

PrimusGFS Audit Food Safety Management Systems (Module 1) Guidelines

Used in conjunction with PrimusGFS V1.6 audit

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These guidelines help interpret/support the principles, requirements and expectations of the PrimusGFS v1.6 Food Safety Management Section (Module 1) as noted in the [Scheme normative documents](#). These guidelines are not exhaustive nor exclusive and detail minimum requirements only by means of statements related to audit questions and expectations. There will be variations in applicability to an operation based on the process(es) and commodities involved. Auditors and auditees should interpret the questions and criteria in different situations, with the food safety and risk minimization being the key concerns.

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

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

Please be aware that there is additional information on the PrimusGFS website including the actual audit templates <http://www.primusgfs.com/Documentation/Documentation.aspx>. The Primusgfs website also has access to the official PrimusGFS General Regulations which explains the overall scheme scoring systems and other details of the scheme

The following is a modified excerpt from PrimusGFS General Regulations V 1.6. It is provided here as an introduction to the audit notes. For full and current text please refer to the most recent version of PrimusGFS General Regulations at <http://www.primusgfs.com/Documentation/Documentation.aspx> .

Audit Execution

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

- Module 1 - Food Safety Management System
- Module 2 - GAP and/or GMP options
- Module 3 – HACCP program

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

Scoring System

The audit format is updated as needed. This may include the layout, the questions themselves and point assignments. The following is the scoring system used for the PrimusGFS audits:

| Module 1 | Module 2 | | Module 3 |
|---|--|---|---|
| Food Safety Management System | GAP Option | GMP Option | HACCP |
| Possible answers: <ul style="list-style-type: none"> • Total Compliance • Minor Deficiency • Major Deficiency • Non Compliance • Non Applicable | Possible answers: <ul style="list-style-type: none"> • Yes • No • Not Applicable | Possible answers: <ul style="list-style-type: none"> • Total Compliance • Minor Deficiency • Major Deficiency • Non Compliance • Non Applicable | Possible answers: <ul style="list-style-type: none"> • Total Compliance • Minor Deficiency • Major Deficiency • Non Compliance • Non Applicable |

For questions in Module 1, Module 2 – GMP option and Module 3, the amount of deficiencies and the associated risks have to be considered to assign the severity of the finding, which can be Minor Deficiency, Major Deficiency and Non Compliance. When no deficiencies are found, a Total Compliance is given. Some general statements for the scoring decision are described in the table below. These statements are superseded by the criteria described in the question's expectations and users should be aware that some questions do not follow these general statements e.g. automatic failure questions. The possible answers to the questions in each Module are listed in the following table:

| Scoring system for questions in Module 1, Module 2 – GMP option and Module 3 | | | | |
|---|---|-----------|----------|----------|
| Possible answer | Possible Points for the question | | | |
| Total compliance | 15 points | 10 points | 5 points | 3 points |
| Minor deficiency | 10 points | 7 points | 3 points | 2 points |
| Major deficiency | 5 points | 3 points | 1 points | 1 points |
| Non-compliance | 0 points | 0 points | 0 points | 0 points |
| Not applicable | 0 points | 0 points | 0 points | 0 points |

For questions in Module 2 GAP option, the scoring system is described in the table below:

| Scoring system for questions in Module 2 – GAP option | | | | | | | | |
|--|---|-----------|-----------|----------|----------|----------|----------|----------|
| Possible answer | Possible Points for the question | | | | | | | |
| Total compliance (may be Yes or No) | 20 points | 15 points | 10 points | 7 points | 5 points | 3 points | 2 points | 0 points |
| Non-compliance (may be Yes or No) | 0 points | 0 points | 0 points | 0 points | 0 points | 0 points | 0 points | 0 points |
| Not applicable | 0 points | 0 points | 0 points | 0 points | 0 points | 0 points | 0 points | 0 points |

Each question and compliance has to be looked at individually and scored according to the severity of the deficiency, the number of deficiencies and the associated risks. Detailed compliance requirements are noted in this Auditor Guidelines document, but some general statements are described below. These statements are superseded by the compliance criteria and users should be aware that some questions do not follow the general statements below e.g. automatic failure questions.

| Compliance for questions in Module 1, Module 2 – GMP option and Module 3 | |
|---|--|
| Answer | Criteria used |
| Total compliance | <ul style="list-style-type: none"> • To meet the question and/or compliance criteria in full. |
| Minor deficiency | <ul style="list-style-type: none"> • To have minor deficiencies against the question and/or compliance criteria. • To have single or isolated non-severe deficiencies (usually up to three) against the question and/or compliance criteria. • To have covered most of the question compliance criteria, but not all. |
| Major deficiency | <ul style="list-style-type: none"> • To have major deficiencies against the question and/or compliance criteria. • To have numerous non-severe deficiencies (usually more than three) against the question and/or compliance criteria. • To have single or isolated severe deficiencies against the question and/or compliance criteria. • To have covered some of the question compliance criteria, but not most of it. |
| Non-compliance | <ul style="list-style-type: none"> • To have not met the question and/or compliance criteria requirements at all. • Having systematic deficiencies against the question and/or compliance criteria (severe or non-severe issues). |
| Not applicable | <ul style="list-style-type: none"> • The requirement described in the question is not applicable for the operation being audited. Justification should be provided in the auditor's comments. Be aware that there are some questions that do not allow to answer Non-applicable. |

For questions in Module 2 – GAP option, if deficiencies for the question and/or the applicable expectations for that question are found, assign the answer to each question as described below in the general statement of the table. These statements are superseded by the criteria described in the question’s expectations and applicants and users should be aware that some questions do not follow these general statements e.g. automatic failure questions

| Compliance for questions in Module 2 – GAP option | |
|---|---|
| Answer | Criteria used |
| Total compliance (can be Yes or No, depending on the question) | To meet the question and/or compliance criteria in full. This is when the answer Yes or No is the same as the “earning points answer”. |
| Non-compliance (can be Yes or No, depending on the question) | The question or compliance criteria has not been fully met. This is when the answer Yes or No is NOT the same as the “earning points answer”. |
| Not applicable | The requirement described in the question is not applicable for the operation being audited. Justification should be provided in the auditor’s comments. Be aware that there are some questions that do not allow to answer Non-applicable. |

Automatic Failure

There are some questions that if down scored will lead to an automatic failure and an overall score of 0% for the corresponding Module.

