents that have been covered by these laws.
Internal and external inspections	1.04.03	Are there records of regulatory inspections and/or contracted inspections, company responses and corrective actions, if any?	Reports of previous inspections are on file and any deficiencies noted have been responded to (date of response, action taken, and signature). Inspections include regulatory (e.g., Federal and State) and third-party audits.			No Change in v3.2	Reports of previous food safety inspections are on file and any deficiencies noted have been responded to (date of response, action taken, and signature). Inspections include regulatory (e.g., Federal and State) and third-party audits.	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.
Internal and external inspections	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?	Equipment used for measuring and monitoring processes related to food safety and/or verification of label requirements (e.g., for weight or volume) should be identified (i.e., catalog, roster, list) and SOPs should be available. Scales/weight or volume measuring devices should have verification of accuracy and/or calibration regularly to ensure correct and accurate operation. Calibration procedures should describe the frequency of testing, the testing method and the acceptable range of variation. Corrective actions should be detailed when applicable. Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency.	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. Equipment used for measuring and monitoring processes related to food safety and/or verification of label requirements (e.g. for weight or volume). 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. For GMP, this includes equipment used for measuring and monitoring processes (hand held and automated) related to food safety e.g. ATP testing systems, thermometers, metal detectors, ORP meters, flow meters and pH meters. Equipment is calibrated regularly to ensure correct and accurate operation. Calibration procedures 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. Hand application of fertilizers is not recommended as it is difficult to assure an even distribution of fertilizer or crop protection product. If done however, it is important to choose a pace that is easy to maintain and duplicate		No Change in v3.2	Equipment used for measuring and monitoring processes related to food safety should be identified (i.e., catalog, roster, list) and SOPs should be available. Scales/weight or volume measuring devices (e.g. for pesticide measurement) should have verification of accuracy and/or calibration regularly to ensure correct and accurate operation, where relevant to food safety. Calibration procedures should describe the frequency of testing, the testing method and the acceptable range of variation. Corrective actions should be detailed when applicable. Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency. 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. Pesticides 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 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.	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. Pesticides 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 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.
Internal and external inspections	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?	Calibration and/or accuracy verification records should be available for all applicable equipment and show frequency of testing, the testing method and the acceptable range of variation. Corrective actions should be recorded.	Total compliance (5 points). Calibration and/or accuracy verification records should be available for all applicable equipment and show frequency of testing, the testing method and the acceptable range of variation. Corrective actions should be recorded.		No Change in v3.2	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.	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.
Release of items/product	1.05.01	Is there a written procedure for handling on hold and rejected items?			1.05.03	Is there a documented procedure for handling on hold and rejected items?	No Change in v3.2	No Change in v3.2

Release of items/product	1.05.02	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 should be kept to provide information about of 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, 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.	1.05.04	No Change in v3.2	No Change in v3.2	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.
Release of items/product	1.05.03	Is there a documented product release procedure available?			1.05.01	No Change in v3.2	No Change in v3.2	No Change in v3.2
Release of items/product	1.05.04	Are there records of product releases kept on file?		Total compliance (5 points): Records showing product releases should be 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 organization's that only have authority over the growing activities and operation(s), and not the harvesting activities.	1.05.02	No Change in v3.2	No Change in v3.2	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.
Release of items/product	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?	There should be a documented procedure detailing how to handle food safety related complaints, rejections and feedback. The procedure should require the recording to include (where applicable): • Date/Time of complaint/rejection/feedback • Who made the complaint/gave feedback, • Contact information, • Product description, • Where the product was purchased, • Amount of product, • Product code/date, • Nature of complaint/rejection/feedback, • Corrective actions (including details of cause if known) • Corrective actions taken to prevent reoccurrence. Where appropriate, a trend analysis of food safety feedback should be performed to assist with the development of corrective actions.	If a corporate office/sales department or other parties handle the incoming food safety related complaints, then these should be communicated to relevant personnel. 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.		No Change in v3.2	There should be a documented procedure detailing how to handle food safety related complaints, rejections and feedback. The procedure should require the recording to include (where applicable): • Date/Time of complaint/rejection/feedback • Who made the complaint/gave feedback, • Contact information, • Product description, • Where the product was purchased, • Amount of product, • Product code/date, • Nature of complaint/rejection/feedback, • Corrective actions (including details of cause if known) • 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.	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. 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.
Supplier Monitoring/ Control	1.06.01	Is there a list of approved suppliers and service providers?	There should be a list of approved suppliers and service providers. All incoming products, ingredients, materials (including packaging) and services that relate to food safety should be sourced from approved entities. Where exceptions are made (e.g., market conditions), approval from management should be justified and documented.	Total compliance (5 points): There is a list of approved suppliers of materials and services. All incoming agricultural inputs, ingredients, products, materials (including 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. Minor deficiency (3 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 (1 point) 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.	1.06.02	Is there a list of approved suppliers and service providers including justification for use of any emergency (temporary) suppliers or providers? **Point change 5 to 10**	There should be a list of approved suppliers and service providers. All incoming products, ingredients, materials (including primary packaging) and services that relate to food safety should be sourced from approved entities. Where exceptions are made (e.g., market conditions), approval from management should be justified and documented as per procedure (1.06.01).	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).
Supplier Monitoring/ Control	1.06.02	Are there current written food safety related specifications for all incoming products, ingredients, materials (including primary packaging), services provided on-site, and outsourced services?			1.06.03	No Change in v3.2 **Point change 5 to 10**	No Change in v3.2	No Change in v3.2
Supplier Monitoring/ Control	1.06.03	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 Module 7.*	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. The procedure should also detail what is needed (minimum requirements) in the case of working with a supplier in an emergency situation that has not yet been approved.	Total compliance (5 points): There is a written procedure detailing how service providers and suppliers (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. The procedure should also detail what is needed (minimum requirements) in the case of working with a supplier in an emergency situation that has not yet been approved. 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 or third party audits where relevant, at least for raw materials and primary packaging) • Methods of approving approved 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 (3 points) if: • If one of the above elements of the procedure is missing. Major deficiency (1 point) 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 is not available for review.	1.06.01	No Change in v3.2 **Point change 5 to 10**	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. The procedure should also detail what is needed (minimum requirements) in the case of working with a supplier in an emergency situation that has not yet been approved including requiring approval from named management is justified and documented.	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. 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 • 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.

