

PrimusGFS Audit Farm (Module 2) Guidelines

Used in conjunction with the PrimusGFS v3.2 Audit

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

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

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

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

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

Audit Execution

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

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

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

Explanatory note: In the Spanish version, the use of the term "Farm" refers to any of the following terms: field, ranch, farm, orchard, agricultural production, etc. It is understood as an agricultural production site that excludes animal production.

Scoring System

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

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

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

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

Automatic Failure

There are some questions that if down scored will lead to an automatic failure and an overall score of 0% for the corresponding Module. On being immediately informed of the automatic failure by the auditor during the audit, the auditee has the option to have the auditor continue the audit or to have the audit halt at that point (all charges will apply). **The auditor should explain the advantages of finishing the audit, including the ability for the auditee to learn of other potential non-conformances and to show their buyers the status of their food safety system despite the automatic failure issue.**

Special Circumstances for Not Certifying

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

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

Audit Termination

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

Documentation Requirements

Organization’s Food Safety Systems:

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

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

New PrimusGFS Auditees/First-Time PrimusGFS Auditees

- **In operations that operate for more than three consecutive months throughout the year** – auditee should have at least three months of documentation (i.e. records of monitoring, training, meetings, etc.) available for review. If the auditee has less than three months of most of their documentation available for review, a pre-assessment audit is strongly advised. If the auditee has less than three months of most of their documentation available for review and decides to have a regular scheduled audit, they should be aware that they **cannot receive full compliance for**

paperwork questions relating to monitoring and that the down score will be based on the amount of paperwork available.

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

Existing PrimusGFS Auditees

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

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

Visual versus Verbal Confirmation

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

How to Use Point Assignment Guidelines

The following sections of this guidance manual are designed to help auditors choose the right score for each question, thereby helping to ensure consistency. This document does not cover all situations and is intended to be a guideline, as opposed to a rule. Auditors are expected to follow the guidelines as much as possible, but it is understood that there will be situations where an auditor should use their discretion. If an auditor does have to make a judgment call and/or tackle a situation not covered by this manual, then

the auditor should note the circumstances in the audit report with full justifications. (The auditor should also forward these details to their Certification Body and Azzule Systems, LLC in a separate note, so that this can be reviewed for future versions of the manual.)

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

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

Module 2: Farm

General

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

Total compliance (10 points): There should be a designated **on-site** person/persons in charge of the operation's food safety program, including food safety document control and verification of food safety activities and ideally be independent of production. They should have documented formal training or trained by someone that has the documented formal credentials. This training should meet all state and federal requirements. **Cross reference with 1.01.04.**

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.
- **There is a designated, appropriately trained person who is responsible for the operation's food safety program and is part of the management structure (e.g. corporate) however they are not normally on-site.**

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.
- **An outside consultant is the designated, appropriately trained person responsible for the operation's food safety program however they are not normally on-site.**

Non-compliance (0 points) if:

- Fundamental 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 food safety programs, including food safety document control and verification of sanitation activities.

2.01.02: If the operation is growing under organic principles, is there written documentation of current certification by an accredited organic certification organization? Information gathering question.

Total Compliance (0 points): 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>). Information gathering question. 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.

2.01.03: 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.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of errors and omissions in the food safety hygiene and health policy.

- **The policy is** not in the relevant language(s).
- Single/isolated instance(s) of workers and/or visitors not signing a document stating that they will comply with the operations' personal hygiene and health policies.

Major deficiency (5 points) if:

- Numerous instances of errors and omissions in the food safety hygiene and health policy.
- Numerous cases of workers and/or visitors not signing a document stating that they will comply with the operations' personal hygiene and healthy policy.

Non-compliance (0 points) if:

- No records **available**.
- Failure to maintain records.
- The company does not have a document for workers and/or visitors to sign stating that they will comply with the operations' personal hygiene and health policies.
- Fundamental failure of workers and/or visitors to sign a **document** stating that they will comply with the operations' personal hygiene and health policies.

Site

2.02.01: 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 source/fixture missing from the map.

Major deficiency (1 point) if:

- Numerous water sources/fixtures are missing from 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.

2.02.02: 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. farm name or reference code, blocks of the growing area(s), or number(s)) should be in sufficient detail to enable trace back and trace forward through the distribution system. There should be field 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.).

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) if:

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

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

Total compliance (15 points): A documented risk assessment of the growing area (including potential food safety issues from previous crop volunteers e.g. potatoes (solanine) before leafy greens), each water source and surrounding areas should be performed prior to the first seasonal planting and at least annually, and when any changes are made to the growing area, water sources and/or adjacent land. This should detail known or reasonably foreseeable risks/hazards, the 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 source risks from animal access, upstream contamination/runoff, proper well condition, water treatment, water capture, backflow, maintenance, cross contamination from leaching, cross connections, recirculating water, sewage and septic systems, etc., (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 (% slope, soil type), prevailing weather conditions or weather events, and any other applicable areas. Farms and indoor agriculture operations following the CA or AZ LGMA should reference current metrics e.g., 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
- ii) 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

<https://www.epa.gov/waterresilience>

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

Minor deficiency (10 points):

- Single/isolated instance(s) of errors or omissions on the risk analysis e.g. missing a physical, chemical or biological hazard.

Major deficiency (5 points):

- Numerous instance(s) of errors or omissions on the risk analysis e.g. missing a physical, chemical or biological hazard.
- Last documented risk assessment was done over 12 months ago.
- A single water source is not included in the risk assessment when multiple water sources are being used.

Non-compliance (0 points):

- Fundamental errors on the risk analysis.
- More than one water source is not included in the risk assessment when multiple water sources are being used.
- No documented risk analysis.

2.02.03a: If any risk is identified, have corrective actions and/or preventive measures been documented and implemented?

Total compliance (15 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 preventive measures have been taken when any risk was identified and were adequate for the specific situation. If overhead, flood or furrow irrigation is used, there needs to be examples of how the operation is minimizing the risk.

Minor deficiency (10 points):

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

Major deficiency (5 points):

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

Non-compliance (0 points):

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

2.02.04: 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 (food defense, sometimes known as food security). These measures should be based on the risk associated with the operation, as detailed in the food defense plan (1.08.02). Some high-risk areas of the field include: water sources, storage areas for chemicals, equipment, packaging, utensils or other items used in the growing area, etc. The auditor down score if a lack of signage to prevent trespassing.

A down score for any unprotected (open) water sources (ponds, reservoirs, rivers, etc) should only be given if the operation did not identify the water source in 1.08.02 and has not implemented the necessary controls for preventing intentional contamination to the water source.

Defense Guidance Documents & Regulatory Information

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/>

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

- Fundamental failure to implement necessary food defense controls, based on the risks associated with the operation.

2.02.05: Is the exterior area immediately outside the growing area, 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 growing area 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 of the growing area, 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.

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.

2.02.06: 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 growing area)?

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. Growers 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.

2.02.07: Are 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/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 are lacking covers.

2.02.08: 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? A ZERO POINT DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.

Total compliance (15 points): Soil, substrates and fertilizer (e.g., compost, compost teas, fish emulsions, fish meal, blood meal, bio-fertilizers, etc.) are stored in a manner to prevent contamination to the growing areas, product, or water sources. Containers should be structurally sound and not a source of runoff or contamination. There should be appropriate and effective barriers, coverings, soil berms, pits or lagoons to divert or collect potential run-off or threats from wind, as applicable.

Minor deficiency (10 points) if:

Single/isolated instance risk to the growing areas, product, or water sources.

