Primus Standard™
Audits

# Indoor Agriculture Interpretation Guidelines

Version 20.06

PRIMUS
STANDARD
AUDITS

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# Indoor Agriculture

# Interpretation Guidelines

***Used in conjunction with the Primus Standard Audits v20.06***

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These guidelines are written to help interpret/support the principles, requirements, and expectations of the Primus Standard Audits v20.06, as noted in the Scheme normative documents. These guidelines are neither exhaustive nor exclusive and detail minimum requirements only by means of statements related to audit questions and expectations. There will be variations in applicability to an operation based on the process(es) and commodities involved. Auditors and auditees should interpret the questions and criteria in different situations, with food safety and risk minimization being the key concerns.

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

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

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

## Audit Execution

The audit should be performed using the most recent version of the Primus Standard Audits normative documents.

The Primus Standard Audits Scheme is divided into different audit types. The Guidelines for the facility audits include applicability charts to help determine which questions apply in each audit type.

- **Farm:** A tract of land (not necessarily a "lot" for production purposes), under common management and common water supply, ideally contiguous (if not contiguous, similar risk is demonstrated) and used for agricultural production.
- **Indoor Agriculture:** Where crops are grown in a controlled environment in a temporary or permanent enclosed structure. This does not include shade or hoop houses.
- **Harvest Crew:** A designated group of workers under common supervision, harvesting the same product.
- **Storage & Distribution:** A facility that is only receiving and storing finished goods for further shipment e.g. regional distribution warehouses. Goods may be stored at controlled or ambient temperatures.
- **Cooling and Cold Storage (with or without HACCP):** A facility that is receiving and storing finished goods and performing some kind of pre-cooling and/or cooling activities. In this type of facility, no packing or processing activities are being performed.
- **Packinghouse (with or without HACCP):** A facility where commodities are sorted and/or sized, may be minimally trimmed (not altered in form), washed or not washed, may have post-harvest treatments applied (e.g. fungicide, wax, sprout inhibitor) and packed for commercial distribution and use by consumer or retail establishment.
- **Processing with HACCP:** Washing, slicing, dicing, cutting, shredding, peeling, grading, pasteurization, cooking, chilling, juicing, pressing, freezing, packing in modified atmosphere, packed in vacuum packing or any other activity that significantly transforms the product from its original whole state.

Each audit type is divided into sections, related to specific topics. Please note that there may be some generic questions in all audit types that contain descriptions for both GAP and GMP audit types. For those questions and guidance criteria, you should only focus on the type of audit being conducted.

Depending on commodity specific requirements, buyer requirements, and circumstances at the operation, there are optional addendums which may be added on to the audit.

## Audit Template Structures

- *Food Safety Management System - Covers food safety systems*

- *GAP and/or GMP Section - Covers the physical tour of the operation and documentation*
- *HACCP - Covers the HACCP program*
- *Preventive Controls - Covers the Preventive Controls program*
- *Additional Questions* - These questions are not part of the overall score of the audit. Please note that these questions will help assess the auditee's readiness to achieve certification against a GFSI recognized certification programs.

## Scoring System

For each question, the amount of deficiencies and the associated risks have to be considered to assign the severity of the finding, which can be Minor Deficiency, Major Deficiency and Non-Compliance. When no deficiencies are found, a Total Compliance is given. The possible points for the questions are listed in the following table:

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

**Compliance for Questions**

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

## Automatic Failure

There are some questions that if down scored will lead to an automatic failure and an overall score of 0%. The report will still include a breakdown of the scores for each section, even if an automatic failure occurs. On being immediately informed of the automatic failure by the auditor during the audit, the auditee has the option to have the auditor continue the audit or to have the audit halt at that point (all charges will apply).

## Special Circumstances

Please also note, that under special circumstances and upon finding serious food safety risks, a "not certified" decision can be given. The auditee

should be immediately informed of the automatic failure by the auditor during the audit. The auditee has the option to have the auditor continue the audit or to have the audit halt at that point (all charges will apply).

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

## Audit Termination

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

## Change of Audit Service

Once a standard certification audit has been started it cannot be converted into a pre-assessment audit. This includes when an automatic failure question has been scored down, as noted above. Vice versa, a pre-assessment audit cannot be converted into a standard certification audit once the service has begun. The only time a standard certification audit can be optionally turned into a pre-assessment audit is when the operation is found not to be running on the day of the audit, which can result in the cancellation of the audit (with charges) or the audit can be turned into a pre-assessment (see texts below).

At the opening meeting, an auditor may suggest that the wrong audit template has been chosen and recommend an optimal template for the auditee operation. For example, if a Packinghouse with HACCP Audit is booked but the auditor learns that processed ready-to-eat baby leaf spinach production is occurring on a weekly basis, the auditor will recommend switching to a Processing with HACCP Audit template if processing is observed on the day of the audit. If the auditee decides not to use the template that the auditor/Certification Body recommends, the auditor will indicate in the audit scope which processes were not covered by the audit. In the above example, this would be "audited packinghouse operation, but did not audit the processed leafy greens operation". If an auditee does decide to change service requirements, then the auditor will inform the Certification Body as soon as possible.

## Audit Agenda

Audit agendas vary, but the normal pattern of events is as follows:

- **Opening Meeting.** Confirm the appointment details, introduce the auditor(s) and auditee team, confirm scope and the day's agenda.
- **Tour of Operations.** Areas toured depend on the type of operation. A GMP operation might include raw material storage areas, production, finished goods storage, personnel facilities, maintenance, chemical storage, packaging storage and external areas (e.g., where the dumpsters are located). A GAP operation might include the harvest process, chemical storage, growing areas, portable toilets, and greenhouse. The auditor might also interview some workers.
- **Food Safety File Requirements (paper work section).** Paperwork (documents and records) is reviewed. Please note that the auditor cannot accept documentary evidence after the audit has ended. For example, if a pest control document is missing at the time of the audit and the auditee tries to fax it the next day, it cannot be used to alter the score.
- **HACCP and/or Preventive Controls Section (if relevant).** The auditor might look at the HACCP and/or PC files in the opening meeting in order to orientate themselves about the site program and CCPs/PCs. Auditor will interview CCP/PC operators.
- **Additional Questions.** Might be covered at any point in the audit, as the topics arise.
- **Auditor "Quiet" Time.** Time required for the auditor to organize notes before delivering the closing meeting.
- **Closing Meeting.** Discuss all findings with the auditee team. Auditors are not able to provide either a final score or pass/fail commentary at the end of the audit due to the high number of questions that are asked in the template and the scoring system that is applied. However, auditors do submit audit reports quickly and auditees should contact the Certification Body if reports have not been received electronically two weeks after the audit has occurred (at the latest).

## Documentation Requirements

**Operation's Food Safety Systems:**

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

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

**New Primus Standard Auditees/First-Time Primus Standard Auditees**

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

**Existing Primus Standard Auditees**

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

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

## Visual versus Verbal Confirmation

Visual confirmation is the default method of auditing, whether on the visual inspection portion or the paperwork section. Scores and comments are assumed to have been visually confirmed, unless stated otherwise. Verbal confirmation should be the exception to the rule and, if auditing

properly, these should be rarely used. If a verbal confirmation is accepted, the auditor should write this in the comments section of the report for that specific question.

## How to Use Point Assignment Guidelines

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

In order to be consistent with the voluntary nature of requesting a third-party audit, and in order not to seem to be a legal document, the requirements within the questions are written as "should" and can be scored against. In other questions that use the term "ideally", these statements cannot be scored against, but give the auditee an opportunity for improvement.

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

# SECTION 1: FOOD SAFETY MANAGEMENT

## General

**1.1.1: Was the operation free from any significant threat to the safety of the product that may be considered critical and warrants an automatic failure? Explain. ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): There should be no observation of any issue that the auditor considers a significant threat to the safety of the product. Issues covered by this question are critical food safety situations that might not be considered in the audit template questions and conformance criteria. Alternatively, there may be question and conformance criteria that cover the topic of the issue within the audit, but the situation discovered warrants an automatic failure as opposed to a point down score; the auditor will note the issue in this question. Specific directions for pest and other adulteration (direct observation of product contamination and/or adulteration) are covered in relevant questions. This question is intended for other issues that may not be covered by those questions. Scoring reverts back to this question where the auditor must detail their concern. If the auditor spots an issue that is a serious threat to food safety (as opposed to a pre-requisite) and corrective actions are not being implemented, issue may also be scored here. https://www.fda.gov/regulatory-information/federal-food-drug-and-cosmetic-act-fdc-act/fdc-act-chapter-iv- food

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There is a significant threat to the safety of the product.**

## Control of Documents and Records

**1.2.1: Is there a documented and implemented procedure that requires all records to be stored for a minimum period of 24 months (or greater if legally required) or for at least the shelf life of the product if it is greater than 24 months?**

Total compliance (5 points): There should be a written procedure in place requiring that all records are retained for auditing purposes, in case where there are legal issues, customer queries, etc. All monitoring and process control records should be held for a minimum of 24 months, 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 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. 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 process control 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).

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 24 months).

Non-compliance (0 points) if:

- Process control records are kept less than 24 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.

**1.2.2: Are both paper and electronic food safety related documents and records created, edited, stored and handled in a secure manner?**

Total compliance (5 points): Both paper and electronic food safety documentation that are part of the food safety program (e.g. procedures,

policies, training records, testing results, monitoring records, etc.) should be created, edited, stored 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 1.2.3) and have secure digital signature (including and 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 instances of electronic records 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 and records lacking digital signature capabilities.
- Electronic documents and records are not being backed-up.

Non-compliance (0 points) if:

- Hard copy documents and records are not stored securely.
- Electronic documents and records are not being stored securely.
- No control over editing of hard copy and/or computerized records.
- Widespread failure to use electronic signatures and/or software lacks secure electronic signature capability.

### 1.2.3: Are records maintained in an organized and retrievable manner?

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

Minor deficiency (2 points) if:

- Single/isolated instance(s) of records and/or documents not being organized and easy to retrieve.

Major deficiency (1 point) if:

- Numerous instances of records and/or documents not being organized and easy to retrieve.

Non-compliance (0 points) if:

- No organization of records and/or documents.
- Many missing records and/or documents.

## Procedures and Corrective Actions

**1.3.1: Is there an incident reporting system, also known as a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA)?**

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

Minor Deficiency (3 points) if:

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

Major Deficiency (1 point)

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

Non-compliance (0 points)

- No records.
- Failure to maintain records.

## Internal and External Inspections

**1.4.1: 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 of responsible person (if applicable)). Inspections include regulatory (e.g., Federal and State) and third-party audits. This question is not applicable if there have been no regulatory or third-party inspections in the past year. Evidence of corrective actions (and their follow-up) is important, since there are legal implications if a company was warned of an issue and cannot prove that it has taken corrective actions and later has a serious incident which could have been prevented.

https://www.fda.gov/ICECI/Inspections/ucm256377.htm

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.

**1.4.2: Are there documented calibration and/or accuracy verification procedures for measuring and monitoring devices used in the operations that are related to the safety of the product?**

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

For GAP, this covers items such as fertilizer and pesticide application equipment, pesticide measuring equipment (e.g. scales), ORP and pH meters, and other equipment related to the safety of the product. Pesticide application equipment (e.g. sprayers), and corresponding measuring equipment (e.g. scales, cups) should be verified and when required calibrated (or replaced) regularly to ensure correct and accurate operation. Calibration and/or verification procedures should describe frequency, method and the acceptable range of variation (when applicable). Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency. Where service providers are used (e.g., calibration of pesticide application equipment when applications are performed by an external service provider) score calibration requirements under Supplier Monitoring/Control (unscored questions).

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.

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.

https://www.pubs.ext.vt.edu/content/dam/pubs_ext_vt_edu/424/424-100/PDF_part16.pdf

http://www.ugaurbanag.com/content/calibrating-your-spreader

Minor Deficiency (7 points) if:

- Single/isolated instance(s) of omissions in the procedure(s).
- Single/isolated instance(s) of piece/set of equipment omitted from the procedure(s).

Major Deficiency (3 points) if:

- Numerous instances of omissions in the procedure(s).
- Numerous instances of pieces/sets of equipment omitted from the procedure(s).

Non-compliance (0 points) if:

- No procedure

**1.4.3: Are calibration and/or accuracy verification records maintained and are they consistent with the requirements outlined in the SOP(s) for instruments and measuring devices requiring calibration?**

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

Minor Deficiency (3 points) if:

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

Major Deficiency (1 point)

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

Non-compliance (0 points)

- No records.
- Failure to maintain records.

## Traceability and Recall

**1.5.1: Is there a document that indicates how the company product tracking system works, thereby enabling trace back and trace forward to occur in the event of a potential recall issue?**

Total compliance (10 points): The tracking system is shown in writing or in the form of a flow diagram and demonstrates the product tracking system that is used by the operation. The system should be able to show that it can trace back to the supplier(s) of materials, packaging, ingredients, processing aids, work- in-progress, etc., and show that the system can trace forward and indicate which customer(s) received products. This is usually accomplished by lot coding materials throughout a process and recording these lot codes at different points in the process. The traceability system should be in evidence when touring the operation and also when checking paperwork. The auditor should choose a finished product lot code to test the traceability system and have the auditee demonstrate how the code traces back to raw material supplier(s) and traces forward to the customer(s). The traceability system should include any product, ingredient, packaging and/or service related to the food safety that is outsourced.

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

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

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm#SEC201

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.

**1.5.2: Does the organization have a documented recall program including procedures, recall team roles and contact details, external contact listings, requirement for recall effectiveness checks, explanation of different recall classes and handling of recalled product?**

Total compliance (15 points): To facilitate an efficient recall there should be a written procedure describing how to perform a product recall, recall team details (contact details, alternates, roles and responsibilities), referral to customer and supplier contact details, explanations of relevant laws e.g. product withdrawal, class of recalls (if USA is production or destination country), etc.

Documentation should include basic procedures and responsibilities, current facility contact listing with alternates and out of hour's numbers.

Contact listings for customers and suppliers should also be part of the recall program, although these might be viewed as confidential (if so, then these listings must at least be referred to in the recall program). Listings should be reviewed regularly. An explanation of recall classes (Classes I, II, and III in the USA) should be in the recall program. Ideally contact details for the Certification Body, attorneys, media specialists (for getting the recall information to the various press outlets), local enforcement officials e.g. State and City Health Boards are a good idea (these are optional and should not cause a down score if missing).

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

Potentially useful websites:

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

Minor deficiency (10 points) if:

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

Major deficiency (5 points) if:

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

Non-compliance (0 points) if:

- The facility does not have a recall program.

**1.5.3: Is testing of recall procedures (including trace back) performed and documented at least every six months and the company can demonstrate the ability to trace materials (one step forward, one step back) effectively?**

Total compliance (10 points): Testing of recall procedures should be performed at least every six months. (For short season crops where the operation runs 6 months or less throughout the year, only one mock recall is required.) 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, 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 crew)) operations may create a mock scenario where they receive information from a client indicating there is a problem that warrants a recall. An alternate GAP mock scenario is that the grower is informed of a problem with an input that may warrant a recall e.g. some form of crop contamination. They should show how they know which lots were affected and the associated records of agricultural inputs, they should also be able to show who the field was harvested by and where the 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, primary 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, primary 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

## Food Defense

**1.6.1: Are visitors and contractors to the company operations required to adhere to food defense procedures?**

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

Minor deficiency (2 points) if:

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

Major deficiency (1 point) if:

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

Non-compliance (0 points) if:

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

**1.6.2: Is there a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies?**

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

Minor deficiency (2 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the list.
- The list has not been updated in more than two years.

Non-compliance (0 points) if:

- A list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies has not been docmented.

# SECTION 2: INDOOR AGRICULTURE

## General

**2.1.1: Is there a designated person responsible for the operation's food safety program?**

Total compliance (10 points): There should be a designated person(s) in charge of the operation's food safety program, including food safety document control and verification of food safety activities. They should be trained accordingly (including to all state and federal requirements) e.g. operations covered under US FDA FSMS must have at least one responsible person who has completed training at least equivalent to that under a standardized curriculum recognized by the FDA.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of errors and omissions in the records showing person/persons in charge of the operation's food safety program training and/or their relevant experience in food safety.

Major deficiency (3 points) if:

- Numerous instance(s) of errors and omissions in the records showing person/persons in charge of the operation's food safety program training and/or their relevant experience in food safety.

Non-compliance (0 points) if:

- Systematic failure to document person/persons in charge of the operation's food safety program training and/or their relevant experience in food safety.
- No-one is in charge of the food safety programs, including food safety document control and verification of sanitation activities.

**2.1.2: If the operation is growing under organic principles, is there written documentation of current certification by an accredited organic certification organization?**

Total points 0: Information gathering question. Organic principles are defined as: a system that relies on ecosystem management rather than external agricultural inputs (http://www.fao.org/docrep/003/ac116e/ac116e02.htm). Current certification by an accredited organic certification agency following a governmental organic program should cover the audited crops, be on file, and available for the auditor to review. Where an inspection has recently taken place, but new certificate is not yet available, there should be documented proof of a recent inspection for the auditor to review. N/A if not growing under organic principles. Information gathering question.

**2.1.3: Does the operation have a written food safety hygiene and health policy covering at least worker and visitor hygiene and health, infants and toddlers, animal presence in growing and storage areas, fecal matter, dropped product, blood and bodily fluids?**

Total compliance (15 points): There should be a written food safety policy regarding worker and visitor personal hygiene, GAPs, and health requirements. The policy should cover the rules related to hygiene and health (e.g., hand washing, eating/drinking, smoking, specific clothing rules, foreign material issues, cuts/wounds, illness rules, etc.), no infants and toddlers allowed in the growing area, what to do in the case of evidence of animals and/or fecal matter in the growing and/or storage areas, and what to do in the case of dropped product and if the product comes into contact with blood or other bodily fluids. All workers and visitors should be issued the policy rules in the relevant languages and confirm by signing that they understand and agree to abide. Training provided and associated records should meet all local and national regulations.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of errors and omissions in the records or food safety hygiene and health policy.
- Up to three points missing off the worker and visitor personal hygiene, GAPs and health requirements listing.
- Training materials are not in the relevant language(s).
- Single/isolated instance(s) of workers and visitors not being trained or not signing a document stating that they will comply with the opera tions' personal hygiene and health policies.

Major deficiency (5 points) if:

- Numerous instances of errors and omissions in the records or food safety hygiene and health policy.
- Over three points missing off the visitor personal hygiene, GAPs and health requirements listing.
- Numerous cases of workers and visitors not signing a document stating that they will comply with the operations' personal hygiene and healthy policy.
- Training occurring after starting work, and within the first month.
- Numerous instances of workers not being trained.

Non-compliance (0 points) if:

- No records of training or workers are not being trained.
- No specific orientation given before starting work or within the first month.
- Failure to maintain records.
- The company does not have a document for workers and visitors to sign stating that they will comply with the operations' personal hygiene and health policies.
- Fundamental failure of workers and visitors to sign a log stating that they will comply with the operations' personal hygiene and health policies.

#### 2.1.4: Are signs supporting GMPs posted appropriately?

Total compliance (10 points): Signs for proper GMP's need to be posted visibly and in the language of the workers (picture signs are allowed) to remind them of proper practices. Signs should be posted in the following areas:

- Before entering areas that require (PPE), including production and storage areas.
- Before areas that prohibit food consumption, drinking, tobacco products, chewing gum.
- Bathrooms and break-room(s) should have hand-washing signs as reminders to wash hands before eating, returning to work, after using the toilet.

Signage reminding workers and visitors of GMP rules around the site are very useful (but should not cause down score) such as additional PPE rules, hand dip/gel use (where relevant), not allowing personal items in the production areas, etc.

Minor deficiency (7 points) if:

- The signs are not in the workers' language (pictures are acceptable)
- Single/isolated instance(s) of required signs not being in position.

Major deficiency (3 points) if:

- Numerous instances of required signs not being in position.

Non-compliance (0 points) if:

- Fundamental failure to place signs in the required positions.

#### 2.1.5: Are the necessary food defense controls implemented in the operation?

Total compliance (10 points): The operation should have implemented the necessary controls for preventing intentional contamination of the product and high-risk areas. These measures should be based on the risk associated with the operation, as detailed in the food defense plan (1.9.2). Some high-risk areas of the indoor agriculture operation include: 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 auditor should down score if there are any unprotected water sources (ponds, reservoirs, rivers, etc.), a lack of signage to prevent trespassing, etc.

FSIS has created a self-assessment guideline for food processors titled "Food Security Guidelines for Food Processors". These guidelines are

available at: http://www.fsis.usda.gov/Oa/topics/SecurityGuide.pdf.

The associated self-assessment checklist is available at https://www.fsis.usda.gov/wps/wcm/connect/9fb1c725-4aae-4e06-b56e-217e0fc08f43/Self_Assessment_Checklist_Food_Security.pdf?MOD=AJPERES

FDA Guidance for Industry, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/

Minor deficiency (7 points) if:

- Single/isolated instance(s) is observed of an area lacking necessary food defense controls, based on the risks associated with the opera tion.

Major deficiency (3 points) if:

- Numerous instances are observed of areas lacking necessary food defense controls, based on the risks associated with the operation.

Non-compliance (0 points) if:

- Systematic non-conformance to implement necessary food defense controls, based on the risks associated with the operation.

## Site

**2.2.1: Is there a map that accurately shows all aspects of the operation, including water sources and fixtures used to deliver water used in the operation?**

Total compliance (5 points): There is a map or similar document (photograph, drawing) that accurately shows the growing area(s), adjacent land use features, location of permanent water fixtures and the flow of the water system, including any holding tanks and water captured for re-use. Permanent fixtures include wells, gates, reservoirs, returns and other above ground features. Septic systems, effluent lagoons or ponds, surface water bodies are also identified. Document should enable location of the water sources and the production blocks they serve.

Minor deficiency (3 points) if:

- Single/isolated water source/fixture missing from the map.
- Single/isolated instance(s) of errors or omissions in the map.
- Adjacent land use features are not shown.

Major deficiency (1 points)

- Numerous water sources/fixtures are missing from the map.
- Numerous instances of errors or omission in the map.

Non-compliance (0 points) if:

- There is no map or similar document (photograph, drawing).
- The map provided does not represent the growing operations observed during the audit.

**2.2.2: Are growing areas adequately identified or coded to enable trace back and trace forward in the event of a recall?**

Total compliance (15 points): Coding details (e.g. location name or reference code, blocks of the growing area(s), indoor growing area/building code or number(s)) should be in sufficient detail to enable trace back and trace forward through the distribution system. There should be maps or other documentation available demonstrating the coding details. Coding should link to the record keeping system (e.g., pesticide, fertilizer records, microbiological testing reports, etc.). There should be field maps available demonstrating the coding details used in the operation(s).

Minor deficiency (10 points) if:

- Single/isolated instance of errors and omissions in the coding details and linkage to the record keeping system.

Major deficiency (5 points)

- Numerous instances of errors and omissions in the coding details and linkage to the record keeping system.

Non-compliance (0 points) if:

- There are no maps demonstrating the coding details.

- The coding details presented do not reflect the coding system used by the operation.

**2.2.3: Has a documented risk assessment been conducted at least annually for the operation?**

Total compliance (10 points): A documented risk assessment of the growing area and surrounding areas should be performed and documented annually, and when any changes are made to the growing area or adjacent land. This should detail known or reasonable foreseeable risks/hazards, specific microbial, chemical and physical risks and their severity and likelihood of occurring in the following areas: previous use of the growing area, adjacent land use (e.g. CAFO), water sources (chemical hazards e.g. heavy metals, perchlorate, etc., and microbial hazards e.g. pathogenic E. coli), water use, fertilizers, crop protection chemicals, worker health and hygiene, equipment and tools used for harvest, storage, transportation, topography of the land for runoff, prevailing weather conditions or weather events. and any other applicable areas. Farms and indoor agriculture operations following the CA or AZ LGMA should have a buffer zone of approximately 1,200 ft. (365m) for CAFO's with >1,000 head or 1 mile (1609m) for 80,000 head CAFO, which may increase or decrease after assessing the risks, determining, and deploying mitigation measures. A detailed risk assessment should have been conducted and documented.
One approach:

i) Identify hazards.

ii) Determine who may be harmed and how

iii) Evaluate the risks and decide on actions to control the risks

iv) Document findings and implement actions

v) Review and update assessment as necessary

http://www.fsc.go.jp/sonota/foodsafety_riskanalysis.pdf

http://water.epa.gov/infrastructure/watersecurity/

https://www.epa.gov/sustainable-water-infrastructure

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instance(s) of errors or omissions on the risk analysis.
- Last documented risk assessment was done over 12 months ago.

Non-compliance (0 points) if:

- Multiple systematic errors on the risk analysis.
- No documented risk analysis.

**2.2.3a: If any risk is identified, have corrective actions and/or preventative measures been documented and implemented?**

Total compliance (10 points): For any risks identified in the assessment, the operation should detail what practice is being done to minimize identified risk/hazard, how to measure/monitor the effectiveness of the practice, how often to measure, and how it is verified and recorded. There should be documented evidence that corrective actions and/or preventative measures have been taken when any risk was identified and were adequate for the specific situation. Auditor must detail any mitigation steps for identified risks.

Minor deficiency (7 points):

- Single/isolated instance(s) of corrective action and/or preventative measure records missing details or not being adequate.

Major deficiency (3 points):

- Numerous instances of corrective action and/or preventative measure records missing details or not being adequate.

Non-compliance (0 points):

- No corrective actions and/or preventative measures were performed or are inadequate to control risk(s).
- Corrective actions and/or preventative measures were not recorded.

**2.2.4: Is the exterior area immediately outside the facility, including roads, yards and parking areas, free of litter, weeds and standing water?**

Total compliance (5 points): Litter, waste, refuse, uncut weeds or grass and standing water within the immediate vicinity of the building may constitute an attractant or breeding place for rodents, insects or other pests, as well as microorganisms that may cause contamination. Weeds and grass should be maintained in order to help avoid pest harborage. There should be no excessive standing water and/or foul smelling odors. If there is a designated smoking area outside, then there should be a disposal can for cigarette butts – butts should not be found on the ground. Car parking areas should be free from litter, butts, etc., especially if workers are using their cars at break times. When locating a suitable designated smoking area, auditees should consider the need for hand washing prior to returning to the work place.

Minor deficiency (3 points) if:

- Single/isolated instance of an area not maintained properly.

Major deficiency (1 point) if:

- Numerous instances of areas not maintained properly.

Non-compliance (0 points) if:

- The exterior area immediately outside the growing area is not maintained.

**2.2.5: Are control measures being implemented for the outside storage of equipment, pallets, tires etc. (i.e. out of the mud, stacked to prevent pest harborage, away from the building perimeter)?**

Total compliance (5 points): Incorrectly stored pallets and equipment can provide areas for pest harborage and/or cross contamination. Equipment should be stored at least 4" (10 cm) off the ground. Workers should check the stored equipment (e.g., irrigation pipes) periodically to ensure that it has not become a pest harborage area or dirty due to rains. Inventory checks should occur in order to ensure that these storage areas do not become full of unnecessary items.

Minor deficiency (3 points) if:

- Single/isolated instance of equipment not stored properly.
- Excessive storage of old, obsolete equipment.

Major deficiency (1 point) if:

- Numerous instances of improper storage of equipment.

Non-compliance (0 points) if:

- No provisions are made to keep equipment from harboring pests.
- Evidence of pest infestation e.g. multiple occurrences of fecal contamination, nests and live pests.

**2.2.6: Is the dumpster/cull truck/trash area clean?**

Total compliance (3 points): The dumpster/cull truck/trash area should be located away from facility entrances, where traffic flow may be a source of cross contamination. The area around the dumpster/cull truck/trash area should be maintained in a clean condition. There should not be any spillage on the ground. There should not be any standing water or liquid seepage around the dumpster/cull truck/trash area and there should not be any foul odor present. The dumpster/cull truck/trash area should be cleaned on a regular basis.

Minor deficiency (2 points) if:

- Minor amount of debris around the dumpster(s)/cull truck/trash area.

Major deficiency (1 point) if:

- Major amount of debris around the dumpster(s)/cull truck/trash area.
- Strong odor around dumpster/cull truck/trash area.
- Visible liquid leakage from the dumpster(s)/cull truck/trash area.

Non-compliance (0 points) if:

- Evidence of old trash and spillage around the dumpster/cull truck/trash area, indicating that spills are not cleaned up as they happen.

