

2019

An internationally recognized Global Food Safety Initiative (GFSI) food safety audit scheme

INTERPRETATION **GUIDELINES**

PrimusGFS v3.1

MODULE 2

FARM

Used in conjunction with the PrimusGFS v3.1 audit









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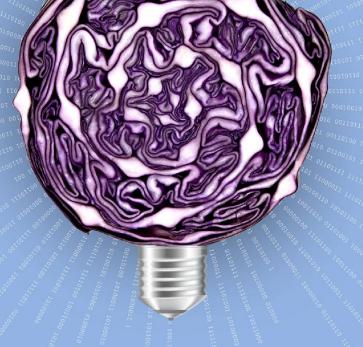
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PrimusGFS v3.1

Interpretation Guidelines

Module 2: Farm

Used in conjunction with the PrimusGFS v3.1 audit

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MODULE 2: FARM

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MODULE 2: FARM

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These guidelines help interpret/support the principles, requirements and expectations of the PrimusGFS v3.1 Modules 1, 2, 3, 4, 5, 6 and 7 as noted in the <u>Scheme normative documents</u>. 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 <u>audit checklist templates</u>. 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 is a modified excerpt from the PrimusGFS General Regulations v3.1. 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 points | 1 points | |
| 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 systematic deficiencies against the question and/or compliance criteria (severe or non-severe issues). | | | |
| Not applicable | The requirement described in the question is not applicable for the operation being audited. Justification should be provided in the auditor's comments. Be aware that there are some questions that do not allow a non-applicable response. | | | |



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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).

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





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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="" th="" year<=""><th>Operates >three months/year</th></three> | Operates >three months/year |
|----------------------------|---|--|
| New PrimusGFS Auditee | Three months of records (may include last season's records). | 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 conformance criteria have changed significantly since the previous version. Many of the changes are to improve clarification, but some are changes to the actual requirements. Please read carefully to see if these changes impact your particular situation.



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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 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.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

- Systematic failure to document person/persons in charge of the operation's food safety program training and/or their relevant experience in food safety.
- No-one is in charge of 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? Informational 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). 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. Training provided and associated records should meet all local and national regulations.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of errors and omissions in the records or food safety hygiene and health policy.
- Up to three points missing off the worker and visitor personal hygiene, GAPs and health requirements listing.





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- Training materials are not in the relevant language(s).
- Single/isolated instance(s) of workers and visitors not being trained or not signing a document stating that they will comply with the
 operations' personal hygiene and health policies.

Major deficiency (5 points) if:

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

Non-compliance (0 points) if:

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

2.01.04: Are the necessary food defense controls implemented in the operation?

Total compliance (5 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 field, handling facilities, etc. The auditor should down score if there are any unprotected water sources, a lack of signage to prevent trespassing, etc.

FDA Guidance for Industry,

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

Minor deficiency (3 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 (1 point) 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:

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



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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), 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: 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.





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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.

2.02.04: 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.

2.02.05: 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.





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2.02.06: 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:

· Systematic failure to prevent contamination.

<u>Automatic Failure</u> (0 points) if:

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

2.02.07: 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 is not a risk of contamination to the product, water sources, production areas, equipment, packaging materials, etc.

Minor deficiency (10 points) if:

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

Major deficiency (5 points) if:

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

Non-compliance (0 points) if:

• Systematic failure to prevent contamination.

2.02.08: Is the audited area free from animal presence and/or animal activity (wild or domestic)? If Yes, go to 2.02.09.

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:





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

Major deficiency (5 points) if:

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

Non-compliance (0 points) if:

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

2.02.08a: Is there any evidence of fecal matter in the audited area?

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.

Minor deficiency (10 points) if:

• Single/isolated instance of fecal matter found in the audited area.

Major deficiency (5 points) if:

- Numerous instances of fecal matter found throughout the audited area.
- A "no harvest zone" is implemented, but the radius is less than 5ft.

Non-compliance (0 points) if:

- Fecal matter is found in the audited area and a "no harvest zone" was not implemented.
- Fecal matter is found, but a food safety assessment is not conducted.

2.02.08b: Is the fecal matter found in the audited area, a systematic event (not sporadic)? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.

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

Automatic Failure (0 points) if:

- · Any observation of systematic 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.

2.02.09: Is the audited area free of evidence of infants and toddlers?





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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:

• Systematic 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 for human consumption last season?