Major deficiency (5 point) if:

Numerous instances of risk to the growing areas, product, or water sources.

Non-compliance (0 points) if:

- Fundamental failure to prevent contamination.

Automatic Failure (0 points) if:

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

2.02.09: 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:

- **Widespread failure to prevent contamination.**
- **Direct contamination of the crop, ingredients (including water), food contact packaging or food contact surfaces. Auditor should consider reverting to Q. 2.05.04, the automatic adulteration failure question.**

2.02.10: Is the audited area free from animal presence and/or animal activity (wild or domestic)? If Total compliance, go to 2.02.11.

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 storage areas (e.g., 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:

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

2.02.10a: Is the audited 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 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 2.02.11).

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 5 ft..

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 risk assessment is not conducted.

Automatic Failure (0 points) if:

- Any observation of widespread 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 2.02.11.

2.02.11: Is the audited 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.

2.02.12: Is the audited area free of evidence of infants and 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.

Ground History

2.03.01: Were growing area(s) used for growing food crops last season?

Total points 0: Information gathering question. Land should be purchased or leased that has previously been successfully utilized for growing crops without incidence.

2.03.02: Has the growing area(s) been used for any non-agricultural functions? If No, go to 2.03.03.

Total points 0: **Information gathering question.** Purchase or lease of ground previously used for non-agricultural functions (e.g., toxic waste site, landfill, mining, extraction of oil or natural gas) should be avoided. Land should be purchased or leased that has previously been successfully utilized for growing **crops** without incidence. <https://www.epa.gov/superfund>

2.03.02a: If the growing area has been used previously for non-agricultural functions, have soil tests been conducted showing soil was negative or within an appropriate regulatory agency's approved limits for contaminants?

Total compliance (15 points): If the growing area has been used previously used for non-agricultural functions, soil testing should be conducted to determine if the soil is free of contaminants (e.g. heavy metals, residues of persistent organic contaminants) that may still be present in the soil.

Minor deficiency (10 points) if:

- Soil tests performed did not include a potential contaminant (e.g. heavy metals, residues of persistent organic contaminants).
- Soil tests demonstrate that one of the contaminants tested for is still present in the soil.

Major deficiency (5 points) if:

- Soil tests performed did not include more than one of the potential contaminants (e.g. heavy metals, residues of persistent organic contaminants).
- Soil tests demonstrate that more than one of the contaminants tested for is still present in the soil.

Non-compliance (0 points) if:

- No soil testing was performed.
- If soil tests demonstrate positive results for contaminants and the grower does not have evidence of the appropriate regulatory limits.

2.03.03: Has the growing area(s) been used for animal husbandry or grazing land for animals in the last 12 months? If no, go to 2.03.04.

Total points 0: **Information gathering question.** If the land was used previously for animal husbandry or grazing land for livestock, there should be a sufficient buffer time before growing a crop for human consumption.

2.03.03a: If the land was used previously for animal husbandry or grazing land for livestock, has a risk assessment been performed?

Total compliance (10 points): A risk assessment should be documented that includes recording the details of the animal grazing (commercial or domestic) and any risk reduction steps.

Minor deficiency (7 points) if:

- Single/isolated detail missing from the risk assessment.

Major deficiency (3 points) if:

- Numerous details missing from the risk assessment.

Non-compliance (0 points) if:

- There is no risk assessment.

2.03.04: Has flooding from uncontrolled causes occurred on the growing area(s) since the previous growth cycle?

Total points 0: **Information gathering question.** Uncontrolled causes includes the uncontrolled flowing or overflowing of a field with water that is reasonably likely to contain microorganisms or chemicals of significant public health concern and is reasonably likely to cause adulteration of edible portions of fresh produce in that field.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-evaluating-safety-flood-affected-food-crops-human-consumption>

2.03.04a: If the growing area(s) and product was affected from the flood waters, is there documented evidence of a risk assessment and that corrective measures were taken to affected land and product?

Total compliance (15 points): If the growing area and/or product were affected from the flood waters, there should be a documented risk assessment and evidence (archived for 2 years) that corrective measures were taken with affected land and/or product (e.g., photographs, sketched maps, etc.). There should be proof that affected product and product within approximately 30ft (9.1m) of the flooding should not have been harvested for human consumption and that replanting on formerly flooded production ground did not occur for approximately 60 days, unless testing as noted in 2.03.04b has occurred.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-evaluating-safety-flood-affected-food-crops-human-consumption>

<https://extension.colostate.edu/docs/pubs/flood/soil-test.pdf>

<https://lqmatech.com/wp-content/uploads/2017/06/CALGMA-Flooding-Fact-Sheet.pdf>

Minor deficiency (10 points) if:

- Single/isolated instance(s) of errors or omissions on the risk analysis
- Single/isolated instance of missing evidence of corrective actions performed.

Major deficiency (5 points) if:

- Numerous instance(s) of errors or omissions on the risk analysis
- Numerous instances of missing evidence of corrective actions performed.

Non-compliance (0 points) if:

- Multiple widespread errors on the risk analysis
- No documented risk analysis
- No documented corrective actions were performed.
- Product affected by flooding was harvested for human consumption.

2.03.04b: Have soil tests been conducted on the flooded area(s) showing the soil was negative or within an appropriate regulatory agency's approved limits for contaminants?

Total compliance (15 points): If flooding has occurred on the farm, soil clearance testing should be conducted prior to planting. Soil testing should indicate microorganisms lower than the standards for processed compost including <1,000 mpn/g fecal coliforms and negative for *Salmonella* and *E. coli* O157:H7. Additional parameters to measure (e.g. heavy metals, pesticides, hydrocarbons) will depend on the characteristics of the flooding event. Suitable representative samples should be collected for the entire area suspected to have been exposed. If results indicate no issues, then the replanting time line can be reduced from approximately 60 days to approximately 30 days.

<https://extension.colostate.edu/docs/pubs/flood/soil-test.pdf>

<https://lqmatech.com/wp-content/uploads/2017/06/CALGMA-Flooding-Fact-Sheet.pdf>

Minor deficiency (10 points) if:

- Suitable representative samples of the affected area(s) were not sampled.

Major deficiency (5 points) if:

- Soil tests were conducted but did not consider all microorganisms of significant public health concern.
- Soil tests did not consider additional parameters relevant to the flooding event.

Non-compliance (0 points) if:

- No soil tests were performed.
- Where soil tests demonstrated contamination, replanting occurred sooner than 60 days after flooding.
- Where soil tests demonstrated no contamination, replanting occurred sooner than 30 days after flooding.

2.03.04c: If septic or sewage systems adjacent to the growing area were affected by the flood waters, is there a documented inspection after flooding to ensure they are functioning properly and are not a source of contamination?

Total compliance (10 points): There should be records demonstrating that the sewage/septic systems were inspected after flooding, showing that they are functioning properly and are not a source of contamination (e.g. overflow).

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.

Non-compliance (0 points) if:

- No inspections were performed.
- Inspections found issues, but no corrective actions were performed.

Adjacent Land Use

2.04.01: Is the adjacent land to the growing area a possible source of contamination from intensive livestock production (e.g., feed lots, dairy operations, poultry houses, meat rendering operation)? If No, go to 2.04.02.

Total points 0: **Information gathering question.** Adjacent refers to all parcels of land next to the growing operation or within a distance where the crop in question may be affected. Intensive livestock production involves large numbers of animals on limited land. Examples of intensive livestock production are concentrated animal feeding operations (CAFO), cattle feed lots, dairy operations, poultry houses, etc. Consideration should be made for the topography of the land for runoff, potential flooding issues, and prevailing winds for manure related dust issues.