- Evidence of insects or other pests in or around dumpster/cull truck/trash area.

**2.2.7: Are outside garbage receptacles and dumpsters kept covered or closed?**

Total compliance (5 points): All dumpsters and garbage receptacles should have a cover and be kept covered to prevent the attraction of insects, rodents and other pests. Fine mesh lids are acceptable. Just having the lids is not acceptable i.e. when not in use, the dumpsters and garbage receptacles should be closed. Dumpsters that are only used for dry non-food waste (e.g., paper, cardboard, etc.) are exempt from this requirement.

Minor deficiency (3 points) if:

- Dumpster(s)/garbage receptacle(s) have covers, but they are not being used.

Major deficiency (1 point) if:

- In the case of operations with multiple dumpsters/garbage receptacles, the majority have covers and are covered, but some are lacking covers.

Non-compliance (0 points) if:

- In the case of operations with multiple dumpsters/garbage receptacles, the minority have covers and are covered, but majority are lacking covers.
- All garbage dumpsters/receptacles lacking covers.

**2.2.8: Where soil, substrates or fertilizer (e.g., compost) are stored or handled, are measures in place to ensure seepage and runoff is collected or diverted and does not reach growing areas, product, or any of the water sources? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Soil, substrates and fertilizer (e.g., compost) are stored in a covered area to protect from pests and prevent run-off. Where run-off exists, there are barriers, soil berms, pits or lagoons to divert or collect run-off. Any observation of runoff reaching the growing area is an automatic failure.

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question Major deficiency (5 points) if:
- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There are no barriers to collect run-off.**
- **Runoff was observed entering the growing area during the audit.**

**2.2.9: Where there are fill stations for fuel or pesticides, is it evident that the location and/or use is not a risk of contamination to the product, water sources, growing areas, equipment, packaging materials, etc.?**

Total compliance (15 points): Fill station area should not be a risk of contamination to the product, water sources, production areas, equipment, packaging materials, etc.

Minor deficiency (10 points) if:

- Single/isolated instance of the fill station(s) being a risk of contamination.

Major deficiency (5 points) if:

- Numerous instances of the fill station(s) being a risk of contamination.

Non-compliance (0 points) if:

- Systematic failure to prevent contamination.

**2.2.10: Is the growing area free from evidence of animal presence and/or animal activity (wild or domestic)? If Yes, go to 2.2.11.**

Total compliance (15 points): Animals can represent potential contamination to the growing area, to the crop, to the field equipment, etc., and

therefore, should not be present in the operations. Evidence of animal presence can include tracks, fecal matter, feathers, etc. Note: This includes any packaging or equipment storage areas (e.g. packaging, equipment, agronomic inputs, chemicals).

Minor deficiency (10 points) if:

- Single/isolated instance of evidence of animal presence and/or animal activity.

Major deficiency (5 points) if:

- Numerous instances of evidence of animal presence and/or animal activity.

Non-compliance (0 points) if:

- Systematic failure to prevent animal presence and/or animal activity in the audited area.

**2.2.10a: Is the growing area free from any evidence of animal fecal matter? A ZERO POINT (NON- COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.**

Total compliance (15 points): Fecal matter is a potential contaminant to the product being grown. Produce that has come into direct contact with fecal matter is not to be harvested. A "no harvest zone" of approximately 5ft (1.5 m) radius should be implemented unless or until adequate mitigation measures have been considered. If evidence of fecal matter is found, a food safety risk assessment should be conducted by a qualified worker and include appropriate corrective and preventative actions. Consideration of the maturity stage and type of crop involved is required. Any evidence of human fecal matter in the growing area is an automatic failure (scored in 2.2.11).

Minor deficiency (10 points) if:

- Single instance of fecal matter found in the audited area and a food safety risk assessment was implemented correctly.
- A “no harvest zone” is implemented, but the radius is less than 5ft.

Major deficiency (5 points) if:

- More than one instance of fecal matter found in the audited area and a food safety risk assessment was implemented correctly.
- Any instance of fecal matter is found in the audited area and a “no harvest zone” was not implemented.
- Any instance of fecal matter is found, and a food safety assessment is not conducted.

**Automatic Failure (0 points) if:**

- **Any observation of systematic animal fecal contamination in the audited area is an automatic failure.**
- **Any observation of any human fecal matter in the audited area is an automatic failure. Score under 2.2.11.**

**2.2.11: Is the growing area free from any evidence of human fecal matter? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Human fecal matter is a potential contaminant to the product being grown. Any evidence of human fecal matter in the growing area is an automatic failure.

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **Any observation of any human fecal matter in the audited area is an automatic failure.**

**2.2.12: Is the growing area free from evidence of infants or toddlers?**

Total compliance (10 points): Infants and toddlers can represent potential contamination to the growing area, to the crop, to packaging and should not be present in the operations, including chemical or equipment storage areas.

Minor deficiency (7 points) if:

- Single/isolated instance or evidence of infants or toddlers in the audited area.

Major deficiency (3 points) if:

- Numerous instances or evidence of infants or toddlers in the audited area.

Non-compliance (0 points) if:

- Fundamental failure to keep infants or toddlers out of the audited area.

## Pest Control

**2.3.1: Is there a written policy prohibiting animals in the facility, including the growing areas and any packaging or equipment storage areas?**

Total compliance (10 points): Domestic and wild animals, including birds, are not permitted in the facility, including packaging and storage areas. There should be a written policy in place to affirm this.

Minor deficiency (7 points) if:

- Single/isolated instance of missing action items in the policy.

Major deficiency (3 points) if:

- Numerous instances of missing action items in the policy.

Non-compliance (0 points) if:

- There is no policy prohibiting animals in the operation.

**2.3.2: Is there an effective pest control program in place? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): There should be an effective, proactive pest control program (in-house or contracted) to control rodents (also insects, reptiles and birds where necessary) and prevent infestation.

Potentially useful website:

National Pest Management Standards, Pest Management Standards for Food Plants http://npmapestworld.org/default/assets/File/2016%20Pest%20Management%20Standards%20for %20Food%20Processing-Electronic.pdf

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

Automatic Failure (0 points) if:

- The operation does not have an effective pest control program.

**2.3.3: Is there a documented pest control program, detailing the scope of the program, target pests and frequency of checks, including a copy of the contract with the extermination company (if used), Pest Control Operator license(s)/training (if baits are used), and insurance documents?**

Total compliance (15 points): There should be a documented pest control program in place detailing the scope of the program, target pests and frequency of checks. If performed in-house, the pest-control operators or equivalent should be registered, licensed or have documented formal training (if regulation does not require certification or registration). Note that the person's training and/or license should specify structural pest control or equivalent or have documentation to show that the license includes structural pest control training if not specified on license. Any substitute operator's license credentials should also be on file. If the service is contracted, the pest control contract service/company should be licensed in structural pest control, insured and the contract should be documented (quoting the scope of the program, types of pests it covers and frequency of visits). When licensing legislation does not apply (e.g., in certain countries), there should be evidence of on-going training. Auditors

should check documentation for expiry dates.

Minor deficiency (10 points) if:

- One piece of documentation is not in place or is not current.
- Single/isolated omission(s) in the written program.

Major deficiency (5 points) if:

- Two pieces of documentation are not in place or are not current, such as evidence of the training and/or license for one pest control operator.
- Numerous omissions in the written program,

Non-compliance (0 points) if:

- More than two pieces of documentation are not in place or are not current.
- There is no documented pest control program.
- Written program does not resemble what is happening in practice at all.
- There is no evidence of the training and/or license of the pest control operator(s).

**2.3.4: Is there a schematic drawing/plan of the indoor agriculture operation, showing numbered locations of all pest monitoring devices (e.g., rodent traps, bait stations, insect light traps, etc.) both inside and outside the facility?**

Total compliance (10 points): A schematic drawing or trap map is on file, current and details internal and external traps. All devices (e.g., tin cats, Ketch-Alls, bait stations, glue boards, insect light traps, electronic fly killer units, etc.) should be numbered and clearly identified on the map. The numbers should match what is in the operation. The document should be accurate, dated and should show the type of device.

Minor deficiency (7 points) if:

- The location map does not distinguish between the different types of devices.
- Single/isolated instance(s) of trap(s) being missed off the plan.
- Single/isolated instance(s) of trap(s) numbering being incorrect.

Major deficiency (3 points) if:

- Numerous instances of traps being missed off the plan.
- Numerous instances of traps numbering being incorrect.

Non-compliance (0 points) if:

- No map available for review.
- Majority of traps are not included on the map.
- Map does not represent actual physical placement of traps at all.

**2.3.5: Are service reports created for pest control checks detailing inspection records, application records, and corrective actions of issues noted (in-house and/or contract)?**

Total compliance (10 points): Service reports from the contract pest control company should be available for review if pest control is contracted out. In-house inspection records should be available for review if pest control is conducted in-house. Records should include services performed, date of service, chemicals used (see below), signs of activity with corrective actions, and trend reports. Match Pest Control Operator (PCO) signature on service logs with licenses/certificates on file. Records should show when electric fly killing unit bulbs are changed. Where the contracted pest control has left their client details of an issue or a recommendation (e.g., excessive gap at the bottom of a door), then the client should acknowledge the issue(s) and note corrective action completion(s) where relevant.

Where chemicals are used, records should detail:

- Product name of materials applied
- The EPA or product registration number (as required by law)

- Target pest
- Rate of application (percent of concentration)
- Location or site of application
- Method of application (if applicable)
- Amount of pesticide used
- Date and time of application
- Signature of applicator
- Corrective actions
- Trend reports

National Pest Management Standards, Pest Management Standards for Food Plants

http://npmapestworld.org/default/assets/File/2016%20Pest%20Management%20Standards%20for %20Food%20Processing-Electronic.pdf

Minor deficiency (7 points) if:

- Single/isolated instance(s) of missing or incomplete information/records e.g. pest activity, device replacement etc.
- Single/isolated instance(s) where contracted pest operators action points have not been acknowledged and completed.
- Single/isolated instance(s) of not noting chemical use details.

Major deficiency (3 points) if:

- Numerous instances of missing or incomplete information/records e.g. pest activity, device replacement, etc.
- Numerous instances where contracted pest operators action points have not been acknowledged and completed.
- Numerous instances of not noting chemical use details.

Non-compliance (0 points) if:

- No service reports.
- Fundamental failure to maintain service reports.
- Fundamental failure to record chemical use details.

### 2.3.6: Are closed doors, and windows to the outside pest proof?

Total compliance (10 points): All doors, windows, louvers and screens to the outside should be designed and properly fitted out to prevent the ingress of rodents and insects into the facility. Doors should have no gaps greater than approximately 1/8 inch (3 mm). If doors, windows or louvers have screens, the openings should be no greater than 1/8 inch (3 mm). Gaps are often at bottom of doors and at the top of roller doors. Air curtains are acceptable, provided they are operating properly. Personnel doors to the outside should be loaded so that they close properly. Rule of thumb is that if you can see daylight gaps, then further investigation is required.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of there being a gap greater than1/8 inch (3 mm).
- Single/isolated instance(s) of personnel doors not closing properly or improper mesh size (where screens are used).
- Single/isolated instance(s) of an air curtain not operating properly.

Major deficiency (3 points) if:

- Numerous instances of there being gaps greater than 1/8 inch (3 mm).
- Numerous instances of personnel doors not closing properly or improper mesh size (where screens are used).
- Numerous instances of air curtains not operating properly.

Non-compliance (0 points) if:

- Widespread observations of there being gaps with greater than 1/8 inch (3mm).
- Widespread observations of personnel doors not closing properly or improper mesh size (where screens are used).
- Widespread observations of air curtains not working properly.

**2.3.7: Is the area outside the facility free of evidence of pest activity?**

Total compliance (10 points): All areas should be free of recurring/existing external pest activity. Specifically, there should be:

- No recurring/existing rodent or animal (e.g. dogs, birds, etc.) activity/spoors (significant burrows, trails, feces, tracks) in active areas within operation's property perimeter e.g. storage (packaging, bone yards), outbuildings (e.g. shade structures), etc.
- No bird nesting/activity observed around the exterior perimeter of the operation or external storage/outbuildings e.g. pallets, trailers/con tainers, bone yards, etc.
- No decomposed rodent(s) or other animals (frogs, lizards, etc.) in bait stations or along perimeter.

There should be no down scores attributed to finding a few (three or less) "fresh" rodents and/or evidence of rodent feeding in the external traps.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of recurring/existing rodent or animal (e.g. dogs, birds, etc.) activity/spoors (burrows, trails, feces, tracks, etc.)
- Single/isolated instance(s) of bird nesting observed around the exterior perimeter of the operation or external storage/outbuildings e.g. pallets, trailers/containers, bone yards, etc.

Major deficiency (3 point) if:

- Numerous instances of recurring/existing rodent or animal (e.g. dogs, birds, etc.) activity/spoors (burrows, trails, feces, tracks, etc.).
- Numerous instances of bird nesting observed around the exterior perimeter of the operation or external storage/outbuildings e.g. pallets, trailers/containers, bone yards, etc.
- Single instance of a decomposed rodent or other animal (frog, lizard etc.) in external traps or along perimeter.

Non-compliance (0 points) if:

- Evidence of significant (infestation level) rodent activity (burrows, trails, feces, tracks, animal spoor)
- Significant bird activity in traffic zones.
- More than one decomposed rodent or other animals (frogs, lizards, etc.) in external traps or along perimeter.
- Any observation of contaminated product or packaging contact qualifies as an automatic failure under 2.5.9.

**2.3.8: Are pest control devices located away from exposed raw materials (e.g., seeds, transplants, soil, media), finished goods and packaging, and poisonous bait stations are not used within the facility?**

Total compliance (10 points): Pest control devices should be located away from exposed food products, packaging materials or equipment to prevent any physical or microbial contamination. Poisonous bait stations should not be located within the facility.

Care should be taken to place pest control devices in such a manner that they do not pose a threat of contaminating product, packaging or raw materials. This includes the following restrictions:

- Poisonous bait stations and other pesticides should only be used outside the facility.
- There should be no domestic fly sprays used within the production and storage areas.
- Block bait as opposed to grain and pellet bait should be used (except for the external use of National Organic Program approved materials).
- If used, insect light traps (ILTs), electrical fly killers (EFKs) or pheromone traps should be regularly cleaned out (kept free from a build-up of insects and debris). Sticky type ILTs should be monitored at least monthly and the sticky board replaced if ineffective. ILTs that use sticking as opposed to zapping methods (EFKs) are preferred.
- If used, insect light traps or electric fly killers should not be placed above or in close proximity (10 feet, 3 meters) to product, food contact surfaces, equipment, or packaging material. Electric fly killers or insect light traps should not be located above dock doors (due to potential

forklift damage) or in front of doorways (so attracting insects into the facility). Hallways or dock areas where product passes through are exempt from these distances, as long as product does not stop or is not stored in hallway or dock.

- If used, insect light trap bulbs should be replaced at least every 12 months (this should be recorded), or more frequently if directed by manufacturers.
- No fly swatters should be evident in production or storage areas.
- No bait should be found outside of bait stations.
- If used, snap traps should be placed inside a trap box and should not use allergen containing baits (e.g., peanut butter). Any snap traps inside stations should be checked at least weekly and checks recorded (scored in 2.3.9). Any indoor use of chemicals e.g. knock down sprays should be done without contaminating food, packaging, and equipment (see the next bullet point regarding poisonous rodent baits). All applications should be recorded properly (scored in 2.3.5), detailing where and when the application occurred, and any special methods used to avoid contamination. All applications should be made by experienced, licensed operators following any and all legal requirements and best practices.
- The use of poisonous bait within the facility should not occur. If this use is required, then the area that is being trapped should have all the product and packaging removed prior to the use of the poisonous baits.

Minor deficiency: (7 points) if:

- Single/isolated instance(s) of improperly positioning or maintaining electrical fly traps or insect light traps.
- Single/isolated instance(s) of a fly swatter found in production or storage area.
- Single/isolated instance(s) of grain or pellet baits being used in an outside bait station (external trap).
- Single can of fly spray (or other insecticide) found in the production/storage areas (including chemical/sanitation storage).
- Single/isolated instance (up to three snap traps) of snap traps being used outside a trap box (not presenting risk to product or packaging).
- Single/isolated instance(s) of any other issues noted on the compliance criteria.

Major deficiency (3 points) if:

- Numerous instances of improperly positioning or maintaining electrical fly traps or insect light traps.
- Numerous instances fly swatters found in production or storage area.
- Numerous instances of grain or pellet bait being used in an outside bait station (external trap).
- More than one can of fly spray (or other insecticide) found in the production/storage areas (including chemical/sanitation storage).
- Single instance of bait/poison inside the facility (inside of a trap).
- Single instance of bait/poison found outside of a trap, outside the facility.
- Numerous instances of snap traps being used outside a trap box.
- Snap traps using an allergenic bait.
- Numerous instance(s) of any other issues noted on the compliance criteria.

Non-compliance (0 points) if:

- More than one instance of bait/poison inside the facility (inside of a trap).
- Single instance of bait/poison inside the facility (outside of a trap).
- More than one instance of bait/poison found outside of a trap, outside the facility.
- More than one major deficiency.
- Systematic use of snap traps outside of trap boxes.
- Any observation of contamination of product or product contact material (this qualifies for an automatic failure and applies under 2.5.9.

**2.3.9: Are pest control devices maintained in a clean and intact condition and marked as monitored (or bar code scanned) on a regular basis?**

Total compliance (5 points): All pest control devices should be maintained clean, in working order and replaced when damaged in order to accomplish their intended use. Date of inspections should be posted on the devices as well as kept on file (unless barcode scanned). This includes any in-house service inspections.

The following criteria are met:

- If non-toxic glue boards are used, they should be located inside a trap box or PVC piping, etc., and changed frequently ensuring that the surface has a shiny glaze with no build-up of dust or debris.
- If cardboard traps are used (interior and dry areas only) they should be in good repair and marked as monitored (see below).
- If mechanical wind-up traps are used, they should be wound. Winding is checked by triggering the spring device to operate the trap. The trap should be rewound after testing.
- Approximately 10% of the traps, glue boards and bait stations should be checked by the auditor.
- Record of service verification such as stickers, cards or bar codes should be on the inside of the station and on bottom of glue boards requiring the station to be opened to record data (date and initial of inspector) or to scan. External labeling is allowed on traps with a clear window on top.
- Bait and other poisons should be controlled and applied by a licensed applicator.
- Bait in bait stations should be secured inside the bait station on a rod above the floor of the station, or the bait station is designed so bait cannot be removed by a rodent or "float away" in a heavy rain. Bait stations should be tamper resistant. A key should be made available at the time of the audit.
- No bait stations should be missing entire bait.
- No old or moldy bait observed.
- Bait stations and traps should not be fouled with weeds, dirt, and other debris.
- External pest control devices should be checked at least monthly these checks to be recorded.
- Internal pest control devices should be checked at least weekly – these checks to be recorded.
- Any snap traps used should be inside stations and should be checked at least weekly – these checks to be recorded.

Local regulations may require exceptions/differences to above guidelines. At all times, local regulations should be met but if the audit system requirements are more stringent, these should also be adhered to. Some contractors use barcode systems that automatically check to see if all traps are monitored on a scheduled visit.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of traps, bait stations and glue boards not working properly or adequately maintained (check cards, cleanliness, etc.)
- Single/isolated instance(s) of unsecured bait inside bait stations.
- Single/isolated instance(s) of bait stations having moldy bait.
- Single/isolated instance(s) of any other issues noted on the compliance criteria.

Major deficiency (1 point) if:

- Numerous instances of traps, bait stations or glue boards not working properly or adequately maintained (check cards, cleanliness, etc.)
- Numerous instances of unsecured bait inside bait station.
- Numerous instances of bait stations having moldy bait.
- Numerous instance(s) of any other issues noted on the compliance criteria.

Non-compliance (0 points) if:

- Systematic failure to maintain the pest control devices.
- Systematic failure to monitor the pest control devices.

**2.3.10: Are interior and exterior building perimeter pest control devices adequate in number and location?**

Total compliance (5 points): The distance between traps should be determined based on the activity and the needs of the operation. As a guide (i.e. not expecting the use of tape measures) to number and placement of traps and bait stations:

- Multiple catch traps or glue boards in stations or PVC pipes should be positioned between 20 to 40 feet (6 to 12 meters) intervals around the inside perimeter of all rooms. Spacing might be affected by the structure, storage and types activities occurring.
- Multiple-catch traps may be supplemented with snap traps in stations if necessary in certain areas (e.g., in areas with high dust levels) or box mezzanines where large traps or glue boards are not practical.
- Inside the facility, traps should be placed within 6 feet (about 2 meters) of both sides of all outside exit/entry doors. This includes either side of the pedestrian doors. Effort should be made to avoid placing traps on curbing.
- Bait stations or multiple-catch traps should be positioned between 50-100 feet (15-30 meters) intervals around the exterior of the building perimeter and within 6 feet (about 2 meters) of both sides of all outside exit/entry doors, except where there is public access (public access is defined as access easily gained by the general public such as parking lots or sidewalks, school areas or areas of environmental concern). Trap placement might be affected by the structure, external storage and type of area (urban, rural etc.).
- Bait stations (where used) should be positioned within 100 feet (30 m) of structures. This may impact fence line/property boundary baiting i.e. bait stations must be within 100 feet (30 m) of buildings and at 50-100 feet (15-30 m) intervals. If an exterior fence line/property perimeter program is utilized at distances greater than 100 feet (30 m) from buildings, then non-bait traps (e.g. multiple-catch traps) should be positioned at 50-100 feet (15-30 m) intervals along perimeter. Auditor should check label for bait and ensure compliance to distance requirements on label.
- Outside packaging and any outside food storage should be protected by an adequate number of pest control devices.

https://www.epa.gov/rodenticides/restrictions-rodenticide-products#types

http://npmapestworld.org/default/assets/File/2016%20Pest%20Management%20Standards%20for %20Food%20Processing-Electronic.pdf

Minor deficiency (3 points) if:

- Single/isolated instance(s) of traps positioned at longer intervals than mentioned above.
- Single/isolated instance(s) of traps missing or not within 6 feet (about 2 meters) of exit/entry doors.
- No bait stations along facility property fence line (auditor discretion on necessity for fence line trapping).
- Traps not located in a single area that should be trapped e.g. break area, etc.

Major deficiency (1 point) if:

- Numerous instances of bait stations positioned at longer intervals than mentioned above.
- Numerous instances of traps missing or not within 6 feet (about 2 meters) of exit/entry doors.
- Traps not located in more than one area that should be trapped e.g. building perimeters (see text above).
- No exterior traps.

Non-compliance (0 points) if:

- Trap positioning is such that the number of traps is nowhere near adequate in terms of spacing and coverage of entry points, e.g. one or two traps to cover a large production area.
- Traps not located in numerous areas that should be trapped.

**2.3.11: Are all pest control devices identified by a number or other code (e.g. barcode)?**

Total compliance (5 points): The devices are numbered and a coding system is in place to identify the type of device on a map. Auditor should check that the pest control map numbering and positions, match reality. All internal stations should be located with a wall sign (that states the device number and that it is a pest device identifier), in case they are moved.

Minor deficiency (3 points) if:

- Single/isolated instance(s) pest control devices having no visible numbers on them or on the station location.
- Single/isolated instance(s) of missing wall signs.

- Wall signs are not unique i.e. not clear that they are device identifiers e.g. just a number.

Major deficiency (1 point) if:

- The devices are marked on the map but the devices themselves are not numbered or the numbering sequence is incorrect.
- Numerous instances of pest control devices having no visible numbers on them or the station location
- Numerous instances of missing wall signs.

Non-compliance (0 points) if:

- None of the devices are numbered.

**2.3.12: Are all pest control devices effective and bait stations secured?**

Total compliance (5 points): All devices should be correctly orientated with openings parallel with and closest to wall. Bait stations should be secured to minimize movement of the device and be tamper resistant, and only block bait (no pellets) should be used. Bait stations should be secured with a ground rod, chain, cable or wire, or glued to the wall/ground, or secured with a patio stone (wall signs are required if using patio stones) to prevent the bait from being removed by shaking, washed away, etc. Bait stations should be tamper resistant through the use of screws, latches, locks, or by other effective means. Note – only traps containing bait are required to be secured. Live traps used indoors are not required to be secured to the ground; auditee may use metal "sleeves" or similar solutions to prevent displacement, crushing by forklifts, etc. Glue boards should be inside a device (e.g. trap box, PVC pipe, etc.) rather than loose on the floor. Auditor discretion applies to traps placed on curbing.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of bait stations not being secured.
- Single/isolated instance(s) of devices "out of position"
- Lacking wall signs for external traps that are secured to a patio block.

Major deficiency (1 point) if:

- Numerous instances of bait stations not being secured.
- Numerous instances of devices "out of position"

Non-compliance (0 points) if:

- Systematic failure to secure bait stations.
- Systematic failure to properly position interior traps.

## General Chemicals

**2.4.1: Are there chemical inventory logs for chemicals, including pesticides, fertilizers and cleaning and sanitizing chemicals?**

Total compliance (3 points): Chemical inventories should be on file. Chemicals within the scope of this question include pesticides, fertilizers, cleaners and sanitizers i.e. sanitation chemicals and food contact chemicals. Primary information in the product inventory includes: the product or chemical names, quantity available, and location of containers. Inventory by storage area/type of chemical is optimal. The inventory should take into account the arrival of new stocks and any discrepancies should be explained. Minimum frequency for inventory checks should be monthly during production season and a copy should be maintained separate from the chemical storage location(s) and available for auditor review. The frequency of the inventory checks may decrease in short season or off-seasonal operations; auditor discretion applies.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of missing chemical usage logs and/or inventories.
- Single/isolated instance(s) of omission(s) or error(s) in the chemical usage logs and/or inventories.
- Single/isolated instance(s) of new deliveries not being accounted for.
- Single/isolated instance(s) of minimum inventory frequency not being maintained (if usage logs are not being utilized).

Major deficiency (1 point) if:

- Numerous instances of missing chemical usage logs/inventories.

- Numerous instances of omissions or errors in the chemical usage logs and/or inventories.
- Numerous instances of new deliveries not being accounted for.
- Numerous instances of minimum inventory frequency not being maintained (if usage logs are not being utilized).

Non-compliance (0 points) if:

- No chemical usage logs/inventories are on file.
- Chemical inventory is not available for review.

**2.4.2: Are all chemicals (pesticides, sanitizers, detergents, lubricants, etc.) stored securely, safely and are they labeled correctly?**

Total compliance (15 points): Chemicals located on-site are required to be stored in a well vented, designated (with a sign), dedicated, secure (locked) area. Storage area is maintained clean. Access to chemicals needs to be controlled, so that only workers who understand the risks involved and have been trained properly are allowed to access these chemicals. The chemical storage area should be located away from any growing areas, raw materials, packaging & finished food products, water sources and living areas. Spill controls should be in place for opened in use containers. All chemical containers should be off the floor, have legible labels of contents; this includes chemicals that have been decanted from master containers into smaller containers. Liquid should not be stored above powders. Where chemicals are stored, adequate liquid containment (spill controls) techniques need to be employed (secondary containment, absorbent materials, angled sealed floors, spill kits etc.). Chemical storage should be designed to help contain spills and leaking containers. Empty containers should be stored and disposed of safely. All federal and state or local laws and regulations for pesticides storage should be considered. Empty pesticide containers should be kept in a secured storage area until they can be recycled or disposed of properly. If containers cannot be refilled, reconditioned, recycled or returned to the manufacturer, they should be crushed, broken or punctured to make them unusable. Containers should be disposed of in accordance with label directions and with federal and state or local laws and regulations. Pesticide containers designed to be returned and refilled should not be reused or tampered with.

Where pesticide storage is not located on-site auditor discretion applies on question applicability.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of chemicals not properly stored.
- Single/isolated instance(s) of improperly labeled or unlabeled chemical containers.
- Single/isolated instance(s) of empty containers either not being stored properly or disposed of properly
- The chemical storage area is not marked to indicate its use.
- Single isolated instance(s) of chemicals being used without proper attention to chemical spillage.

Major deficiency (5 points) if:

- Numerous instances of improperly stored chemicals.
- Numerous instances of improperly labeled or unlabeled chemical containers.
- Chemical storage is segregated in an enclosed, designated area, but not locked.
- Chemical storage area(s) has inadequate liquid containment systems.
- Spilled chemicals found in the chemical storage areas (not cleaned up properly)
- Numerous instances of empty containers either not being properly stored or disposed of properly.
- Numerous chemicals being used without proper attention to chemical spillage.
- Numerous instances of empty containers either not being properly stored or disposed of properly.