These questions have been defined as automatic failure because they represent high risk situations where any deficiency on them represents a sign of an immediate potential food safety risk. These questions are identified with the phrase: “ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE”.

The applicant should be immediately informed of the automatic failure by the auditor during the audit.

Documentation Requirements

New Auditees/First Time Facility Auditees

- **In operation for more than three consecutive months** – auditee should have at least three months of documentation available for review. If the auditee has less than three months of most of their documentation available for review a pre-assessment audit is strongly advised. If the auditee has less than three months of most of their documentation available for review and decides to have a regular audit, they should be aware that they **cannot receive full conformance for paperwork questions relating to monitoring and that the down score will be based on the amount of paperwork available.**

- **Short season operation, in operation for less than three consecutive months** - auditee should have at least three months of documentation available for review (this may include last season's documentation). Where an operation does not have three months of records available (e.g. one month of operation per year) auditee should have at least the previous season's records available for review. If the auditee has less than three months of most of their documentation available for review and decides to have a regular audit, they should be aware that they **may not receive full conformance for paperwork questions relating to monitoring and that the down score will be based on amount of paperwork available.**

Existing Auditees

- **In operation for more than three consecutive months** – auditee should have at least three months of documentation and documentation at least since the last audit.
- **Short season operation, in operation for less than three consecutive months** – auditee should have at least three months of documentation and documentation at least since the last audit (which includes the last season). Where an operation does not have three months of records available (e.g. 1 month of operation per year) auditee should have at least the previous season's records available for review.

| | Operates <three months/year | Operates >three months/year |
|-------------------------|---|--|
| New Auditee | Three months of records (may include last season's records) | Three months of records (may include last season's records) |
| Existing Auditee | Records at least since last audit (or longer) to meet minimum requirement of three consecutive months of records | Records since last audit |

Glossary

Agricultural Inputs

Materials used in the production of crops including seeds, transplants, rootstock, cuttings, fertilizers, crop protection products, adjuvants, growth promoters, predator additions, irrigation water and any other material inputs to the growing process.

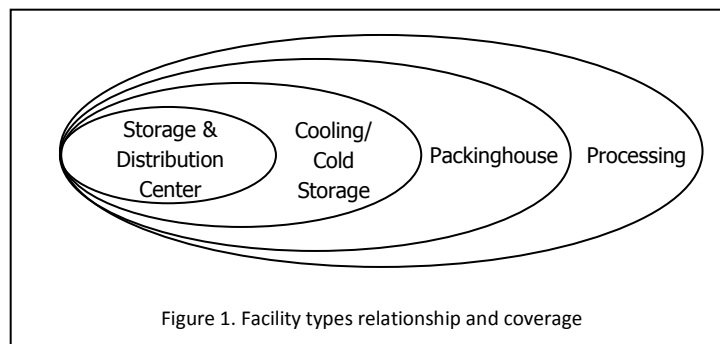
Cooling Cold Storage

This type of facility is where they are not only receiving and storing finished goods but performing some kind of pre-cooling and/or cooling activities. In this type of facility, no packing or processing activities are being performed, if so, a different type of facility operation shall be used. A Cooling Cold Storage facility covers the activities involved in the Storage & Distribution Center type.

Facility operation

A handling operation carried out in one or several buildings where product is being handled. The type of Facility operation can be classified as: “Storage & Distribution Center”, “Cooling Cold Storage”, “Packinghouse” or “Processing”.

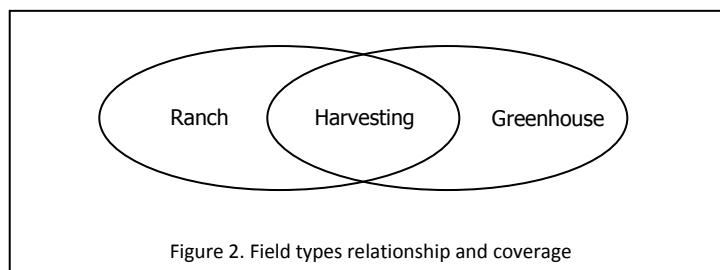
The following image describes the scope of each one of the facility types described in this certification scheme:



Field operation

A growing operation carried out in an open or in a covered area for the production of fresh produce for human consumption. The type of Field operation can be classified as: “Ranch” or “Greenhouse”, they can both include or not include another type of operation named “Harvesting”.

The following image describes the scope of each one of the field types described in this certification scheme:



Greenhouse

A greenhouse is defined as a building constructed of glass or plastic, for the cultivation of plants under controlled environmental conditions. Product grown under this type of operation is marketed as "Greenhouse grown".

Harvest Crew

A "harvest crew" is defined as a crew of harvest personnel under common management.

Packinghouse

This type of facility is where whole commodities are sorted and/or sized, may be minimally trimmed (not altered in form), washed or not washed, possible post-harvest fungicide treatments applied (e.g. wax treatments) and packed for commercial distribution and use by consumer or retail establishment. In this type of facility, no processing activities are being performed, if so, a different type of facility operation shall be used. A Packinghouse facility covers the activities involved in the Storage & Distribution Center and Cooling/Cold Storage facilities.

Processing

This type of facility is where whole commodities are minimally processed and altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing, prior to being packaged for use by the consumer or a retail establishment (e.g., pre-cut, packaged, ready-to-eat salad mixes). In this type of facility, processing activities are being performed, if not, a different type of facility operation shall be used. A Processing facility covers the activities involved in the Storage & Distribution Center, Cooling/Cold Storage and Packinghouse facilities.

Ranch

A "ranch" is defined as a parcel of ground (not necessarily a "lot" for production purposes) with the following characteristics: common management, common water supply and contiguous grounds. For the purpose of farm or ranch audits, manual development or self-audits, a ranch or farm is defined as contiguous ground that is under common management.