Total points 0: Land should be purchased or leased that has previously been successfully utilized for growing produce for human consumption, 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: 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 produce for human consumption without incidence. http://www.epa.gov/superfund/health/index.htm

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? If No, go to 2.03.04.





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Total points 0: 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 growing season? If No, go to 2.03.05.

Total points 0: 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.

 $\underline{\text{http://www.fda.gov/food/guidanceregulation/guidancedocuments}} \\ \underline{\text{regulatoryinformation/emergencyresponse/ucm287808.htm}}$

2.03.04a: If the growing area(s) and product was affected from the flood waters, is there documented evidence 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 documented 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.

 $\underline{http://www.fda.gov/food/guidanceregulation/guidancedocuments regulatory information/emergency response/ucm 287808. htm \\ \underline{http://www.fda.gov/food/guidanceregulation/guidancedocuments regulatory information/emergency response/ucm 287808. htm \\ \underline{http://www.fda.gov/food/guidanceregulatory response/ucm 287808. htm \\ \underline{http://w$

Minor deficiency (10 points) if:

• Single/isolated instance of missing evidence of corrective actions performed.

Major deficiency (5 points) if:

• Numerous instances of missing evidence of corrective actions performed.

Non-compliance (0 points) if:

- No documented corrective actions were performed.
- · Product affected by flooding was harvested for human consumption.





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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, product and/or soil, clearance testing should be conducted prior to planting. Soil testing should indicate microorganisms lower than the standards for processed compost. 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.

http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/emergencyresponse/ucm287808.htm

Minor deficiency (10 points) if:

- · Soil tests demonstrate that the soil was contaminated, but no soil tests were conducted after performing corrective actions
- Product testing was conducted but not representative for the type of crop and/or flood area(s) affected.

Major deficiency (5 points) if:

· Soil tests were conducted but did not consider all microorganisms of significant public health concern.

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.

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.

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

Total Compliance (10 points): A documented risk assessment of the growing area and surrounding areas should be performed and documented annually, and when any changes are made to the growing area, and adjacent land. This should detail known or reasonable 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 sources (chemical hazards e.g. heavy metals, perchlorate, etc., and microbial hazards e.g.





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pathogenic *E. coli*), water use, fertilizers, crop protection chemicals, worker health and hygiene, equipment and tools used for harvest, storage, transportation, topography of the land for runoff, prevailing weather conditions or weather events, and any other applicable areas. Farms and indoor agriculture operations following the CA or AZ LGMA should have a buffer zone of approximately 1,200 ft. (365m) for CAFO's with >1,000 head or 1 mile (1609m) for 80,000 head CAFO, which may increase or decrease after assessing the risks, determining, and deploying mitigation measures.

A detailed risk assessment should have been conducted and documented.

One approach:

- i) Identify hazards
- ii) Determine who may be harmed and how
- 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

http://www.p2pays.org/ref%5C05/04874.pdf

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

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

Minor deficiency (7 points):

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

Major deficiency (3 points):

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

Non-compliance (0 points):

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

2.03.05a: If any risk is identified, have corrective actions and/or preventative measures been documented and implemented?

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

Minor deficiency (7 points):

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

Major deficiency (3 points):





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

Non-compliance (0 points):

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

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 10: 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 (uphill from the crop or downhill from the crop) 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 have a buffer zone of approximately 1,200 ft. (365m) for CAFO's with >1,000 head or 1 mile (1609m) for 80,000 head CAFO, which may increase or decrease after assessing the risks, determining, and deploying mitigation measures.

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:

• Systematic failure to mitigate possible contamination.

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

Total points 10: 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: Have physical measures been put in place to restrain domestic and wild animals, grazing lands (includes homes with hobby farms, and non-commercial livestock) and their waste from entering the growing area (e.g., vegetative strips, wind breaks,





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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 (uphill from the crop or downhill from the crop). 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 mitigiation measures have been ignored.

Non-compliance (0 points) if:

• Systematic 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 10: 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 mitigiation measures have been ignored.

Non-compliance (0 points) if:

• Systematic 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.





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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 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 compliance (10 points): "Higher risk" refers to any nearby activities or operations that could pose a threat to the growing area or facility(s). 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).

Minor deficiency (7 points) if:

· High risk areas occur in the adjacent land, with greater than 400 ft (122m) distance from the growing area.