Supplier Monitoring/ Control	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?	The organization should have the required documentation for approved suppliers to ensure that they are complying with the established supplier/service provider approval procedures, contracts, specifications, regulatory requirements and best practice guidelines. Supplier verification documents should demonstrate that the ongoing approval requirements detailed in 1.06.03 are being met (e.g., third party audits, certificates of analysis, reviews of supplier records, etc.).	Total compliance (15 points): The organization has relevant information from approved suppliers/service providers to ensure that they are complying with the established 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. The evidence should demonstrate the verification activities (including monitoring) detailed in 1.06.03 are being met.		No Change in v3.2	The organization should have the required documentation for approved suppliers to ensure that they are complying with the established supplier/service provider approval procedures, contracts, specifications, regulatory requirements and best practice guidelines. 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.).	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”.
Supplier Monitoring/ Control	1.06.05	Where food safety related testing is being performed by external laboratory service providers, are these licensed and/or accredited laboratories (e.g., ISO 17025 or equivalent, national and local regulations, etc.)?		Minor Deficiency (3 points) if: • Single instance of an omission or incorrect data in the documentation. Major Deficiency (1 point) • More than one instance of omissions or incorrect data in the documentation. Non-compliance (points) • No documentation. • Using a non-licensed or accredited laboratory. • License/accreditation of testing laboratory has expired.		No Change in v3.2	No Change in v3.2	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 is 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. For facilities only, 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 system being used in the production facility should match the written traceability system. 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.		No Change in v3.2	No Change in v3.2	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.
Traceability and Recall	1.07.03	Is testing of recall procedures (including traceback) 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.) Where two mock recalls per year are required, one of the mock recalls should be for primary packaging material include the primary packaging as part of the exercise. The steps taken to conduct the mock recall, as well as the records utilized to demonstrate the program, is 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; 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 crews)) operations may create a mock scenario where they receive information from a client indicating there is a problem that warrants a recall, another alternation 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 harvest 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 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 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		No Change in v3.2	No Change in v3.2	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.) 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 crews)) 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 harvest 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.
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?	There should be a vulnerability 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).	Total compliance (5 points). There should be a vulnerability 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).		No Change in v3.2	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).	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).

Food Defense	1.08.02	Does the company have a documented food defense plan based on the risks associated with the operation?	The company should have a documented food defense plan that includes a written vulnerability assessment, and controls for the identified risks. The food defense plan creation should also meet any national or local regulations (including management oversight and approval). Based on this assessment, the operation should create monitoring, corrective action and verification procedures (where appropriate). These procedures should note the recording requirements of the food defense plan. The plan should be reviewed at least once every 12 months.	Total conformance (5 points): The operation should have a documented food defense plan that outlines the organization's security controls based on the risk 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 plan should be reviewed at least once every 12 months. The document should include relevant food defense risks such as personnel, visitors, contractors, raw material receipt (raw materials, product and packaging), trucks (incoming and outbound), 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. Risk/vulnerability assessment templates can be found at: https://www.fsis.usda.gov/shared/PDF/Self_Assessment_Checklist_Food_Security.pdf Minor deficiency (3 points) if: • Single/isolated instance(s) of errors or omissions in the food defense plan. Major deficiency (1 point) if: • Numerous instances of errors or omissions in the food defense plan. Non-conformance (0 points) if: • Food defense plan has not been documented.		Is there a written food defense vulnerability assessment and food defense plan based on the risks associated with the operation?	The company should have a documented food defense plan that includes a written food defense vulnerability assessment, and controls for the identified risks. Some high-risk areas include: 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. The food defense plan creation should also meet any national or local regulations (including management oversight and approval). Based on this assessment, the operation should create monitoring, corrective action and verification procedures (where appropriate). These procedures should note the recording requirements of the food defense plan. The plan should be reviewed at least once every 12 months e.g. as part of management verification review process.	Total conformance (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-conformance (0 points) if: • Food defense plan has not been documented. • There is no risk assessment.
Food Defense	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 conformance (5 points). The records required in the food defense plan should be maintained, in accordance with the details of the plan and its associated procedures. These records are also subject to the document control and records requirements of this module.		No Change in v3.2	No Change in v3.2	Total conformance (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.