Storage & Distribution Center

This type of facility is where they are only receiving and storing finished goods for further shipment e.g. regional distribution warehouses.

In this type of facility, no cooling, packing or processing activities are being performed, if so, a different type of facility operation shall be used.

Module 1

Management System

1.01.01: Is there a documented food safety policy detailing the company's commitment to food safety?

Total compliance (5points): There should be a 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. The policy may take the form of a "mission statement" provided it meets the requirements detailed above.

Minor deficiency (3 Points) if:

- Policy lacks an element listed above.
- Single/isolated instance(s) of errors or omissions in the policy.

Major deficiency (1 point) if:

- Policy lacks more than one element noted above.
- Numerous instances of errors or omissions in the policy.
- Failure to communicate the policy to employees.
- Policy is not posted in a public place.

Non-compliance (0 points) if:

- No policy exists.
- Systematic failures to keep records and or corrective actions.

1.01.02: Is there a Food Safety Manual or other documented food safety management system covering the scope of business included in this audit and procedures/instructions for all food safety processes?

Total compliance (5 points): The Food Safety Manual is appropriate for the scope to be covered by the audit and include documented policies, standards, procedures* etc., and/or specific reference to them. The Food Safety Manual should be available to relevant staff.

The Manual should include or reference (actual documents may be located in another manual):

1. The company's food safety policy
2. Organizational chart
3. List of products
4. Pre-requisite programs (where applicable)
5. HACCP program (where applicable) e.g. product descriptions, process flows, hazard analysis, etc.
6. Forms used in implementation of food safety management system (actual records may be located elsewhere e.g. another manual).

* Standard operating procedures (SOPs) are scored in 1.03.01 and 1.03.02.

Minor deficiency (3 points) if:

- If one of the above elements is missing.

Major deficiency (1 point) if:

- If two or more elements are missing.

Non-compliance (0 points) if:

- A written Food Safety Manual (or equivalent) is not available for review.

1.01.03: Is there a detailed organizational structure chart of all employees whose activities affect food safety?

Total compliance (3 points): There should be an organizational chart showing job functions, responsibilities and reporting structure of employees whose activities affect food safety. Alternates should be indicated or reference document indicating this information. Responsibilities of employees may be detailed on a separate document. For very small companies, an individual employee may cover many jobs. Document should be dated and reflect current status.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of errors or omissions on the organizational structure chart or responsibilities.
- A document lacks either date or management signature.

Major deficiency (1 point) if:

- Numerous instances of errors or omissions on the organizational structure chart or responsibilities.
- A document lacks both date and management signature.

Non-compliance (0 points) if:

- Systematic errors on the organizational structure chart or responsibilities.
- No process organizational structure chart or responsibilities.

1.01.04: Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?

Total compliance (5 points): There should be an active food safety committee, responsible for the strategic maintenance and development of the 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.

1.01.05: Is there documented management verification of the entire food safety management system on at least an annual basis?

Total compliance (5 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. 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 (this is covered in the HACCP Module of the Scheme). 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
- Analysis of feedback/complaint
- Review and updates to operation's objectives
- Review of organizational chart
- Updates, changes or new SOPs
- Other food safety managements system related activities

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

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

Non-compliance (0 points) if:

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

1.01.06: Is there a documented analysis detailing resources required to implement and improve the food safety management system processes with documented commitment from senior management to provide these resources?

Total compliance (5 points): There should be evidence that management is aware of food safety program requirements. Senior management have documented evidence that they have determined and provided all the resources needed to implement and improve food safety related processes in a timely manner to ensure customer requirements and expectations are fulfilled. This document should include or reference (as a minimum) an analysis of the resources provided for:

1. Personnel training requirements

2. Employee needs (to cover sickness, vacations, etc.).
3. Equipment and services (e.g. computers, testing equipment, etc.).
4. Ensuring effective employee communication (e.g. training needs, etc).
5. Meeting customer requirements/specifications.

Minor deficiency (3 points) if:

- If one of the above elements is missing.

Major deficiency (1 point) if:

- If two or more elements are missing.

Non-compliance (0 points) if:

- Documented evidence is not available for review.

Records Requirements

1.02.01: Are all records free of “correction fluid” (white out), pencil text and erasable ink text? If using computerized records, is there a system that shows record amendments (data history) if the records are changed after initial entry?

Total compliance (3 points): Corrections to records are made without the use of “correction fluid” (“white-out”), correction tape, etc. Records should be in permanent ink, not pencil or erasable ink. If corrections are made they should be crossed out (and initialed by the person making the change) so that the original information is still legible. If records are stored on computer, then there should be a way of tracking any amendments to the records i.e. an amendment history with the ability to see who changed what, and when (this allows one to see what value was changed). Any evidence of records being falsified is a non-compliance e.g. records already filled out for next day.

Minor deficiency (2 points):

- Single/isolated instance(s) of records found with white-out, pencil or erasable ink.
- Single/isolated instance(s) of records with amendments where the original texts are not legible.
- Single/isolated instance(s) of computer records lacking amendment histories.

Major deficiency (1 point) if:

- Numerous instances of records found with white-out, pencil or erasable ink.
- Numerous instances of records with amendments where the original texts are not legible.
- Numerous instances of computer records lacking amendment histories.

Non-compliance (0 points) if:

- Systematic use of white out, pencil or erasable ink in records.
- Systematic failure to ensure that original texts are legible when amendments have been made to records.
- Systematic failure to record amendment histories when records have been computerized.

1.02.02: Are all monitoring and process control records stored for a minimum period of a year or for at least the shelf life of product if greater than a year?

Total compliance (3 points): Records are retained for auditing purposes, in case there are legal issues, customer queries, etc. All monitoring and process control records should be held for a minimum of one year regardless of the production item’s shelf life. For Good Agricultural Practices (GAP) growing area records include all cultivation records; for GAP harvest crew records include harvesting related records.

Any records required by law to be kept longer than one year should be kept 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. 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 (2 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 1 year).

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 1 year).