Major deficiency (3 points) if:

High risk areas occur in the adjacent land, with greater than 300 ft (91m) distance from the growing area.

Non-compliance (0 points) if:

- High risk areas are in the land directly adjacent to the growing area.
- High risk areas are located uphill from the growing area.

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 a buffer area 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 mitigiation measures have been ignored.

Non-compliance (0 points) if:

• Systematic 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?





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Total compliance (10 points): 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.

Minor deficiency (7 points) if:

Single/isolated instance of potential risks to the growing area observed.

Major deficiency (3 points) if:

Numerous instances of potential risks to the growing area observed.

Non-compliance (0 points) if:

• Systematic failure to control risks to the growing area.

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 15: 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 2.05.05).

Minor deficiency (10 points) if:

• Mitigating measures do not consider a single/isolated factor than can be a 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:





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

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, 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 1.04 regarding internal audit schedule.

Minor Deficiency (10 points) if:

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

Major Deficiency (5 points) if:

- Numerous instances of follow up/corrective actions not noted.
- Numerous instances of incomplete or missing records.
- Inspection frequency is not adequate relative to the type of business and the number of issues that require monitoring.
- Numerous instances of areas/issues missing on the inspection program.

Non-compliance (0 points) if:

- Systematic failure to maintain records.
- 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, quantity available, and location of containers. Inventory by storage area/type of chemical is optimal. The inventory should take into account the arrival of new stocks and any discrepancies should be explained. Minimum frequency for inventory checks should be monthly during production season and a copy should be maintained separate from the chemical storage location(s). 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 usage logs and/or inventories.
- Single/isolated instance(s) of omission(s) or error(s) in the chemical usage logs and/or inventories.
- Single/isolated instance(s) of new deliveries not being accounted for.
- Single/isolated instance(s) of minimum inventory frequency not being maintained (if usage logs are not being utilized).





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Major deficiency (1 point) if:

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

Non-compliance (0 points) if:

• No chemical usage logs/inventories are on file.

2.05.03: Are all chemicals 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 designated 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 raw materials, packaging & finished food products. Spill controls should be in place for opened in use containers. All chemical containers should have legible labels of contents; this includes chemicals that have been decanted from master containers into smaller containers. Empty containers should be stored and disposed of safely.

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.

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 a designated area, but not locked.
- Chemical storage area(s) has inadequate liquid containment systems.
- Spilled chemicals found in the chemical storage areas (not cleaned up properly)
- Numerous instances of empty containers either not being properly stored or disposed of properly.

Non-compliance (0 points) if:

- There is no designated area for chemicals.
- There is a designated area for chemicals but it is not an enclosed or locked area.

2.05.04: Are "food grade" and "non-food grade" chemicals used appropriately, according to the label and stored in a controlled manner?

Total compliance (10 points): Food grade chemicals, including lubricants, greases, etc., are used in all product/packaging contact areas. All chemicals applied should be approved by the prevailing authority (e.g., US: EPA/FDA, Canada: CFIA/Environment Canada, Chile: SAG/Ministerio de





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

NSF International: Nonfood Compounds

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

http://www.ceecis.org/iodine/07 legislation/00 mainpage/codex food grade salt.pdf

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

Minor deficiency (7 points) if:

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

Major deficiency (3 point) if:

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

Non-compliance (0 points) if:

- No attempt to split non-food grade from food grade materials.
- Systematic use of non-food grade materials found/used in the production/storage areas.
- Systematic used of a chemical(s) used contrary to label.
- Evidence of the use of a non-food grade that has caused product contamination revert to 2.05.05, automatic failure.

2.05.05: 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 110.3g). If legislation exists, then the contamination should be viewed against this legislation (e.g., USDA Grading Standards often include decay tolerances). Spoilage and adulteration would include any physical, chemical or biological contamination including blood and bodily fluids. Measures should be taken to prevent any known or reasonably foreseeable hazard





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(e.g., Clostridium botulinum in mushrooms). This question is designed to allow an auditor to halt an audit when finding gross contamination issues. Examples might include glass, trash/litter, motor oil in products, etc. Where an issue is observed by an operator in the normal process, auditor should observe the actions of the operator before scoring. Auditors should use their discretion and decide whether the frequency of the contamination warrants an automatic failure. Examples include pieces of glass, one piece of rodent bait, paint on product or packaging, flakes of rust, etc. Is the issue systematic or a one-off issue?