2.04.01a: Where there is intensive livestock production on the adjacent land, have appropriate measures been taken to mitigate this possible contamination source onto the growing area (e.g., buffer areas, physical barriers, foundation, fences, ditches, etc.)?

Total compliance (15 points): Animal or potential contaminant movement should be restricted with acceptable buffer zones, proper fencing and/or other physical barriers. A buffer zone of approximately 400 ft. (122 m) from the edge of the growing area which may increase or decrease depending on the risk variables (i.e., topography (% slope uphill from the crop or downhill from the crop), soil type (sandy, loam, clay)) is needed. Rain induced runoff of animal waste should be diverted by trenching or similar land preparation. Leaking animal waste should be diverted by trenching or similar land preparation. Farms and indoor agriculture operations following the CA or AZ LGMA should reference current metrics e.g., 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.

Minor deficiency (10 points) if:

- Appropriate buffer zones have been implemented, but a single/isolated applicable mitigation measure has been ignored.

Major deficiency (5 points) if:

- Appropriate buffer zones have been implemented, but numerous applicable mitigation measures have been ignored.

Non-compliance (0 points) if:

- Fundamental failure to mitigate possible contamination.

2.04.02: Is there evidence of domestic animals and/or wild animals (includes homes with hobby farms, and non-commercial livestock) in proximity to the growing operation? If No, go to 2.04.03.

Total points 0: **Information gathering question.** This includes all non-intensive livestock production. Other examples include chicken coops, dogs, horses, homes with hobby farms, wild pigs, etc. Auditor must consider the maturity stage and type of crop involved. For example, pig activity around a ground level berry crop is different from a high-level tree crop.

2.04.02a: Where there are domestic and/or wild animals (includes homes with hobby farms, and non-commercial livestock) have physical measures been put in place to restrain the animals and their waste from entering the growing area (e.g., vegetative strips, wind breaks, physical barriers, berms, fences, diversion ditches)?

Total compliance (15 points): Mitigating measures should include a buffer area of approximately 30 ft. (9.1m) from the edge of the crop which may increase or decrease depending on the risk variables (e.g. topography (% slope uphill from the crop or downhill from the crop), soil type (sandy, loam, clay)). Other measures may be used such as vegetative strips, wind breaks, physical barriers, berms, fences, diversion ditches to prevent or control runoff, mitigate particulates, etc.

Minor deficiency (10 points) if:

- Appropriate buffer zones have been implemented, but a single/isolated applicable mitigation measure has been ignored.

Major deficiency (5 points) if:

- Appropriate buffer zones have been implemented, but numerous applicable mitigation measures have been ignored.

Non-compliance (0 points) if:

- Fundamental failure to mitigate possible contamination.

2.04.03: Are untreated animal manure piles, compost, biosolids, or non-synthetic amendment stored and/or applied on adjacent land? If No, go to 2.04.04.

Total points 0: **Information gathering question:** Adjacent refers to all parcels of land next to the growing operation or within a distance where the crop in question may be affected by untreated animal manure piles, compost, biosolids, or non-synthetic amendment stored and/or applied on adjacent land.

2.04.03a: Where present, have physical measures been taken to secure untreated animal manure piles, compost, biosolids, or non-synthetic amendment stored and/or applied on adjacent land?

Total compliance (15 points): Mitigating measures should include a buffer area of approximately 400 ft. (122 m) from the edge of the crop which may increase or decrease depending on the risk variables e.g. topography (uphill from the crop or downhill from the crop). Other measures may include tarping systems, physical barriers, fences, ditches, etc., implementing systems to redirect run off that may contain untreated manure, compost, or biosolids.

Minor deficiency (10 points) if:

- Appropriate buffer zones have been implemented, but a single/isolated applicable mitigation measure has been ignored.

Major deficiency (5 points) if:

- Appropriate buffer zones have been implemented, but numerous applicable mitigation measures have been ignored.

Non-compliance (0 points) if:

- Fundamental failure to mitigate possible contamination.

2.04.03b: If biosolids are stored and/or applied on adjacent land, has the adjacent landowner supplied paperwork confirming the biosolids meet prevailing guidelines, governmental, or local standards?

Total compliance (10 points): The adjacent landowner of where the biosolids are applied or stored should supply paperwork detailing sufficient information regarding the class of biosolids (e.g., Class AA, A, B): Information should be available that would make it possible to trace back to the source if needed. Information should be available to prove the materials meet prevailing guidelines, governmental, or local standards. Biosolid applications should be timed to avoid conflicts with growing schedules in adjacent fields.

Minor deficiency (7 points) if:

- A single/isolated instance of missing or incomplete information.

Major deficiency (3 points)

- Numerous instances of missing or incomplete information.

Non-compliance (0 points) if:

- No documentation is available for the biosolids stored **and/or applied** in the adjacent land.

2.04.04: Is the growing area situated in a higher risk location where contamination could occur from nearby operations or functions (e.g., leach fields, runoff or potential flooding from sewers, toilet systems, industrial facilities, labor camps, etc.)? If No, go to 2.04.05.

Total points 0: **Information gathering question.** "Higher risk" refers to any nearby activities or operations that could pose a threat to the growing area or facility(ies). These might include chemical, microbiological, or physical contamination or pollution. Examples include, but are not limited to, run-off or potential flooding from septic systems, sewers, toilet systems, industrial facilities, labor camps (issues of trash).

2.04.04a: Where the growing area is situated in a higher risk location, have appropriate measures been taken to mitigate risks related to nearby operations?

Total compliance (15 points): Mitigating measures should **include appropriate** buffer areas around the crop. For example, with a properly designed leach field a buffer zone of approximately 30 ft. (9 m). Very high-risk issues should consider approximately 400ft (122 m) or higher buffer zones. Buffer zone distances should be determined by considering the risk variables (e.g. topography, type of crop). Other mitigating measures may include physical barriers, fences, ditches, etc.

Minor deficiency (10 points) if:

- Appropriate buffer zones have been implemented, but a single/isolated applicable mitigation measure has been ignored.

Major deficiency (5 points) if:

- Appropriate buffer zones have been implemented, but numerous applicable mitigation measures have been ignored.

Non-compliance (0 points) if:

- Fundamental failure to mitigate possible contamination.

2.04.05: Are there any other potential risks in the adjacent land that could potentially lead to contamination of the growing area?

Total points 0: **Information gathering question.** If there are any other potential sources of contamination to the growing area, this question is designed to allow the auditor to underline potential risks that are not covered by other more specific questions within the audit.

2.04.05a: Have appropriate measures been taken to mitigate risks related to nearby operations?

Total compliance (15 points): If there are any other potential sources of contamination to the growing area, there should be mitigating measures to prevent contamination.

Minor deficiency (10 points) if:

- A single/isolated instance of mitigating measures not being implemented.

Major deficiency (5 points) if:

- Numerous instances of mitigating measures not being implemented.

Non-compliance (0 points) if:

- No mitigating measures have been implemented.

2.04.06: Is there evidence of human fecal matter in the adjacent land to the audited area? If No, go to 2.05.01.

Total points 0: **Information gathering question.** If the fecal matter found combines with conditions that can increase the potential of contamination to the growing area, the crop or the field equipment, this represents a high-risk situation that should be addressed. Evidence of human fecal matter represents potential of contamination to the growing area, the crop and field equipment. If No, go to 2.05.01.