Non-compliance (0 points) if:

- Process control records are kept less than one year.
- 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.

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

Total compliance (5 points): The written procedures of monitoring and process control operations along with corresponding recording forms are available to the operators involved in performing the activities described in the specific procedures. For facility operations this includes anti-microbial monitoring, metal detector, etc. For farm operations this includes procedures such as irrigation water sampling, crop protection product mixing and loading procedures, etc. In the event of electronic procedures and/or recording forms, access should be allowed to all relevant employees; however there should be controls in place to prevent unauthorized editing.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of written procedures and/or recording forms not being made available to relevant employees.
- Single/isolated instance(s) of written procedures and/or recording forms being omitted from the Master file (SOP Manual).

Major deficiency (1point) if:

- Numerous instances of some written procedures and/or recording forms not being made available to relevant employees.
- Numerous instances of written procedures and recording forms being omitted from the Master file (SOP Manual).

Non-compliance (0 points) if:

- Written procedures and/or recording forms are not accessible to relevant employees.
- A master file (SOP Manual) containing the written procedures and recording forms that are being used, has not been created

Procedures and Corrective Actions

1.03.01: Are there written Standard Operating Procedures (SOPs) that detail work instructions for food safety related activities performed in the field operations?

Total compliance (5 points): There are written SOPs covering food safety related activities performed in the field, for example: fertilizer/crop nutrition, crop protection, irrigation, harvesting, etc. The SOPs should show what is to be done, how it is done, how often, by whom, what records are required and any corrective action procedures to perform when deficiencies occur. SOP's should reflect what is actually being done. Use this question to score down for missing SOP's, if a specific question covering a particular task is not already part of the audit.

At minimum operations should have a written SOP for the following important tasks (if applicable):

- Site selection and adjacent land use
- Irrigation and other water application (frost protection, chemical dilutions, etc.)
- Foreign material control (including animal intrusion)
- Crop protection (mix & load, rinse & clean and disposal)
- Fertilizer/crop nutrition
- Traceability
- Harvesting practices (including harvest tools, equipment use and post harvest water)
- Food safety training (cultural workers and harvesters)
- Sanitation activities (Sanitation Standard Operation Procedures (SSOP's))

Minor deficiency (3 points) if:

- Single/isolated instance(s) of SOP's with errors or omissions in the information within the SOP's.
- Single/isolated instance(s) of important SOP's being omitted.

Major deficiency (1 point) if:

- Numerous instances of SOP's with errors or omissions in the information within the SOP's.
- Numerous instances of important SOP's being omitted.

Non-compliance (0 points) if:

- Majority of SOP's have not been written properly.
- Majority of SOP's are missing.
- SOPs have not been developed.

1.03.02: Are there written Standard Operating Procedures (SOPs) that detail work instructions for food safety related activities in the facility operations?

Total compliance (5 points): There are written SOPs covering food safety related activities performed at the facility, for example: goods receiving, temperature control, pest control, food safety training, shipping, foreign material control, etc. The SOPs should show what is to be done, how it is done, how often, by whom, what records are required and any corrective action procedures to perform when deficiencies occur. SOPs should reflect what is actually being done. Use this question to score down for missing SOP's, if a specific question covering a particular task is not already part of the audit.

At minimum operations should have a written SOP for the following important tasks (if applicable):

- Goods receiving/supplier approval and monitoring
- Traceability
- Temperature control

- Foreign material control e.g. metal detection
- Chemical monitoring procedures (anti-microbial, wax, fungicide, etc.)
- Pest control (if done in-house)
- Maintenance
- Sanitation activities (Sanitation Standard Operation Procedures (SSOP's))
- Allergens
- Shipping
- Personnel hygiene requirements
- Food safety training

Minor deficiency (3 points) if:

- Single/isolated instance(s) of SOP's with errors or omissions in the information within the SOP's.
- Single/isolated instance(s) of important SOP's being omitted.

Major deficiency (1 point) if:

- Numerous instances of SOP's with errors or omissions in the information within the SOP's.
- Numerous instances of important SOP's being omitted.

Non-compliance (0 points) if:

- Majority of SOP's have not been written properly.
- Majority of SOP's are missing.
- SOPs have not been developed.

1.03.03: Is there a corrective action procedure that describes the requirements for follow-up and prevention of future occurrences?

Total compliance (5 points): Written procedures include the corrective actions to be taken in case of any deficiency affecting food safety is identified. 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 Module 2 of the audit).

Corrective action procedure should include:

- the review of the non-conformance
- the determination of the causes
- the establishment of an action plan address such non-conformances and prevent future occurrences
- the implementation of corrective 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.

Minor deficiency (3 points) if:

- Single instance of an error or omission in the information within the corrective action procedure.
- Single instance of corrective action procedure missing a key element from list above.

Major deficiency (1 point) if:

- More than one instance of errors or omissions in the information within the corrective action procedure.
- More than one instance of corrective action procedure missing a key element from list above.

Non-compliance (0 points) if:

- Numerous errors or omissions in the corrective action procedure.

- Corrective action procedures have not been developed.

Internal and External Inspections

1.04.01: Is there a program for periodic self-inspections of the field operations covering any process impacting food safety and are records maintained detailing corrective actions? For Field (GAP option) this includes the growing and harvesting practices and all the related documentation and records generated.

Total compliance (10 points): In depth internal inspections are performed and recorded for each field operation in order to proactively ensure safe food production. Records should show corrective actions taken. Self inspections should include the verification of the practices and the related documents. Recording systems for food safety related topics should be audited on a routine basis to ensure that they are being completed properly e.g. using the correct log, correct frequencies, recording results correctly, recording corrective actions etc. This includes the food safety management system. This question focuses on auditee's self diagnostic checking of their own practices and documentation; if done correctly, this should help the auditee maintain their systems and also aid in any external audits or investigations. An audit checklist should be used as an aid to make sure the inspection covers all the areas. Self-auditing (self diagnostics) is a key part of the operation's food safety program. Zonal, checklist methods, etc., are all acceptable.