Non-compliance (0 points) if:

- Failure to properly store chemicals.
- There is no designated area for chemicals.
- There is a designated area for chemicals but it is not an enclosed or locked area.
- Visible chemical spills in the facility and surrounding grounds that have not been cleaned up.

**2.4.3: Are "food grade" and "non-food grade" chemicals used appropriately, according to the label and stored in a controlled manner (not commingled)?**

Total compliance (10 points): Food grade chemicals, including lubricants, greases, etc., are used in all product/packaging contact areas. All chemicals applied should be approved by the prevailing authority (e.g., US: EPA/FDA, Canada: CFIA/Environment Canada, Chile: SAG/Ministerio de Salud, Mexico: COFEPRIS) for their designated use and used according to label instructions. Only food grade lubricants should be used anywhere near product and packaging materials. Food grade chemicals should be stored apart from non-food grade items to eliminate confusion between types, and adequately labeled. Non-food grade chemicals also include cleaning chemicals and paint, for example use of domestic polishes which are not intended for food contact surfaces and have strong fragrances should not be used on food contact surfaces; office cleaning materials, restroom cleaning material should be stored separately from production cleaning materials. Grease guns and containers should indicate which are for food grade greases and which are for non-food grade use. Non-food grade material use, where required should not be used in food contact areas and be entrusted to workers who know how to use the chemicals to avoid contamination issues. Non-food grade materials should not be found in the growing/storage areas (unless stored securely, with access to entrusted workers only). Chemicals should be used according to label instructions e.g. following correct dilutions, H1 designation on lubricants, etc. Any chlorine bleach that is used for making a sanitizing solution, must be of sufficient purity to be categorized as a "food grade" substance. Some commercially available household chlorine bleaches contain fragrances, thickeners and/or other additives not approved for food use. These products are not suitable for making sanitizing solutions. If any chemicals are used to alter or buffer the pH of a sanitizing solution these should also be "food grade."

NSF International: Nonfood Compounds

http://info.nsf.org/USDA/PSNCListings.asp

http://pods.dasnr.okstate.edu/docushare/dsweb/Get/Document-963/FAPC-116web.pdf

Minor deficiency (7 points) if:

- Single/isolated instance(s) of commingling of non-food grade with food grade chemicals.
- Single/isolated instance(s) of grease guns not being coded for food grade/non-food grade materials.
- Single/isolated instance(s) of non-food grade materials found/used in the production/storage areas.
- Single/isolated instance(s) of a chemical being used contrary to label.

Major deficiency (3 point) if:

- Numerous instances of commingling of non-food grade with food grade chemicals.
- Numerous instances of grease guns not coded for food grade/non-food grade materials.
- Numerous instances of non-food grade materials found/used in the production/storage areas.
- Numerous instances of a chemical(s) being used contrary to label.

Non-compliance (0 points) if:

- No attempt to split non-food grade from food grade materials.
- Widespread use of non-food grade materials found/used in the production/storage areas.
- Widespread use of a chemical(s) used contrary to label.
- Evidence of the use of a non-food grade chemical that has caused product contamination – revert to 2.5.9, automatic failure.

## Production Facility

**2.5.1: Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the indoor agriculture operation and all equipment?**

Total compliance (10 points): There should be written cleaning and sanitation procedures for all equipment (food contact, non-food contact, cooling equipment, etc.), areas (floors, walls, overheads, etc.), internal transport vehicles and in-house owned trailers that should be cleaned and sanitized on a regularly scheduled basis, based on written Sanitation Standard Operating Procedures (SSOPs). There should be SSOPs covering the cleaning and sanitizing operations noted in the master sanitation schedule. SSOPs should also be created for dry cleaning operations (where applicable). This includes equipment (named equipment and equipment parts and surfaces), floors, walls, light covers, pipes, ceilings, evaporators, cooling coils, drip pans, drains, drain lines and reservoirs, internal transport equipment (e.g. forklifts, pallet jacks, trolleys, floor cleaners, etc.). In-house delivery and shuttle trucks should be included in sanitation schedules, have SSOPs and cleaning records. A surface cannot be properly sanitized unless it is effectively cleaned. Use of a sanitizer is required unless there are justified exceptions that are fully documented. Procedures should respect the label (e.g. rinse/no-rinse, sanitizers, dwell time, etc.) and match operations noted on the master sanitation schedule. These procedures

should include:

- Responsibility for cleaning with cleaning methods
- Item/area to be cleaned
- Frequency of cleaning
- Safety precautions (tag outs, personnel safety with respect to chemicals, etc.)
- Chemical (name, dilution and water temperature requirements) and utensils used.
- Specific preparation procedures regarding dilution (unless purchased as ready-to-use) for the specific chemicals or sanitizers being used and verification testing instructions and records (where appropriate)
- Detailed cleaning and sanitation methods, including solution temperature, water pressure, dwell times, any disassembly/reassembly instructions and cleaning verification procedures
- Following the standard order:
  1. Dry clean (note equipment used)
  2. Rinse (note equipment used)
  3. Clean (note equipment used
  4. Rinse (note equipment used)
  5. Sanitize (note equipment used and dwell time)
  6. Rinse (if label requires)
- Special instructions with respect to cleaning
- Responsible person
- Logs/records of cleaning and responsibility for verification
- Verification procedures (visual, ATP, microbial) and acceptance criteria

https://www.fsis.usda.gov/shared/PDF/RTE_Sanitation.pdf

Minor deficiency (7 points) if:

- Single/isolated instance(s) of errors and omissions within the SSOPs.
- Single/isolated instance(s) of omitted procedure(s) for a piece of equipment, internal transport vehicle or facility area.

Major deficiency (3 points) if:

- Numerous instances of errors and omissions within the SSOPs.
- Numerous instances of omitted procedures for a piece of equipment, internal transport vehicle or facility area.

Non-compliance (0 points) if:

- No written procedures have been developed.
- Procedures exist but they are not reflecting what actually occurs.

**2.5.2: Are cleaning and sanitation logs on file that show what was done, when and by who?**

Total compliance (10 points): The company has sanitation logs that cover all areas of the facility (e.g., production areas, storage areas, break areas, restrooms, maintenance, etc.), detailing walls, floors, overhead and all equipment (e.g., production equipment (food contact and non-food contact), pallet jacks, forklifts, carts, floor scrubbers, trash cans, cooling equipment, lift trucks, company owned trailers, etc.). The logs should be cross-checked against the master sanitation program. Logs of infrequent cleaning should be checked. Logs should include:

- Date
- List of areas/equipment that were cleaned and sanitized
- The individual accountable who signed-off for each task completed

- Verification of task completed
- Any deviations against the set SSOPs

Minor deficiency (7 points) if:

- Single/isolated instance(s) of incomplete records, discrepancies against the master sanitation schedule or other omissions.

Major deficiency (3 points) if:

- Numerous instances of incomplete records, discrepancies against the master sanitation schedule or other omissions.
- Missing infrequent cleaning logs.

Non-compliance (0 points) if:

- No sanitation logs.
- Sanitation logs exist but they are not reflecting what actually occurs.

**2.5.3: Where used, are there records showing cooling units are maintenance serviced and cleaned at least every 12 months or more frequently as required?**

Total compliance (10 points): Records should be available to verify that the cooling units are serviced and cleaned on a scheduled basis. Records might include in-house sanitation records, maintenance records and/or contractor records/invoices. Note contracts, invoices etc., must clearly state the services provided as per any other record. A cleaning and servicing at least once in the last 12 months is a minimum requirement, but usually frequency is higher, especially in high humidity and also with chiller units that are known to become dirty at a faster rate than others, e.g. next to open doors.

Minor Deficiency (7 points) if:

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

Major Deficiency (3 points)

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

Non-compliance (0 points)

- No records.
- Failure to maintain records.

**2.5.4: If fans or other blowing equipment are used, are they operated in a manner that minimizes the potential for contaminating product, equipment, or packaging materials?**

Total compliance (5 points): All fan guards (cooling units and general ventilation) in the facility are clean. There is no build-up of dust or other materials on the fan guards. Other blowing equipment (e.g. swamp coolers) are kept clean and properly maintained.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of unclean fans/blowing equipment and/or evidence of potential contamination to product or packaging.

Major deficiency (1 point) if:

- Numerous instances of unclean fans/blowing equipment and/or evidence of potential contamination to product or packaging.

Non-compliance (0 points) if:

- Fundamental failure to maintain clean fan guards and evidence of potential contamination to product or packaging.
- **There is a single gross incidence of evidence of unacceptable limits of spoilage or adulteration in raw materials, finished goods, or packaging. In this case the score reverts back to 2.5.9.**

**2.5.5: Is there a documented glass and brittle plastic management procedure (including company glass and brittle plastic policy, glass breakage procedure and where necessary a glass register)?**

Total compliance (10 points). There should be a written glass and brittle plastic policy and procedure, which should state:

- Where glass and brittle plastic is prohibited and where glass and brittle plastic is allowed.
- Policy should state how workers should report missing or broken spectacles or contact lenses and to whom they report the issue.
- If certain glass and brittle plastic items are allowed, then a glass register should exist describing each item, location and quantity. The glass register should only list items that could not be replaced with a less dangerous material. The glass register should not be abused by allowing glass items on site that are usually viewed as poor GMP e.g. allowing glass drinking bottles into production areas, unprotected glass light bulbs. Glass register items should be checked on a routine basis (at least monthly) to ensure they are not damaged/cracked etc. Checks should be documented.
- Glass breakage procedure including requiring recording what happened, recording what happens to potentially affected product, recording future preventative actions and especially where to record the incident details e.g. in the NUOCA log.
- Clean-up procedure after glass or brittle plastic breakage should indicate what equipment to use and include boot and tool checks/decontamination procedures to ensure broken glass or brittle plastic is not unintentionally transported out of the area.
- A no glass policy in production, storage or maintenance areas should be the target.

Minor deficiency (7 points) if:

- Policy lacks an element listed above.
- Single/isolated instance(s) where glass breakage details have not been recorded properly.
- Single/isolated instance(s) of glass register items not being checked on a routine basis.

Major deficiency (3 points) if:

- Policy lacks more than one element noted above.
- Numerous instances where glass breakage details are not being recorded properly
- Numerous instances of glass register items not being checked on a routine basis.

Non-compliance (0 points) if:

- No policy exists
- There has been a glass breakage, but no records exist.
- Fundamental failure to check glass register items on a routine basis.

**2.5.6: Has the operation eliminated or adequately controlled any potential metal, glass or brittle plastic contamination issues?**

Total compliance (10 points): No metal, glass or plastic issues noted (excluding issues noted under specific questions already noted within this audit). This question is designed to allow the auditor to underline potential foreign material contaminants to the auditee that are not covered by other more specific questions within the audit. Examples include: pins in sign boards within the facility, using "snappable" blades instead of one-piece blades, noting broken and brittle plastic issues on re-useable totes and finding uncontrolled glass items like coffee pots, computer screens, clock faces, eye glasses, office window glass, brittle plastic from any source, staples, etc. in production areas. Plastic coated shatterproof light bulbs are also acceptable without further protection. Auditors should take precaution not to bring glass items into the facility during inspections. If a glass or brittle plastic item cannot be replaced immediately or glass is necessary, e.g. a high-pressure gauge, then use of a glass register might be considered, ~~see question in 2.5.7.~~

Minor deficiency (7 points) if:

- Single/isolated instance(s) of potential foreign material contaminants observed.
- Single/isolated instance(s) of glass or brittle plastic item noted in the production/storage areas, but is not accounted for on the glass register.

Major deficiency (3 points) if:

- Numerous instances of potential foreign material contaminants observed.

- Numerous glass or brittle plastic items noted in the production/storage areas, but are not accounted for on the glass register.
- Single instance of a broken glass or brittle plastic item found within the facility.

Non-compliance (0 points) if:

- Widespread failure to control potential foreign objects on site.
- More than one instance of a broken glass or brittle plastic item found within the facility.
- **Any incident of direct product contamination with a foreign material like glass, metal or plastic constitutes a health hazard and is viewed as adulteration. Revert to Q 2.5.9.**

**2.5.7: Are all lights in the facility that could potentially contaminate raw materials (e.g. seeds, transplants, soil, media), product, equipment or packaging shielded, coated or otherwise shatter resistant to protect product from contamination in the event of a breakage?**

Total compliance (15 points): All glass lights in the facility that can potentially contaminate finished products, raw materials, equipment, or packaging should be shielded, coated or manufactured of shatter- resistant materials to protect from product contamination in the event of a breakage. This includes, but is not limited to items such as light bulbs, emergency lights, windows, truck loading lights (dock lamps), insect light trap lights, forklift lights, lights in bathrooms or maintenance shops that open into the production area, etc. End piece fittings on tube lights should be secure. Precautions should be taken to prevent glass contamination in the event of glass breakage. Windows and computer monitors in production areas should be covered with a plastic film to prevent shatter.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of unprotected glass in an area that could potentially contaminate finished product, raw materials, processing/packaging equipment, or packaging materials.
- Observed missing end piece tube light fittings.

Major deficiency (5 points) if:

- Numerous instances of unprotected glass in an area that could potentially contaminate finished product, raw materials, processing/packaging equipment, or packaging materials.
- Single instance of a broken light found within the facility.

Non-compliance (0 points) if:

- Majority of lights are not protected.
- More than one instance of broken lights found within the facility.

**2.5.8: Is the storage area fully enclosed?**

Total compliance (15 points): To protect the product and packaging materials from the elements and pests, it is necessary to keep the storage area enclosed and pest proof. Main doors should be kept closed unless in use. Food contact packaging should not be stored outside (including RPCs if used as primary packaging). Non-food contact packaging e.g. cardboard outers should be stored inside if possible. If some non-food contact packaging is stored outside, then this outside storage area should be included in the pest control program. Outside stored, non-food materials should be covered with a waterproof and dust proof shroud (often made of plastic material). Yards or dock areas where product passes through are exempt, as long as the product is being transferred and is not actually being stored. Auditor discretion applies.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of a door left open.
- Non-food contact packaging is stored outside, with shroud and storage area is included in the pest control program.

Major deficiency (3 points) if:

- Open areas in the ceiling/roof.
- Food contact packaging is stored outside (even if covered with shroud).
- Non-food contact packaging stored outside but not included in the pest control program and/or is not shrouded.
- Numerous instances of doors left open.

- Storage area is open on one to three sides.

Non-compliance (0 points) if:

- Products and ingredients are stored outside (even if shrouded)
- Storage area has roof but no walls.
- Food contact packaging items are stored outside, without shrouds.

**2.5.9: Are raw materials (e.g. seeds, transplants, soil, media), finished goods and food contact packaging within accepted tolerances for spoilage and free from adulteration? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Raw materials (e.g. seeds, transplants, soil, media), finished goods, food contact packaging and food contact surfaces should be free from spoilage, adulteration and/or gross contamination (21 CFR 110.3g). If legislation exists, then the contamination should be viewed against this legislation (e.g., USDA Grading Standards often include decay tolerances). Spoilage and adulteration would include any physical, chemical or biological contamination including blood and bodily fluids. Measures should be taken to prevent any known or reasonably foreseeable hazard (e.g., Clostridium botulinum in mushrooms). This question is designed to allow an auditor to halt an audit when finding gross contamination issues (note pests are covered by 2.3.2). Examples might include glass, trash/litter, motor oil in products, etc. Where an issue is observed by an operator in the normal process, auditor should observe the actions of the operator before scoring. Auditors should use their discretion and decide whether the frequency of the contamination warrants an automatic failure.

Examples include pieces of glass, one piece of rodent bait, paint on product or packaging, flakes of rust, etc. Is the issue systematic or a one-off issue?

CPG Sec. 555.425 Foods, Adulteration Involving hard or Sharp Foreign Objects,

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555425-foods- adulteration-involving-hard-or-sharp-foreign-objects

US FDA/CFSAN Defect Levels Handbook, The Food Defect Action Levels

http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ sanitationtransportation/ucm056174.htm

US EPA Water Quality Standards for Coastal and Great Lakes Recreation Waters

https://www.epa.gov/beach-tech/final-water-quality-standards-bacteria-rule-coastal-and-great-lakes- recreation-waters

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

Automatic Failure (0 points) if:

- Numerous incidences of spoilage or adulteration of product.
- There is a single gross incidence of evidence of unacceptable limits of spoilage or adulteration in raw materials, finished goods, or packaging.

**2.5.10: Does the process flow, facility layout, worker control, utensil control, internal vehicle use, etc. ensure that finished goods are not contaminated by raw materials (e.g., seeds, transplants, soil, media)?**

Total compliance (15 Points): Process flow of workers, raw materials (e.g. seeds, transplants, soil media), equipment, waste, etc., should be managed to ensure they are not a source of contamination to the growing area and/or finished goods. There should be plenty of space and separation to help avoid cross contamination issues. Workers who handle raw products should not then handle packaged products without first ensuring that they are free of raw material contaminants. This should include hand washing, glove change etc., but might also include changing into a new set of garments; ideally workers should be dedicated to handling raw or packaged goods, but not both within a shift. Utensils, cleaning implements, internal vehicles etc. should not be allowed to be vectors for cross contamination; ideally dedicated coded equipment should be provided for raw and processed goods. Failing this, there should be equipment sanitation steps between uses.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of worker/utensil/internal vehicle cross contamination.
- Minor process issues where packaged materials come into the same area as raw materials, but the two products do not touch in any way, i.e. no potential risk of cross contamination.
- Some potential space issues where the process flow is being forced to bring packaged and raw materials into close proximity.

Major deficiency (5 points) if:

- Numerous instances of worker/utensil cross contamination.
- Serious process flow issues where raw material can potentially cross contaminate packaged goods.
- Numerous space issues where the process flow is being forced to bring packaged and raw materials into close proximity.

Non-compliance (0 points) if:

- Systematic instances/issues with worker and/or utensil cross contamination.
- Process flow issues are observed to result in product raw/packaged goods cross contamination.

**2.5.11: Are all exposed materials (product, packaging, etc.) protected from overhead contamination (e.g. ladders, motors, condensation, lubricants, walkways, loose panels, degrading insulation, etc.)?**

Total compliance (15 points): Ceilings and/or any overhead fixtures above storage are free from condensation or dust. Ladders or walkways (catwalks) above exposed product or packaging material have kick plates at least 3.5 inches (8 cm) high and are covered in some way that protects the product underneath. Drips or condensate (e.g., from roof, fixtures, ducts, pipes, etc.) should not contaminate food, food contact surfaces or packaging material. Adequate measures should be in place to protect from condensate.

OSHA: CFR 29 Part 1910k(1)(iii) https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9721

Minor deficiency (10 points) if:

- Single/isolated instance(s) of possible overhead contamination.

Major deficiency (5 points) if:

- Numerous instances of possible overhead contamination

Non-compliance (0 points) if:

- No protective devices have been installed to eliminate potential contamination.
- **Any observation of direct contamination of raw materials, work in progress, finished product, or packaging materials. In this case the score reverts back to 2.5.9**

**2.5.12: Is there proper storage and adequate separation of raw materials (e.g. seeds, transplants, soil, media), products and packaging?**

Total compliance (15 points): All raw materials, products and packaging should be stored off the ground (i.e. on racks, pallets, shelves, etc.). Materials should be properly protected during storage to prevent contamination (e.g., away from chemicals, battery chargers, etc.). Raw materials, finished product and packaging materials should be stored in separate areas to prevent cross contamination. When separate room storage is not possible, the auditor should assess the risks, especially with respect to cross contamination. Raw materials should not be able to contaminate packaged items. Packaging storage, especially dust from cardboard storage should not contaminate produce items.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of products or packaging materials stored on the floor or not protected properly.
- Single instance of a pallet or boxes/bags of packaged product stored too close to raw product.

Major deficiency (5 points) if:

- Numerous instances of products or packaging materials not protected properly.
- Numerous instances of products or packaging materials stored directly on the ground.

- Isolated instances (no more than three) of raw product stored in the same room as packaged product where there is not adequate physical separation and demarcation within the room.

Non-compliance (0 points) if:

- Different food items being stored together in a way that poses a cross contamination risk.
- Widespread storage of product or packaging materials directly on the ground.
- Numerous instances of raw product and packaged product stored in the same room without adequate segregation.

**2.5.13: Are all growing areas clean and well maintained; especially lights, ducts, fans, floor areas by walls and equipment, and other hard to reach areas?**

Total compliance (10 points): All areas should be maintained in a clean and sanitary state. Auditors should check the ceilings, lights, corners, against walls and alongside equipment (look up, look down, look all around). Inside light covers should be clean, free of algae, insects and excessive dirt.

This question is designed to capture any hygiene issues that are not covered by specific issues noted in other questions. Auditors should carefully note which areas are dirty when down scoring in this question.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of floors, walls, ledges or other areas being unclean.
- Single/isolated instance(s) of dirty lights/light covers.

Major deficiency (3 points) if:

- Numerous instances of floors, walls, ledges or other areas being unclean.
- Numerous instances of dirty lights/light covers.

Non-compliance (0 points) if:

- Production areas very dirty – little or no evidence of cleaning occurring.
- Widespread failure to maintain lights/light covers in a clean condition.

**2.5.14: Are single service containers used for their intended purpose only so that potential cross contamination is prevented?**

Total compliance (5 points): Single service containers are used for their intended purpose only (food contact use, not to hold nuts, bolts, trash or other miscellaneous items) and should not be re-used. Returnable plastic containers (RPCs) (e.g., CHEP, IFCO) should be treated like single service container and only used for product. If a single service container is used for any other reason than the storage and distribution of food, it should be clearly differentiated as such (e.g., painted another color and labeled).

Minor deficiency (3 points) if:

- Single/isolated instance(s) of single service containers used for other than intended purpose.

Major deficiency (1 point) if:

- Numerous instance(s) of single service containers used for other than intended purpose.

Non-compliance (0 points) if:

- Widespread miss-use of single services containers used for other than intended purpose.

**2.5.15: Are re-usable containers cleanable and clearly designated for the specific purpose (finished product, trash, etc.) such that cross contamination is prevented?**

Total compliance (5 points): All re-usable containers should be able to be cleaned (smooth, non-porous, non-toxic) or used with a clean liner to protect against contamination. Cleaning type and frequency should be determined based on the products and processes involved. Bins, boxes, hoppers, barrels, baskets, etc. used for the storage of raw materials (e.g., seeds, transplants, soil, media), finished goods or packaging should be kept in a clean state. In-house re-usable containers should be identifiable (color- coded or labeled in the language understood by the workers) so that their designated purpose can be easily known. Returnable plastic containers (RPCs) (e.g., CHEP, IFCO) should be treated like single service

containers and only used for product (score in 2.5.14). If the trash container is the only re-used container on site and is a specific and unique design, so that it cannot be mistaken for another use, then it should not be down scored.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of a dirty re-usable container (there is no direct product contamination).
- Single/isolated instance(s) of re-usable containers made of inferior materials e.g. porous material construction, wood, non-food grade materials).
- Single/isolated instance(s) of a re-usable container not labeled or color-coded.

Major deficiency (1 point) if:

- Numerous instances of dirty re-usable containers (there is no direct product contamination).
- Numerous instances of re-usable containers made of inferior materials e.g. porous material construction, wood, non-food grade materials).
- Numerous instances of re-usable containers not properly labeled or color-coded.

Non-compliance (0 points) if:

- Condition and/or design of re-usable containers will not allow for effective cleaning under normal conditions.
- Re-usable containers are used for multiple purposes without the containers being labeled or color-coded.
- **Any observation of direct contamination of product, ingredients or packaging material – revert to 2.5.9, automatic failure.**

**2.5.16: Are all utensils, hoses, and other items not being used, stored clean and in a manner to prevent contamination?**

Total compliance (10 points): All utensils, hoses and other items not being used are stored clean, and in a manner to prevent contamination (off ground, dedicated areas, etc.). Hoses should be stored coiled, off the floor and ideally used in such a manner that ground contact is avoided.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of items not in use stored inappropriately. There is little potential hazard to product or packaging.

Major deficiency (3 points) if:

- Numerous instances of items not in use, stored inappropriately. There is little potential hazard to product or packaging.

Non-compliance (0 points) if:

- Any items not in use stored in a manner that may contaminate product or packaging.

**2.5.17: Do floor drains flow in a manner that prevents contamination (e.g., from high to low risk areas, from high risk directly to drain system), are they covered, appear clean, free from odors and are well maintained?**

Total compliance (5 points):

- All facility floor drains, including covers and internal channels are clean, and free of decayed/old material.
- Drains flow from high risk to low risk areas, from high risk directly to drain system.
- All facility floor drains are free of odors.
- There is no overflow or excessive standing water in the floor drains.
- Drains should have smooth walls and bases that allow free flow of water without catching debris, and also aid in the cleaning of the drains.
- Water from refrigeration drip pans is drained and disposed of away from product and product contact surfaces.

Where possible, auditor should request floor drain covers to be removed for inspection. Use a flashlight to illuminate the bottom of deep drains.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of a facility floor drain that is failing in one of the requirements listed above.

Major deficiency (1 point) if:

- Numerous instances of facility floor drains that are not maintained under acceptable sanitary conditions.
- Numerous instances of facility floor drains that are failing in one of the requirements listed above.

Non-compliance (0 points) if:

- Widespread failure to maintain the facility floor drains in a clean condition.

**2.5.18: Are internal transport vehicles (e.g., forklifts, bobcats, pallet jacks, carts, floor cleaners, etc.), clean, do not emit toxic fumes and are being used in a sanitary manner?**

Total compliance (5 points) if:

- Vehicles and equipment used for moving raw materials, packaged products, and packaging throughout and within the facility are clean, well maintained, and do not transport goods outside the facility (unless cleaned and sanitized before re-entering). Open dock areas are accepted as being within the facility in this instance.
- Internal transport vehicles (forklifts, bobcats (or similar type vehicle), pallet jacks, carts, floor cleaners, etc.) used to transport food are in a good state of repair, clean, odor free, free of rodents and insects.
- Internal transport vehicles (forklifts, bobcats (or similar type vehicle), pallet jacks, carts, floor cleaners, etc.) used in food areas should not be gasoline or diesel powered; propane (LPG) powered vehicles are permitted although electric powered are ideal. Trucks and forklifts should not be left idling in enclosed spaces or during loading or unloading of products to reduce health risk and possible tainting of foods.
- A sanitation program for internal transport vehicles is established to assure proper sanitation levels.
- Internal transport vehicles should not be mobile "break areas" i.e. food and drink should not be stored on the vehicles.
- Floor cleaners should be kept in good condition and cleaned in order to prevent cross contamination.

Where relevant, the brushes and fixtures on the floor cleaner might need to be changed or cleaned when moving from one risk area to another.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of finding the issues mentioned above.

Major deficiency (1 point) if:

- Numerous instances of finding the issues mentioned above.

Non-compliance (0 points) if:

- Widespread failure to maintain the transport vehicles in a clean and sanitary condition.
- Widespread use of gasoline or diesel-powered vehicles in food areas.
- Multiple instances of failure to maintain the transport vehicles in a sanitary condition that may lead to potential product contamination.
- The auditor should consider whether the issue is adulteration and should be applied to Q 2.5.9 and scored as an automatic failure.

## Inspection

**2.6.1: Is there documented evidence of the internal audits performed, detailing findings and corrective actions?**

Total compliance (15 points): There should be records of the internal audits performed at each operation, with the frequency defined in the internal audit program. Frequency depends on the type and size of the operation, but should be at least quarterly. The records should include the name/location of operation, date of the audit, name of the internal auditor, justification for the answers (not just checked √ or all Y/N), (not just checked √ or all Y/N), detail any deficiencies found and the corrective action(s) taken. An audit checklist (ideally Primus Standard Audits) should be used that covers all areas of the Primus Standard audit, including growing area, storage area, worker amenities, external areas, worker practices, documentation, etc. No down score if another audit checklist is used, as long as all areas are covered. Internal audit program requirement frequency details for 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.

Minor Deficiency (10 points) if:

- Single/isolated instance(s) of follow up/corrective actions not noted.
- Single/isolated instance(s) of incomplete answers or missing records.
- Single/isolated instance(s) of areas/issues missing on the inspection.

Major Deficiency (5 points) if:

- Numerous instances of follow up/corrective actions not noted.
- Numerous instances of incomplete answers 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 areas/issues missing on the inspection.