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

https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/webcontent/ucm074554.pdf

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

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

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

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

Minor deficiency (10 points) if:

• There is no minor deficiency category for this question

Major deficiency (5 points) if:

• There is no major deficiency category for this question.

Automatic Failure (0 points) if:

- Numerous incidences of spoilage or adulteration of product.
- There is a single gross incidence of evidence of unacceptable limits of spoilage or adulteration in 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 and then some topics covered at least quarterly, but ideally monthly. Full annual food safety refresher training sessions are encouraged but do not replace the ongoing more frequent training. Training material covering the content of the company policies and requirements regarding food safety and hygiene should be available. These trainings should cover food safety and hygiene, the importance of detecting food safety and/or hygiene issues with co-workers and visitors, and all food safety or hygiene issues in which they are responsible. Training logs should have a clearly defined topic(s) covered, trainer(s) and material(s) used/given. Food safety training should cover at least the basic topics such as 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. There should be records of workers who have attended each session.

Minor Deficiency (10 points) if:

- Single/isolated instance(s) of logs having errors or incomplete information e.g. missing one of the following: training topic, trainer or material information.
- Training has occurred but on a few occasions full attendance logs have not been kept and/or not all workers were covered.





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- 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 or not signing a document stating that they will comply with the operations' food safety hygiene program.

Major Deficiency (5 points) if:

- Numerous instances of logs having errors or incomplete information e.g. missing one of the following: training topic, trainer or material
 information.
- Training has occurred but on many occasions full attendance logs have not been maintained.
- Some key topics e.g. hand washing, have been omitted from the training.
- Only annual refresher training has occurred and the operation runs for more than 3 months of the year.
- Numerous cases of workers not signing a document stating that they will comply with the operations' food safety hygiene program.
- 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.
- Many major topics have been omitted from the training program e.g. hand washing, eating/drinking rules, jewelry policy etc.
- No specific orientation given or given after the worker has been working for more than one month.
- The company does not have a document for workers to sign stating that they will comply with the operations' food safety hygiene program.
- Systematic failure of workers to sign a log stating that they will comply with the operations' food safety hygiene program.

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.

Major deficiency (3 points) if:

· Numerous instances of errors or omissions in the procedure.

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.





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

Total compliance (3 points): A worker non-conformance should be recorded when workers are found systematically 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:

· Option for minor down score exists but as present no known good examples exist.

Major Deficiency (1 point) if:

• Disciplinary system is not used for GAP violations.

Non-compliance (0 points) if:

No records or no disciplinary system.

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. If pit toilets are used, consider proximity to crop and water sources.





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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 the catch basins of the toilets designed and maintained to prevent contamination (e.g., free from leaks and cracks)?

Total compliance (5 points): Catch basins from toilets must be designed and maintained properly to prevent contamination onto field, product, packaging and equipment. Catch basins should be free of leaks, cracks and constructed of durable materials (e.g. plastic) that will not degrade or decompose (no wood). Note: pit toilets cannot be considered to be properly designed to prevent contamination.

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

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

Non-compliance (0 points) if:

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

2.07.01c: Is there a documented procedure for emptying the catch basin 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 self-contained toilets are used, the toilet basins 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.

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.

2.07.01d: Are toilets constructed of materials that are easy to clean?

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





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and the floor and sidewalls should be watertight.

Minor Deficiency (2 points) if:

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

Major Deficiency (1 point) if:

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

Non-compliance (0 points) if:

• Toilets are not constructed of non-porous materials.

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

Total compliance (3 points): Toilets 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.

2.07.01f: Are toilets supplied with toilet paper and is the toilet paper maintained properly (e.g., toilet paper rolls are not stored on the floor or in the urinals)?

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

Minor Deficiency (3 points) if:

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

Major Deficiency (1 point) if:

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

Non- compliance (0 points) if:

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





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2.07.01g: Are the toilet facilities and hand washing stations clean and are there records showing toilet cleaning, servicing and stocking is occurring regularly?

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

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

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

2.07.02: 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 (visual signs are allowed). The visuals or 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.





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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

https://www.osha.gov/laws-regs/regulations/standardnumber/1928/1928.110

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:

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

2.07.03b: 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.





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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 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, http://www.hi-tm.com/Documents/Handwash-FL99.html

Minor deficiency (10 points) if:

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

Major deficiency (5 points) if:

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

Non-compliance (0 points) if:





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

2.07.05: Is there no sign of any worker with boils, sores, open wounds or exhibiting signs of foodborne illness working directly or indirectly with food?