Inspection should include:

- Inspection frequency. Frequency depends on type and size of operation; auditor discretion applies. For field (GAP option) at least a pre-season assessment and a full GAP self-assessment during harvest season should be on file covering growing and harvesting operations. More frequent inspections may be necessary depending on the type of crop, field location and associated risk pressures. These factors will also affect the need for pre-harvest inspections.
- Fields, storage, harvesting and associated paperwork.
- Who conducted the inspection
- Documented findings
- Note corrective actions (including completion date)

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 an area(s) missing on the inspection program.
- Single/isolated instance(s) of self-inspections not being done at stated 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.
- Numerous instances of an area(s) missing on the inspection program.
- Numerous instances of self-inspections not being done at stated frequency.

Non-compliance (0 points) if:

- Systematic failure to maintain records.
- No records.

1.04.02: Is there a program for periodic self-inspections of the facility operations covering any process impacting food safety and are records maintained detailing corrective actions? For Facility (GMP option) includes the observation of the facility practices and all the related documentation and records generated.

Total compliance (10 points): In depth internal inspections are performed and recorded for each facility operation in order to proactively ensure safe food production. Records should show corrective actions taken. Self inspections should include the verification of the practices and the documents related. Recording systems for food safety related topics should be audited on a routine basis to ensure that they are being completed properly e.g. using the correct log, correct frequencies, recording results correctly, recording corrective actions etc. This includes the food safety management system. This question focuses on auditee's self diagnostic checking of their own practices and documentation; if done correctly, this should help the auditee maintain their systems and also aid in any external audits or investigations. An audit checklist should be used as an aid to make sure the inspection covers all the areas. Self-auditing (self diagnostics) is a key part of the operation's food safety program.

Inspection should include:

- Inspection frequency. Frequency depends on type and size of operation; auditors discretion. 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.
- Zonal, checklist methods, etc. are all acceptable. Entire facility (inside and out) should be included.
- Who conducted the inspection
- Documented findings
- Note corrective actions (including completion date)

Self-auditing (self diagnostics) is key part of the facility's food safety program.

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 an area(s) missing on the inspection program.
- Single/isolated instance(s) of self-inspections not being done at required 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.
- Numerous instances of area(s) missing on the inspection program.
- Numerous instances of self-inspections not being done at required frequency.

Non-compliance (0 points) if:

- Systematic failure to maintain records.

1.04.03: Are there written procedures for handling regulatory inspections?

Total compliance (3 points): Written procedures for handling regulatory inspections are available for employees to follow when regulatory agencies inspect the operation. Regulatory agencies could be FDA, USDA, Health Department, State enforcement organizations, etc. The procedures should include at a minimum rules for always accompanying inspections and rules on taking samples. This policy should be communicated to key personnel including the receptionists, field staff and crew supervisors. Inspection policies must not contravene bio-terrorism laws and restrict access to documents that have been covered by these laws.

Minor deficiency (2 points) if:

- If one of the above elements of the policy is missing.
- If the receptionist(s) has/have not been briefed properly.

Major deficiency (1 point) if:

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

Non-compliance (0 points) if:

- A written procedure for handling regulatory inspections is not available for review.

1.04.04: Are there records of regulatory inspections and/or contracted inspections, company responses and corrective actions, if any?

Total compliance (5 points): 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. Auditors are requested not to look at second party audits, since sometimes they include confidential quality and product development information. 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.

Minor Deficiency (3 points) if:

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

Major Deficiency (1 point) if:

- Numerous instances of corrective actions not being recorded.
- More than one audit inspection report is missing in the last year.

Non-compliance (0 points) if:

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

1.04.05: Are there documented policies and/or procedures for the calibration for measuring and monitoring devices used in the field operations such as fertilizer and crop protection application equipment, and other equipment related to the safety of the product?

Total compliance (10 points): There are documented policies and/or procedures for the calibration for measuring and monitoring devices used in the field operations such as fertilizer and crop protection application equipment, crop protection measuring equipment (e.g. scales) and other equipment related to the safety of the product. Equipment used for measuring and monitoring devices (e.g. ORP meter) used in the field related to food safety, should be 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

http://pubs.ext.vt.edu/436/436-048/PDF_64-68Calibration.pdf
<http://www.ugaurbanag.com/content/calibrating-your-spreader>

Minor Deficiency (7 points) if:

- Single/isolated instance(s) of omissions in the procedure(s).

- Single/isolated instance(s) of omissions or incorrect data in the records.
- Single/isolated instance(s) of piece/set of equipment omitted from the scheme.

Major Deficiency (3 point) if:

- Numerous instances of omissions in the procedure(s).
- Numerous instances of omissions or incorrect data in the records.
- Numerous instances of pieces/sets of equipment omitted from the scheme.

Non compliance (0 points) if:

- No procedure
- No records
- Failure to maintain records.

1.04.06: Are there documented policies and/or procedures for the calibration for measuring and monitoring devices used in the facility operations such as chemical application equipment, thermometers, metal detectors, ORP meters, pH meters and other equipment related to the safety of the product?

Total compliance (10 points): Equipment used for measuring and monitoring processes (hand held and automated) related to food safety e.g. thermometers, metal detectors, ORP meters, flow meters and pH meters, 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. 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.

Minor Deficiency (7 points) if:

- Single/isolated instance(s) of omissions in the procedure(s).
- Single/isolated instance(s) of omissions or incorrect data in the records.
- Single/isolated instance(s) of piece/set of equipment omitted from the scheme.

Major Deficiency (3 point) if:

- Numerous instances of omissions in the procedure(s).
- Numerous instances of omissions or incorrect data in the records.
- Numerous instances of pieces/sets of equipment omitted from the scheme.

Non compliance (0 points) if:

- No procedure
- No records
- Failure to maintain records.

Rejection and Release of Product

1.05.01: Is there a written procedure for handling on hold or rejected products?