2.04.06a: Where there is evidence of human fecal matter in the adjacent land, are there adequate controls in place to mitigate risk (e.g., access controls (barriers), distance from the growing area and equipment, crop type and maturity, land condition, etc.)?

Total compliance (15 points): If the fecal matter found combines with conditions that can increase the potential of contamination to the growing area, the crop or the field equipment, this represents a high-risk situation that should be addressed. There should be adequate controls in place, and records of any corrective or preventive actions taken. It is up to auditor discretion to determine whether issue should be scored as an automatic failure (Q 2.02.11 or 2.05.04). **See Automatic Failure text below.**

Minor deficiency (10 points) if:

- Mitigating measures do not consider a single/isolated factor that can be considered a low risk to the growing area.

Major deficiency (5 points) if:

- Mitigating measures do not consider numerous factors that can be a risk to the growing area.
- No preventive actions have been taken.

Non-compliance (0 points) if:

- No mitigating measures have been implemented.
- No corrective actions have been documented.

Automatic Failure (0 points) if:

- **There is a single incidence of human fecal matter (score under 2.02.11) found in the growing area or contamination of growing area (score under 2.05.04).**

Inspection

2.05.01: 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. The records should include the date of the audit, name of the internal auditor, justification for the answers (**not just checked ✓ or all Y/N**), detail any deficiencies found and the corrective action(s) taken. An audit checklist (ideally PrimusGFS) should be used that covers all areas of the PrimusGFS audit, including growing area, storage area, worker amenities, external areas, worker practices, etc. No down score if another audit checklist is used, as long as all areas are covered. See **also 1.04.01 for specific details.**

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

2.05.02: Are there chemical inventory logs for chemicals, including pesticides and fertilizers?

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, such as chlorine, etc. Primary information in the product inventory includes: the product or chemical names, **container volumes, number on hand**, 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-season operations; auditor discretion applies.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of missing chemical **inventory records**.
- Single/isolated instance(s) of omission(s) or error(s) in the chemical **inventory records**.
- Single/isolated instance(s) of new deliveries not being accounted for.
- Single/isolated instance(s) of minimum inventory frequency not being maintained.

Major deficiency (1 point) if:

- Numerous instances of missing chemical **inventory records**.
- Numerous instances of omissions or errors in the chemical **inventory records**.
- Numerous instances of new deliveries not being accounted for.
- Numerous instances of minimum inventory frequency not being maintained.

Non-compliance (0 points) if:

- **Chemical inventory is not available for review.**

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

Total compliance (15 points): Chemicals (i.e., pesticides, sanitizers, detergents, lubricants, etc.) located on-site are required to be stored in a well vented, designated (with a sign), secure (locked) area. 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. Food grade chemicals should not be commingled with non-food grade chemicals.

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.
- Numerous instances of empty containers either not being properly stored or disposed of properly.
- Numerous instances of chemicals being used without proper attention to chemical spillage.

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.
- Spilled chemicals found in the chemical storage areas (not cleaned up properly)

2.05.04: Are the crop, ingredients (including water), food contact packaging and food contact surfaces 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): The crop, ingredients (including water), food contact packaging and food contact surfaces should be free from spoilage, adulteration and/or gross contamination (21 CFR 110). 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. Examples might include glass, trash/litter, motor oil in products, etc. Is the issue widespread or a one-off issue? This question is designed to allow an auditor

to halt an audit when finding gross contamination issues. 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. Food Defect Levels Handbook

<https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/food-defect-levels-handbook>

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

<https://www.fda.gov/media/71953/download>

US FDA/CFSSAN 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 the crop, harvested product, ingredients (including water), food contact packaging or food contact surfaces.**

Training

2.06.01: 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 irrigation, 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** 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 **(2.01.03) and training** should cover 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. Training provided and associated records should meet all local and national regulations.**

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 does not include the importance of recognizing food safety and/or hygiene issues with co-workers and visitors and/or correcting problems and reporting problems to a supervisor.
- 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.
- Single/isolated instance(s) of workers not being trained.

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.
- Up to 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.
- 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.

2.06.02: Are there written and communicated procedures in place that require food handlers to report any cuts or grazes and/or if they are suffering from 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 actual records)

Total compliance (10 points): There should be documented procedures that are communicated to food handlers (signed records), 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 evidence that workers are 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.

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

Total compliance (3 points): There should be a disciplinary system in place. 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 action not noted.**

Major Deficiency (1 point) if:

- **Numerous instance(s) of follow up/corrective actions not noted.**

Non-compliance (0 points) if:

- No records or no disciplinary system.
- **Widespread failure to record follow up/corrective actions.**

Field Worker Hygiene (applies to on-the-farm workers, not the harvesting workers)

2.07.01: 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. 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 ¼ 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 ¼ 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.

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.**

2.07.01a: 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 **and have a minimum 15 ft (4.5 m) buffer distance in the event of a spill or leak.** 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.

2.07.01b: Are toilet facilities designed and maintained to prevent contamination (e.g., free from leaks and cracks)?

Total compliance (5 points): Toilet facilities 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). Each toilet should be ventilated to outside air. Note: pit toilets cannot be considered to be properly designed to prevent contamination.

<https://www.waterpathogens.org/book/pit-toilets-latrines>

Minor deficiency (3 points) if:

- Single observation of one of the waste holding tank(s) not designed or maintained improperly.
- Single observation of a toilet facility not being well maintained (e.g. cracks, holes, leaks) or not vented to outside air.

Major deficiency (1 point) if:

- More than one observation of the waste holding tank(s) designed or maintained improperly.
- More than one observation of a toilet facility not being well maintained (e.g. cracks, holes, leaks) or not vented to outside air.

Non-compliance (0 points) if:

- Waste holding tank(s) poses a risk of contamination to the growing area, product, packaging, and equipment, such as observing leaks or being improperly constructed.
- Failure to provide adequately maintained toilet facilities.

2.07.01c: Are toilet facilities 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.

Minor Deficiency (2 points) if:

- Single/isolated instance of toilet facilities not being constructed of non-porous materials.

Major Deficiency (1 point) if:

- Numerous instances of toilet facilities not being constructed of non-porous materials.

Non-compliance (0 points) if:

- Toilet facilities are not constructed of non-porous materials.

2.07.01d: Are the toilet facility materials constructed of a light color allowing easy evaluation of cleaning performance?

Total compliance (3 points): Toilet facilities 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.

2.07.01e: Are toilet facilities 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.

2.07.01f: 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.

2.07.01g: Are the toilet facilities and hand washing stations clean and are there records showing 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.
- Single/isolated instance(s) of incomplete or missing records.

Major deficiency (3 points) if:

- Numerous instances of non-compliance to the above requirements.
- Numerous observations of soiled toilet tissues being placed in trash cans.
- Numerous instances of incomplete or missing records.

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.

2.07.02: 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.

2.07.03: Are hand washing stations adequate in number and appropriately located for worker access and monitoring usage? 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.

2.07.03a: Are the hand wash stations designed and maintained properly (e.g., ability to capture or control rinse water to prevent contamination onto product, packaging, and growing area, free of clogged drains, etc.)?

Total Compliance (5 points): Hand wash stations should be free of clogged drains, designed and maintained properly to capture or control rinse water that could cause contamination onto product, packaging, equipment and growing area(s).

Minor Deficiency (3 points) if:

- Single/isolated instance of hand wash stations not draining properly.

Major Deficiency (1 point) if:

- Numerous instances of hand wash stations not draining properly.