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

Minor deficiency (7 points) if:

• There is no minor deficiency for this question.

Major deficiency (3 points) if:

• There is no major deficiency for this question.

Non-compliance (0 points) if:

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

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

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

2.07.07: Worker personal items are not being stored 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 security risks.

Minor deficiency (3 points) if:





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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:

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

2.07.08: 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

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:

- Systematic consumption of food and beverages outside of designated areas.
- Systematic evidence of smoking outside the designated area.
- Systematic evidence of using chewing tobacco in growing and storage areas.
- Designated area lacks access to a hand wash station.
- Systematic non-compliance to the above criteria.

2.07.09: 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:





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• 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.

2.07.09a: Are single use cups provided (unless a drinking fountain is used) and made available near the drinking water?

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

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.

2.07.10: 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:

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

2.07.11: Are there adequate trash cans placed in suitable locations?

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

Minor deficiency (3 points) if:





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Single/isolated instance of containers not being maintained.

Major deficiency (1 point) if:

Numerous instances of containers not being maintained.

Non-compliance (0 points) if:

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

2.07.12: Have any potential foreign material issues (e.g., metal, glass, plastic) contamination issues been 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:

• Systematic failure to prevent against foreign material issues.

AGRONOMIC INPUTS

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

Total points 0: Information gathering question. Human sewage sludge (biosolids), which are by-products of 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).

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

Automatic Failure if:

 There is a single incidence of sewage sludge (biosolids) being used in the growing cycle of indoor growing operations or where prohibited under best management practices.

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

Automatic Failure (0 points) if:





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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.

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:

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

2.08.01c: Are applications incorporated into the soil prior to planting or bud burst for tree crops and not applied during the growing season?

Total compliance (10 points): If used, the applications should be incorporated into the soil prior to planting or bud burst for tree crops.

Minor deficiency (7 points) if:

• Single/isolated instance(s) of missing records to verify timelines.

Major deficiency (3 points) if:

• Numerous instances of missing records to verify timelines.

Non-compliance (0 points) if:

- Systematic failure to apply compost prior to planting or bud burst for tree crops.
- No records are available.

2.08.01d: 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., Cadmium (Cd) Arsenic (As), Chromium (Cr), Lead (Pb), Mercury (Hg), Nickel (Ni), and Vanadium (V).). 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/





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http://www.health.state.mn.us/divs/eh/risk/studies/metals.html

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

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

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

2.08.01e: 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 0157: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* 0157: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.

U.S. State regulations for compost;

https://www.compostingcouncil.org/page/StateRegulations

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:





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

2.08.01f: 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., Cadmium (Cd) Arsenic (As), Chromium (Cr), Lead (Pb), Mercury (Hg), Nickel (Ni), and Vanadium (V).). 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.

http://www.calrecycle.ca.gov/laws/Regulations/Title14/ch31a5.htm

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

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

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

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

2.08.02a: 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): Only fertilizer approved for that specific crop should be used. Some commodity specific guidelines have rules regarding the use of specific fertilizer types, e.g. Californian Leafy Green Commodity Specific Guidelines bans the use of biosolids and untreated animal manure.

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





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non-synthetic crop treatments and compost, and an interval of at least 120 days (but ideally 9 months) for untreated animal manure. A shorter interval is possible if the fertilizer has been through a physical/chemical/biological process to inactivate human pathogens and the auditee has validation study documentation that shows that the material is safe. Validation studies must be applicable to the situation at hand and care should be taken not to over extrapolate. There should be confirmation that monitoring records of the validation study's key requirements are being kept and that these monitoring records are being verified.

Minor deficiency (10 points) if:

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

Major deficiency (5 points) if:

Numerous instances of missing records.

Non-compliance (0 points) if:

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

2.08.02c: Are applications incorporated into the soil prior to planting or bud burst for tree crops and not applied during the growing season?

Total compliance (10 points): If used, the applications should be incorporated into the soil prior to planting or bud burst for tree crops.

Minor deficiency (7 points) if:

• Single/isolated instance(s) of missing records to verify timelines.

Major deficiency (3 points) if:

• Numerous instances of missing records to verify timelines.

Non-compliance (0 points) if:

- Systematic failure to apply compost prior to planting or bud burst for tree crops.
- · No records are available.