Total compliance (10 points): A documented procedure exists that explains how products (includes ingredients and packaging) should be handled, that has either been rejected or placed on hold. For harvested product in the field and the facility the procedure should include details on how the affected product lot(s) is/are separated from other lots in terms of tagging systems (date showing when the product was placed on hold/rejected and the reason for being on hold/rejected and the name of the person who put the product on hold) and any other physical separation to ensure that affected product is

not commingled with other goods in such a way that their disposition is not clear. For the pre-harvest materials, procedures should include how the affected product is indicated in the field e.g. cordoned off, any buffer zones used, how these details are recorded, etc.). 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 (may be covered under 1.05.02).

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Procedure missing more than one part, but SOP exists.
- Numerous instances of the procedure not being applied in the field, production and/or storage areas.

Non-compliance (0 points) if:

- No procedure.
- Procedure created bares no resemblance to what is being applied in the field, production and/or storage areas.

1.05.02: Are product release procedures implemented (e.g. lot signed out, when a product lot sample is undergoing an analysis, etc.) and are records available for review?

Total compliance (5 points): Product release procedures assure that a lot is only released for shipment (sale) when lot meets agreed standards (e.g. specification) and/or meets agreed testing requirements (e.g. results confirmed negative or within limits results from testing, etc.). Products should not be released for shipment without assuring that all food safety evaluations have been completed. Designated personnel are responsible for signing off. Procedures should be properly documented, implemented and pertinent records retained.

Minor deficiency (3 points) if:

- Single part of the procedure is omitted.
- Single/isolated instance(s) of omissions or incorrect data in the records.
- Single/isolated instance(s) of the procedure not being applied in the field, production and/or storage areas.

Major deficiency (1 point) if:

- Procedure missing more than one part, but SOP exists.
- Numerous instances of omissions or incorrect data in the records.
- Numerous instances of the procedure not being applied in the field, production and/or storage areas.

Non-compliance (0 points) if:

- No procedure.
- No records.
- Procedure created bares no resemblance to what is being applied in the field, production and/or storage areas.

1.05.03: Is there a documented system for dealing with customer complaints and buyer food safety complaints and are those on file, along with company responses, including corrective actions?

Total compliance (10 points): There is a documented policy/procedure detailing how to handle food safety and food quality complaints and feedback. Food quality issues are relevant if they have the potential to also be food safety issues. It is important to keep the complaints and feedback related records

on file to support company policy/procedure. The policy and records should include (where applicable and please refer to questions 1.01.05): -

- Date/Time of complaint/rejection,
- Who made the complaint/gave feedback,
- Contact information,
- Product description,
- Where the product was purchased,
- Amount of product,
- Product code/date,
- Nature of complaint/feedback,
- Corrective actions,
- Corrective actions taken to prevent reoccurrence.

Complaints and feedback information, along with any corrective actions that are taken or associated with the operation should be available for review. For example, a blue colored Band Aid in a product could have come from either a facility or a harvest crew so details of the issue(s) should be sent to both facility and harvesting company. Ideally foreign material issues should include photographs of the issue found (where possible). Other examples of issues that are viewed as potentially food safety related include tainting, sickness and sometimes decay issues. Where there are many (e.g. more than 5 in a month) complaints, a degree of analysis and review is expected to determine if trends are present.

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.

Minor Deficiency (7 points) if:

- Single/isolated instance(s) of omissions and incorrect data in the records including corrective actions.
- More than 100 complaints/rejections received, but no trend analysis or review carried out.

Major Deficiency (3 points) if:

- Numerous instances of omissions and incorrect data in the records including corrective actions.

Non-compliance (0 points) if:

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

Supplier Monitoring

1.06.01: Are there current written specifications for all ingredients, materials, products and services purchased &/or provided that relate to product safety, are they easily accessed and is there a review process in place for the specifications?

Total compliance (5 points): A specification is an explicit set of requirements to be met. Specifications are accurate, acceptable and ensure conformance with relevant customer and legislative requirements. There are documented specifications for all the following (where applicable) that have an effect on product safety: -

- seeds (e.g. immature lettuce or leafy greens, sprouts, microgreens)
- transplants,
- fertilizer/crop protection materials,
- ingredients (e.g. product raw materials, ice)
- processing aids (e.g. anti-microbials, buffers, post-harvest fungicides)
- packaging materials (material/components manufactured with)
- other materials with potential for direct product contact based on risk assessment

- services (contract sprayers, pest control, chemical suppliers, water and waste utilities, transport, maintenance and sanitation services) purchased/provided.

Documented specifications are easily accessible to users and there is a documented procedure for review, amendment and approval of all specifications.

Minor Deficiency (3 points) if:

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

Major Deficiency (1 point) if:

- Numerous instances of omissions or incorrect data in the records.

Non compliance (0 points) if:

- No records.
- Failure to maintain records.

1.06.02: Is there a list of approved suppliers?

Total compliance (5 points): There is a list of approved suppliers of materials and services. All agricultural inputs, ingredients, products, materials and services that relate to food safety are purchased from &/or provided by approved suppliers; where exceptions are made (e.g. market conditions, emergency situations) approval from management is documented, please refer to question 1.06.03.

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.

1.06.03: Is there a written procedure detailing the selection, evaluation, approval and monitoring process of approved suppliers?

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, packaging items) are evaluated, approved and monitored. This procedure includes methods of removal of approved suppliers. An approved supplier list should be maintained along with any inspections and audits of approved suppliers.

As a minimum the procedure should detail the following where relevant:

- Agreed specifications
- Letters of guarantee
- Methods of evaluating approved suppliers
- Methods of approving approved suppliers
- Methods and frequency of monitoring approved suppliers

- Methods of reviewing approved supplier 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.

1.06.04: Does the organization have documented evidence to ensure that raw material, processing aids and ingredients suppliers comply with specifications, regulatory requirements and best practice guidelines?

Total compliance (15 points): The organization has relevant information from approved suppliers to ensure that they are complying with the established specifications, regulatory requirements and best practice guidelines. This applies to agricultural inputs, raw material, packaging, processing aids and other ingredients suppliers.

There should be:

- A list of raw material (e.g. seeds, transplants, products) and packaging specifications (includes methods and responsibility for developing and approving specifications).
- Validation that packaging material is suitable for its intended purpose (e.g. certificate of conformance for all food contact packaging, tests/analysis confirming no chemical migration to food contents).
- Verification that all customer requirements (if applicable) are being met.