Non-compliance (0 points) if:

- Fundamental failure to maintain records.
- Fundamental failure to complete inspection records with detailed responses.
- No documented internal audits have been performed.

**2.6.2: Is there a daily inspection log, including but not limited to, checking worker hygiene, housekeeping of bathrooms, break area, growing area, and storage area?**

Total compliance (10 points): Operations are inspected daily. This should be a start-up check of all potential issues.

The daily inspection should include:

- General housekeeping of storage areas, growing areas, break areas and bathrooms.
- Checking personnel meet the hygiene requirements
- Corrective actions in case of non-compliance.

Minor Deficiency (7 points) if:

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

Major Deficiency (3 points) if:

- Numerous instances of omissions or incorrect data in the records.
- Persistent repetition of corrective action without long-term solution.

Non-compliance (0 points) if:

- No records.
- Failure to maintain records.

## Training

**2.7.1: Is there a food safety hygiene training program covering new and existing workers and are there records of these training events?**

Total compliance (15 points): There should be a formal training program to inform all workers (including planting and weeding crews) of the current policies and requirements of the company regarding hygiene. Trainings should be in the language understood by the workers, and training type and intensity should reflect the risks associated with the products/processes. Frequency should be at the start of the season before starting work,

and then some topics covered at least quarterly, but ideally monthly. Full annual food safety refresher training sessions are encouraged but do not replace the ongoing more frequent training. Training material covering the content of the company policies and requirements regarding food safety and hygiene and training should include the basic food safety and hygiene topics (e.g., toilet use, hand washing, protective clothing (where applicable), recognizing and reporting injury and illness, blood and other bodily fluids, jewelry, dropped product, animal intrusion, food consumption/taking breaks, foreign material requirements, food defense, etc.), the importance of recognizing and detecting food safety and/or hygiene issues with co-workers and visitors, and all food safety or hygiene issues for which they are responsible (e.g. recognizing contaminated produce that should not be harvested, inspecting harvest containers and equipment for contamination issues), correcting problems and reporting problems to a supervisor. Workers should also be trained on any new practices and/or procedures and when any new information on best practices becomes available. There should be records of training with date of training, clearly defined topic(s) covered, trainer(s), material(s) used/given and the names and signatures of workers trained.

Minor Deficiency (10 points) if:

- Single/isolated instance(s) of logs having errors or incomplete information e.g. missing one of the following: training topic, trainer or material information.
- Training has occurred but, on a few occasions, full attendance logs have not been kept and/or not all workers were covered.
- Training materials and/or company food safety policy are not in the relevant language(s).
- Training occurring, not before starting to work but within the first week.

Major Deficiency (5 points) if:

- Numerous instances of logs having errors or incomplete information e.g. missing one of the following: training topic, trainer or material information.
- Training has occurred but, on many occasions, full attendance logs have not been maintained.
- Some key topics e.g. hand washing, reporting injury/illness, blood and other bodily fluids, jewelry, dropped produce, animal intrusion, etc. have been omitted from the training.
- Only annual refresher training has occurred, and the operation runs for more than 3 months of the year.
- Training occurring, not before starting to work but within the first month.
- Numerous instances of workers not being trained.

Non-compliance (0 points) if:

- Failure to maintain records.
- No records of training or workers not being trained.
- More than three key topics e.g. hand washing, reporting injury/illness, blood and other bodily fluids, jewelry, dropped produce, animal intrusion, etc., have been omitted from the training program.
- No specific orientation given or given after the worker has been working for more than one month.

**2.7.2: Are there written and communicated procedures in place that require food handlers to report any cuts or grazes and/or if they are suffering any illnesses that might be a contamination risk to the products being produced, and return to work requirements? (In countries with health privacy/confidentiality laws, e.g. USA, auditors can check procedure/policy but not the actual records).**

Total compliance (10 points): There should be documented procedures that are communicated (e.g., worker signature on a training log) to food handlers, requiring them to report any cuts, grazes and/or any illnesses that might be a food safety cross contamination risk. The procedures should indicate return to work requirements for affected workers: to whom the food handlers should report, how the issue is recorded and appropriate actions to be taken for a particular issue. Auditors should not request to review records where countries have laws covering privacy/confidentiality of health records, and therefore a verbal confirmation should be gained.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of errors or omissions in procedure.
- Single/isolated instance(s) of evidence that workers are unaware of the procedure requirements

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the procedure.

- Numerous instances of workers being unaware of procedure requirements

Non-compliance (0 points) if:

- There is not a documented procedure in place.
- A procedure is in place, but it has not been communicated to food handlers.

**2.7.3: Are there worker food safety non-conformance records and associated corrective actions (including retraining records)?**

Total compliance (3 points): A worker non-conformance should be recorded when workers are found not following food safety requirements. The auditee should have a record for worker non-compliance, corrective actions and evidence that retraining has occurred (where relevant). Auditee records might be viewed as confidential, and therefore, a verbal confirmation should be gained. There might be a tier system, which includes re-training, verbal and written disciplinary actions and allowance for immediate termination for gross misconduct.

Minor Deficiency (2 points) if:

- Single/isolated instance(s) of follow up/corrective actions not noted.

Major Deficiency (1 point) if:

- Numerous instances of follow up/corrective actions not noted.

Non-compliance (0 points) if:

- No records or systematic failure to record follow up/corrective actions.

## Worker Hygiene

**2.8.1: Are toilet facilities adequate in number and location? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.**

Total compliance (15 points): Toilet facilities should be available to all workers and visitors, while work is actively occurring. Toilet facilities should not open directly into growing or storage areas. At least one toilet per 20 workers should be provided, or if more stringent, as per prevailing national/ local guidelines. Toilet facility placement should be within 1⁄4 mile or 5 minutes walking distance of where workers are located, or if more stringent, as per prevailing national/ local guidelines. A 5 minute drive is not acceptable, while farm work is actively occurring with groups of three or more workers. Where there are two or less workers present (e.g., spray activities, irrigation check) and workers have transportation that is immediately available to toilets within a 5 minute drive, it is acceptable to score as total compliance.

United States Department of Labor 1928 Title Field Sanitation https://www.osha.gov/laws-regs/regulations/standardnumber/1928/1928.110

Minor deficiency (10 points) if:

- The toilet facilities are not within 1⁄4 mile or 5 minutes walking distance for crews of three or more.
- The toilet facilities are not within a 5 minute driving distance for crews of two or less.
- Toilet facilities open directly into indoor growing or storage areas.

Major deficiency (5 points) if:

- The operation is not meeting the 1 toilet per 20 workers criteria.

**Automatic failure (0 points) if:**

- **There are insufficient or inadequate toilet facilities.**

**2.8.1a: Are toilet facilities in a suitable location to prevent contamination to product, packaging, equipment, and growing areas?**

Total compliance (15 points): Placement of toilet facilities should be in a suitable location to prevent contamination to product, packaging, equipment, water sources, and growing areas. Consideration should be given when portable units are used so that they are not situated too close to the edge of the crop. If pit toilets are used, consider proximity to crop and water sources.

Minor deficiency (10 points) if:

- Option for minor down score exists but at present, no known good examples exist.

Major deficiency (5 points) if:

- Toilet facilities pose a potential risk to product, packaging and equipment areas.

Non-compliance (0 points) if:

- Toilet facilities are located too close to the growing area or water source.

**2.8.1b: Are toilets designed and maintained to prevent contamination (e.g., free from leaks and cracks)?**

Total compliance (5 points): Toilets should be free from cracks and leaks and any waste holding tanks from toilets must be designed and maintained properly to prevent contamination. Waste holding tanks should be free of leaks, cracks and constructed of durable materials (e.g. plastic) that will not degrade or decompose (no wood). Note: pit toilets cannot be considered to be properly designed to prevent contamination.

Minor deficiency (3 points) if:

- Single observation of one of the catch basin(s) not designed or maintained improperly.

Major deficiency (1 point) if:

- More than one observation of the catch basin(s) designed or maintained improperly.

Non-compliance (0 points) if:

- Catch basin(s) poses a risk of contamination to the growing area, product, packaging, and equipment, such as observing leaks or being improperly constructed.

**2.8.1c: Are toilets constructed of materials that are easy to clean?**

Total compliance (3 points): Toilet facilities should be constructed of non-porous materials that are easy to clean and sanitize. The floors, walls, ceiling, partitions and doors should be made of a finish that can be easily cleaned. Each toilet should be maintained and ventilated to outside air, and the floor and sidewalls should be watertight.

Minor Deficiency (2 points) if:

- Single/isolated instance of toilets not being constructed of non-porous materials.
- Single/isolated instance of floor and sidewalls not being watertight.

Major Deficiency (1 point) if:

- Numerous instances of toilets not being constructed of non-porous materials.
- Numerous instances of floor and sidewalls not being watertight.

Non- compliance (0 points) if:

- Toilets are not constructed of non-porous materials.

**2.8.1d: Are the toilet materials constructed of a light color allowing easy evaluation of cleaning performance?**

Total compliance (3 points): Toilet materials should be constructed of materials light in color, allowing easy evaluation of cleaning performance.

Minor Deficiency (2 points) if:

- Single/isolated instance of toilets not being constructed of light materials.

Major Deficiency (1 point) if:

- Numerous instances of toilets not being constructed of light materials.

Non-compliance (0 points) if:

- Toilets are not constructed of light materials.

**2.8.1e: Are toilets supplied with toilet paper and is the toilet paper maintained properly (e.g., toilet paper rolls are not stored on the floor or in the urinals)?**

Total compliance (5 points): Toilet paper should be provided in a suitable holder in each toilet facility. Toilet paper should be maintained properly (e.g., toilet paper rolls are not stored on the floor, sink or in the urinals).

Minor Deficiency (3 points) if:

- Single/isolated instance of toilet paper rolls not being maintained properly (e.g., stored on the floor, sink or in the urinals).

Major Deficiency (1 point) if:

- Numerous instances of toilet paper rolls not being maintained properly (e.g., stored on the floor, sink or in the urinals).
- One of the toilet facilities is out of toilet paper and has not been restocked.

Non- compliance (0 points) if:

- There was no toilet paper available at the time of the audit.

**2.8.1f: Where used, is there a documented procedure for emptying the waste holding tanks in a hygienic manner and also in a way that prevents product, packaging, equipment, water systems and growing area contamination?**

Total compliance (5 points): If toilets have waste holding tanks, they should be emptied, pumped, and cleaned in a manner to avoid contamination to product, packaging, equipment, water systems and growing area(s). Equipment used in emptying/pumping must be in good working order. A documented procedure should exist and should include a response plan for major leaks or spills, as well as indicating where pumped waste is disposed of and requiring communication to the designated person(s) responsible for the food safety program regarding the actions taken when a major leak or spill occurred.

Minor Deficiency (3 points) if:

- Single/isolated instance(s) of incomplete or missing details in the procedure.

Major Deficiency (1 point) if:

- Numerous instances of incomplete or missing details in the procedure.

Non-compliance (0 points) if:

- There is no documented procedure.

**2.8.1g: Are the toilet facilities and hand washing stations clean, and are there records showing toilet cleaning, servicing and stocking is occurring regularly?**

Total compliance (10 points): Toilet facilities and hand washing stations should be cleaned and sanitized on a regular basis. Servicing records (either contracted or in-house) should be available for review showing toilet cleaning, servicing and stocking is occurring regularly. Soiled tissue should be flushed down the toilet/placed in the holding tank (not placed in trash cans and/or on the floor).

- Toilet facility (including hand washing stations) fixtures are in good operating condition and clean.
- Cleaning and sanitizing is occurring on a regular basis.
- No soiled toilet tissue either on the floor or in trash cans.
- Trash cans are available for hand wash paper towels.
- Hand washing stations are clean and not blocked.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of non-compliance to above requirements.
- Single/isolated instance(s) of soiled toilet tissues being placed in trash can.

Major deficiency (3 points) if:

- Numerous instances of non-compliance to the above requirements.
- Systematic observation of soiled toilet tissues being placed in trash cans.

Non-compliance (0 points) if:

- Failure to properly maintain areas.
- Single instance of soiled toilet tissues being left on the floor of the toilet facility.
- No cleaning and service records available.

**2.8.2: Is hand washing signage posted appropriately?**

Total compliance (5 points): Toilet facilities should have hand washing signs as a reminder to wash hands before and after eating, returning to work and after using the toilet. Signs need to be posted visibly and in the language of the workers (picture signs are allowed). The signs should be permanent and placed in key areas where workers can easily see them.

Minor deficiency (3 points) if:

- Single/isolated instance of signage not being permanent.
- Single/isolated instance of signage not being in the language of the workers.
- Single/isolated instance of signage not posted visibly.

Major deficiency (1 point) if:

- Numerous instances of signage not being permanent.
- Numerous instances of signage not being in the language of the workers.
- Numerous instances of signage not posted visibly.

Non-compliance (0 points) if:

- There is no signage.

**2.8.3: Are hand washing stations adequate in number and appropriately located? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.**

Total compliance (15 points): An adequate number of hand washing stations, in working order, should be provided to ensure efficient worker flow (1 per 20 people on site), and available to all workers and visitors while work is actively occurring. Hands free is an optimum system. Hand washing stations should be visible and located within close proximity of toilet facilities and 1/4 mile or 5 minutes walking distance of where workers are located.

United States Department of Labor 29 CFR 1910.141(c)(1)(i): Toilet Facilities

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790

Minor deficiency (10 points) if:

- Only about 75% of needed hand washing stations are present.

Major deficiency (5 points) if:

- Only about 50% of needed hand washing stations are present.

**Automatic failure (0 points) if:**

- **Hand washing stations are inadequate in both number and location (less than 25% of the needed hand washing stations are provided).**
- **There are no functioning hand wash stations.**

**2.8.3a: Are hand washing stations in working order (no leaks, free of clogged drains, etc.) and restricted to hand washing purposes only?**

Total compliance (15 points): Hand washing facilities should be used only for hand washing (no storage, food handling, etc.) and be maintained in good working order with proper drainage or designed to capture rinse water.

Minor Deficiency (10 points) if:

- Single/isolated instance of hand wash stations not draining properly.
- Single instance of hand washing station being used for another purpose.

Major Deficiency (5 point) if:

- Numerous instances of hand wash stations not draining properly.
- More than one instance of a hand washing station being used for another purpose.

Non-compliance (0 points) if:

- Systematic failure for hand wash stations to drain properly.
- Systematic failure for hand wash stations not containing a system to catch the rinse water.

**2.8.3b: Are hand wash stations clearly visible (e.g., situated outside the toilet facility) and easily accessible to workers?**

Total compliance (5 points): Hand wash stations should be clearly visible (i.e. situated outside the toilet facility) in order to verify hand washing activities, and easily accessible to workers.

Minor Deficiency (3 points) if:

- Single/isolated instance of a hand wash station located inside a toilet facility.

Major Deficiency (1 point) if:

- Numerous instances of hand wash stations located inside the toilet facilities.

Non-compliance (0 points) if:

- All hand wash stations are located inside the toilet facilities.

**2.8.3c: Are hand wash stations adequately stocked with unscented soap and paper towels?**

Total compliance (5 points): All hand washing facilities should be properly stocked with liquid unscented/non-perfumed, neutral or antiseptic soap. Single use paper towels should be used; hot air driers are acceptable if properly located (e.g. not located within production areas since they create aerosols).

Minor Deficiency (3 points) if:

- Single/isolated instance of a hand wash station out of soap and/or paper towels.
- Single/isolated instance(s) of soap with a lingering fragrance being used.

Major Deficiency (1 point) if:

- Numerous instances of hand wash stations out of soap and/or paper towels.
- Numerous instances or widespread use of soap with a lingering fragrance being used.

Non-compliance (0 points) if:

- There is no soap and/or paper towels available to workers.

**2.8.4: Are workers washing and sanitizing their hands before starting work each day, after using the restroom, after breaks, before putting on gloves and whenever hands may be contaminated?**

Total compliance (15 points): Worker conformance to hand washing and sanitizing procedures should be assessed, as washing hands is the first step in avoiding food contamination. Workers should be observed washing their hands prior to beginning work, after breaks, after using the toilet, before putting on gloves, and whenever hands may have become a source of contamination (e.g., after eating, after using a handkerchief or tissue, smoking, drinking, etc.).

Auditors are expected to view hand washing disciplines – in operations where hand washing stations are not visible, this means watching worker movements after breaks (are they using the toilet facility hand wash stations); are there signs of soap and paper towel use? Hand washing is a

critical part of the food suppliers' food safety program – this should be stressed to the auditee.

Potentially useful website:

A "Safe Hands" Hand Wash Program, https://www.cdc.gov/handwashing/index.html

Minor deficiency (10 points) if:

- Single/isolated instance(s) of a worker who is not complying with the hand washing policy.

Major deficiency (5 points) if:

- Numerous instances of workers that are not complying with the hand washing policy.

Non-compliance (0 points) if:

- Majority of or widespread failure of workers to comply with hand washing policies.

**2.8.5: Are secondary hand sanitation stations (e.g., touch-free dispensers) adequate in number and location, and are the stations properly maintained?**

Total compliance (5 points): Secondary hand sanitation is required for items that may be "ready-to-eat" (e.g., herbs, stone fruit, tomatoes, citrus, edible flowers, etc.). Secondary hand sanitation (hand dips, gels or sprays) does not replace hand washing requirements (lack surfactant qualities). Secondary hand sanitation stations should be unscented/non-perfumed, have 60% to 95% ethanol or isopropanol isopropanol (benzalkonium chloride is also acceptable) and conveniently located in traffic zones but should not be obstructive. Hand dips (if used) should contain a USDA approved food grade sanitizer at a determined concentration. Refer to hand sanitizer manufacturer label for dilutions. Hand dips should be regularly monitored (recorded anti-microbial strength checks) to ensure their effectiveness with corrective actions recorded (e.g. dip solution replenishment and anti-microbial additions). Hand gel and spray stations should be well stocked with a sanitizer approved for direct hand to food contact and regularly monitored (recorded checks) to ensure availability with corrective actions recorded (e.g. pack replenishment); use of a refill alert type dispenser is ideal practice. The auditor should check that gel pack type stations are stocked and have the auditee check the strength of anti-microbial chemicals in hand dips while touring the facility.

http://www.qualityassurancemag.com/qa0612-proper-hand-sanitation-practices.aspx

https://www.cdc.gov/handwashing/index.html https://nelsonjameson.com/learn/sanitation-maintenance/hand-hygiene/

https://www.fda.gov/food/guidanceregulation/retailfoodprotection/ industryandregulatoryassistanceandtrainingresources/ucm113827.htm

Minor deficiency (3 points) if:

- Single/isolated instance(s) of secondary hand sanitation stations not in place or being empty.
- Single/isolated instance(s) of hand dips containing under-strength solutions.
- Single/isolated instance of dispensers not properly located (e.g., too close to the growing area, not conveniently located).

Major deficiency (1 point) if:

- Numerous instances of secondary hand sanitation stations not in place or being empty.
- Numerous instances of hand dips containing under-strength solutions.
- Numerous instances of dispensers not properly located (e.g., too close to the growing area, not conveniently located).
- Use of hand gel or spray sanitizer that is not approved for direct hand to food contact (e.g., USDA approved or national equivalent).

Non-compliance (0 points) if:

- There are no secondary hand sanitation stations where needed or all are empty.
- All hand dips checked found containing under-strength solutions.

**2.8.6: Are foot baths, foamers or dry powdered sanitizing stations provided at entrances to growing areas (where appropriate), and are the stations maintained properly?**

Total compliance (3 points): Foot (boot) stations (foot dip mats, baths, sprays) should be located in areas when crossing into a "clean" zone from an area of potential contamination (e.g., from outside into the growing area, from growing areas into storage areas, from bathrooms into growing areas, etc.) for some crops (e.g., mushrooms, aeroponics). Foot dips should contain a food grade sanitizer at a determined concentration. Refer to

sanitizer manufacturer label for dilutions. Foot dips should be regularly monitored for volume and concentration (recorded anti-microbial strength checks) and the dip solution regularly changed to ensure their effectiveness with corrective actions recorded (e.g. dip solution replenishment and anti-microbial additions). Dry products should be EPA registered and applied as per the label instructions (label dosage directions should be followed for EPA registered floor sanitizers) and regular renewal should be monitored. The auditor should have the auditee check the strength of anti-microbial chemicals while touring the facility. This question should be scored based on auditor discretion, considering the risk of the products/ processes. N/A where there are no foot baths, foamers or dry powdered sanitizing stations when it is not a requirement for the operation.

http://www.foodsafetymagazine.com/magazine-archive1/december-2004january-2005/the-dos-and-donts- of-food-plant-personal-hygiene-practices/

http://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2011/sanitizers-and- disinfectants-the-chemicals-of-prevention/

http://www.foodqualityandsafety.com/article/dry-floor-products-wont-slip-up/2/

21 CFR 178.1010: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=178.1010

Minor deficiency (2 points) if:

- Single/isolated instance(s) of foot dips not in place.
- Single/isolated instance(s) of the under-strength foot dips or volume not maintained.
- Single/isolated instance(s) of the workers not using the foot dips.

Major deficiency (1 point) if:

- Numerous instances of foot dips not in place.
- Numerous instances of the under-strength foot dips or volume not maintained.
- Numerous instance(s) of the workers not using the foot dip.

Non-compliance (0 points) if:

- No foot dip stations where needed.
- All foot dips checked being found to contain under strength solutions or volume not maintained.
- All workers avoiding using the foot dips.

### 2.8.7: Are workers' fingernails clean, short and free of nail polish?

Total compliance (5 points): Fingernails can harbor dirt and debris and can be a source of cross contamination. Therefore, nails should be clean and short to reduce the risk of cross contamination. Fingernail polish and false nails should not be worn, even when gloves are worn. Use of fingernail brushes might assist in nail cleaning, however care should be taken to ensure that these brushes are kept clean and regularly replaced or they might they become a cross contamination vector.

Potentially useful website:

Food Code (section 2-302.11) https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ UCM374510.pdf

Minor deficiency (3 points) if:

- Single/isolated instance(s) of dirty and/or long fingernails.
- Single/isolated instance(s) of fingernail polish being worn.
- Single/isolated instance(s) of false fingernails being worn.

Major deficiency (1 point) if:

- Numerous instances of dirty and/or long fingernails.
- Numerous instances of fingernail polish being worn.
- Numerous instances of false fingernails being worn.

Non-compliance (0 points) if:

- Widespread failure to ensure that fingernails are short and clean.

- Widespread failure to ensure that fingernail polish and/or false fingernails are not worn.

**2.8.8: Are workers who are working directly or indirectly with food, free from signs of boils, sores, open wounds and are not exhibiting signs of foodborne illness?**

Total compliance (10 points): Workers who have exposed boils, sores, exposed infected wounds, foodborne illness or any other source of abnormal microbial contamination should not be allowed to work in contact with the product, packaging or food contact surfaces. Workers should be requested to notify their supervisors if they have any concerning symptoms. All bandages should be covered with a non- porous covering such as non-latex or vinyl gloves.

Minor deficiency (7 points) if:

- (There is no minor deficiency for this question).

Major deficiency (3 points) if:

- (There is no major deficiency for this question).

Non-compliance (0 points) if:

- One or more workers are observed working in contact with food, food contact surfaces or packaging that has or have exposed boils, sores, infected wounds, showing signs of food borne illness or any other source of abnormal microbial contamination that is a hazard.

**2.8.9: Is jewelry confined to a plain wedding band and watches are not worn?**

Total compliance (5 points): Workers are not observed wearing jewelry (including earrings, ear gauges, necklaces, bracelets, rings with stones, rings or studs in nose, lip and eyebrow, watches) in the growing area. Plain wedding bands are the only exception. Other examples of foreign items that may be a source of foreign material contamination include studs, false eye lashes, eye lash extensions, etc.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of a worker observed wearing jewelry or watches or any other personal item that may be a foreign contaminant.

Major deficiency (1 point) if:

- Numerous instances of workers observed wearing jewelry or watches or any other personal item that may be a foreign contaminant.

Non-compliance (0 points) if:

- Majority of workers wearing jewelry or watches or any other personal item that may be a foreign contaminant i.e. jewelry policy does not exist and/or jewelry policy exists but is not being implemented.

**2.8.10: Are all items removed from garment (shirt, blouse, etc.) top pockets, and unsecured items are not worn (e.g., pens, glasses on top of head, Bluetooth devices, etc.)?**

Total compliance (3 points): There should be no items stored in workers' shirt, blouse and smock top pockets. Ideally, top pockets are sewn up or non-existent. Remember to also check maintenance workers in the production area. Special exception allowed for security identification tags, as long as they are securely fastened to the person and/or below the waist.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of items observed in shirt, blouse or smock top pocket.

Major deficiency (1 point) if:

- Numerous instances of items observed in shirt, blouse or smock top pockets.

Non-compliance (0 points) if:

- Widespread use of shirts, blouse or smock top pockets.

**2.8.11: Are all workers wearing protective outer garments suitable for the operation (e.g. appropriate clean clothes, smocks, aprons, sleeves and non-latex gloves)?**

Total compliance (5 points): If the operation has taken a decision to establish an outer garment policy based on risks this should consider the following: customer requirements, national and local legal requirements, potential cross contamination and foreign material risks, etc. Suitable clothing is required for workers handling products that are potentially ready-to-eat (e.g., tomatoes, leafy greens, etc.). Provided items should be laundered in-house or by contract laundering agency. Individual workers should not take garments home for cleaning. Where items are laundered in-house the auditee should have documented SOP and GMP rules about how these garments are cleaned. Glove policy should be clear to workers – auditors will establish policy before making scoring decisions and note this policy for the audit report. Gloves are not allowed to replace hand-washing requirements. Gloves should be changed after break periods, using toilet facilities, any activity other than handling of food items or when gloves are soiled, torn or otherwise contaminated. If re-useable gloves are used, then they should be made of material that can be readily cleaned and sanitized, clean gloves should be issued at least daily and as needed throughout the day and stored properly in-between uses. Gloves should not be taken home for cleaning. Where gloves are used they should be non-latex (e.g. vinyl, nitrile, etc.), intact and appropriate for purpose. This includes gloves in first-aid kits.

Where dedicated protective clothing is not required/worn, it must be clear that outer street clothes are clean and not a potential source of contamination. Workers should not wear personal clothes with sequins, pom-poms, fur, etc. No sleeveless tops without an over garment.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of outer garments or gloves being taken home.
- Single/isolated instance(s) of gloves not being replaced when contaminated.
- Single/isolated instance(s) of protective garments not being worn where required.
- Single/isolated instance(s) of outer clothing not clean or being a potential source of contamination.

Major deficiency (1 point) if:

- Numerous instances of outer garments or gloves being taken home.
- Numerous instances of gloves not being replaced when contaminated.
- Numerous instances of protective garments not being worn where required.
- Numerous instance(s) of outer clothing not clean or being a potential source of contamination.

Non-compliance (0 points) if: (one of the following is found)

- An outer garment policy is not established.
- Widespread failure to replace gloves when contaminated.
- Widespread failure to wear protective garments where required.
- Widespread failure to wear clean outer clothing or of clothing being a potential source of contamination.
- Widespread non-compliance to the above and/or company policy.

**2.8.11a: Do workers remove protective outer garments (e.g., smocks, aprons, sleeves, and gloves) when on break, before using the toilets and when going home at the end of their shift?**

Total compliance (5 points): When worn, protective clothing (e.g., aprons, smocks, sleeves and gloves) are to be removed when workers leave the work area (e.g., when they go to the toilet facility, lunchroom, outside, smoking breaks, etc.). Workers cannot smoke, eat, go outside the building or use the restroom while wearing these garments.

Minor deficiency (3 points) if:

- Single/isolated instance(s) are observed of non-compliance to the above

Major deficiency (1 point) if:

- Numerous instances are observed of non-compliance to the above

Non-compliance (0 points) if:

- Widespread non-compliance to the above

**2.8.11b: Is there a designated area for workers to leave protective outer garments (e.g., smocks, aprons, sleeves, and gloves) when on break and before using the toilets?**

Total compliance (5 points): There should be a designated area for workers to leave protective clothing when they are worn (e.g., aprons, smocks, sleeves and gloves). Workers are observed using the designated area when they leave the work area (e.g., when they go to the toilet facility, lunchroom, outside, etc.). Workers should not leave protective outer garments on floors, work tables, equipment or packaging materials. Designated area should not be within the toilet facilities, inside the break room, next to worker clothing or any other area that might be a risk to the outer garments. Garments should not be left touching product, packaging or food contact surfaces.