2.08.02d: 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., Cadmium (Cd) Arsenic (As), Chromium (Cr), Lead (Pb), Mercury (Hg), Nickel (Ni), and Vanadium (V).). 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 quidelines.

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

http://www.health.state.mn.us/divs/eh/risk/studies/metals.html





MODULE 2: FARM

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

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

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

2.08.02e: 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* 0157: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* 0157: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 **Reference:** means of verifying the heat treatments systems applied to compost has been effective.

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

U.S. State regulations for compost;

https://www.compostingcouncil.org/page/StateRegulations

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:





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

2.08.02f: 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., Cadmium (Cd) Arsenic (As), Chromium (Cr), Lead (Pb), Mercury (Hg), Nickel (Ni), and Vanadium (V).). 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. http://www.calrecycle.ca.gov/laws/Regulations/Title14/ch31a5.htm

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

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

2.08.03: Is the operation using untreated animal manure as an input? (e.g., raw manure &/or uncomposted, incompletely composted animal manure &/or green waste or nonthermally treated animal manure, etc.).

Total compliance (0 points): 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): Only fertilizer approved for that specific crop should be used. Some commodity specific guidelines have rules regarding use of specific fertilizer types, e.g. Californian Leafy Green Commodity Specific Guidelines ban the use of biosolids and untreated animal manure.

Automatic Failure (0 points) if:

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





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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.

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:

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

2.08.03c: Are applications incorporated into the soil prior to planting or bud burst for tree crops and not applied during the growing season?

Total compliance (10 points): If used, the applications should be incorporated into the soil prior to planting or bud burst for tree crops.

Minor deficiency (7 points) if:

• Single/isolated instance(s) of missing records to verify timelines.

Major deficiency (3 points) if:

• Numerous instances of missing records to verify timelines.

Non-compliance (0 points) if:

- Systematic failure to apply manure prior to planting or bud burst for tree crops.
- No records are available.

2.08.03d: 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., Cadmium (Cd) Arsenic (As), Chromium (Cr), Lead (Pb), Mercury (Hg), Nickel (Ni), and Vanadium (V)). 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.





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

http://www.health.state.mn.us/divs/eh/risk/studies/metals.html

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

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

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

2.08.03e: 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* 0157: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* 0157: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 |

| Frequency |
|----------------------------|
| Annually |
| Quarterly |
| Bimonthly (Every 2 months) |
| 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.

U.S. State regulations for compost;

https://www.compostingcouncil.org/page/StateRegulations

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.





MODULE 2: FARM

Non-compliance (0 points) if:

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

2.08.03f: 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., Cadmium (Cd) Arsenic (As), Chromium (Cr), Lead (Pb), Mercury (Hg), Nickel (Ni), and Vanadium (V).). 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. http://www.calrecycle.ca.gov/laws/Regulations/Title14/ch31a5.htm

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

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

2.08.04: Is the operation using non-synthetic crop treatments as an input? (e.g., compost teas, fish emulsions, fish meal, blood meal, bio-fertilizers, etc.) Informational Gathering Question.

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

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





MODULE 2: FARM

it possible to trace an application back to the site if needed. There should be an interval between application and harvest of at least 45 days for non-synthetic crop treatments and compost, and an interval of at least 120 days (but ideally 9 months) for untreated animal manure. A shorter interval is possible, if the fertilizer has been through a physical/chemical/biological process to inactivate human pathogens and the auditee has validation study documentation that shows that the material is safe. Validation studies must be applicable to the situation at hand and care should be taken not to over extrapolate. There should be confirmation that monitoring records of the validation study's key requirements are being kept and that these monitoring records are being verified.

Minor deficiency (10 points) if:

Single/isolated instance(s) of missing records.

Major deficiency (5 points) if:

Numerous instances of missing records.

Non-compliance (0 points) if:

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

2.08.04c: Is the material applied in a manner that does not contact the edible portions of the crop?

Total compliance (15 points): Non-synthetic treatments that contain animal products or animal manures should not be applied to the edible portions of crops.

Minor deficiency (10 points) if:

• Single/isolated instance(s) of missing records to verify the application method.

Major deficiency (5 points) if:

• Numerous instances of missing records to verify the application method.

Non-compliance (0 points) if:

- Fertilizer is systematically applied to the edible portion of the crop.
- There are no records to verify the application method.
- Any incident of direct product contamination constitutes as a health hazard and is viewed as adulteration. Revert to Q 2.05.05.