The auditee should have on file current (within last 12 months) third party audit certificates, audit reports or letters of guarantee for agricultural inputs, product raw material, processing aids and other ingredients that are purchased. Letters of guarantee (also certificate of conformance) should indicate that the items supplied meet any and all legal standards, best practice guidelines and agreed specifications. Letters of guarantee should be current (within last 12 months) or indicate they are "on-going". Letters of guarantee for products are not required if own product e.g. "in-house grown" is being packed, although certificates for auditing are worth noting. Pay special attention for letters of guarantee/certifications/audit reports for imported goods.

Minor Deficiency (10 points) if:

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

Major Deficiency (5 points) if:

- Numerous instances of omissions or incorrect data in the records.

Non compliance (0 points) if:

- No records.
- Failure to maintain records.

1.06.05: Does the organization have documented evidence to ensure that packaging materials and services suppliers comply with specifications, regulatory requirements and best practice guidelines?

Total compliance (15 points): The organization has relevant information from approved suppliers to ensure that they are complying with the established specifications, regulatory requirements and best practice guidelines. This applies to packaging, other materials (non-products or ingredients) and services suppliers.

The auditee should have on file current (within last 12 months) third party audit certificates, audit reports or letters of guarantee for food contact and non-food contact items (e.g. packaging and film) that are purchased. Letters of guarantee (also certificate of compliance) should indicate that the materials supplied meet any and all legal standards, best practice guidelines and agreed specifications. Letters of guarantee should be current (within last 12 months) or indicate they are "on-going". Pay special attention for letters of guarantee/certifications/audit reports for imported goods.

Minor Deficiency (10 points) if:

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

Major Deficiency (5 points) if:

- Numerous instances of omissions or incorrect data in the records.

Non compliance (0 points) if:

- No records.
- Failure to maintain records.

1.06.06: Are appropriate supplier controls in place (e.g. results of pesticide multi-residue analysis) to ensure product pesticide residues of raw material/ingredients do not exceed published MRLs?

Total compliance (5 points): Supplier control procedures should ensure that the Maximum Residue Level (MRL)/Tolerance for supplied product are in compliance with the published MRLs/Tolerances for the country of consumption. Records are maintained. This question is only applicable where products are bought from a supplier. This may be found under 1.08.01 and hazard analysis questions in Module 3 (if applicable).

In country or countries of consumption (multiple markets) raw materials/ingredients should meet MRL/Tolerance legislation; note some of these countries have default MRL's where no crop/ pesticide MRL legislation exists.

Procedures should detail:

- Responsibility, methods and criteria used to ensure product pesticide residues of raw material/ingredients do not exceed published MRLs/Tolerances
- Methods of analysis (if used). All analyses are nationally recognized/validated as equivalent to nationally recognized methods.
- Contractual agreements
- Recording requirements

Minor Deficiency (3 points) if:

- Single/isolated instance(s) of omissions in the procedure(s).
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (1 point) if:

- Numerous instances of omissions in the procedure(s).
- Numerous instances of omissions or incorrect data in the records.

Non compliance (0 points) if:

- No procedure
- Where required, no records were available
- Where required, failure to maintain records.

Traceability and Recall

1.07.01: Is there is a documented account 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. The system should be able to show that it can trace back to the supplier(s) of materials and also 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 written traceability system should match the system that is being used in the operation. The traceability system should include any product, ingredient, packaging and/or service related to the food safety that is outsourced.

The written traceability system should match the system that is being used in the field or production facility (as applicable). Recording batches of packaging is required for some products where packaging recalls might occur e.g. modified atmosphere packaging, juice bottles, etc. Recording packaging batches is not required for packaging that is not usually the cause of recall e.g. cardboard boxes. Cooling/Cold Storage & Storage and Distribution auditees that operate in a third party capacity for their clients might have their own traceability system, or have adopted their client(s'). Growers may have access to customer traceback system or create their own tracking seed/transplant to field/block code, input dates (water, fertilizer, pesticides) to harvest dates and onto facility. While either route is acceptable, if the individual client(s') traceability systems are used then the auditor will check each individual traceability system on site. Cooling/Cold Storage & Storage and Distribution operations should have a system that can traceback from outgoing lots back through their process to the incoming lots.

The tracking system must meet the requirements for "one step back, one step forward" as per the FDA requirements. Any national, local or importing country legal requirements should be considered.
<http://www.fda.gov/OHRMS/DOCKETS/98fr/04-26929.htm>,
<http://www.cfsan.fda.gov/~dms/fsbtac12.html>.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

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

contacted in the case of a recall. The production step not properly recording what raw material lots are processed on a certain day.

- No written down traceability system.

1.07.02: Does the organization have a documented recall program including: procedures, recall team roles and contact details, external contact listings, explanation of different types (classes) of recalls?

Total compliance (15 points): To facilitate an efficient recall there should be written recall procedures, recall team details (contact details, roles and responsibilities), referral to customer and supplier contact details, explanations of relevant laws e.g. class of recalls (US only), etc.

Documentation should include basic procedures and responsibilities, current facility contact listing with alternates and out of hour's numbers. Contact listings for customers and suppliers should also be part of the recall program, although these might be viewed as confidential (if so, then these listings must at least be referred to in the recall program). Listings should be reviewed regularly. An explanation of recall classes (Class I, II, III in the USA) should be in the recall program. Ideally contact numbers for attorneys, media specialists (for getting the recall information to the various press outlets), local enforcement officials e.g. State and City Health Boards are a good idea (these are optional and should not cause a down score if missing).

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

Potentially useful websites:-

ORA Recall Guidelines, http://www.fda.gov/ora/conformance_ref/recalls/ggp_recall.htm

Minor deficiency (10 points) if:

- One element of the written recall program is missing or is outdated

Major deficiency (5 points) if:

- Two or more elements of the written recall program are missing or are outdated

Non-compliance (0 points) if:

- The facility does not have a recall program.