Minor deficiency (3 points) if:

- Single/isolated instance(s) are observed of non-compliance to the above

Major deficiency (1 point) if:

- Numerous instances are observed of non-compliance to the above

Non-compliance (0 points) if:

- There is not a designated area for workers to leave aprons, sleeves and gloves when on a break.
- There is a designated area; however, no workers use this area.
- Any of the items are observed being placed on the floor.
- Widespread non-compliance to the above.

**2.8.12: Are worker personal items being stored appropriately (i.e. not in the growing areas or material storage areas)?**

Total compliance (5 points): Workers should have a designated area for storing personal items such as coats, shoes, purses, medication, phones, etc. Areas set aside for workers' personal items should be far enough away from growing area(s) and material storage area(s) to prevent contamination and avoid food security risks. Lockers or cubbies are ideal if maintained properly, mounted off the floor and with sloping tops and located outside growing and storage areas. Wire, see-through lockers are ideal.

Minor deficiency (3 points) if:

- Single or isolated instance(s) of personal belongings, personal food, etc. being found in growing or storage areas.

Major deficiency (1 point) if:

- Numerous instances of personal belongings, personal food, etc. being found in growing or storage areas.

Non-compliance (0 points) if:

- Widespread failure to prevent personal belongings, personal food, etc. being taken into the growing area.

**2.8.13: Is smoking, eating, chewing and drinking confined to designated areas, and spitting is prohibited in all areas?**

Total compliance (5 points): Smoking, chewing tobacco, chewing gum, drinking and eating is permitted in designated areas that are away from growing and storage areas. Spitting should be prohibited in all areas. Smoking should not be permitted in eating and drinking areas. Drinking is not permitted near the growing area. Check work areas refuse containers and look in out of sight areas. If food consumption areas are designated within production offices or maintenance areas then the control of cross contamination, GAPs and access to hand washing facilities should be considered.

21 CFR Part 110.10 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=110.10

29 CFR Part 1910.41 http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790

Minor deficiency (3 points) if:

- Single/isolated instance(s) are observed of non-compliance to the above (includes evidence of smoking, eating, spitting, chewing gum, improper storage of break time food or drinking containers in interior refuse containers).
- Single/isolated instance(s) of designated area not meeting appropriate GMP standards.

Major deficiency (1 point) if:

- Numerous instances are observed of non-compliance to the above (includes evidence of smoking, eating, spitting, chewing gum, improper

storage of break time food or drinking containers in interior refuse containers).

- No designated smoking area (unless the site has a non-smoking policy).
- Numerous instances of designated area not meeting appropriate GMP standards.

Non-compliance (0 points) if:

- Widespread consumption of food and beverages outside of designated areas.
- No temperature control storage of break time food.
- Widespread evidence of smoking outside the designated area.
- Widespread evidence of using chewing tobacco in growing and storage areas.
- Designated area lacks access to a hand wash station.
- Widespread non-compliance to the above criteria.

**2.8.14: Is fresh potable drinking water readily accessible to workers?**

Total compliance (10 points): Fresh potable water meeting the quality standards for drinking water should be provided and placed in locations readily accessible to all workers on-site following local and national laws. Portable drinking water dispensers should be designed, constructed and maintained in a sanitary condition, capable of being closed, and equipped with a tap. The term "potable" meaning that the water is of drinking water quality (e.g., the EPA Drinking Water Standard or equivalent). Auditors should verbally verify the source of the water at the time of the audit. If there is evidence (i.e. visual observation or documentation) the water is coming from a questionable source, the auditor should review water quality test results.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of an unclean water container being used.

Major deficiency (3 points) if:

- Numerous instances of an unclean water containers being used.

Non-compliance (0 points) if:

- There is no water provided.
- The water provided is not potable.

**2.8.14a: Are single use cups provided (unless a drinking fountain is used) and made available near the drinking water?**

Total compliance (5 points): Single use cups should be provided so that cross contamination issues are avoided from person to person. Examples include single-use paper cups, drinking fountains, etc. Common drinking cups and other common utensils are prohibited.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of single-use cups missing from one of the water containers.

Major deficiency (1 point) if:

- Numerous instances of single-use cups missing from the water containers.
- A drinking fountain is being used, but is not in a sanitary condition.

Non-compliance (0 points) if:

- Single-use cups are not provided for the water containers.

**2.8.15: Are first aid kits adequately stocked and readily available?**

Total compliance (5 points): First aid kit(s) should be adequately supplied to reflect the kinds of injuries that occur (including any chemicals stored on-site) and should be stored in an area where they are readily available for emergency access. Date-coded materials should be within dates of expiration. Bandages used should ideally be waterproof and blue in color for easy visual detection. Gloves should be worn over all band aids on

hands. Auditors should verify by checking the first-aid kit(s).

Minor deficiency (3 points) if:

- Single/isolated instance(s) of first aid kit(s) not having adequate supplies, supplies out-of-date or kit not readily accessible.

Major deficiency (1 point) if:

- Numerous instances of first aid kit(s) not having adequate supplies, supplies out-of-date or kit not readily accessible.

Non-compliance (0 points) if:

- Widespread failure to provide first aid kit(s) with adequate supplies, supplies out-of-date or kit not readily accessible.

**2.8.16: Are there adequate trash cans placed in suitable locations?**

Total compliance (5 points): There should be adequate measures for trash disposal so that the growing and storage areas are not contaminated. Containers (e.g. dumpsters, cans) should be available and placed in suitable locations for the disposal of waste and trash, e.g., near toilets. N/A option available if there is no work taking place at the time of the audit.

Minor deficiency (3 points) if:

- Single/isolated instance of containers not being maintained.

Major deficiency (1 point) if:

- Numerous instances of containers not being maintained.

Non-compliance (0 points) if:

- Systematic failure to maintain containers to protect against potential contamination of the crop.

## Agronomic Inputs

**2.9.1: Is human sewage sludge (biosolids) used in the growing cycle?**

Total points 0: Information gathering question. Human sewage sludge (biosolids), which are by-products of wastewater treatment, should not be used in the growing cycle for indoor growing operations, and also where specifically prohibited under best management practices (e.g., LGMA, T-GAPs). https://toxics.usgs.gov/regional/emc/municipal_biosolids.html

**2.9.1a: Is fertilizer being used where the country regulations/guidelines ban the use of such materials (e.g., Californian Leafy Green Commodity Specific Guidelines)? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Only fertilizer approved for that specific crop should be used. Some commodity specific guidelines have rules regarding the use of specific fertilizer types, e.g. Californian Leafy Green Commodity Specific Guidelines bans the use of biosolids and untreated animal manure.

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There is a single incidence of fertilizer being used where the country regulations/guidelines ban their use.**

**2.9.1b: Are there fertilizer use records available for each growing area, including application records?**

Total compliance (15 points): Records should be legible and at least detail the date of application, type of fertilizer, amount, method of application (drip, bulk, etc.), where it was applied and operator name. There should be sufficient identification information in the records that would make it possible to trace an application back to the site if needed. There should be an interval between application and harvest of at least 45 days for non-synthetic crop treatments and compost, and an interval of at least 120 days (but ideally 9 months) for untreated animal manure. A shorter interval is possible if the fertilizer has been through a physical/chemical/biological process to inactivate human pathogens and the auditee has

validation study documentation that shows that the material is safe. Validation studies must be applicable to the situation at hand and care should be taken not to over extrapolate. There should be confirmation that monitoring records of the validation study's key requirements are being kept and that these monitoring records are being verified. The applications should be incorporated into the soil prior to planting or bud burst for tree crops.

Minor deficiency (10 points) if:

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

Major deficiency (5 points) if:

- Numerous instances of errors or omissions in the records.

Non-compliance (0 points) if:

- Fundamental failure to maintain records.
- No records are available.
- The interval between application and harvest is not being respected, and there is no validation study to verify application timelines.
- **Any incident of direct product contamination constitutes as a health hazard and is viewed as adulteration. Revert to Q 2.5.9.**

**2.9.1c: Are there Certificate(s) of Analysis (CoA), specifications, product label or other documents available for review provided by the supplier stating the components of the material?**

Total compliance (10 points): Certificate(s) of Analysis (CoA), letters of guarantee or other formal documentation from the fertilizer manufacturer(s) or supplier(s) should be current and state any inert or active ingredient substances used as "fillers" (e.g., clay pellets, granular limestone). Concerns are for heavy metals that may affect human health (e.g. Arsenic (As), Cadmium (Cd), Chromium (Cr), Copper (Cu), Lead (Pb), Mercury (Hg), Molybdenum (Mo), Nickel (Ni), Selenium (Se), Zinc (Zn). There should be sufficient identification information that would make it possible to trace back to the source if needed, therefore, only approved suppliers should be used limited to those firms demonstrating consistent compliance with prevailing national/local standards and guidelines.

https://apps1.cdfa.ca.gov/fertilizerproducts/

http://library.state.or.us/repository/2007/200701251422434/index.pdf

https://agr.wa.gov/pestfert/fertilizers/productdatabase.aspx

https://cms.agr.wa.gov/WSDAKentico/Documents/Pubs/707-382HeavyMetalsTestRequirements.pdf?/707- 382HeavyMetalsTestRequirements

Minor deficiency (7 points) if:

- Documentation is available, but there is no reference to the inert material that is used.

Major deficiency (3 points) if:

- The documentation demonstrates that heavy metals that can affect human health are used as fillers without specific concentration information indicating standards.

Non-compliance (0 points) if:

- There is no documentation available detailing the components of the material.
- Documentation is provided, but is not in sufficient detail to be able to trace back to the source.

**2.9.1d: Are there Certificate(s) of Analysis (CoA) from the supplier(s) that cover pathogen testing (plus any other legally/best practice required testing) and does the grower have relevant letters of guarantee regarding supplier SOPs and logs?**

Total compliance (15 points): Certificates of analysis should be available for each lot (containing animal materials) used. As a minimum, microbial testing should include Salmonella spp., Listeria monocytogenes and E. coli O157:H7 for non-synthetic crop treatments (e.g., compost teas, fish emulsions, fish meal, blood meal, "bio fertilizers") and for animal-based compost, using approved sampling and testing methods (e.g., AOAC and an accredited laboratory). Where legally allowed, a reduced sampling rate is possible if the material is produced by the auditee (e.g. mushroom growing operations with in-house compost production) and has been through a physical/chemical/biological process to inactivate human pathogens and the auditee has validation study documentation that shows that the material is safe and proper process control records (e.g., time/temperature records and calibration records, such as, temperature probe) are maintained and available during the audit. Validation studies must be applicable to the situation at hand and care should be taken not to over extrapolate. All local and national legislation should also be followed. The

grower should have proof that compost suppliers have cross contamination SOPs and temperature/turning logs (scored under 3.6.4).

Sampling Plan Options below may be used to determine the definition of a lot. There should be an indication from the supplier/producer of how lots are determined (i.e. from the information here or from another method). The sampling plans below are taken from current regulations in the state of California (related to bio-solids) and recognized manure-based compost guidelines included under the Leafy Greens Marketing Agreement.

**Option 1**
**Amount of Biosolids Compost Feedstock**

| Metric Tons per 365-day Period | Frequency |
|---|---|
| Greater than zero but annually fewer than 290 | Annually |
| Equal to or greater than 290 but fewer than 1,500 | Quarterly |
| Equal to or greater than 1,500 but fewer than 15,000 | Bimonthly (Every 2 months) |
| Equal to or greater than 15,000 | Monthly |
| Source: State of California Regulations: Title 14, Natural Resources--Division 7, CIWMB Chapter 3.1. Composting Operations Regulatory Requirements | |

**Option 2**

| |
|---|
| Testing Frequency: Each lot (post Phase II, before use with mushroom production). A lot is defined as a unit of production equal to or less than 5,000 cubic yards (3,823 cubic meters) |
| Source: Adapted from Composted Soil Amendments (containing animal manure or animal products included in the LGMA Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens". |
| Rationale: A "lot" of compost may vary depending upon the process implemented. The objective of the audit scheme is to provide a means of verifying the heat treatments systems applied to compost has been effective. |

Refer to 21 CFR Part 112 Subpart F- Biological Soil Amendments of Animal Origin and Human Waste,for details on treatment processes and microbial testing standards.

California state regulations for compost (CCR Title 14 - Chapter 3.1 - Article 7; https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations? guid=I558133D9B36C4A57972EBCA0C0EDFF38&originationContext=documenttoc&transitionType=Defa ult&context-Data=(sc.Default)

NOP 5021 Guidance Compost and Vermicompost in Organic Crop Production;

https://www.ams.usda.gov/sites/default/files/media/5021.pdf

Minor deficiency (10 points) if:

- Single/isolated instance(s) of a missing test on an individual lot used.

Major deficiency (5 points) if:

- Numerous instances of missing tests on an individual lot used.
- Single/isolated instance(s) of the same missing test from multiple lots used.

Non-compliance (0 points) if:

- There are no CoAs for the material being used.
- Fundamental failure to provide evidence for required tests performed on the lots used.

**2.9.1e: Are there Certificate(s) of Analysis (CoA), letters of guarantee or other documents from the supplier(s) that cover heavy metal testing?**

Total compliance (10 points): Certificate(s) of Analysis (CoA), letters of guarantee or some other documents from the supplier(s) that covers heavy metal testing should be available. Concerns are for heavy metals that may affect human health (e.g. Arsenic (As), Cadmium (Cd), Chromium (Cr), Copper (Cu), Lead (Pb), Mercury (Hg), Molybdenum (Mo), Nickel (Ni), Selenium (Se), Zinc (Zn). See Table 2-1 Ceiling Concentrations for Pollutants, EPA Guide to 40 CFR Part 503 Rule. All local and national legislation should also be followed.

https://www.epa.gov/sites/production/files/2018-12/documents/plain-english-guide-part503-biosolids- rule.pdf

https://www.govinfo.gov/content/pkg/CFR-2018-title40-vol32/xml/CFR-2018-title40-vol32- part503.xml#seqnum503.13

Minor deficiency (7 points) if:

- Single/isolated instance(s) of a missing test on an individual lot used.

Major deficiency (3 points) if:

- Numerous instances of missing tests on an individual lot used.
- Single/isolated instance(s) of the same missing test from multiple lots used.

Non-compliance (0 points) if:

- There are no CoAs or other documentation available for the material being used.
- Fundamental failure to provide evidence for required tests performed on the lots used.

**2.9.2: Is compost produced from animal derived materials used by the grower?**

Total points 0: Information gathering question. This question is specifically targeting compost produced from raw animal manures, as opposed to green waste.

**2.9.2a: Is fertilizer being used where the country regulations/guidelines ban the use of such materials (e.g., Californian Leafy Green Commodity Specific Guidelines)? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Only fertilizer approved for that specific crop should be used. Some commodity specific guidelines have rules regarding the use of specific fertilizer types, e.g. Californian Leafy Green Commodity Specific Guidelines bans the use of biosolids and untreated animal manure.

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There is a single incidence of fertilizer being used where the country regulations/guidelines ban their use.**

**2.9.2b: Are there fertilizer use records available for each growing area, including application records?**

Total compliance (15 points): Records should be legible and at least detail the date of application, type of fertilizer, amount, method of application (drip, bulk, etc.), where it was applied and operator name. There should be sufficient identification information in the records that would make it possible to trace an application back to the site if needed. There should be an interval between application and harvest of at least 45 days for non-synthetic crop treatments and compost, and an interval of at least 120 days (but ideally 9 months) for untreated animal manure. A shorter

interval is possible if the fertilizer has been through a physical/chemical/biological process to inactivate human pathogens and the auditee has validation study documentation that shows that the material is safe. Validation studies must be applicable to the situation at hand and care should be taken not to over extrapolate. There should be confirmation that monitoring records of the validation study's key requirements are being kept and that these monitoring records are being verified. The applications should be incorporated into the soil prior to planting or bud burst for tree crops.

Minor deficiency (10 points) if:

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

Major deficiency (5 points) if:

- Numerous instances of errors or omissions in the records.

Non-compliance (0 points) if:

- Fundamental failure to maintain records.
- No records are available.
- The interval between application and harvest is not being respected, and there is no validation study to verify application timelines.
- **Any incident of direct product contamination constitutes as a health hazard and is viewed as adulteration. Revert to Q 2.5.9.**

**2.9.2c: Are there Certificate(s) of Analysis (CoA), specifications, product label or other documents available for review provided by the supplier stating the components of the material?**

Total compliance (10 points): Certificate(s) of Analysis (CoA), letters of guarantee or other formal documentation from the fertilizer manufacturer(s) or supplier(s) should be current and state any inert or active ingredient substances used as "fillers" (e.g. Arsenic (As), Cadmium (Cd), Chromium (Cr), Copper (Cu), Lead (Pb), Mercury (Hg), Molybdenum (Mo), Nickel (Ni), Selenium (Se), Zinc (Zn). See Table 2-1 Ceiling Concentrations for Pollutants, EPA Guide to 40 CFR Part 503 Rule. There should be sufficient identification information that would make it possible to trace back to the source if needed, therefore, only approved suppliers should be used limited to those firms demonstrating consistent compliance with prevailing national/local standards and guidelines.

https://apps1.cdfa.ca.gov/fertilizerproducts/

http://library.state.or.us/repository/2007/200701251422434/index.pdf

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https://cms.agr.wa.gov/WSDAKentico/Documents/Pubs/707-382HeavyMetalsTestRequirements.pdf?/707- 382HeavyMetalsTestRequirements

Minor deficiency (7 points) if:

- Documentation is available, but there is no reference to the inert material that is used.

Major deficiency (3 points) if:

- The documentation demonstrates that heavy metals that can affect human health are used as fillers without specific concentration information indicating standards.

Non-compliance (0 points) if:

- There is no documentation available detailing the components of the material.
- Documentation is provided, but is not in sufficient detail to be able to trace back to the source.

**2.9.2d: Are there Certificate(s) of Analysis (CoA) from the supplier(s) that cover pathogen testing (plus any other legally/best practice required testing) and does the grower have relevant letters of guarantee regarding supplier SOPs and logs?**

Total compliance (15 points): Certificates of analysis should be available for each lot (containing animal materials) used. As a minimum, microbial testing should include Salmonella spp., Listeria monocytogenes and E. coli O157:H7 for non-synthetic crop treatments (e.g., compost teas, fish emulsions, fish meal, blood meal, "bio fertilizers") and for animal-based compost, using approved sampling and testing methods (e.g., AOAC and an accredited laboratory). Where legally allowed, a reduced sampling rate is possible if the material is produced by the auditee (e.g. mushroom growing operations with in-house compost production) and has been through a physical/chemical/biological process to inactivate human pathogens and the auditee has validation study documentation that shows that the material is safe and proper process control records (e.g., time/temperature records and calibration records, such as, temperature probe) are maintained and available during the audit. Validation studies must be

applicable to the situation at hand and care should be taken not to over extrapolate. All local and national legislation should also be followed. The grower should have proof that compost suppliers have cross contamination SOPs and temperature/turning logs (scored under 3.6.4).

Sampling Plan Options below may be used to determine the definition of a lot. There should be an indication from the supplier/producer of how lots are determined (i.e. from the information here or from another method). The sampling plans below are taken from current regulations in the state of California (related to bio-solids) and recognized manure-based compost guidelines included under the Leafy Greens Marketing Agreement.

**Option 1**
**Amount of Biosolids Compost Feedstock**

| Metric Tons per 365-day Period | Frequency |
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| Equal to or greater than 290 but fewer than 1,500 | Quarterly |
| Equal to or greater than 1,500 but fewer than 15,000 | Bimonthly (Every 2 months) |
| Equal to or greater than 15,000 | Monthly |
| Source: State of California Regulations: Title 14, Natural Resources--Division 7, CIWMB Chapter 3.1. Composting Operations Regulatory Requirements | |

**Option 2**

| |
|---|
| Testing Frequency: Each lot (post Phase II, before use with mushroom production). A lot is defined as a unit of production equal to or less than 5,000 cubic yards (3,823 cubic meters) |
| Source: Adapted from Composted Soil Amendments (containing animal manure or animal products included in the LGMA Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens". |
| Rationale: A "lot" of compost may vary depending upon the process implemented. The objective of the audit scheme is to provide a means of verifying the heat treatments systems applied to compost has been effective. |

Refer to 21 CFR Part 112 Subpart F- Biological Soil Amendments of Animal Origin and Human Waste,.for details on treatment processes and microbial testing standards.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of a missing test on an individual lot used.

Major deficiency (5 points) if:

- Numerous instances of missing tests on an individual lot used.
- Single/isolated instance(s) of the same missing test from multiple lots used.

Non-compliance (0 points) if:

- There are no CoAs for the material being used.
- Fundamental failure to provide evidence for required tests performed on the lots used.

**2.9.2e: Are there Certificate(s) of Analysis (CoA), letters of guarantee or other documents from the supplier(s) that cover heavy metal testing?**

Total compliance (10 points): Certificate(s) of Analysis (CoA), letters of guarantee or some other documents from the supplier(s) that covers heavy metal testing should be available. Concerns are for heavy metals that may affect human health (e.g. Arsenic (As), Cadmium (Cd), Chromium (Cr), Copper (Cu), Lead (Pb), Mercury (Hg), Molybdenum (Mo), Nickel (Ni), Selenium (Se), Zinc (Zn). See Table 2-1 Ceiling Concentrations for Pollutants, EPA Guide to 40 CFR Part 503 Rule. All local and national legislation should also be followed.

https://www.epa.gov/sites/production/files/2018-12/documents/plain-english-guide-part503-biosolids- rule.pdf

https://www.govinfo.gov/content/pkg/CFR-2018-title40-vol32/xml/CFR-2018-title40-vol32- part503.xml#seqnum503.13

Minor deficiency (7 points) if:

- Single/isolated instance(s) of a missing test on an individual lot used.

Major deficiency (3 points) if:

- Numerous instances of missing tests on an individual lot used.
- Single/isolated instance(s) of the same missing test from multiple lots used.

Non-compliance (0 points) if:

- There are no CoAs or other documentation available for the material being used.
- Fundamental failure to provide evidence for required tests performed on the lots used.

**2.9.3: Is untreated animal manure used?**

Total points 0: Information gathering question. Untreated animal manure refers to manure that is raw and has not gone through a treatment process. Examples include raw manure and/or uncomposted, incompletely composted animal manure and/or green waste or non-thermally treated animal manure. Untreated animal manure should not be used in indoor growing operations or where prohibited under best management practices.

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There is a single incidence of untreated animal manure being used in the growing cycle of indoor growing operations or where prohibited under best management practices.**

**2.9.3a: Is fertilizer being used where the country regulations/guidelines ban the use of such materials (e.g., Californian Leafy Green Commodity Specific Guidelines)? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Only fertilizer approved for that specific crop should be used. Some commodity specific guidelines have rules regarding use of specific fertilizer types, e.g. Californian Leafy Green Commodity Specific Guidelines ban the use of biosolids and untreated animal manure.

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There is a single incidence of fertilizer being used where the country regulations/guidelines ban their use.**

**2.9.3b: Are there fertilizer use records available for each growing area, including application records?**

Total compliance (15 points): Records should be legible and at least detail the date of application, type of fertilizer, amount, method of application (drip, bulk, etc.), where it was applied and operator name. There should be sufficient identification information in the records that would make it possible to trace an application back to the site if needed. There should be an interval between application and harvest of at least 45 days for non-synthetic crop treatments and compost, and an interval of at least 120 days (but ideally 9 months) for untreated animal manure. A shorter interval is possible if the fertilizer has been through a physical/chemical/biological process to inactivate human pathogens and the auditee has validation study documentation that shows that the material is safe. Validation studies must be applicable to the situation at hand and care should be taken not to over extrapolate. There should be confirmation that monitoring records of the validation study's key requirements are being kept and that these monitoring records are being verified. The applications should be incorporated into the soil prior to planting or bud burst for tree crops.

Minor deficiency (10 points) if:

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

Major deficiency (5 points) if:

- Numerous instances of errors or omissions in the records.

Non-compliance (0 points) if:

- Fundamental failure to maintain records.
- No records are available.
- The interval between application and harvest is not being respected, and there is no validation study to verify application timelines.
- **Any incident of direct product contamination constitutes as a health hazard and is viewed as adulteration. Revert to Q 2.5.9.**

**2.9.3c: Are there Certificate(s) of Analysis (CoA), specifications, product label or other documents available for review provided by the supplier stating the components of the material?**

Total compliance (10 points): Certificate(s) of Analysis (CoA), letters of guarantee or other formal documentation from the fertilizer manufacturer(s) or supplier(s) should be current and state any inert or active ingredient substances used as "fillers" (e.g., clay pellets, granular limestone). Concerns are for heavy metals that may affect human health (e.g. Arsenic (As), Cadmium (Cd), Chromium (Cr), Copper (Cu), Lead (Pb), Mercury (Hg), Molybdenum (Mo), Nickel (Ni), Selenium (Se), Zinc (Zn). There should be sufficient identification information that would make it possible to trace back to the source if needed, therefore, only approved suppliers should be used limited to those firms demonstrating consistent compliance with prevailing national/local standards and guidelines.

https://apps1.cdfa.ca.gov/fertilizerproducts/

http://library.state.or.us/repository/2007/200701251422434/index.pdf

https://agr.wa.gov/pestfert/fertilizers/productdatabase.aspx

Minor deficiency (7 points) if:

- Documentation is available, but there is no reference to the inert material that is used.

Major deficiency (3 points) if:

- The documentation demonstrates that heavy metals that can affect human health are used as fillers without specific concentration information indicating standards.

Non-compliance (0 points) if:

- There is no documentation available detailing the components of the material.
- Documentation is provided, but is not in sufficient detail to be able to trace back to the source.

**2.9.3d: Are there Certificate(s) of Analysis (CoA), letters of guarantee or other documents from the supplier(s) that cover heavy metal testing?**

Total compliance (10 points): Certificate(s) of Analysis (CoA), letters of guarantee or some other documents from the supplier(s) that covers heavy metal testing should be available. Concerns are for heavy metals that may affect human health (e.g. Arsenic (As), Cadmium (Cd), Chromium (Cr), Copper (Cu), Lead (Pb), Mercury (Hg), Molybdenum (Mo), Nickel (Ni), Selenium (Se), Zinc (Zn). See Table 2-1 Ceiling Concentrations for Pollutants,

EPA Guide to 40 CFR Part 503 Rule. All local and national legislation should also be followed.

https://www.epa.gov/sites/production/files/2018-12/documents/plain-english-guide-part503-biosolids- rule.pdf

https://www.govinfo.gov/content/pkg/CFR-2018-title40-vol32/xml/CFR-2018-title40-vol32- part503.xml#seqnum503.13

Minor deficiency (7 points) if:

- Single/isolated instance(s) of a missing test on an individual lot used.

Major deficiency (3 points) if:

- Numerous instances of missing tests on an individual lot used.
- Single/isolated instance(s) of the same missing test from multiple lots used.

Non-compliance (0 points) if:

- There are no CoAs or other documentation available for the material being used.
- Fundamental failure to provide evidence for required tests performed on the lots used.

**2.9.4: Are other non-synthetic crop treatments used (e.g. compost teas, fish emulsions, fish meal, blood meal, "bio fertilizers")?**

Total points 0: Information gathering question. Examples include but are not limited to compost teas (also known as agricultural teas), fish emulsions, fish meal, blood meal, inoculants (beneficial microbes), and "bio fertilizers" that are produced from animal materials.

**2.9.4a: Is fertilizer being used where the country regulations/guidelines ban the use of such materials (e.g., Californian Leafy Green Commodity Specific Guidelines)? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Only fertilizer approved for that specific crop should be used. Some commodity specific guidelines have rules regarding the use of specific fertilizer types, e.g. Californian Leafy Green Commodity Specific Guidelines bans the use of biosolids and untreated animal manure.

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There is a single incidence of fertilizer being used where the country regulations/guidelines ban their use.**

**2.9.4b: Are there fertilizer use records available for each growing area, including application records?**

Total compliance (15 points): Records should be legible and at least detail the date of application, type of fertilizer, amount, method of application (drip, bulk, etc.), where it was applied and operator name. There should be sufficient identification information in the records that would make it possible to trace an application back to the site if needed. There should be an interval between application and harvest of at least 45 days for non-synthetic crop treatments and compost, and an interval of at least 120 days (but ideally 9 months) for untreated animal manure. A shorter interval is possible, if the fertilizer has been through a physical/chemical/biological process to inactivate human pathogens and the auditee has validation study documentation that shows that the material is safe. Validation studies must be applicable to the situation at hand and care should be taken not to over extrapolate. There should be confirmation that monitoring records of the validation study's key requirements are being kept and that these monitoring records are being verified. The applications should be applied in a manner that does not contact the edible portions of the crop.