2.08.04d: 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., Cadmium (Cd) Arsenic (As), Chromium (Cr), Lead (Pb), Mercury (Hg), Nickel (Ni), and Vanadium (V).). 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.





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

http://www.health.state.mn.us/divs/eh/risk/studies/metals.html

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

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

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

2.08.04e: 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* 0157: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 0157: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.



| AMOUNT OF BIOSOLIDS COMPOST FEEDSTOCK | OPTION 1 | |
|---------------------------------------|-------------------------------|----------|
| | AMOUNT OF BIOSOLIDS COMPOST F | EEDSTOCK |

| 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.

U.S. State regulations for compost;

https://www.compostingcouncil.org/page/StateRegulations

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.





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Non-compliance (0 points) if:

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

2.08.04f: 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., Cadmium (Cd) Arsenic (As), Chromium (Cr), Lead (Pb), Mercury (Hg), Nickel (Ni), and Vanadium (V).). 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. http://www.calrecycle.ca.gov/laws/Regulations/Title14/ch31a5.htm

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

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

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

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

2.08.05a: 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): Only fertilizer approved for that specific crop should be used. Some commodity specific guidelines have rules regarding the use of specific fertilizer types, e.g. Californian Leafy Green Commodity Specific Guidelines bans the use of biosolids and untreated animal manure.

Automatic Failure (0 points) if:

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





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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.

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:

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

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., Cadmium (Cd) Arsenic (As), Chromium (Cr), Lead (Pb), Mercury (Hg), Nickel (Ni), and Vanadium (V).). 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 quidelines.

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

http://www.health.state.mn.us/divs/eh/risk/studies/metals.html

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

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

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



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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:

- · Systematic failure to maintain records.
- No records are available.

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

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

2.08.06a: 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): Only fertilizer approved for that specific crop should be used. Some commodity specific guidelines have rules regarding the use of specific fertilizer types, e.g. Californian Leafy Green Commodity Specific Guidelines bans the use of biosolids and untreated animal manure.

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.





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Non-compliance (0 points) if:

- Systematic 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. Cadmium (Cd) Arsenic (As), Chromium (Cr), Lead (Pb), Mercury (Hg), Nickel (Ni), and Vanadium (V).). 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://www.health.state.mn.us/divs/eh/risk/studies/metals.html

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

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-compliance (0 points) if:

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

IRRIGATION/WATER USE

2.09.01: Is the water used for the growing operation sourced from municipal or district water pipeline systems? 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 source 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





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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, these 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.

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.





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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 sampling SOPs.
- 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* 0157: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 2.05.05.)

2.09.01e: Are there records of any anti-microbial water treatment (e.g. chlorination, U.V., ozone, etc.), and is testing current and available?

Total compliance (15 points): Any water treatment performed at the source (e.g., well, canal, holding tank) should be monitored. The strength of





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anti-microbial chemicals should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction-based test, test probe, ORP meter or as recommended by the disinfectant supplier).

Minor deficiency (10 points) if:

• Single/isolated instance(s) of an error or omission in the records.

Major deficiency (5 points) if:

Multiple instances of errors or omissions in the records.

Non-compliance (0 points) if:

• There are no available testing records.

2.09.01f: Are records kept for periodic visual inspection and disinfection (if occurring) 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, and any action taken. If using a disinfection injection system (e.g. chlorination), there should be monitoring logs completed on at least a daily basis. The appropriate support documentation should be available for review.

Minor deficiency (3 points) if:

• Single/isolated instance(s) of an error or omission in the records.

Major deficiency (1 point) if:

Multiple instances of errors or omissions in the records.

Non-compliance (0 points) if:

There are no available records.

2.09.02: Is the water used for the growing operation sourced from wells? 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 source 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,





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national or local requirements, these 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.

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.





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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.
- 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* 0157: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 2.05.05.)

2.09.02e: Are there records of any anti-microbial water treatment (e.g. chlorination, U.V., ozone, etc.), and is testing current and available?

Total compliance (15 points): Any water treatment performed at the source (e.g., well, canal, holding tank) 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, ORP meter or as recommended by disinfectant supplier).





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Minor deficiency (10 points) if:

• Single/isolated instance(s) of an error or omission in the records.

Major deficiency (5 points) if:

Multiple instances of errors or omissions in the records.