Non- compliance (0 points) if:

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

2.07.03b: 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.

2.07.03c: 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 and units properly located. There should be an adequate stock of soap and paper towels.

Minor Deficiency (3 points) if:

- Single/isolated instance of a hand wash station out of soap and/or paper towels.

Major Deficiency (1 point) if:

- Numerous instances of hand wash stations out of soap and/or paper towels.

Non- compliance (0 points) if:

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

2.07.04: Are total coliforms (TC) and generic *E. coli* tests conducted on the water used for hand washing at the required and/or expected frequency?

Total compliance (15 points): Total coliforms (TC) and generic *E. coli* testing should occur prior to use and at least annually. Water samples should be taken from as close to the point of use as is practical e.g. hand wash spigot/faucet. If there are multiple hand wash units, then samples should be taken from a different location each test (randomize or rotate locations). If there are multiple sources for hand wash water, testing should also account for each source used.

Reference:

<https://extension.psu.edu/coliform-bacteria>

<https://www.govinfo.gov/content/pkg/CFR-2011-title40-vol23/pdf/CFR-2011-title40-vol23-part141.pdf>

<https://www.epa.gov/dwstandardsregulations>

Minor deficiency (10 points) if:

- Single instance of water testing not occurring at the right frequency.
- Sample(s) was not taken from the closest practical point of use.
- A single water source (where there is more than one) has not been tested.

Major deficiency (5 points) if:

- More than one instance of water testing not occurring at the right frequency.
- More than one water source (where there are more than two) has not been tested.

Non-compliance (0 points):

- No microbiological test results are available.
- Last test was done over 12 months ago.

2.07.04a: 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 a documented procedure in place detailing how water samples are to be taken, including stating how samples should be identified i.e. clearly naming the location that the sample was taken, identifying the hand wash station, the water source and the date.

Minor Deficiency (7 points) if:

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

Major Deficiency (3 points) if:

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

Non-compliance (0 points) if:

- There is no documented procedure.

2.07.04b: 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 testing results, but also as a preparation on how to handle such findings.

Minor Deficiency (7 points) if:

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

Major Deficiency (3 points) if:

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

Non-compliance (0 points) if:

- There is no documented procedure.

2.07.04c: If unsuitable or abnormal results have been detected, have documented corrective measures been performed?

Total compliance (15 points): For total coliforms (TC) and generic *E. coli*, there should be negative or < detection limit (MPN or CFU/100mL). Where thresholds have been exceeded, there should be recorded corrective actions, including investigations and water retests.

Minor Deficiency (10 points) if:

- Single/isolated instance(s) of records showing unsuitable or abnormal test results for total coliforms without adequate documented corrective actions.

Major Deficiency (5 points) if:

- Numerous instances of records showing unsuitable or abnormal test results for total coliforms without adequate documented corrective actions.

Non-compliance (0 points) if:

- No corrective actions have been performed.
- A single out of specification result for generic *E. coli* without proper corrective actions.

2.07.05: 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. 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://sproutnet.com/hand-washing-program/>

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 fundamental failure of workers to comply with hand washing policies.

2.07.06: 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:

- A single instance of a worker with exposed boils, sores, exposed infected wounds, foodborne illness or any other source of abnormal microbial contamination. There is not a threat of product or packaging contamination.

Major deficiency (3 points) if:

- More than one instance of workers with exposed boils, sores, exposed infected wounds, foodborne illness or any other source of abnormal microbial contamination. There is not a threat of product or packaging contamination.

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.
- The auditor should consider whether this is adulteration and whether to apply 2.05.04 and score an automatic failure.

2.07.07: Is jewelry confined to a plain wedding band and watches, studs, false eyelashes, etc., 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 finger nails and finger nail polish, 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.

2.07.08: Are worker personal items being stored appropriately (i.e. not in the growing area(s) or material storage area(s))?

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 defense** risks.

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of personal belongings, personal food, etc. being found in the growing or material storage area(s).

Non-compliance (0 points) if:

- Fundamental failure to prevent personal belongings, personal food, etc. being taken into the growing or material storage area(s).

2.07.09: 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.

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

21 CFR Part 117.10

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=117.10>

21 CFP Part 112.32

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=112.32>

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 refuse containers located in the growing area).
- Single/isolated instance(s) of designated area not meeting appropriate GAP 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 refuse containers located in the growing area).
- No designated smoking area (unless the site has a non-smoking policy).
- Numerous instances of designated area not meeting appropriate GAP standards.

Non-compliance (0 points) if:

- Widespread consumption of food and beverages outside of designated areas.
- 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.

2.07.10: 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 to prevent dehydration. 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 water containers are used, they should be maintained in a clean condition, free from residues and contamination to ensure workers are not adversely affected by contaminated water from unclean containers. 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.

2.07.10a: 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 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.

2.07.11: 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. 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:

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

2.07.12: 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 **handwash stations**. **All dumpsters and garbage receptacles should have a cover and be kept covered to prevent the attraction of insects, rodents and other pests.** 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 **available and/or** being maintained **to protect against potential contamination of the crop.**

Major deficiency (1 point) if:

- Numerous instances of containers not **available and/or** being maintained **to protect against potential contamination of the crop.**

Non-compliance (0 points) if:

- Fundamental failure to **provide adequate trash disposal.**
- **Fundamental failure** to maintain containers to protect against potential contamination of the crop.

2.07.13: Are any potential foreign material issues (e.g., metal, glass, plastic) controlled?

Total compliance (5 points): There should be no foreign material issues that are or could be potential risks to the product in the growing area(s). Examples include, but are not limited to, glass bottles, unprotected lights on equipment, staples on wooden crates, hair pins, using “snappable” blades instead of one-piece blades, broken and brittle plastic issues on re-useable totes.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of a foreign material issue.

Major deficiency (1 point) if:

- Numerous instances of foreign material issues.

Non-compliance (0 points) if:

- Fundamental failure to prevent against foreign material issues.

Agronomic Inputs

2.08.01: Is **human sewage sludge (biosolids) used as an input?**

Total points 0: Information gathering question. Human sewage sludge (biosolids), which are by-products of waste water treatment, should not to be used in the growing cycle for indoor growing operations, and also where specifically prohibited under best management practices (e.g., LGMA, T-GAPs). **The use of untreated biosolids is prohibited.**

https://toxics.usgs.gov/regional/emc/municipal_biosolids.html

2.08.01a: 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): 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.

Automatic Failure (0 points) if:

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

2.08.01b: 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 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 2.05.04.**

2.08.01c: 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). 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://www.epa.gov/biosolids/plain-english-guide-epa-part-503-biosolids-rule>
- <https://apps1.cdfa.ca.gov/fertilizerproducts/>
- <http://library.state.or.us/repository/2007/200701251422434/index.pdf>
- <https://agr.wa.gov/departments/pesticides-and-fertilizers/fertilizers/product-database>

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.

2.08.01d: 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): There should be evidence that each laboratory test result (certificate of analysis) provided is traceable to each material used. (e.g., CoA is traced to each lot of crop treatment used). Tests should include microbiological analyses. As minimum, for non-synthetic crop treatments (e.g., compost teas, fish emulsions, fish meal, blood meal, "bio fertilizers") and for animal based compost microbial testing should include *Salmonella* spp., *E. coli* O157:H7, and *Listeria monocytogenes* at Negative or <DL and include fecal coliforms/gram at < 1000 MPN of total solids and any other pathogens appropriate for the source of material using approved sampling and testing methods (e.g., AOAC and an accredited laboratory). All local and national legislation should also be followed.