Minor deficiency (10 points) if:

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

Major deficiency (5 points) if:

- Numerous instances of errors or omissions in the records.

Non-compliance (0 points) if:

- No records are available.
- Fundamental failure to maintain records.
- Records do not verify the application method.
- The interval between application and harvest is not being respected, and there is no validation study to verify application timelines.
- Any incident of direct product contamination constitutes as a health hazard and is viewed as adulteration. Revert to Q 2.5.9.

**2.9.4c: Are there Certificate(s) of Analysis (CoA), specifications, product label or other documents available for review provided by the supplier stating the components of the material?**

Total compliance (10 points): Certificate(s) of Analysis (CoA), letters of guarantee or other formal documentation from the fertilizer manufacturer(s) or supplier(s) should be current and state any inert or active ingredient substances used as "fillers" (e.g., clay pellets, granular limestone). Concerns are for heavy metals that may affect human health (e.g. Arsenic (As), Cadmium (Cd), Chromium (Cr), Copper (Cu), Lead (Pb), Mercury (Hg), Molybdenum (Mo), Nickel (Ni), Selenium (Se), Zinc (Zn). There should be sufficient identification information that would make it possible to trace back to the source if needed, therefore, only approved suppliers should be used limited to those firms demonstrating consistent compliance with prevailing national/local standards and guidelines.

https://apps1.cdfa.ca.gov/fertilizerproducts/

http://library.state.or.us/repository/2007/200701251422434/index.pdf

https://agr.wa.gov/pestfert/fertilizers/productdatabase.aspx

Minor deficiency (7 points) if:

- Documentation is available, but there is no reference to the inert material that is used.

Major deficiency (3 points) if:

- The documentation demonstrates that heavy metals that can affect human health are used as fillers without specific concentration information indicating standards.

Non-compliance (0 points) if:

- There is no documentation available detailing the components of the material.
- Documentation is provided, but is not in sufficient detail to be able to trace back to the source.

**2.9.4d: Are there Certificate(s) of Analysis (CoA) from the supplier(s) that cover pathogen testing (plus any other legally/best practice required testing) and does the grower have relevant letters of guarantee regarding supplier SOPs and logs?**

Total compliance (15 points): Certificates of analysis should be available for each lot (containing animal materials) used. As a minimum, microbial testing should include Salmonella spp., Listeria monocytogenes and E. coli O157:H7 for non-synthetic crop treatments (e.g., compost teas, fish emulsions, fish meal, blood meal, "bio fertilizers") and for animal-based compost, using approved sampling and testing methods (e.g., AOAC and an accredited laboratory). Where legally allowed, a reduced sampling rate is possible if the material is produced by the auditee (e.g. mushroom growing operations with in-house compost production) and has been through a physical/chemical/biological process to inactivate human pathogens and the auditee has validation study documentation that shows that the material is safe and proper process control records (e.g., time/temperature records and calibration records, such as, temperature probe) are maintained and available during the audit. Validation studies must be applicable to the situation at hand and care should be taken not to over extrapolate. All local and national legislation should also be followed. The grower should have proof that compost suppliers have cross contamination SOPs and temperature/turning logs.

Sampling Plan Options below may be used to determine the definition of a lot. There should be an indication from the supplier/producer of how lots are determined (i.e. from the information here or from another method). The sampling plans below are taken from current regulations in the state of California (related to bio-solids) and recognized manure-based compost guidelines included under the Leafy Greens Marketing Agreement.

| Option 1<br>Amount of Biosolids Compost Feedstock | |
|---|---|
| Metric Tons per 365-day Period | Frequency |
| Greater than zero but annually fewer than 290 | Annually |
| Equal to or greater than 290 but fewer than 1,500 | Quarterly |
| Equal to or greater than 1,500 but fewer than 15,000 | Bimonthly (Every 2 months) |
| Equal to or greater than 15,000 | Monthly |
| Source: State of California Regulations: Title 14, Natural Resources--Division 7, CIWMB Chapter 3.1. Composting Operations Regulatory Requirements | |

| Option 2 |
|---|
| Testing Frequency: Each lot (post Phase II, before use with mushroom production). A lot is defined as a unit of production equal to or less than 5,000 cubic yards (3,823 cubic meters) |
| Source: Adapted from Composted Soil Amendments (containing animal manure or animal products included in the LGMA Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens". |
| Rationale: A "lot" of compost may vary depending upon the process implemented. The objective of the audit scheme is to provide a means of verifying the heat treatments systems applied to compost has been effective. |

Refer to 21 CFR Part 112 Subpart F- Biological Soil Amendments of Animal Origin and Human Waste for details on treatment processes and microbial testing standards.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of a missing test on an individual lot used.

Major deficiency (5 points) if:

- Numerous instances of missing tests on an individual lot used.
- Single/isolated instance(s) of the same missing test from multiple lots used.

Non-compliance (0 points) if:

- There are no CoAs for the material being used.
- Fundamental failure to provide evidence for required tests performed on the lots used.

**2.9.4e: Are there Certificate(s) of Analysis (CoA), letters of guarantee or other documents from the supplier(s) that cover heavy metal testing?**

Total compliance (10 points): Certificate(s) of Analysis (CoA), letters of guarantee or some other documents from the non-synthetic crop treatment supplier(s) that covers heavy metal testing should be available. Concerns are for heavy metals that may affect human health (e.g. Arsenic (As), Cadmium (Cd), Chromium (Cr), Copper (Cu), Lead (Pb), Mercury (Hg), Molybdenum (Mo), Nickel (Ni), Selenium (Se), Zinc (Zn). See Table 2-1 Ceiling Concentrations for Pollutants, EPA Guide to 40 CFR Part 503 Rule. All local and national legislation should also be followed.

https://www.epa.gov/sites/production/files/2018-12/documents/plain-english-guide-part503-biosolids- rule.pdf

https://www.govinfo.gov/content/pkg/CFR-2018-title40-vol32/xml/CFR-2018-title40-vol32- part503.xml#seqnum503.13

Minor deficiency (7 points) if:

- Single/isolated instance(s) of a missing test on an individual lot used.

Major deficiency (3 points) if:

- Numerous instances of missing tests on an individual lot used.
- Single/isolated instance(s) of the same missing test from multiple lots used.

Non-compliance (0 points) if:

- There are no CoAs or other documentation available for the material being used.
- Systematic failure to provide evidence for required tests performed on the lots used.

**2.9.5: Is the operation using soil or substrate amendments as an input? (e.g., plant by-products, humates, seaweed, inoculants, and conditioner, etc.)**

Total points 0: Information gathering question. This refers to soil or substrate amendments (except inorganic nutrients/fertilizers) used that do not contain animal products and/or animal manures. Examples include but are not limited to plant by-products (e.g., coir), humates (e.g., peat), seaweed, conditioners (e.g., vermiculite), etc.

**2.9.5a: Is fertilizer being used where the country regulations/guidelines ban the use of such materials (e.g., Californian Leafy Green Commodity Specific Guidelines)? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Only fertilizer approved for that specific crop should be used. Some commodity specific guidelines have rules regarding the use of specific fertilizer types, e.g. Californian Leafy Green Commodity Specific Guidelines bans the use of biosolids and untreated animal manure.

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There is a single incidence of fertilizer being used where the country regulations/guidelines ban their use.**

**2.9.5b: Are there fertilizer use records available for each growing area, including application records?**

Total compliance (15 points): Records should be legible and at least detail the date of application, type of fertilizer, amount, method of application (drip, bulk, etc.), where it was applied and operator name. There should be sufficient identification information in the records that would make it possible to trace an application back to the site if needed. There should be an interval between application and harvest of at least 45 days for non-synthetic crop treatments and compost, and an interval of at least 120 days (but ideally 9 months) for untreated animal manure. A shorter interval is possible if the fertilizer has been through a physical/chemical/biological process to inactivate human pathogens and the auditee has validation study documentation that shows that the material is safe. Validation studies must be applicable to the situation at hand and care should be taken not to over extrapolate. There should be confirmation that monitoring records of the validation study's key requirements are being kept and that these monitoring records are being verified.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of missing records.

Major deficiency (5 points) if:

- Numerous instances of missing records.

Non-compliance (0 points) if:

- Fundamental failure to maintain records.
- No records are available.
- The interval between application and harvest is not being respected, and there is no validation study to verify application timelines.

**2.9.5c: Are there Certificate(s) of Analysis (CoA), specifications, product label or other documents available for review provided by the supplier stating the components of the material?**

Total compliance (10 points): Certificate(s) of Analysis (CoA), letters of guarantee or other formal documentation from the fertilizer manufacturer(s) or supplier(s) should be current and state any inert or active ingredient substances used as "fillers" (e.g., clay pellets, granular limestone). Concerns are for heavy metals that may affect human health (e.g. Arsenic (As), Cadmium (Cd), Chromium (Cr), Copper (Cu), Lead (Pb), Mercury (Hg), Molybdenum (Mo), Nickel (Ni), Selenium (Se), Zinc (Zn). There should be sufficient identification information that would make it possible to trace back to the source if needed, therefore, only approved suppliers should be used limited to those firms demonstrating consistent compliance with prevailing national/local standards and guidelines.

https://apps1.cdfa.ca.gov/fertilizerproducts/

http://library.state.or.us/repository/2007/200701251422434/index.pdf

https://agr.wa.gov/pestfert/fertilizers/productdatabase.aspx

Minor deficiency (7 points) if:

- Documentation is available, but there is no reference to the inert material that is used.

Major deficiency (3 points) if:

- The documentation demonstrates that heavy metals that can affect human health are used as fillers without specific concentration information indicating standards.

Non-compliance (0 points) if:

- There is no documentation available detailing the components of the material.
- Documentation is provided, but is not in sufficient detail to be able to trace back to the source.

**2.9.5d: Are there Certificate(s) of Analysis (CoA) and/or letters of guarantee stating that the materials used are free from animal products and/or animal manures?**

Total compliance (15 points): There should be Certificate(s) of Analysis (CoA) and/or letters of guarantee from the fertilizer supplier, stating that the materials they are supplying are free from animal products and/or animal manures. A statement of ingredients or letter from suppliers attesting this fact is acceptable. Auditor should match the names of the materials being used with the CoA's and/or letters of guarantee.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of missing records.

Major deficiency (5 points) if:

- Numerous instances of missing records.

Non-compliance (0 points) if:

- Fundamental failure to maintain records.
- No records are available.

**2.9.6: Is the operation using inorganic fertilizers as an input? (e.g., ammonium nitrate, ammonium sulfate, chemically synthesized urea, etc.) Informational Gathering Question.**

Total points 0: Information gathering question. Examples of manufactured inorganic fertilizers include ammonium nitrate, ammonium sulfate, chemically synthesized urea, etc. These are sometimes called synthetic fertilizers.

**2.9.6a: Is fertilizer being used where the country regulations/guidelines ban the use of such materials (e.g., Californian Leafy Green Commodity Specific Guidelines)? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Only fertilizer approved for that specific crop should be used. Some commodity specific guidelines have rules regarding the use of specific fertilizer types, e.g. Californian Leafy Green Commodity Specific Guidelines bans the use of biosolids and untreated animal manure.

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There is a single incidence of fertilizer being used where the country regulations/guidelines ban their use.**

**2.9.6b: Are there fertilizer use records available for each growing area, including application records?**

Total compliance (15 points): Records should be legible and at least detail the date of application, type of fertilizer, amount, method of application (drip, bulk, etc.), where it was applied and operator name. There should be sufficient identification information in the records that would make it possible to trace an application back to the site if needed.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of missing records.

Major deficiency (5 points) if:

- Numerous instances of missing records.

Non-compliance (0 points) if:

- Fundamental failure to maintain records.
- No records are available.

**2.9.6c: Are there Certificate(s) of Analysis (CoA), specifications, product label or other documents available for review by the supplier stating the components of the material?**

Total compliance (10 points): Certificate(s) of Analysis (CoA), letters of guarantee or other formal documentation from the fertilizer manufacturer(s) or supplier(s) should be current and state any inert or active ingredient substances used as "fillers" (e.g., clay pellets, granular limestone). Concerns are for heavy metals that may affect human health (e.g. Arsenic (As), Cadmium (Cd), Chromium (Cr), Copper (Cu), Lead (Pb), Mercury (Hg), Molybdenum (Mo), Nickel (Ni), Selenium (Se), Zinc (Zn). There should be sufficient identification information that would make it possible to trace back to the source if needed, therefore, only approved suppliers should be used limited to those firms demonstrating consistent compliance with prevailing national/local standards and guidelines.

https://apps1.cdfa.ca.gov/fertilizerproducts/

http://library.state.or.us/repository/2007/200701251422434/index.pdf

https://agr.wa.gov/pestfert/fertilizers/productdatabase.aspx

Minor deficiency (7 points) if:

- Documentation is available, but there is no reference to the inert material that is used.

Major deficiency (3 points) if:

- The documentation demonstrates that heavy metals that can affect human health are used as fillers, without specific concentration information indicating standards.

Non-compliance (0 points) if:

- There is no documentation available detailing the components of the material.

- Documentation is provided but is not in sufficient detail to be able to trace back to the source.

## Irrigation/Water Use

**2.10.1: Is municipal or district water used in the growing operation?**

**What is this water source used for (e.g., irrigation, crop protection sprays, fertigation, frost/freeze protection, cooling, dust abatement, etc.)?**

**What type of irrigation methods are used (e.g., micro-irrigation, drip, overhead, flood irrigation, furrow irrigation, seepage irrigation, hydroponic (specify type))?**

**Does the water come into contact with the edible portion of the crop?**

Total points 0: Information gathering question.

**2.10.1a: Are generic *E. coli* tests conducted on the water (taken from the closest practical point of use) at the required and/or expected frequency? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.**

Total compliance (15 points): Microbial water testing, including generic *E. coli*, should occur for all water sources used for any growing activities like crop protection/fertilizer and frost or freeze prevention programs. Water samples should be taken from as close to the point of use as is practical. At least one sample per distribution system is required. If there are multiple sampling points in a distribution system, then samples should be taken from a different location each test (randomize or rotate locations).

For farm and indoor growing operations, one sample per water source should be collected and tested prior to use if >60 days since the last test of the water source. Additional samples should be taken at least monthly during use of the water source. For farm operations, if supported by a valid risk assessment, less frequent testing is acceptable although there should be at least one water test per season. Where there are more stringent federal, national or local requirements, these requirements should be followed.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water testing not occurring at the right frequency.
- Sample was not taken from the closest practical point of use.

Major deficiency (5 points) if:

- Numerous instances of water testing not occurring at the right frequency.

**Automatic Failure (0 points) if:**

- **No microbiological test results are available.**
- **A water test has not been performed within the past 12 months.**

**2.10.1b: Do written procedures (SOPs) exist covering proper sampling protocols which include where samples should be taken and how samples should be identified?**

Total compliance (10 points): There should be documented procedures in place detailing how water samples are taken in the field, including stating how samples should be identified i.e. clearly naming the location that the sample was taken, the water source and the date (this is important in order to be able to calculate geometric means). Samples should be taken at a point as close to the point of use as possible where water contacts the crop, so as to test both the water source and the water distribution system.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no sampling SOPs.

**2.10.1c: Do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?**

Total compliance (10 points): Written procedures (SOPs) should exist covering corrective measures not only for the discovery of unsuitable or abnormal water test results but also as a preparation on how to handle such findings.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no SOPs covering corrective action measures.

**2.10.1d: If unsuitable or abnormal results have been detected, have documented corrective measures been performed?**

Total compliance (15 points): For generic *E. coli* (unless more stringent guidelines/laws in existence) <126MPN (or CFU)/100mL (rolling geometric mean n=5) and <235MPN (or CFU)/100mL for any single sample. Where thresholds have been exceeded, there should be recorded corrective actions, including investigations, water retests and if required, crop testing (*E. coli* O157:H7 and Salmonella - zero tolerance). Failure to take corrective actions when there is evidence of high levels or an upward trend of *E. coli* may result in an automatic failure of the audit. Auditor must detail corrective actions and preventative measures taken. For farms or indoor agriculture operations following the FDA's Produce Safety Rule, the operation needs to ensure they are meeting the requirements for samples to calculate the Geometric Mean (GM) and Statistical Threshold (STV).

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water sources being used without corrective actions being performed upon receipt of unsuitable or abnormal water test results showing >235 MPN for any single sample or >126 MPN for a geometric mean.

Major deficiency (5 points) if:

- Numerous instances of water sources being used without corrective actions being performed after receipt of unsuitable or abnormal water test results showing >235 MPN for any single sample or >126 MPN for a geometric mean.

Non-compliance (0 points) if:

- No corrective measures have been performed.
- Retests were performed greater than one month after receiving the unsuitable or abnormal water test results.
- The written SOPs were not followed when unsuitable or abnormal water testing results were recorded in the last 12 months.
- **Contaminated water is being consistently used for product contact use without evidence of corrective actions being implemented. (This qualifies as an automatic failure and should be scored under 2.5.9.)**

**2.10.1e: Where anti-microbial water treatments (e.g. chlorination, U.V., ozone, etc.) are used, are there records of the monitoring frequencies, results and where necessary the corrective actions?**

Total compliance (15 points): Where any water treatment is performed at the source (e.g., well, canal, holding tank) this should be monitored. The strength of anti-microbial chemicals should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction-based test, test probe, test strips or as recommended by the disinfectant supplier). If using an anti-microbial treatment system (e.g. chlorination), there should be monitoring logs completed on at least a daily basis when the system is being used. Any well "shocking" should be recorded.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of an error or omission in the records or corrective action details.
- Single/isolated instance(s) of checks not carried out at the required frequencies.
- Single/isolated instance(s) of incorrect parameters being monitored.

Major deficiency (5 points) if:

- Multiple instances of errors or omissions in the records or corrective action details.
- Numerous instances of checks not carried out at the required frequencies.

- Numerous instances of incorrect parameters being monitored.
- No supporting documentation of the monitoring method and/or frequency being used.

Non-compliance (0 points) if:

- No records.
- Monitoring frequency is insufficient to verify the process is in control.
- Monitoring parameters in use are insufficient to verify the process is in control.
- Failure to maintain records properly.
- Failure to record corrective action details.

**2.10.1f: Are there records kept for periodic visual inspection of the water source with corrective actions (where necessary)?**

Total compliance (5 points): "Records" may include calendar books with commentary regarding what was checked, the condition, unusual occurrences, (e.g. issues regarding well cap, well casing, seals, piping tanks, treatment equipment, cross connections, trash, animal presence, pooled water, etc.), and any action taken. The appropriate documentation should be available for review.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of an error or omission in the records or corrective action details.

Major deficiency (1 point) if:

- Multiple instances of errors or omissions in the records or corrective action details.

Non-compliance (0 points) if:

- Failure to maintain records properly. Failure to record corrective action details.

**2.10.2 Is well water used in the growing operation?**

**What is this water source used for (e.g., irrigation, crop protection sprays, fertigation, frost/freeze protection, cooling, dust abatement, etc.)?**

**What type of irrigation methods are used (e.g., micro-irrigation, drip, overhead, flood irrigation, furrow irrigation, seepage irrigation, hydroponic (specify type))?**

**Does the water come into contact with the edible portion of the crop?**

Total points 0: Information gathering question.

**2.10.2a: Are generic *E. coli* tests conducted on the water (taken from the closest practical point of use) at the required and/or expected frequency? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.**

Total compliance (15 points): Microbial water testing, including generic *E. coli,* should occur for all water sources used for any growing activities like crop protection/fertilizer and frost or freeze prevention programs. Water samples should be taken from as close to the point of use as is practical. At least one sample per distribution system is required. If there are multiple sampling points in a distribution system, then samples should be taken from a different location each test (randomize or rotate locations).

For farm and indoor growing operations, one sample per water source should be collected and tested prior to use if >60 days since the last test of the water source. Additional samples should be taken at least monthly during use of the water source. For farm operations, if supported by a valid risk assessment, less frequent testing is acceptable although there should be at least one water test per season. Where there are more stringent federal, national or local requirements, these requirements should be followed.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water testing not occurring at the right frequency.
- Sample was not taken from the closest practical point of use.

Major deficiency (5 points) if:

- Numerous instances of water testing not occurring at the right frequency.

**Automatic Failure (0 points) if:**

- **No microbiological test results are available.**
- **A water test has not been performed within the past 12 months**.

**2.10.2b: Do written procedures (SOPs) exist covering proper sampling protocols which include where samples should be taken and how samples should be identified?**

Total compliance (10 points): There should be documented procedures in place detailing how water samples are taken in the field, including stating how samples should be identified i.e. clearly naming the location that the sample was taken, the water source and the date (this is important in order to be able to calculate geometric means). Samples should be taken at a point as close to the point of use as possible where water contacts the crop, so as to test both the water source and the water distribution system.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no sampling SOPs.

**2.10.2c: Do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?**

Total compliance (10 points): Written procedures (SOPs) should exist covering corrective measures not only for the discovery of unsuitable or abnormal water test results but also as a preparation on how to handle such findings.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no SOPs covering corrective action measures.

**2.10.2d: If unsuitable or abnormal results have been detected, have documented corrective measures been performed?**

Total compliance (15 points): For generic *E. coli* (unless more stringent guidelines/laws in existence) <126MPN (or CFU)/100mL (rolling geometric mean n=5) and <235MPN (or CFU)/100mL for any single sample. Where thresholds have been exceeded, there should be recorded corrective actions, including investigations, water retests and if required, crop testing (*E. coli* O157:H7 and Salmonella - zero tolerance). Failure to take corrective actions when there is evidence of high levels or an upward trend of E. coli may result in an automatic failure of the audit. Auditor must detail corrective actions and preventative measures taken. For farms or indoor agriculture operations following the FDA's Produce Safety Rule, the operation needs to ensure they are meeting the requirements for samples to calculate the Geometric Mean (GM) and Statistical Threshold (STV).

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water sources being used without corrective actions being performed upon receipt of unsuitable or abnormal water test results showing >235 MPN for any single sample or >126 MPN for a geometric mean.

Major deficiency (5 points) if:

- Numerous instances of water sources being used without corrective actions being performed one week after receipt of unsuitable or abnormal water test results showing >235 MPN for any single sample or >126 MPN for a geometric mean.

Non-compliance (0 points) if:

- No corrective measures have been performed.
- Retests were performed greater than one month after receiving the unsuitable or abnormal water test results.
- The written SOPs were not followed when unsuitable or abnormal water testing results were recorded in the last 12 months.
- Contaminated water is being consistently used for product contact use without evidence of corrective actions being implemented. (This qualifies as an automatic failure and should be scored under 2.5.9.)

**2.10.2e: Where anti-microbial water treatments (e.g. chlorination, U.V., ozone, etc.) are used, are there records of the monitoring frequencies, results and where necessary the corrective actions?**

Total compliance (15 points): Where any water treatment is performed at the source (e.g., well, canal, holding tank) this should be monitored. The strength of anti-microbial chemicals should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction-based test, test probe, test strips or as recommended by the disinfectant supplier). If using an anti-microbial treatment system (e.g. chlorination), there should be monitoring logs completed on at least a daily basis when the system is being used. Any well "shocking" should be recorded.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of an error or omission in the records or corrective action details.
- Single/isolated instance(s) of checks not carried out at the required frequencies.
- Single/isolated instance(s) of incorrect parameters being monitored.

Major deficiency (5 points) if:

- Multiple instances of errors or omissions in the records or corrective action details.
- Numerous instances of checks not carried out at the required frequencies.
- Numerous instances of incorrect parameters being monitored.
- No supporting documentation of the monitoring method and/or frequency being used.

Non-compliance (0 points) if:

- No records.
- Monitoring frequency is insufficient to verify the process is in control.
- Monitoring parameters in use are insufficient to verify the process is in control.
- Failure to maintain records properly.
- Failure to record corrective action details.

**2.10.2f: Are there records kept for periodic visual inspection of the water source with corrective actions (where necessary)?**

Total compliance (5 points): "Records" may include calendar books with commentary regarding what was checked, the condition, unusual occurrences, and any action taken. The appropriate documentation should be available for review.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of an error or omission in the records or corrective action details.

Major deficiency (1 point) if:

- Multiple instances of errors or omissions in the records or corrective action details.

Non-compliance (0 points) if:

- Failure to maintain records properly.
- Failure to record corrective action details.

**2.10.3: Is non-flowing surface water used in the growing operation? (e.g., pond, reservoir, watershed)**

**What is this water source used for (e.g., irrigation, crop protection sprays, fertigation, frost/freeze protection, cooling, dust abatement, etc.)?**

**What type of irrigation methods are used (e.g., micro-irrigation, drip, overhead, flood irrigation, furrow irrigation, seepage irrigation, hydroponic (specify type))?**

**Does the water come into contact with the edible portion of the crop?**

Total points 0: Information gathering question. Water sourced from ponds, reservoirs, watersheds or other non-flowing surface water systems may carry more of a risk for contamination than closed water sources. For surface waters, consider the impact of storm events on irrigation practices. Bacterial loads in surface water are generally much higher than normal, and caution should be exercised when using these waters for irrigation.

**2.10.3a: Are generic *E. coli* tests conducted on the water (taken from the closest practical point of use) at the required and/or expected frequency? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT**

Total compliance (15 points): Microbial water testing, including generic *E. coli*, should occur for all water sources used for any growing activities like crop protection/fertilizer and frost or freeze prevention programs. Water samples should be taken from as close to the point of use as is practical. At least one sample per distribution system is required. If there are multiple sampling points in a distribution system, then samples should be taken from a different location each test (randomize or rotate locations).

For farm and indoor growing operations, one sample per water source should be collected and tested prior to use if >60 days since the last test of the water source. Additional samples should be taken at least monthly during use of the water source. For farm operations, if supported by a valid risk assessment, less frequent testing is acceptable although there should be at least one water test per season. Where there are more stringent federal, national or local requirements, these requirements should be followed.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water testing not occurring at the right frequency.
- Sample was not taken from the closest practical point of use.

Major deficiency (5 points) if:

- Numerous instances of water testing not occurring at the right frequency.

**Automatic Failure (0 points) if:**

- **No microbiological test results are available.**
- **A water test has not been performed within the past 12 months.**

**2.10.3b: Do written procedures (SOPs) exist covering proper sampling protocols which include where samples should be taken and how samples should be identified?**

Total compliance (10 points): There should be documented procedures in place detailing how water samples are taken in the field, including stating how samples should be identified i.e. clearly naming the location that the sample was taken, the water source and the date (this is important in order to be able to calculate geometric means). Samples should be taken at a point as close to the point of use as possible where water contacts the crop, so as to test both the water source and the water distribution system.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no sampling SOPs.

**2.10.3c: Do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?**

Total compliance (10 points): Written procedures (SOPs) should exist covering corrective measures not only for the discovery of unsuitable or abnormal water test results but also as a preparation on how to handle such findings.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no SOPs covering corrective action measures.

**2.10.3d: If unsuitable or abnormal results have been detected, have documented corrective measures been performed?**

Total compliance (15 points): For generic *E. coli* (unless more stringent guidelines/laws in existence) <126MPN (or CFU)/100mL (rolling geometric mean n=5) and <235MPN (or CFU)/100mL for any single sample. Where thresholds have been exceeded, there should be recorded corrective actions, including investigations, water retests for samples to calculate the Geometric Mean (GM) and Statistical Threshold (STV). and if required, (*E. coli* O157:H7 and *Salmonella* - zero tolerance). Failure to take corrective actions when evidence of high levels or an upward trend of *E. coli* may result in an automatic failure of the audit. Auditor must detail corrective actions and preventative measures taken. For farms or indoor agriculture operations following the FDA's Produce Safety Rule, the operation needs to ensure they are meeting the requirements.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water sources being used without corrective actions being performed upon receipt of unsuitable or abnormal water test results showing >235 MPN for any single sample or >126 MPN for a geometric mean.

Major deficiency (5 points) if:

- Numerous instances of water sources being used without corrective actions being performed one week after receipt of unsuitable or abnormal water test results showing >235 MPN for any single sample or >126 MPN for a geometric mean.