1.07.03: Is testing of recall procedures (including trace back) performed and documented annually? Can the company identify where affected product was sent?

Total compliance (10 points): Testing of recall procedures should be performed at least annually. Documentation should indicate the date and time the mock recall was initiated, the product 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 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 (ranch and crew)) operations may create a mock scenario where they receive information from a client indicating there is a problem that warrants a recall, another alternative 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
- 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
- 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.

Non-compliance (0 points) if:

- Mock recall has not been performed on an annual basis.
- Mock recall was initiated, but could not be completed

1.07.04: Is there a daily incidents report, sometimes called a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA)?

Total compliance (5 points): There is a log or report detailing deviations, incidents, process failures, and unusual occurrences, etc. (e.g. foreign objects, chemical spills, rejected packaging, equipment failure, downtime). These should have corrective action records where relevant. This log helps avoid creating multiple logs for events that do not occur very often. Often called a NUOCA log (Notice(s) of Unusual Occurrence and Corrective Action Log). Useful to consider recording issues that might or might not temporarily affect production e.g. loss of power, blocked drains, weather damage, flooding, adjacent land issues, earthquakes, etc., since at a later date, if there are product issues, these events might be of significance.

Minor Deficiency (3 points) if:

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

Major Deficiency (1 point)

- Numerous instances of omissions or incorrect data in the records.

Non compliance (0 points)

- No records.
- Failure to maintain records.

Product Testing

1.08.01: Based on risk assessment, is there a scheduled testing program for raw materials, work in progress, packaging and finished goods?

Total compliance (5 points): If the documented risk assessment determined that tests for raw materials, work in progress, packaging or finished goods are necessary, there should be documented evidence of a scheduled testing program based on risk assessment. Tests are carried out at the frequencies determined by the risk assessment and results are recorded.

There are many ways to document a product risk assessment which then helps aid in the decision of what to test, what to test for and when to test. Documented product risk assessment may consider the risks and controls for:-

- raw materials using to grow or manufacture the product
 - raw material production processes
 - raw material storage requirements
 - raw material history of food safety issues
 - raw material country of origin (infrastructure, legislation, etc.)
 - actual process which the raw materials will go through
- auditee production processes,
 - a HACCP style approach that identifies hazards and their risks and the associated mitigation controls
 - food safety history of the processes being used
- finished product
 - finished product storage requirements and expected shelf life
 - are finished products consumed with or without further customer preparation (washing, cooking and other handling)
 - finished product country of consumption (for example legislation)
 - finished product intended consumer groups (young, elderly, etc.)

The testing program could include microbiological (indicators, pathogens), chemical (e.g. residues, allergens, aflatoxins) and physical tests as identified in the risk assessment for the operation(s). If tests are necessary, test methods and frequencies are included in the program. Some of the requirements for this question may also be covered under Hazard Analysis in the HACCP module.

If risk assessment/hazard analysis has determined that there are no significant risks then score this question as N/A. Where suppliers have a testing program, they may provide the auditee with test results as part of a supplier agreement. The auditee is still required to have documentation of the results, test methods and frequencies.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of errors or omissions on the risk assessment.

Major deficiency (1 point) if:

- Numerous instance(s) of errors or omissions on the risk assessment.

- In an operation with multiple products/processes that are not similar, a few details of the risk assessment are not available, but the majority is available.

Non-compliance (0 points) if:

- Multiple systematic errors on the risk assessment.
- No risk assessment(s).
- In an operation with multiple products/processes that are not similar, many of details of the risk assessment are not available.

1.08.02: If tests are necessary from the risk assessment, is there evidence of the test results for raw materials, work in progress, packaging and finished goods, at the scheduled frequencies and with follow-up for identified deviations?

Total compliance (5 points): If the risk assessment determined that tests for raw materials (including seeds, transplants and products) work in progress, packaging and finished goods are necessary, there should be documented evidence of the test results at the scheduled frequencies with corrective actions for identified deviations. If risk assessment determines no testing is necessary score this question non-applicable.

Any non-conforming materials should be stored in a way that avoids accidental use of these materials in the production process or shipment, handled and disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product. Records should be maintained.

This testing program could include microbiological, chemical (e.g. residues) and physical) tests as identified in the risk assessment for the operation(s). If tests are necessary, test methods and frequencies are included in the program. The requirements for this question may also be covered under Hazard Analysis in the HACCP module.

Where suppliers have a testing program, they may provide the auditee with test results as part of a supplier agreement. The auditee is still required to have documentation of the results, test methods and frequencies.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of testing not occurring at the frequency determined by the risk assessment.
- Single/isolated instance(s) of omissions or incorrect data in the records.
- Single/isolated instance(s) of a record or records showing deviation(s) but no corrective action documentation.
- Single instance of an error or omission in the information within the corrective action procedure.

Major deficiency (1 point) if:

- Numerous instances of testing not occurring at the frequency determined by the risk assessment.
- Numerous instances of omissions or incorrect data in the records.
- Numerous records showing deviation(s) but no corrective action documentation.
- More than one instance of errors or omissions in the information within the corrective action procedure.

Non-compliance (0 points) if:

- Systematic failure to follow testing frequencies determined by the risk assessment.
- No records/failure to remain records.
- Systematic errors or omissions in the corrective action procedure.
- Corrective action procedures have not been developed.

1.08.03: Are testing and analysis performed by licensed/accredited laboratories (e.g. ISO 17025 or equivalent, National Regulations, State Department, etc.)?

Total compliance (5 points): All testing, e.g. water, pesticide residue and microbial should be done by laboratories with current licenses and/or accreditations. These can be ISO 17025 or equivalent, National Regulations or State Department approvals in the country of production. Documented evidence of this licenses and/or accreditations should be available indicating the scope of the license/accreditation and date of expiration. Auditor should confirm that the laboratory has the appropriate licenses and/or accreditations for the analyses being done i.e. product testing, water testing, pesticide residue testing, etc.

Minor Deficiency (3 points) if:

- Single/isolated instance(s) of omissions or incorrect data in the documentation.

Major Deficiency (1 point)

- Numerous instances 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.