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 validated physical/chemical/biological process to inactivate human pathogens (*Salmonella* spp., *E. coli* O157:H7, *Listeria monocytogenes*) and show fecal coliforms/gram <1000 MPN. The auditee has the test analyses that show 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 used must be applicable to the situation at hand and care should be taken not to over extrapolate. 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 lots produced. 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.

Reference:

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

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=112&showFR=1&ubpartNode=21:2.0.1.1.12.6>

California state regulations for compost (CCR Title 14 - Chapter 3.1 - Article 7;

<https://govt.westlaw.com/calregs/Document/I978C116BD2DF4472ACEADBAE443C29D1?contextData=%28sc.Default%29&transitionType=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.

2.08.01e: 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 compost 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/biosolids/plain-english-guide-epa-part-503-biosolids-rule>

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

<https://www.planetnatural.com/composting-101/compost-concerns/heavy-metals/>

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.

2.08.02: Is compost produced from animal derived materials used as an input?

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

2.08.02a: 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): 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.

Automatic Failure (0 points) if:

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

2.08.02b: 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 2.05.04.**

2.08.02c: 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/departments/pesticides-and-fertilizers/fertilizers/product-database>
- <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.

2.08.02d: 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): There should be evidence that each laboratory test result (certificate of analysis) provided is traceable to each material used. (e.g., CoA is traced to each lot of crop treatment used). Tests should include microbiological analyses. As minimum, for non-synthetic crop treatments (e.g., compost teas, fish emulsions, fish meal, blood meal, "bio fertilizers") and for animal based compost microbial testing should include *Salmonella* spp., *E. coli* O157:H7, and *Listeria monocytogenes* at Negative or <DL and include fecal coliforms/gram at < 1000 MPN of total solids and any other pathogens appropriate for the source of material using approved sampling and testing methods (e.g., AOAC and an accredited laboratory). All local and national legislation should also be followed.

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 validated physical/chemical/biological process to inactivate human pathogens (*Salmonella* spp., *E. coli* O157:H7, *Listeria monocytogenes*) and show fecal coliforms/gram <1000 MPN. The auditee has the test analyses that show 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 used must be applicable to the situation at hand and care should be taken not to over extrapolate. 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 lots produced. 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.

Reference:

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

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=112&showFR=1&ubpartNode=21:2.0.1.1.12.6>

California state regulations for compost (CCR Title 14 - Chapter 3.1 - Article 7;

<https://govt.westlaw.com/calregs/Document/I978C116BD2DF4472ACEADBAE443C29D1?contextData=%28sc.Default%29&transitionType=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.

2.08.02e: 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 Section 17868.2. Maximum Metal Concentrations for reference levels for an example of local State laws. 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>

<https://www.planetnatural.com/composting-101/compost-concerns/heavy-metals/>

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.

2.08.03: Is untreated animal manure used as an input (e.g. raw manure &/or uncomposted, incompletely composted animal manure, green waste, non-thermally treated animal manure)?

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.

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.**

2.08.03a: 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): 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.

Automatic Failure (0 points) if:

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

2.08.03b: 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 2.05.04.**

2.08.03c: 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/departments/pesticides-and-fertilizers/fertilizers/product-database>

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

[382HeavyMetalsTestRequirements.pdf?/707-382HeavyMetalsTestRequirements](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.

2.08.03d: 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>

<https://www.planetnatural.com/composting-101/compost-concerns/heavy-metals/>

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.

2.08.04: Are other non-synthetic crop treatments used as an input (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.

2.08.04a: 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): 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.

Automatic Failure (0 points) if:

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

2.08.04b: 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 2.05.04.**

2.08.04c: 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>
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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.

2.08.04d: 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): There should be evidence that each laboratory test result (certificate of analysis) provided is traceable to each material used. (e.g., CoA is traced to each lot of crop treatment used). Tests should include microbiological analyses. As minimum, for non-synthetic crop treatments (e.g., compost teas, fish emulsions, fish meal, blood meal, "bio fertilizers") and for animal based compost microbial testing should include *Salmonella* spp., *E. coli* O157:H7, and *Listeria monocytogenes* at Negative or <DL and include fecal coliforms/gram at < 1000 MPN of total solids and any other pathogens appropriate for the source of material using approved sampling and testing methods (e.g., AOAC and an accredited laboratory). All local and national legislation should also be followed.

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 validated physical/chemical/biological process to inactivate human pathogens (*Salmonella* spp., *E. coli* O157:H7, *Listeria monocytogenes*) and show fecal coliforms/gram <1000 MPN. The auditee has the test analyses that show 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 used must be applicable to the situation at hand and care should be taken not to over extrapolate. 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 lots produced. 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.

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Equal to or greater than 290 but fewer than 1,500	Quarterly
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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.

Reference:

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

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=112&showFR=1&ubpartNode=21:2.0.1.1.12.6>

California state regulations for compost (CCR Title 14 - Chapter 3.1 - Article 7;

<https://govt.westlaw.com/calregs/Document/I978C116BD2DF4472ACEADBAE443C29D1?contextData=%28sc.Default%29&transitionType=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.

2.08.04e: 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)). 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>

<https://www.planetnatural.com/composting-101/compost-concerns/heavy-metals/>

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.

2.08.05: Are any soil or substrate amendments used as an input (e.g. plant by-products, humates, seaweed, inoculants, conditioners, 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.

2.08.05a: 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): 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.

Automatic Failure (0 points) if:

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

2.08.05b: 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 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 2.05.04.**

2.08.05c: 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/departments/pesticides-and-fertilizers/fertilizers/product-database>
<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.

2.08.05d: 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.

2.08.06: Are inorganic fertilizers used as an input (e.g. ammonium nitrate, ammonium sulfate, chemically synthesized urea, etc.)?

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.

2.08.06a: 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): 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.

Automatic Failure (0 points) if:

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

2.08.06b: 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 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.

2.08.06c: 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/departments/pesticides-and-fertilizers/fertilizers/product-database>

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

[382HeavyMetalsTestRequirements.pdf?/707-382HeavyMetalsTestRequirements](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.

Irrigation/Water Use

2.09.01: 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.

2.09.01a: 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 (NONCOMPLIANCE) DOWN SCORE 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 are taken from a different location each test (randomize or rotate locations).

For farm and indoor agriculture operations, one sample per water source is collected and tested prior to use if >60 days since the last test of the water source. Additional samples are taken at least monthly during use of the water source. A less frequent testing is acceptable if supported by a valid documented risk assessment although there should be at least one water test per season. Where there are more stringent federal, national or local requirements, those requirements should be followed. If a risk assessment is used to define the frequency, it should include at a minimum the water source, method of application (edible product contact vs non-edible product contact), reference or evidence to the microbial historical data of the water source, and its vulnerability to contamination. A vulnerable water source is one for which there is a potential risk of contamination by fecal matter (e.g. animals grazing upstream of a river abstraction point, overloading of a sewage treatment plant by storm water) or other potential risk factors. As examples, vulnerable sources may be surface water (rivers, lakes, natural ponds), reservoirs supplied by well water or rain water, groundwater collected from shallow wells. Other sources may be vulnerable under specific circumstances and the degree of vulnerability should be established by the grower's risk assessment. In the event the risk assessment indicates contamination risks, the operation should implement adequate measures to prevent and/or mitigate product contamination.