Non-compliance (0 points) if:

- No corrective measures have been performed.
- Retests were performed greater than one month after receiving the unsuitable or abnormal water test results.
- The written SOPs were not followed when unsuitable or abnormal water testing results were recorded in the last 12 months.
- **Contaminated water is being consistently used for product contact use without evidence of corrective actions being implemented. (This qualifies as an automatic failure and should be scored under 2.5.9.)**

**2.10.3e: Where anti-microbial water treatments (e.g. chlorination, U.V., ozone, etc.) are used, are there records of the monitoring frequencies, results and where necessary the corrective actions?**

Total compliance (15 points): Where any water treatment is performed at the source (e.g., well, canal, holding tank) this should be monitored. The strength of anti-microbial chemicals should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction-based test, test probe, test strips or as recommended by the disinfectant supplier). If using an anti-microbial treatment system (e.g. chlorination), there should be monitoring logs completed on at least a daily basis when the system is being used. Any well "shocking" should be recorded.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of an error or omission in the records or corrective action details.
- Single/isolated instance(s) of checks not carried out at the required frequencies.
- Single/isolated instance(s) of incorrect parameters being monitored.

Major deficiency (5 points) if:

- Multiple instances of errors or omissions in the records or corrective action details.
- Numerous instances of checks not carried out at the required frequencies.

- Numerous instances of incorrect parameters being monitored.
- No supporting documentation of the monitoring method and/or frequency being used.

Non-compliance (0 points) if:

- No records.
- Monitoring frequency is insufficient to verify the process is in control.
- Monitoring parameters in use are insufficient to verify the process is in control.
- Failure to maintain records properly.
- Failure to record corrective action details.

**2.10.3f: Are there records kept for periodic visual inspection of the water source with corrective actions (where necessary)?**

Total compliance (5 points): "Records" may include calendar books with commentary regarding what was checked, the condition, unusual occurrences, and any action taken. The appropriate documentation should be available for review.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of an error or omission in the records or corrective action details. Major deficiency (1 point) if:
- Multiple instances of errors or omissions in the records or corrective action details.

Non-compliance (0 points) if:

- Failure to maintain records properly.
- Failure to record corrective action details.

**2.10.4: Is open flowing surface water used in the operation? (e.g., river, canal, ditch)**

**What is this water source used for (e.g., irrigation, crop protection sprays, fertigation, frost/freeze protection, cooling, dust abatement, etc.)?**

**What type of irrigation methods are used (e.g., micro-irrigation, drip, overhead, flood irrigation, furrow irrigation, seepage irrigation, hydroponic (specify type))?**

**Does the water come into contact with the edible portion of the crop?**

Total points 0: Information gathering question. Water sourced from canals, rivers, ditches or other open flowing surface water systems may carry more of a risk for contamination than closed water sources. For surface waters, consider the impact of storm events on irrigation practices. Bacterial loads in surface water are generally much higher than normal, and caution should be exercised when using these waters for irrigation.

**2.10.4a: Are generic *E. coli* tests conducted on the water (taken from the closest practical point of use) at the required and/or expected frequency? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT**

Total compliance (15 points): Microbial water testing, including generic *E. coli*, should occur for all water sources used for any growing activities like crop protection/fertilizer and frost or freeze prevention programs. Water samples should be taken from as close to the point of use as is practical. At least one sample per distribution system is required. If there are multiple sampling points in a distribution system, then samples should be taken from a different location each test (randomize or rotate locations).

For farm and indoor growing operations, one sample per water source should be collected and tested prior to use if >60 days since the last test of the water source. Additional samples should be taken at least monthly during use of the water source. For farm operations, if supported by a valid risk assessment, less frequent testing is acceptable although there should be at least one water test per season, unless there are more stringent federal requirements.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water testing not occurring at the right frequency.
- Sample was not taken from the closest practical point of use.

Major deficiency (5 points) if:

- Numerous instances of water testing not occurring at the right frequency.

**Automatic Failure (0 points) if:**

- **No microbiological test results are available.**
- **A water test has not been performed within the past 12 months.**

**2.10.4b: Do written procedures (SOPs) exist covering proper sampling protocols which include where samples should be taken and how samples should be identified?**

Total compliance (10 points): There should be documented procedures in place detailing how water samples are taken in the field, including stating how samples should be identified i.e. clearly naming the location that the sample was taken, the water source and the date (this is important in order to be able to calculate geometric means). Samples should be taken at a point as close to the point of use as possible where water contacts the crop, so as to test both the water source and the water distribution system.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no sampling SOPs.

**2.10.4c: Do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?**

Total compliance (10 points): Written procedures (SOPs) should exist covering corrective measures not only for the discovery of unsuitable or abnormal water test results but also as a preparation on how to handle such findings.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no SOPs covering corrective action measures.

**2.10.4d: If unsuitable or abnormal results have been detected, have documented corrective measures been performed?**

Total compliance (15 points): For generic *E. coli* (unless more stringent guidelines/laws in existence) <126MPN (or CFU)/100mL (rolling geometric mean n=5) and <235MPN (or CFU)/100mL for any single sample. Where thresholds have been exceeded, there should be recorded corrective actions, including investigations, water retests and if required, (*E. coli* O157:H7 and Salmonella - zero tolerance). Failure to take corrective actions when evidence of high levels or an upward trend of *E. coli* may result in an automatic failure of the audit. Auditor must detail corrective actions and preventative measures. For farms or indoor agriculture operations following the FDA's Produce Safety Rule, the operation needs to ensure they are meeting the requirements for samples to calculate the Geometric Mean (GM) and Statistical Threshold (STV).

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water sources being used without corrective actions being performed upon receipt of unsuitable or abnormal water test results showing >235 MPN for any single sample or >126 MPN for a geometric mean.

Major deficiency (5 points) if:

- Numerous instances of water sources being used without corrective actions being performed one week after receipt of unsuitable or abnor mal water test results showing >235 MPN for any single sample or >126 MPN for a geometric mean.

Non-compliance (0 points) if:

- No corrective measures have been performed.
- Retests were performed greater than one month after receiving the unsuitable or abnormal water test results.
- The written SOPs were not followed when unsuitable or abnormal water testing results were recorded in the last 12 months.
- **Contaminated water is being consistently used for product contact use without evidence of corrective actions being implemented. (This qualifies as an automatic failure and should be scored under 2.5.9.)**

**2.10.4e: Where anti-microbial water treatments (e.g. chlorination, U.V., ozone, etc.) are used, are there records of the monitoring frequencies, results and where necessary the corrective actions?**

Total compliance (15 points): Where any water treatment is performed at the source (e.g., well, canal, holding tank) this should be monitored. The strength of anti-microbial chemicals should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction-based test, test probe, test strips or as recommended by the disinfectant supplier). If using an anti-microbial treatment system (e.g. chlorination), there should be monitoring logs completed on at least a daily basis when the system is being used. Any well "shocking" should be recorded.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of an error or omission in the records or corrective action details.
- Single/isolated instance(s) of checks not carried out at the required frequencies.
- Single/isolated instance(s) of incorrect parameters being monitored.

Major deficiency (5 points) if:

- Multiple instances of errors or omissions in the records or corrective action details.
- Numerous instances of checks not carried out at the required frequencies.
- Numerous instances of incorrect parameters being monitored.
- No supporting documentation of the monitoring method and/or frequency being used.

Non-compliance (0 points) if:

- No records.
- Monitoring frequency is insufficient to verify the process is in control.
- Monitoring parameters in use are insufficient to verify the process is in control.
- Failure to maintain records properly.
- Failure to record corrective action details.

**2.10.4f: Are there records kept for periodic visual inspection of the water source with corrective actions (where necessary)?**

Total compliance (5 points): "Records" may include calendar books with commentary regarding what was checked, the condition, unusual occurrences, and any action taken. The appropriate documentation should be available for review.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of an error or omission in the records or corrective action details.

Major deficiency (1 point) if:

- Multiple instances of errors or omissions in the records or corrective action details.

Non-compliance (0 points) if:

- Failure to maintain records properly.
- Failure to record corrective action details.

**2.10.5: Is reclaimed water used in the growing operation? NOTE: This refers to wastewater that has gone through a treatment process.**

**What is this water source used for (e.g., irrigation, crop protection sprays, fertigation, frost/freeze protection, cooling, dust abatement, etc.)?**

**What type of irrigation methods are used (e.g., micro-irrigation, drip, overhead, flood irrigation, furrow irrigation, seepage irrigation, hydroponic (specify type))?**

**Does the water come into contact with the edible portion of the crop?**

Total points 0: Information gathering question. Reclaimed water should be treated with adequate disinfection systems and tested frequently, ideally under the direction of a water reclamation authority or other management body. Reclaimed water should be subject to applicable local and national regulations and standards. Prior to using this water for agricultural purposes, growers should check with regulatory bodies to determine the appropriate parameters and tolerances to be used.

**2.10.5a: Are generic *E. coli* tests conducted on the water (taken from the closest practical point of use) at the required and/or expected frequency? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT**

Total compliance (15 points): Microbial water testing, including generic *E. coli*, should occur for all water sources used for any growing activities like crop protection/fertilizer and frost or freeze prevention programs. Water samples should be taken from as close to the point of use as is practical. At least one sample per distribution system is required. If there are multiple sampling points in a distribution system, then samples should be taken from a different location each test (randomize or rotate locations).

For farm and indoor growing operations, one sample per water source should be collected and tested prior to use if >60 days since the last test of the water source. Additional samples should be taken at least monthly during use of the water source. For farm operations, if supported by a valid risk assessment, less frequent testing is acceptable although there should be at least one water test per season. Where there are more stringent federal, national or local requirements, these requirements should be followed.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water testing not occurring at the right frequency.
- Sample was not taken from the closest practical point of use.

Major deficiency (5 points) if:

- Numerous instances of water testing not occurring at the right frequency.

**Automatic Failure (0 points) if:**

- **No microbiological test results are available.**
- **A water test has not been performed within the past 12 months.**

**2.10.5b: Do written procedures (SOPs) exist covering proper sampling protocols which include where samples should be taken and how samples should be identified?**

Total compliance (10 points): There should be documented procedures in place detailing how water samples are taken in the field, including stating how samples should be identified i.e. clearly naming the location that the sample was taken, the water source and the date (this is important in order to be able to calculate geometric means). Samples should be taken at a point as close to the point of use as possible where water contacts the crop, so as to test both the water source and the water distribution system.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no sampling SOPs.

**2.10.5c: Do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?**

Total compliance (10 points): Written procedures (SOPs) should exist covering corrective measures not only for the discovery of unsuitable or abnormal water test results but also as a preparation on how to handle such findings.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no SOPs covering corrective action measures.

**2.10.5d: If unsuitable or abnormal results have been detected, have documented corrective measures been performed?**

Total compliance (15 points): For generic *E. coli* (unless more stringent guidelines/laws in existence) <126MPN (or CFU)/100mL (rolling geometric mean n=5) and <235MPN (or CFU)/100mL for any single sample. Where thresholds have been exceeded, there should be recorded corrective actions, including investigations, water retests and if required, (*E. coli* O157:H7 and Salmonella - zero tolerance). Failure to take corrective actions when evidence of high levels or an upward trend of *E. coli* may result in an automatic failure of the audit. Auditor must detail corrective actions and preventative measures taken. For farms or indoor agriculture operations following the FDA's Produce Safety Rule, the operation needs to ensure they are meeting the requirements for samples to calculate the Geometric Mean (GM) and Statistical Threshold (STV).

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water sources being used without corrective actions being performed upon receipt of unsuitable or abnormal water test results showing >235 MPN for any single sample or >126 MPN for a geometric mean.

Major deficiency (5 points) if:

- Numerous instances of water sources still being used without corrective actions being performed one week after receipt of unsuitable or abnormal water test results showing >235 MPN for any single sample or >126 MPN for a geometric mean.

Non-compliance (0 points) if:

- No corrective measures have been performed.
- Retests were performed greater than one month after receiving the unsuitable or abnormal water test results.
- The written SOPs were not followed when unsuitable or abnormal water testing results were recorded in the last 12 months.
- **Contaminated water is being consistently used for product contact use without evidence of corrective actions being implemented. (This qualifies as an automatic failure and should be scored under 2.5.9.)**

**2.10.5e: Where anti-microbial water treatments (e.g. chlorination, U.V., ozone, etc.) are used, are there records of the monitoring frequencies, results and where necessary the corrective actions?**

Total compliance (15 points): Where any water treatment is performed at the source (e.g., well, canal, holding tank) this should be monitored. The strength of anti-microbial chemicals should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction-based test, test probe, test strips or as recommended by the disinfectant supplier). If using an anti-microbial treatment system (e.g. chlorination), there should be monitoring logs completed on at least a daily basis when the system is being used. Any well "shocking" should be recorded.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of an error or omission in the records or corrective action details.
- Single/isolated instance(s) of checks not carried out at the required frequencies.
- Single/isolated instance(s) of incorrect parameters being monitored.

Major deficiency (5 points) if:

- Multiple instances of errors or omissions in the records or corrective action details.
- Numerous instances of checks not carried out at the required frequencies.

- Numerous instances of incorrect parameters being monitored.
- No supporting documentation of the monitoring method and/or frequency being used.

Non-compliance (0 points) if:

- No records.
- Monitoring frequency is insufficient to verify the process is in control.
- Monitoring parameters in use are insufficient to verify the process is in control.
- Failure to maintain records properly.
- Failure to record corrective action details.

**2.10.5f: Are there records kept for periodic visual inspection of the water source with corrective actions (where necessary)?**

Total compliance (5 points): "Records" may include calendar books with commentary regarding what was checked, the condition, unusual occurrences, and any action taken. The appropriate documentation should be available for review.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of an error or omission in the records or corrective action details.

Major deficiency (1 point) if:

- Multiple instances of errors or omissions in the records or corrective action details.

Non-compliance (0 points) if:

- Failure to maintain records properly.
- Failure to record corrective action details.

**2.10.6: Is tail water (including hydroponics) used in the growing operation?**

**What is this water source used for (e.g., irrigation, crop protection sprays, fertigation, frost/freeze protection, cooling, dust abatement, etc.)?**

**What type of irrigation methods are used (e.g., micro-irrigation, drip, overhead, flood irrigation, furrow ,m irrigation, seepage irrigation, hydroponic (specify type))?**

**Does the water come into contact with the edible portion of the crop?**

Total points 0: Information gathering question. Tail water return systems, including hydroponics, catch spilled or runoff water and pump the water back to the top of the field/growing area.

**2.10.6a: Are generic *E. coli* tests conducted on the water (taken from the closest practical point of use) at the required and/or expected frequency? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT**

Total compliance (15 points): Microbial water testing, including generic *E. coli*, should occur for all water sources used for any growing activities like crop protection/fertilizer and frost or freeze prevention programs. Water samples should be taken from as close to the point of use as is practical. At least one sample per distribution system is required. If there are multiple sampling points in a distribution system, then samples should be taken from a different location each test (randomize or rotate locations).

For farm and indoor growing operations, one sample per water source should be collected and tested prior to use if >60 days since the last test of the water source. Additional samples should be taken at least monthly during use of the water source. For farm operations, if supported by a valid risk assessment, less frequent testing is acceptable although there should be at least one water test per season. Where there are more stringent federal, national or local requirements, these requirements should be followed.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water testing not occurring at the right frequency.

- Sample was not taken from the closest practical point of use.

Major deficiency (5 points) if:

- Numerous instances of water testing not occurring at the right frequency.

**Automatic Failure (0 points) if:**

- **No microbiological test results are available.**
- **A water test has not been performed within the past 12 months.**

**2.10.6b: Do written procedures (SOPs) exist covering proper sampling protocols which include where samples should be taken and how samples should be identified?**

Total compliance (10 points): There should be documented procedures in place detailing how water samples are taken in the field, including stating how samples should be identified i.e. clearly naming the location that the sample was taken, the water source and the date (this is important in order to be able to calculate geometric means). Samples should be taken at a point as close to the point of use as possible where water contacts the crop, so as to test both the water source and the water distribution system.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no sampling SOPs.

**2.10.6c: Do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?**

Total compliance (10 points): Written procedures (SOPs) should exist covering corrective measures not only for the discovery of unsuitable or abnormal water test results but also as a preparation on how to handle such findings.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no SOPs covering corrective action measures.

**2.10.6d: If unsuitable or abnormal results have been detected, have documented corrective measures been performed?**

Total compliance (15 points): For generic *E. coli* (unless more stringent guidelines/laws in existence) <126MPN (or CFU)/100mL (rolling geometric mean n=5) and <235MPN (or CFU)/100mL for any single sample. Where thresholds have been exceeded, there should be recorded corrective actions, including investigations, water retests and if required, (*E. coli* O157:H7 and Salmonella - zero tolerance). Failure to take corrective actions when evidence of high levels or an upward trend of *E. coli* may result in an automatic failure of the audit. Auditor must detail corrective actions and preventative measures. For farms or indoor agriculture operations following the FDA's Produce Safety Rule, the operation needs to ensure they are meeting the requirements for samples to calculate the Geometric Mean (GM) and Statistical Threshold (STV).

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water sources being used without corrective actions being performed upon receipt of unsuitable or abnormal water test results showing >235 MPN for any single sample or >126 MPN for a geometric mean.

Major deficiency (5 points) if:

- Single/isolated instance(s) of water sources being used without corrective actions being performed one week after receipt of unsuitable or

abnormal water test results showing >235 MPN for any single sample or >126 MPN for a geometric mean.

Non-compliance (0 points) if:

- No corrective measures have been performed.
- Retests were performed greater than one month after receiving the unsuitable or abnormal water test results.
- The written SOPs were not followed when unsuitable or abnormal water testing results were recorded in the last 12 months.
- **Contaminated water is being consistently used for product contact use without evidence of corrective actions being implemented. (This qualifies as an automatic failure and should be scored under 2.5.9.)**

**2.10.6e: Where anti-microbial water treatments (e.g. chlorination, U.V., ozone, etc.) are used, are there records of the monitoring frequencies, results and where necessary the corrective actions?**

Total compliance (15 points): Where any water treatment is performed at the source (e.g., well, canal, holding tank) this should be monitored. The strength of anti-microbial chemicals should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction-based test, test probe, test strips or as recommended by the disinfectant supplier). If using an anti-microbial treatment system (e.g. chlorination), there should be monitoring logs completed on at least a daily basis when the system is being used. Any well "shocking" should be recorded.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of an error or omission in the records or corrective action details.
- Single/isolated instance(s) of checks not carried out at the required frequencies.
- Single/isolated instance(s) of incorrect parameters being monitored.

Major deficiency (5 points) if:

- Multiple instances of errors or omissions in the records or corrective action details.
- Numerous instances of checks not carried out at the required frequencies.
- Numerous instances of incorrect parameters being monitored.
- No supporting documentation of the monitoring method and/or frequency being used.

Non-compliance (0 points) if:

- No records.
- Monitoring frequency is insufficient to verify the process is in control.
- Monitoring parameters in use are insufficient to verify the process is in control.
- Failure to maintain records properly.
- Failure to record corrective action details.

**2.10.6f: Are there records for periodic visual inspection of the water source with corrective actions (where necessary)?**

Total compliance (5 points): "Records" may include calendar books with commentary regarding what was checked, the condition, unusual occurrences (e.g. issues regarding well cap, well casing, seals, piping tanks, treatment equipment, cross connections, trash, animal presence, pooled water, etc.), and any action taken.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of an error or omission in the records or corrective action details.

Major deficiency (1 point) if:

- Multiple instances of errors or omissions in the records or corrective action details.

Non-compliance (0 points) if:

- Failure to maintain records properly.
- Failure to record corrective action details.

**2.10.7: Is there a documented assessment for each water source covering animal access, upstream contamination/runoff, proper well condition, water treatment, backflow, maintenance, cross contamination from leaching, recirculating water systems, etc., as applicable?**

Total compliance (15 points): There should be a documented assessment for each water source used in the growing area. Prior to the first seasonal planting and at least annually and when any changes are made to the system, there should be a documented risk assessment for each water source including any risk mitigations in place, covering potential physical, chemical and biological hazards from animal access, upstream contamination/runoff, proper well condition, water treatment, water capture, backflow, maintenance, cross contamination from leaching, cross connections, recirculating water systems, etc. If flood or furrow irrigation is used, there needs to be examples of how the operation is minimizing the risk.

Farms and indoor agriculture operations following the CA or AZ LGMA, where the risk assessments suggest a need, surface waters passing within 400 feet (121 meters) of a CAFO with more than 80,000 head, must be treated to meet microbial acceptance criteria for Generic *E.coli* of negative or < detection limit (MPN or CFU/100mL) if used in any overhead irrigation application at the field level within two weeks of scheduled harvest.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of a risk assessment missing a physical, chemical and biological hazard.

Major deficiency (5 points) if:

- Numerous instances of physical, chemical and biological hazards missing from the risk assessments.
- A single water source is not included in the risk assessment when multiple water sources are being used in the growing area.

Non-compliance (0 points) if:

- Fundamental failure to include physical, chemical and biological hazards on the risk assessments.
- Numerous water sources used in the growing area are missing risk assessments.
- No risk assessments have been performed.

**2.10.8: Are there backflow prevention devices on all main lines, including where chemical, fertilizer and pesticide applications are made?**

Total compliance (10 points): Water systems should be fitted with backflow prevention devices to prevent contamination of the water supply. Irrigation systems should utilize effective devices which can minimize the potential risk of accidentally allowing any injected chemical/fertilizer to flow back into the irrigation well, surface water source, or to discharge onto the land where not intended. Main water lines should be fitted with back-flow protection for the incoming water (no matter what the source). Individual water lines should be fitted with backflow protection where practical.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of a minor water line that is not protected in some way e.g. hose pipe, lacking an air gap for a dump tank inlet.

Major deficiency (3 points) if:

- Numerous instances of minor water lines that are not protected in some way e.g. hose pipe, lacking an air gap for a dump tank inlet.

Non-compliance (0 points) if:

- There is no backflow protection on primary main water line(s).

**2.10.9: If the operation stores water (tank, cistern, container), is the storage container well maintained?**

Total compliance (15 points): Container should be structurally sound with no evidence of damage or rust, no vegetation growing on or in the container. The base of the container should be free from debris and weeds. Access lids are properly secured and any vents, overflow and drains are screened. Air gaps are present and should be at least twice the diameter of the water supply inlet and not be less than 25 mm (1 inch).

Minor deficiency (10 points) if:

- Single/isolated instance(s) of debris, weeds or other potential contaminants.

Major deficiency (5 points) if:

- Multiple instances of debris, weeds or other potential contaminants.

Non-compliance (0 points) if:

- The storage container(s) are not well maintained.

## Pesticide Usage

**2.11.1: Are there up-to-date records of all pesticides applied during the growth cycle (including soil and substrate pre-plant treatments)? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.**

Total compliance (15 points): The growing operation should follow a pesticide application record keeping program that at least includes the following: date and time of application, crop name, treated area size and location (must be traceable), brand/product name, EPA registration number (or country of production equivalent registration information), active ingredient, amount applied (rate/dosage), applicator identification, pre-harvest interval, restricted entry interval, application equipment identification and target pests. Records should include biopesticides (http://www2.epa.gov/pesticides/biopesticides). Information may be recorded on separate documents providing all information is available and consistent.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of missing required information (e.g. missing target pest, applicator identification, equipment identification, etc.)

Major deficiency (5 points) if:

- Numerous instances of missing required information (e.g. missing target pest, applicator identification, equipment identification, etc.)

**Automatic Failure (0 points) if:**

- **Any failure to record critical required information. (e.g. brand/product name, date, amount applied, location, etc.)**
- **Fundamental failure to record required information.**

**2.11.2: Are all pesticides applied during the growth cycle authorized/registered by the authority/government of the country of production? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Application records show all pesticides applied during the growth cycle are officially registered by the country of production for the target crop (e.g. EPA in the US, COFEPRIS in Mexico, SAG in Chile, Pest Management Regulatory Agency (PMRA) in Canada).

In countries where there is approval for its use, this is acceptable when operated by the government and considers as a minimum the target crop, pesticide trade name and active ingredient, formulation, dosage, pre-harvest intervals and target pest(s) or in cases where the government authorizes an active ingredient but not a trade name, there must be evidence of compliance with the MRLs of the destination countries for the applied "authorized" active ingredient (see 2.11.5)

When pesticide product registration/authorization information does not exist for the target crop in the country of production or there are not enough products registered/authorized to control a pest or disease (partial registration/authorization), extrapolation is possible if that practice is allowed by the country of production (e.g. in Mexico "Anexo Técnico 1. Requisitos Generales para la Certificación y Reconocimiento de Sistemas de Riesgos de Contaminación (SRRC) Buen Uso y Manejo de Plaguicidas (BUMP) o Buenas Prácticas Agrícolas en la Actividad de Cosecha (BPCo) durante la producción primaria de vegetales – Section 12.3 should be considered. ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There is a single incidence of pesticides being used without being registered or authorized by the country of production government.**

**2.11.3: Are all pesticides used during the growth cycle applied as recommended/directed in the label? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Application records should show that pesticides used during the growth cycle are applied in accordance with label directions and any federal, state or local regulation(s).

In operations applying pesticides "authorized" by the government, where use directions are not in the label, application records show should "authorization program" use/applications directions are followed.

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There is a single incidence of pesticides being used without following label directions.**

**2.11.4: Where harvesting is restricted by pre-harvest intervals, are required pre-harvest intervals on product labels, national (e.g., EPA) registration and any federal, state or local regulations and guidelines being adhered to? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Pesticide application records and harvest records should show pre-harvest intervals, as directed by the label, have been adhered to.

In operations applying pesticides "authorized" by the government, where use directions are not in the label, application and harvest records show the "authorization program" directions for pre-harvest intervals are followed.

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question Major deficiency (5 points) if:
- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There is a single incidence of pre-harvest intervals not being adhered to.**
- **There is no evidence that pre-harvest intervals are being adhered to (e.g. missing or non-traceable to the location harvest records).**

**2.11.5: Where products are destined for export, is there information for pesticide Maximum Residue Limits (MRL's), compliance considering, country of destination, target crop(s) and active ingredients applied?**

Total compliance (15 points): Where products are destined for export, the operation should have documented evidence about the MRL requirements for each country of destination for each pesticide (active ingredient) applied during the growth cycle. If there is no MRL defined by the country of destination for any active ingredient applied, the operation shall have documented evidence of the applicable regulations in that country (e.g. default MRL, Codex Alimentarius, non-detectable, etc.). In the case where the MRL's have been standardized or harmonized for a group of countries (i.e. European Union) it is acceptable that the operation demonstrate compliance by referencing the "list" of MRLs issued from the formal body that represents those countries for this purpose.

This question is Not Applicable if the product is only sold in the country of production (domestic market).

Minor deficiency (10 points) if:

- Single/isolated instance(s) of missing required information (e.g. missing MRL information for an active ingredient)

Major deficiency (5 points) if:

- Numerous instances of missing required information (e.g. missing MRL information for 3 or more active ingredient)

Non-conformance (0 points) if:

- There is no MRL information for the destination countries (or systematic missing information)

**2.11.6: Where products are destined for export, is there evidence that Maximum Residue Limits (MRL's), of the intended markets are met? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

Total compliance (15 points): Maximum Residue Limits (MRLs) analysis should be performed when the MRLs of the destination countries are lower (stricter) than the country of production. This assumes that grower is meeting country of origin MRL and label requirements. MRL test results and

records should demonstrate that products/crops meet MRL regulations in those intended markets and any non- conforming product is diverted from those markets.

The auditor should review MRL laboratory reports to ensure MRL entry requirements are met for the country of destination or the applicable regulation in the country of destination when there is no MRL set for any active ingredient, (e.g. the Codex Alimentarius Commission, default MRL, under the limit of detection [LOD], etc.). MRL laboratory reports should be traceable to the operation and consider at least the active ingredients applied during the growth cycle.

Other alternative or complementary methods to demonstrate MRL compliance for an active ingredient include:

i) Documented analysis of degradation curves and corresponding dosage and/or pre-harvest intervals modifications. Degradation curves used as reference shall be issued/provided by the manufacturer of the Plant Protection Product or country of production government and correspond to the degradation of the Plant Protection Product active ingredient in the agroclimatic zone where the Plant Protection Product was applied.

ii) Industry guidelines (e.g. "Agenda de Pesticidas" From ASOEX Chile).

Following a procedure for when and where to pull samples for MRL testing based on risk considering factors such as active ingredients applied, timing of the application and harvest, pre-harvest intervals, dosage, etc., is an ideal practice.

This question is Not Applicable if the product is only sold in the country of production (domestic market).

Minor deficiency (10 points) if:

- There is no minor deficiency category for this question

Major deficiency (5 points) if:

- There is no major deficiency category for this question.

**Automatic Failure (0 points) if:**

- **There is a single incidence of an active ingredient with an exceeded MRL.**
- **There is no evidence of MRL compliance for any active ingredient applied.**
- **Evidence provided is not sufficient to support MRL compliance**

**2.11.7: Is there a documented procedure for the pesticide applications, considering mixing and loading, applying and equipment cleaning?**

Total compliance (15 points): There should be a documented procedure describing how to mix and load pesticides, how to apply pesticides and how to rinse and clean pesticide application equipment. The procedure should include adhering to the product label.

Mixing and loading procedures should require activity to be in a well-ventilated, well-lit area away from unprotected people, food and other items that might be contaminated.

Application procedures should include information about the necessary Personal Protective Equipment (PPE), re-entry intervals, excessive winds, posting of treated areas, etc.

Equipment cleaning procedures should include measuring devices, mixing containers, application equipment (e.g. sprayer), rinseable containers, etc., and should address: rinsing empty equipment immediately to prevent residues from drying and becoming difficult to remove, and adding the rinsate (water from rinsing containers or equipment) to spray tanks as part of the pesticide mixing process.

If any of these practices are observed during the inspection, it should be evident that the procedures are being followed.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of an error or omission in the procedure or practice.

Major deficiency (5 points) if:

- Numerous instances of an error or omission in the procedure or practice.

Non-conformance (0 points) if:

- Systematic errors or omissions in the procedure or practice.
- There is no procedure.

**2.11.8: Is there documentation that shows the individual(s) making decisions for pesticide applications is competent?**

Total compliance (15 points): Current valid certificates, licenses, or another form of proof of training recognized by prevailing national/local standards and guidelines should be available for the individual(s) making decisions on pesticide applications (e.g., choice of pesticides, application timings, rates, etc.).

Minor deficiency (10 points) if:

- Single/isolated instance(s) of missing documentation.

Major deficiency (5 points) if:

- Single/isolated instance of a proof of training/certificate/license being out of date.
- Numerous instances of missing documentation.

Non-compliance (0 points) if:

- There is no documentation for the individual(s) making the decision(s).

**2.11.9: Is there documentation that shows that individuals who handle pesticide materials are trained and are under the supervision of a trained person?**

Total compliance (15 points): All workers who handle pesticides must have current certificates, licenses, or other forms of proof of training (recognized by prevailing national/local standards and guidelines) qualifying them to do so independently or they must have proof of training and be under the supervision of a worker who can do so independently.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of missing training documentation.

Major deficiency (5 points) if:

- Numerous instances of missing training documentation.
- Worker who is not qualified to handle pesticide materials independently has training but no supervision

Non-compliance (0 points) if:

- There is no documentation showing training for individuals handling pesticide materials.
- There is no documentation for the supervising person.

# SECTION 3: ADDITIONAL QUESTIONS (NOT PART OF OVERALL FOOD SAFETY PERCENTAGE)

## Management System

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

Total compliance (5 points): There should be a dated, signed (by senior management) documented food safety policy statement and detailed objectives reflecting the organization'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, 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.

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

- Policy lacks more than one element noted above.
- Numerous instances of errors or omissions in the policy.

- Failure to communicate the policy to workers.
- Policy is not posted in a public place.

Non-compliance (0 points) if:

- No policy exists.

**3.1.2: Is there an organizational chart showing all management and workers who are involved in food safety related activities and documentation (job descriptions) detailing their food safety responsibilities?**

Total compliance (10 points): There should be an organizational chart showing positions and reporting structure of workers whose activities affect food safety within the company. Chart is signed and dated 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:

- 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.

Non-compliance (0 points) if:

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

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

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

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.

**3.1.4: Is there a training management system in place that shows what types of trainings are required for various job roles of specific workers, including who has been trained, when they were trained, which trainings they still need to take, and a training schedule?**

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

the applicable section(s).

Minor deficiency (3 points) if:

- Single/isolated instance(s) of trainings for a job role being omitted from the system.

Major deficiency (1 point) if:

- Numerous instances of trainings for job roles being omitted from the system.

Non-compliance (0 points) if:

- There is no training management system.
- There is a training management system, but it does not reflect how workers are actually being trained.

**3.1.5: Is there documented management verification review of the entire food safety management system at least every 12 months, including an evaluation of resources, and are there records of changes made?**

Total compliance (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 verification activities, reasons for amending documents, validations and changes should be available for review.

- Internal Audits
- External Audits (2nd Party and 3rd Party)
- Other audits/visits (official)
- Analysis of feedback/complaints 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 programs
- Worker training review
- Facility and equipment maintenance
- Other food safety managements system related activities

Minor deficiency (7 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 (3 points) if:

- Numerous instances of errors or omissions in the verification activities.

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

Non-compliance (0 points) if:

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

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

Total compliance (3 points). There is a current copy of any specific industry guidelines for the crop and/or product available for review (electronic copies are accepted). Some examples include the Produce Safety Rule, FSMA Seven Rules including Foreign Supplier Verification Programs, Sanitary Transportation of Human and Animal Food, the Leafy Green Marketing Agreement (LGMA), California Cantaloupe Program, Tomato Good Agricultural Practices (T-GAP), Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Processing Unit Operations of Herbs, etc. Not applicable if no specific industry guidelines or best practices exist for the crop and/or product or activity.

FSMA: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm#guidance

FDA Produce & Plant Products Guidance Documents & Regulatory Information: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ ProducePlantProducts/default.htm

Center of Produce Safety Resources: https://www.centerforproducesafety.org/resources.php Penn State Mushroom Resources: https://plantpath.psu.edu/facilities/mushroom/resources

Minor deficiency (2 points) if:

- Missing one copy of specific industry guidelines or best practices where more than one crop or product is handled.
- There is a copy of the best practices, but it is not the current version.
- Missing more than one copy of specific industry guidelines or best practices where more than one crop or product is handled.

Non-compliance (0 points) if:

- Specific industry guidelines or best practices exist for the crop/crop group being audited, but the operation does not have a copy.

## Control of Documents and Records

**3.2.1: Is there a written document control procedure (including document control register/record) describing how documents will be maintained, updated and replaced?**

Total compliance (3 points): There should be a record of all documents used, when they were issued and updated with the current revision status to help avoid using obsolete documents. Document examples include pre-requisite programs, SSOPs, SOPs, forms (record templates), other work instructions, raw material and finished product specifications, etc.

The document control procedure should specify:

- Who is responsible for document control (i.e. making sure documents are updated and securely stored).
- How documents are to be written, coded and approved.
- How documents are updated, and amendments are approved (e.g. how paper versions are approved, computer records password protected, etc.).
- How changes are identified and recorded (e.g. date, issue number, different colored text or font, change history document etc.).
- How the inadvertent use of obsolete documents is prevented.
- Register/record listing all documents used, when issued, when updated and current revision status.

If using an electronic record keeping system, the procedure should cover this.

Minor deficiency (2 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the procedure.

Non-compliance (0 points) if:

- There is no written procedure

**3.2.2: Are all records and test results that can have an impact on the food safety program verified by a qualified person independent of the individual(s) completing the records?**

Total compliance (5 points): Records and test results should be reviewed, signed off and dated by a qualified person within seven (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. PSA qualification, evidence of training, etc.). Examples of monitoring records may include composting records, sanitizer, pH, water turbidity, cleaning and sanitation, etc. If any issues are detected, corrective actions should be recorded.

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

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

Non-compliance (0 points) if:

- Systematic failure for records and/or test results to be reviewed and signed off by a qualified person within 7 days (second signatory).
- Systematic errors on the records and/or test results that are being signed off by a qualified person.

## Procedures and Corrective Actions

**3.3.1: Is there a written and standardized procedure for creating Standard Operating Procedures (SOPs) and their content?**

Total compliance (5 points): There should be a written document that describes how to write Standard Operating Procedures (SOPs) for food safety activities related to good agricultural practices and/or good manufacturing practices that when followed, help prevent food safety hazards from occurring. SOPs should include a date and document number or reference code and 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 organization's document control systems, especially proper version management (see Control of Documents and Records).

Minor deficiency (3 points) if:

- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of SOPs not having the required format.

Major deficiency (1 point) if:

- Numerous instances of errors and omissions within the document.
- Numerous instances of SOPs not having the required format.

Non-compliance (0 points) if:

- A document describing how to write standard operating procedures has not been created.
- Systematic evidence that SOPs are not written following the standardized procedure.

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

Total compliance (5 points): The written procedures (SOPs) should be available to the users and other interested parties involved in performing the activities described in the procedures. A master copy of all SOPs and associated recording forms should be assembled and stored as a reference. SOPs 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 SOPs, 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.

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of some SOPs not being made available to relevant workers.
- Numerous instances of SOPs and recording forms being omitted from the Master SOP file (SOP Manual).

Non-compliance (0 points) if:

- SOPs are not accessible to relevant workers.
- A master file (SOP Manual) containing the SOPs and recording forms that are being used, has not been created.

**3.3.3: Is there a documented corrective action procedure that describes the required basic requirements for handling all non-conformances affecting food safety?**

Total compliance (5 points): The corrective action procedure should outline how the company 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).

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.

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

**3.4.1: 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. 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 changes 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 (documentation) 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. The internal audit records are assessed in specific records questions. 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.
- 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 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.

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-compliance (0 points) if:

- Systematic failure to record self-audits properly.
- Self-audits are not being conducted.
- Numerous instances of self-audits not being required at least at the minimum frequency.

**3.4.2: Are there written procedures for handling regulatory inspections?**

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, identified meeting space, rules on taking samples and taking photographs, how to follow-up after the inspection, corrective actions, etc. 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.

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

Minor deficiency (2 points) if:

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

Major deficiency (1 point) if:

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

Non-compliance (0 points) if:

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

## Release of Items/Product

**3.5.1: Is there a documented product release procedure available?**

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

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

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

Non-compliance (0 points) if:

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

**3.5.2: 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 organizations that only have authority over the growing activities and operation(s), and not the harvesting activities.

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

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

Non-compliance (0 points) if:

- Failure to have signed records of product release.

**3.5.3: Is there a documented procedure for handling on hold and rejected items?**

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

For harvested product in the field and the facility, the procedure should identify who (position/title) is authorized to determine the disposition of materials that are placed on hold and include details on how the affected item(s) is/are separated from other lots in terms of tagging systems (e.g., date showing when the item was placed on hold/rejected, the reason for being on hold/rejected and the name of the person who put the item on hold (details may be recorded electronically as long as products are clearly tagged)) and any other physical separation needed to ensure that affected items are not commingled with other goods in such a way that their disposition is not clear.

For the pre-harvest materials, procedures should include how the affected product is indicated in the field (e.g., cordoned off, any buffer zones used, how these details are recorded, etc.).

Procedure requires authorized personnel should sign (with date and time) a "release" for any item placed on hold or rejected, detailing actions taken (e.g., disposition, re-work, food bank, tilled back into the ground, etc.).

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

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

Non-compliance (0 points) if:

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

**3.5.4: Are there records of the handling of on hold and rejected items kept on file?**

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

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

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

Non-compliance (0 points) if:

- There is no record of on hold or rejected materials.

**3.5.5: Is there a documented procedure for dealing with customer and buyer food safety complaints/feedback, along with records and company responses, including corrective actions?**

Total compliance (10 points): There is a documented procedure detailing how to handle food safety and food quality complaints and feedback. Food quality issues are relevant if they have the potential to also be food safety issues. It is important to keep the complaints and feedback related records on file to support company procedure. The procedure and records should include (where applicable):

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

Where appropriate, a trend analysis of food safety feedback should be performed to assist with the development of corrective actions.

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

Where a corporate office/sales department or other parties handle the incoming food safety related complaints, the operation is still required to have a documented procedure including how complaints/feedback are communicated to the operation and how they are managed internally (e.g. investigation, root cause, corrective action, communication, etc.).

Where the auditee claims to have received no complaints/rejections, the auditor should verify that a complaint recording system is in place and has the necessary elements listed above.

Minor Deficiency (7 points) if:

- Single/isolated instance(s) of omissions and incorrect data in the records including corrective actions.
- More than 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/Control

**3.6.1: Is there a written procedure detailing how suppliers and service providers are evaluated, approved, and include the ongoing verification activities including monitoring?**

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, packaging items) are evaluated, approved and monitored. The procedure for evaluation (including hazard analysis and supplier control of hazards, where applicable), 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 exceptional situation (e.g. market conditions, emergency situation) 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 should ensure requirements of rule are included in this procedure.

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

- Agreed specifications
- Letters of guarantee
- Methods of evaluating approved suppliers and service providers (including second- and third-party audit requirements where relevant)
- 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 (7 points) if:

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

Major deficiency (3 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.

**3.6.2: Is there a list of approved suppliers and service providers?**

Total compliance (5 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.

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.

**3.6.3: Are there current written food safety related specifications for all incoming products, ingredients, materials (including primary packaging), services provided on-site, and outsourced services?**

Total compliance (5 points): A specification is an explicit set of food safety requirements or criteria to be met (e.g., indicating what an item is made of, contract details). Specifications are accurate, acceptable and ensure conformance with relevant customer and legislative requirements. There are written, detailed, up-to-date specifications for all incoming products, ingredients, materials (including primary packaging), services provided on-site, and outsourced services (including when exceptions will be allowed) that have an effect on food safety, addressing the required Good Agricultural and/or Good Manufacturing Practices. Documented specifications are easily accessible to users and there is a documented procedure for review, amendment and approval of all specifications. Government registration and/or label information (e.g. EPA) for crop protection and processing aid products is acceptable in lieu of an actual specification provided there is evidence products are used according to label instructions. Specifications should be reviewed on at least an annual basis and there should be at least the following specifications available to review (where applicable):

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

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

Minor Deficiency (3 points) if:

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

Major Deficiency (1 point) if:

- Numerous instances of errors or omissions in the records.

Non-compliance (0 points) if:

- No records.
- Failure to maintain records.

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

Total compliance (15 points): The organization has relevant information from approved suppliers 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 ingredients suppliers, products and services suppliers. Supplier verification documents should demonstrate that the ongoing approval requirements detailed in 3.6.1 are being met (e.g., third party audits, certificates of analysis, reviews of supplier records, etc.).

The evidence may include (as applicable):

- Verification that packaging material is suitable for its intended purpose. e.g., current 3rd party audit certificate (ideally GFSI standard or equivalent) for all primary/food contact packaging by the manufacture. Ideally, a tests/analysis confirming no chemical migration to food contents if there is history of past occurrences.
- Current (within last 12 months) second and/or third-party audit certificates that includes the scope of certification for suppliers of product and ingredients.

- Letters of guarantee for agricultural inputs, product raw material, processing aids, and other ingredients and service suppliers 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.
- U.S. Importers under the FDA's Rule Foreign Supplier Verification Programs should have documented evidence that foreign suppliers follow requirements to verify that imported food meets U.S. safety standards.

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

Minor Deficiency (10 points) if:

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

Major Deficiency (5 points) if:

- Numerous instances of errors or omissions in the records.

Non-compliance (0 points) if:

- No records.
- Failure to maintain records.

**3.6.5: 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.)?**

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

Minor Deficiency (3 points) if:

- Single instance of an omission or incorrect data in the documentation.

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.

## Food Defense

**3.7.1: Is there a written food fraud vulnerability assessment (FFVA) and protection plan for all types of fraud, including all incoming and outgoing products?**

Total compliance (3 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, product substitution).

Additional resources:

https://www.pwc.com/gx/en/services/food-supply-integrity-services/food-fraud-vulnerability- assessment.html

https://www.federalregister.gov/documents/2015/09/17/2015-21920/current-good-manufacturing- practicehazard-analysis-and-risk-based-preventive-controls-for-human

https://www.mygfsi.com/component/k2/item/89-http-www-mygfsi-com-files-technical-documents-201805- food-fraud-technical-document-final-pdf.html

https://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2018/is-that-a-beet-or-a- banana-unwrapping-food-fraud-in-the-produce-industry/

https://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2017/food-fraud-vulnerability- assessment-and-prefilter-for-fsma-gfsi-and-sox-requirements/

Minor deficiency (2 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the vulnerability assessment.

Non-compliance (0 points) if:

- There is no vulnerability assessment.
- Systematic failure to review food fraud types for the assessment.

**3.7.2: Does the company have a documented food defense plan based on the risks associated with the operation?**

Total compliance (5 points): The operation should have a documented food defense plan that outlines the organization's security controls based on a written 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 plan should be reviewed at least once every 12 months.

The document should include relevant food defense risks such as 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). 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.

Additional resources:

https://www.fsis.usda.gov/wps/wcm/connect/9fb1c725-4aae-4e06-b56e-217e0fc08f43/ Self_Assessment_Checklist_Food_Security.pdf?MOD=AJPERES

https://www.fda.gov/food/food-defense-tools-educational-materials/food-defense-plan-builder

Minor deficiency (3 points) if:

- Single/isolated instance(s) of errors or omissions in the risk assessment or food defense plan.

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the risk assessment or food defense plan.

Non-compliance (0 points) if:

- Food defense plan has not been documented.
- There is no risk assessment.

**3.7.3: Are records associated with the food defense plan and its procedures being maintained, including monitoring, corrective action and verification records (where appropriate)?**

Total compliance (5 points). The records required in the food defense plan should be maintained, in accordance with the details of the plan (3.7.2) and its associated procedures. These records are also subject to the document control and records requirements of this audit.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of errors or omissions in the records.
- Single/isolated instance(s) of records not being maintained as per plan.

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the records.
- Numerous instances of records not being maintained as per plan.

Non-compliance (0 points) if:

- There are no available records.
- Systematic failure to maintain records as per plan.

## Food Defense

**3.7.1: Is there a written food fraud vulnerability assessment (FFVA) and protection plan for all types of fraud, including all incoming and outgoing products?**

Total compliance (3 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, product substitution).

Additional resources:

https://www.pwc.com/gx/en/services/food-supply-integrity-services/food-fraud-vulnerability- assessment.html

https://www.federalregister.gov/documents/2015/09/17/2015-21920/current-good-manufacturing- practicehazard-analysis-and-risk-based-preventive-controls-for-human

http://www.ssafe-food.org/

https://www.mygfsi.com/component/k2/item/89-http-www-mygfsi-com-files-technical-documents-201805- food-fraud-technical-document-final-pdf.html

https://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2018/is-that-a-beet-or-a- banana-unwrapping-food-fraud-in-the-produce-industry/

https://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2017/food-fraud-vulnerability- assessment-and-prefilter-for-fsma-gfsi-and-sox-requirements/

Minor deficiency (2 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the vulnerability assessment.

Non-compliance (0 points) if:

- There is no vulnerability assessment.
- Fundamental failure to review food fraud types for the assessment.

**3.7.2: Does the company have a documented food defense plan based on the risks associated with the operation?**

Total compliance (5 points): The operation should have a documented food defense plan that outlines the organization's security controls based on a written 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 plan should be reviewed at least once every 12 months.

The document should include relevant food defense risks such as 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). 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.

Risk/vulnerability assessment templates can be found at:

https://www.fsis.usda.gov/wps/wcm/connect/9fb1c725-4aae-4e06-b56e-217e0fc08f43/ Self_ Assessment_ Checklist_ Food_ Security.pdf?MOD=AJPERES

https://www.fda.gov/food/food-defense- tools-educational-materials/food-defense-plan-builder

Minor deficiency (3 points) if:

- Single/isolated instance(s) of errors or omissions in the risk assessment or food defense plan.

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the risk assessment or food defense plan.

Non-compliance (0 points) if:

- Food defense plan has not been documented.
- There is no risk assessment.

**3.7.3: Are records associated with the food defense plan and its procedures being maintained, including monitoring, corrective action and verification records (where appropriate)?**

Total compliance (5 points). The records required in the food defense plan should be maintained, in accordance with the details of the plan (3.7.2) and its associated procedures. These records are also subject to the document control and records requirements of this audit.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of errors or omissions in the records.
- Single/isolated instance(s) of records not being maintained as per plan.

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the records.
- Numerous instances of records not being maintained as per plan.

Non-compliance (0 points) if:

- There are no available records.
- Fundamental failure to maintain records as per plan.

## General Chemicals

**3.8.1: Does the operation use the appropriate test strips, test kits or test probes for verifying the concentrations of anti-microbial chemicals (e.g., dip stations, etc.) being used, are they in operational condition and are they being used correctly?**

Total compliance (15 points): The strength of anti-microbial chemicals (product and cleaning) should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction-based test, test probe, ORP meter or as recommended by disinfectant supplier). Any water treatment at source (e.g., well, canal) should be monitored. Solutions that are too weak will be ineffective, while those too strong may be harmful to workers or product. Where necessary, pH of solutions should also be checked. Methods include dip sticks, test strip papers, conductivity meters, titration, color comparison methods e.g. tintometers, etc. All test solutions/strips should be within date code, appropriate for the concentrations

used and stored correctly (especially light and temperature sensitive materials). If the ORP meter controls the pumps that are injecting the anti-microbial and/or buffer, there should be an independent calibrated ORP probe or other method (e.g., test trip papers, titration) in order to verify injector readings. Probe sensors need periodic cleaning and calibration and may become temporarily saturated by over-injection of anti-microbial or buffer. The auditor should have the auditee check the strength of anti-microbial chemicals while touring the facility.

Potentially useful websites:

http://postharvest.ucdavis.edu/files/260798.pdf

http://anrcatalog.ucanr.edu/pdf/8149.pdf

http://ucfoodsafety.ucdavis.edu/files/26414.pdf

Minor deficiency (10 points) if:

- Single/isolated instance(s) of a method not being used correctly.
- Single/isolated instance(s) of a testing procedure being used that is not appropriate for the concentration and/or sanitizer in use.
- Single/isolated instance(s) of out of date verifying chemicals being used.

Major deficiency (5 points) if:

- Numerous instances of a method not being used correctly.
- Numerous instances of a testing procedure being used that is not appropriate for the concentration and/or chemical in use.
- Numerous instances of out of date verifying chemicals being used.
- ORP meter used to control pumps injecting anti-microbial and or/buffer without an independent probe or other method to verify readings.

Non-compliance (0 points) if:

- Equipment to monitor anti-microbial chemical concentrations is not available or is not being used correctly.

## Production Facility

**3.9.1: Is there a written cleaning schedule (Master Sanitation Schedule) that shows what and where is to be cleaned and how often?**

Total compliance (10 points): The operation should have a master sanitation program that covers all the growing areas, storage areas, break areas, restrooms, maintenance and waste areas. The master sanitation program should reflect the type of indoor growing operation (i.e. mushroom production, hydroponic, aeroponic, vertical growing, etc.). Within these areas, areas such as walls, floors, light covers, overhead pipes, etc. should be included. List should include equipment (food contact and nonfood contact), pallet jacks, forklifts, carts, floor scrubbers, trash cans, cooling equipment (evaporators, cooling coils, drip pans, etc., in-house delivery trucks, etc.) The master sanitation schedule should include a detailed list of areas and equipment to be cleaned as well as the frequency.

The schedule should state what is to be cleaned and when (how often). Infrequent schedules i.e. weekly and above, are usually created for several reasons e.g. cleaning areas and equipment that are not cleaned daily, using a different cleaning technique/chemical than what is used on a daily schedule and/or doing a more "in depth" clean on equipment. Note that all cleaning mentioned on the schedule should be covered somewhere in the cleaning procedures and also on the sanitation logs. Schedule should be kept on file in an easily retrievable manner.

Master sanitation schedule should include what is to be cleaned and when, i.e.:

- List of areas, equipment, internal transport vehicles, in-house delivery trucks, etc.
- Frequency of cleaning (daily, weekly, monthly, quarterly, annually, etc.)

Minor deficiency (7 points) if:

- Single/isolated instance(s) of errors or omissions in the schedules i.e. missed areas/equipment (including internal transport vehicles, in-house delivery trucks) and/or no frequencies being set.

Major deficiency (3 points) if:

- Numerous instances of errors or omissions i.e. missed areas/equipment (including internal transport vehicles, in-house delivery trucks) and/or no frequencies being set.

Non-compliance (0 points) if:

- No schedules.
- Schedules exist but they are not reflecting what actually occurs.

**3.9.2: Where used, are there records showing filters in air conditioning, ventilation and air filtration units are regularly cleaned and/or replaced?**

Total compliance (5 points). Records should be made available to verify that filters in air conditioning, ventilation and air filtration units are regularly cleaned and replaced. Records might include in-house sanitation records, maintenance records and/or contractor records/invoices.

Minor compliance (3 points) if:

- Single/isolated instance(s) of incomplete records or omissions.

Major compliance (1 point) if:

- Numerous instances of incomplete records or omissions.

Non-compliance (0 points) if:

- No records.
- Fundamental failure to maintain records.

**3.9.3: Are materials (commodities, packaging, ingredients, etc.) properly marked with rotation codes (receipt dates, manufacture dates, etc.)?**

Total compliance (5 points): All materials should be properly marked with receipt dates and/or tracking information (lot numbers, code dating) for traceability/recall and stock rotation purposes. Finished product coding should consider any specific customer requirements (e.g., as per customer specifications, customer expectation requirements). This coding should be understood by all workers, in order to ensure FIFO and effective traceback/recall procedures. Coding on raw and finished product should also consider any local or national laws where they exist.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of missing receipt dates and/or tracking information on commodities, packaging, processing aids, work in progress, etc.
- Packaging missing receipt dates and/or tracking information.

Major deficiency (1 point) if:

- Numerous instances of missing receipt dates and/or tracking information on commodities, packaging, processing aids, work in progress, etc.

Non-compliance (0 points) if:

- There are no receipt dates and/or tracking information on commodities, packaging, processing aids, work in progress, etc.

**3.9.4: Are materials (commodities, packaging, ingredients, etc.) rotated using FIFO policy?**

Total compliance (5 points): All materials should be rotated using FIFO (First In First Out) policy to ensure items are used in the correct order they are received and within their allocated shelf-life. Materials should be clearly marked or labeled with some kind of rotation coding that is understood by all workers, in order to ensure FIFO and effective traceback/recall procedures. Packaging rotation might be affected by market forces. Having a "Just In Time" ordering policy and thereby having very limited stock volumes, is acceptable as a replacement for FIFO if it can be proven e.g. the auditor can see that hardly any stock is maintained. "Just In Time" ordering policy does not replace the need to tag materials as per question 3.9.3.

Minor deficiency (3 points) if:

- Single/isolated instance(s) where commodities, packaging, ingredients, processing aids, work in progress, etc. are not rotated using FIFO policy.

Major deficiency (1 point) if:

- Numerous instances where commodities, packaging, ingredients, processing aids, work in progress, etc. are not rotated using FIFO policy.

Non-compliance (0 points) if:

- Systematic failure to use FIFO policy on commodities, packaging, ingredients, processing aids, work in progress, etc.

## Training

**3.10.1: Is there a documented training program with training logs for the sanitation workers, including best practices and chemical use details?**

Total compliance (5 points): Sanitation training should ensure that the workers understand the importance of proper sanitation, cleaning efficacy, how to use the cleaning chemicals and how to understand Sanitation Standard Operating Procedures. Unless sanitation workers attend regular food safety trainings, sanitation training should also include elements of food safety training pertinent to sanitation operations (e.g., hand washing, restroom use, foreign material, etc.). Training logs should have a clearly defined topic(s) covered, trainer(s), material(s) used/given and who attended the training (name and signature). Training would also ideally include worker safety issues (e.g., use of personal protective equipment, accident prevention, what to do in case of an accident, procedures for avoiding electrical hazards when cleaning, etc.). Recorded training should occur at least on a 12-month basis.

Minor Deficiency (3 points) if:

- Single/isolated instance(s) of logs having errors or incomplete information e.g. missing one of the following: training topic, trainer or material information.
- Training has occurred, but on a few occasions full attendance logs have not been kept and/or not all workers were covered.

Major Deficiency (1 points) if:

- Numerous instances of logs having errors or incomplete information e.g. missing one of the following: training topic, trainer or material information.
- Training has occurred but, on many occasions, full attendance logs have not been maintained.

Non-compliance (0 points)

- No records or no training has occurred.
- Failure to maintain records.