References:

<https://extension.psu.edu/safe-uses-of-agricultural-water>

<https://gaps.cornell.edu/educational-materials/decision-trees/agricultural-water-production/>

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water testing not occurring at the right frequency.
- **Sample(s) 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.**

2.09.01b: 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.

2.09.01c: 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 measures for unsuitable/abnormal water test results.
- The written SOPs were not followed when unsuitable or abnormal water testing results were recorded in the last 12 months.

2.09.01d: 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 that prevent or mitigate product contamination, including investigations, water retests, and if required, crop testing (*E. coli* O157:H7 and *Salmonella* - zero tolerance). Failure to take corrective actions, prevent or mitigate product contamination when there is evidence of high levels or an upward trend of *E. coli* may result in an automatic failure of the audit. 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).

Reference:

<https://producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule/>

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.
- **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 2.05.04.)**

2.09.01e: Where anti-microbial water treatment (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, 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 being 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 being 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.

2.09.01f: Are records kept for periodic visual inspection of the water source available for review?

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.
- Failure to record corrective action details.

2.09.02: Is well water used in the 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.

2.09.02a: 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 (NONCOMPLIANCE) DOWN SCORE 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 are taken from a different location each test (randomize or rotate locations). For farm and indoor agriculture operations, one sample per water source is collected and tested prior to use if >60 days since the last test of the water source. Additional samples are taken at least monthly during use of the water source. A less frequent testing is acceptable if supported by a valid documented risk assessment although there should be at least one water test per season. Where there are more stringent federal, national or local requirements, those requirements should be followed. If a risk assessment is used to define the frequency, it should include at a minimum the water source, method of application (edible product contact vs non- edible product contact), reference or evidence to the microbial historical data of the water source, and its vulnerability to contamination. A vulnerable water source is one for which there is a potential risk of contamination by fecal matter (e.g. animals grazing upstream of a river abstraction point, overloading of a sewage treatment plant by storm water) or other potential risk factors. Vulnerable sources may be surface water (rivers, lakes, natural ponds), reservoirs supplied by well water or rain water, groundwater collected from shallow wells. Other sources may be vulnerable under specific circumstances and the degree of vulnerability should be established by the grower's risk assessment. In the event the risk assessment indicates contamination risks, the operation should implement adequate measures to prevent and/or mitigate product contamination.

References:

<https://extension.psu.edu/safe-uses-of-agricultural-water>

<https://gaps.cornell.edu/educational-materials/decision-trees/agricultural-water-production/>

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water testing not occurring at the right frequency.
- **Sample(s) 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.**

2.09.02b: 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.

2.09.02c: 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 measures for unsuitable/abnormal water test results.
- The written SOPs were not followed when unsuitable or abnormal water testing results were recorded in the last 12 months.

2.09.02d: 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 that prevent or mitigate product contamination, including investigations, water retests, and if required, crop testing (*E. coli* O157:H7 and *Salmonella* - zero tolerance). Failure to take corrective actions, prevent or mitigate product contamination when there is evidence of high levels or an upward trend of *E. coli* may result in an automatic failure of the audit. 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).

Reference:

<https://producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule/>

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.
- **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 2.05.04.)**

2.09.02e: Where anti-microbial water treatment (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, 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 being 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 being 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.

2.09.02f: Are records kept for periodic visual inspection of the water source and available for review?

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.
- Failure to record corrective action details.

2.09.03: Is non-flowing surface water (e.g., ponds, reservoirs, watersheds, etc.) used in the 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. 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.

2.09.03a: 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 (NONCOMPLIANCE) DOWN SCORE 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 are taken from a different location each test (randomize or rotate locations). For farm and indoor agriculture operations, one sample per water source is collected and tested prior to use if >60 days since the last test of the water source. Additional samples are taken at least monthly during use of the water source. A less frequent testing is acceptable if supported by a valid documented risk assessment although there should be at least one water test per season. Where there are more stringent federal, national or local requirements, those requirements should be followed. If a risk assessment is used to define the frequency, it should include at a minimum the water source, method of application (edible product contact vs non- edible product contact), reference or evidence to the microbial historical data of the water source, and its vulnerability to contamination. A vulnerable water source is one for which there is a potential risk of contamination by fecal matter (e.g. animals grazing upstream of a river abstraction point, overloading of a sewage treatment plant by storm water) or other potential risk factors. As examples, vulnerable sources may be surface water (rivers, lakes, natural ponds), reservoirs supplied by well water or rain water, groundwater collected from shallow wells. Other sources may be vulnerable under specific circumstances and the degree of vulnerability should be established by the grower's risk assessment. In the event the risk assessment indicates contamination risks, the operation should implement adequate measures to prevent and/or mitigate product contamination.

References:

<https://extension.psu.edu/safe-uses-of-agricultural-water>

<https://gaps.cornell.edu/educational-materials/decision-trees/agricultural-water-production/>

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water testing not occurring at the right frequency.
- **Sample(s) 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.**

2.09.03b: 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.

2.09.03c: 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 measures for unsuitable/abnormal water test results.
- The written SOPs were not followed when unsuitable or abnormal water testing results were recorded in the last 12 months.

2.09.03d: 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 that prevent or mitigate product contamination, including investigations, water retests, and if required, crop testing (*E. coli* O157:H7 and *Salmonella* - zero tolerance). Failure to take corrective actions, prevent or mitigate product contamination when there is evidence of high levels or an upward trend of *E. coli* may result in an automatic failure of the audit. 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).

Reference:

<https://producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule/>

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.
- **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 2.05.04.)**

2.09.03e: Where anti-microbial water treatment (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, 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 being 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 being 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.

2.09.03f: Are records kept for periodic visual inspection of the water source and available for review?

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.
- Failure to record corrective action details.

2.09.04: Is open flowing surface water used in the operation (e.g., rivers, canals, ditches, etc.)? 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 other sources, and caution should be exercised when using these waters for irrigation.

2.09.04a: 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 (NONCOMPLIANCE) DOWN SCORE 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 are taken from a different location each test (randomize or rotate locations). For farm and indoor agriculture operations, one sample per water source is collected and tested prior to use if >60 days since the last test of the water source. Additional samples are taken at least monthly during use of the water source. A less frequent testing is acceptable if supported by a valid documented risk assessment although there should be at least one water test per season. Where there are more stringent federal, national or local requirements, those requirements should be followed. If a risk assessment is used to define the frequency, it should include at a minimum the water source, method of application (edible product contact vs non- edible product contact), reference or evidence to the microbial historical data of the water source, and its vulnerability to contamination. A vulnerable water source is one for which there is a potential risk of contamination by fecal matter (e.g. animals grazing upstream of a river abstraction point, overloading of a sewage treatment plant by storm water) or other potential risk factors. As examples, vulnerable sources may be surface water (rivers, lakes, natural ponds), reservoirs supplied by well water or rain water, groundwater collected from shallow wells. Other sources may be vulnerable under specific circumstances and the degree of vulnerability should be established by the grower's risk assessment. In the event the risk assessment indicates contamination risks, the operation should implement adequate measures to prevent and/or mitigate product contamination.

References:

<https://extension.psu.edu/safe-uses-of-agricultural-water>

<https://gaps.cornell.edu/educational-materials/decision-trees/agricultural-water-production/>

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.

2.09.04b: 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.

2.09.04c: 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 measures for unsuitable/abnormal water test results.**
- The written SOPs were not followed when unsuitable or abnormal water testing results were recorded in the last 12 months.

2.09.04d: 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 that prevent or mitigate product contamination, including investigations, water retests, and if required, crop testing (*E. coli* O157:H7 and *Salmonella* - zero tolerance). Failure to take corrective actions, prevent or mitigate product contamination when there is evidence of high levels or an upward trend of *E. coli* may result in an automatic failure of the audit. 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).

Reference:

<https://producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule/>

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.
- **Contaminated water is being consistently used for product contact use without evidence of corrective actions being implemented. (This qualifies as an automatic failure.)**

2.09.04e: Where anti-microbial water treatment (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, 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 being 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 being 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.

2.09.04f: Are records kept for periodic visual inspection of the water source and available for review?

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.
- Failure to record corrective action details.

2.09.05: 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 including World Health Organisation (WHO) guidelines for the safe use of wastewater, excreta and greywater in agriculture. Prior to using this water for agricultural purposes, growers should check with regulatory bodies to determine the appropriate parameters and tolerances to be used.

2.09.05a: 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 (NONCOMPLIANCE) DOWN SCORE 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 are taken from a different location each test (randomize or rotate locations).

For farm and indoor agriculture operations, one sample per water source is collected and tested prior to use if >60 days since the last test of the water source. Additional samples are taken at least monthly during use of the water source. A less frequent testing is acceptable if supported by a valid documented risk assessment although there should be at least one water test per season. Where there are more stringent federal, national or local requirements, those requirements should be followed. If a risk assessment is used to define the frequency, it should include at a minimum the water source, method of application (edible product contact vs non- edible product contact), reference or evidence to the microbial historical data of the water source, and its vulnerability to contamination. A vulnerable water source is one for which there is a potential risk of contamination by fecal matter (e.g. animals grazing upstream of a river abstraction point, overloading of a sewage treatment plant by storm water) or other potential risk factors. As examples, vulnerable sources may be surface water (rivers, lakes, natural ponds), reservoirs supplied by well water or rain water, groundwater collected from shallow wells. Other sources may be vulnerable under specific circumstances and the degree of vulnerability should be established by the grower's risk assessment. In the event the risk assessment indicates contamination risks, the operation should implement adequate measures to prevent and/or mitigate product contamination.

References:

<https://extension.psu.edu/safe-uses-of-agricultural-water>

<https://gaps.cornell.edu/educational-materials/decision-trees/agricultural-water-production/>

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water testing not occurring at the right frequency.
- **Sample(s) 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.**

2.09.05b: 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.

2.09.05c: 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 measures for unsuitable/abnormal water test results.**
- The written SOPs were not followed when unsuitable or abnormal water testing results were recorded in the last 12 months.

2.09.05d: 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 that prevent or mitigate product contamination, including investigations, water retests, and if required, crop testing (*E. coli* O157:H7 and *Salmonella* - zero tolerance). Failure to take corrective actions, prevent or mitigate product contamination when there is evidence of high levels or an upward trend of *E. coli* may result in an automatic failure of the audit. 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).

Reference:

<https://producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule/>

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.
- **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 2.05.04.)**

2.09.05e: Where anti-microbial water treatment (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, 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 being 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 being 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.

2.09.05f: Are records kept for periodic visual inspection of the water source and available for review?

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.
- Failure to record corrective action details.

2.09.06: Is tail water (run off water including hydroponics), used in the 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. Tail water return systems, including hydroponics, catch spilled or runoff water and pump the water back to the top of the field.

2.09.06a: 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 (NONCOMPLIANCE) DOWN SCORE 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 are taken from a different location each test (randomize or rotate locations).

For farm and indoor agriculture operations, one sample per water source is collected and tested prior to use if >60 days since the last test of the water source. Additional samples are taken at least monthly during use of the water source. A less frequent testing is acceptable if supported by a valid documented risk assessment although there should be at least one water test per season. Where there are more stringent federal, national or local requirements, those requirements should be followed. If a risk assessment is used to define the frequency, it should include at a minimum the water source, method of application (edible product contact vs non- edible product contact), reference or evidence to the microbial

historical data of the water source, and its vulnerability to contamination. A vulnerable water source is one for which there is a potential risk of contamination by fecal matter (e.g. animals grazing upstream of a river abstraction point, overloading of a sewage treatment plant by storm water) or other potential risk factors. As examples, vulnerable sources may be surface water (rivers, lakes, natural ponds), reservoirs supplied by well water or rain water, groundwater collected from shallow wells. Other sources may be vulnerable under specific circumstances and the degree of vulnerability should be established by the grower's risk assessment. In the event the risk assessment indicates contamination risks, the operation should implement adequate measures to prevent and/or mitigate product contamination.

References:

<https://extension.psu.edu/safe-uses-of-agricultural-water>

<https://gaps.cornell.edu/educational-materials/decision-trees/agricultural-water-production/>

Minor deficiency (10 points) if:

- Single/isolated instance(s) of water testing not occurring at the right frequency.
- **Sample(s) 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.**

2.09.06b: 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.

2.09.06c: 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 measures for unsuitable/abnormal water test results.**

- The written SOPs were not followed when unsuitable or abnormal water testing results were recorded in the last 12 months.

2.09.06d: 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 that prevent or mitigate product contamination, including investigations, water retests, and if required, crop testing (*E. coli* O157:H7 and *Salmonella* - zero tolerance). Failure to take corrective actions, prevent or mitigate product contamination when there is evidence of high levels or an upward trend of *E. coli* may result in an automatic failure of the audit. 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).

Reference:

<https://producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule/>

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.
- **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 2.05.04.)**

2.09.06e: Where anti-microbial water treatment (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, 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 being 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 being 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.

2.09.06f: Are records kept for periodic visual inspection of the water source and available for review?

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.
- Failure to record corrective action details.

2.09.07: Is dryland farming used in the growing operation?

Total Points: (0 points) Information gathering question. This refers to crop production that relies only on direct rainfall.

2.09.08: 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).

2.09.09: 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

2.10.01: Are there up-to-date records of all pesticides applied during the **growth cycle? 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.**).

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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.**

2.10.02: 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 the program is 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 2.10.05)

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.**

2.10.03: 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 should show “authorization program” use/application 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.**

2.10.04: 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).**

2.10.05: Where products are destined for export, is there information for pesticide Maximum Residue Limits (MRLs) 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. This assumes that grower is meeting country of origin MRL and label requirements. If there is no MRL defined by the country of destination for any active ingredient applied, the operation should have documented evidence of the applicable regulations in that country (e.g. default MRL, Codex Alimentarius, non-detectable, etc.). In the case where the MRLs 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 ingredients)

Non-compliance (0 points) if:

- There is no MRL information for the destination countries (or widespread missing information)

2.10.06: Where products are destined for export, is there evidence that Maximum Residue Limits (MRLs) of the intended markets are met?

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 interval modifications. Degradation curves used as reference should be issued/provided by the manufacturer of the pesticide or country of production government and correspond to the degradation of the pesticide 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 deficiency category for this question.

Non-compliance (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.
- Automatic failure if corrective actions are not provided and accepted by the certification body.

2.10.07: 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-compliance (0 points) if:

- Widespread errors or omissions in the procedure or practice.
- There is no procedure.

2.10.08: 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).

2.10.09: 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 (in-house or external) 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

Document Revision History		
Date	Rev.#	Description
2/18/21	0	Initial
10/8/21	1	Changes to questions 2.02.03a, 2.02.04, 2.08.01 & 2.09.05
4/8/22	2	Question 2.02.03a changed Preventative to Preventive; question 2.03.04 removed text "If No, go to 2.03.05".