Non-compliance (0 points) if:

• There are no available testing records.

2.09.02f: Are records kept for periodic visual inspection and disinfection (if occurring) 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, and any action taken. If using a disinfection injection system (e.g. chlorination), there should be monitoring logs completed on at least a daily basis. The appropriate support documentation should be available for review.

Minor deficiency (3 points) if:

• Single/isolated instance(s) of an error or omission in the records.

Major deficiency (1 point) if:

• Multiple instances of errors or omissions in the records.

Non-compliance (0 points) if:

• There are no available records.

2.09.03: Is the water used for the growing operation sourced from non-flowing surface water (e.g., ponds, reservoirs, watersheds, 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 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 source 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, these 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





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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.

Major deficiency (5 points) if:

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

Autmatic 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.





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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.
- 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* 0157: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 2.05.05.)

2.09.03e: Are there records of any anti-microbial water treatment (e.g. chlorination, U.V., ozone, etc.), and is testing current and available?

Total compliance (15 points): Any water treatment performed at the source (e.g., well, canal, holding tank) 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, ORP meter or as recommended by disinfectant supplier).





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Minor deficiency (10 points) if:

• Single/isolated instance(s) of an error or omission in the records.

Major deficiency (5 points) if:

• Multiple instances of errors or omissions in the records.

Non-compliance (0 points) if:

• There are no available testing records.

2.09.03f: Are records kept for periodic visual inspection and disinfection (if occurring) 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, and any action taken. If using a disinfection injection system (e.g. chlorination), there should be monitoring logs completed on at least a daily basis. The appropriate support documentation should be available for review.

Minor deficiency (3 points) if:

• Single/isolated instance(s) of an error or omission in the records.

Major deficiency (1 point) if:

• Multiple instances of errors or omissions in the records.

Non-compliance (0 points) if:

• There are no available records.

2.09.04: Is the water used in the growing operation sourced from open flowing surface water (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 normal, 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 source 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, these 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





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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.

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.





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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.
- 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* 0157: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 I 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: Are there records of any anti-microbial water treatment (e.g. chlorination, U.V., ozone, etc.), and is testing current and available?

Total compliance (15 points): Any water treatment performed at the source (e.g., well, canal, holding tank) 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, ORP meter or as recommended by disinfectant supplier).



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Minor deficiency (10 points) if:

• Single/isolated instance(s) of an error or omission in the records.

Major deficiency (5 points) if:

• Multiple instances of errors or omissions in the records.

Non-compliance (0 points) if:

• There are no available testing records.

2.09.04f: Are records kept for periodic visual inspection and disinfection (if occurring) 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, and any action taken. If using a disinfection injection system (e.g. chlorination), there should be monitoring logs completed on at least a daily basis. The appropriate support documentation should be available for review.

Minor deficiency (3 points) if:

• Single/isolated instance(s) of an error or omission in the records.

Major deficiency (1 point) if:

• Multiple instances of errors or omissions in the records.

Non-compliance (0 points) if:

• There are no available records.

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. 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 source 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, these requirements should be followed. If a risk assessment is used to define the frequency, it should include at a





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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.

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.





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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.
- 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* 0157: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 2.05.05.)

2.09.05e: Are there records of any anti-microbial water treatment (e.g. chlorination, U.V., ozone, etc.), and is testing current and available?

Total compliance (15 points): Any water treatment performed at the source (e.g., well, canal, holding tank) 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, ORP meter or as recommended by disinfectant supplier).



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Minor deficiency (10 points) if:

• Single/isolated instance(s) of an error or omission in the records.

Major deficiency (5 points) if:

• Multiple instances of errors or omissions in the records.

Non-compliance (0 points) if:

• There are no available testing records.

2.09.05f: Are records kept for periodic visual inspection and disinfection (if occurring) 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, and any action taken. If using a disinfection injection system (e.g. chlorination), there should be monitoring logs completed on at least a daily basis. The appropriate support documentation should be available for review.

Minor deficiency (3 points) if:

• Single/isolated instance(s) of an error or omission in the records.

Major deficiency (1 point) if:

• Multiple instances of errors or omissions in the records.

Non-compliance (0 points) if:

• There are no available records.

2.09.06: Are tail water (run off water) systems, including hydroponics, used in the growing operation? What is this water source used for (e.g., irrigation, crop protection sprays, fertigation, frost/freeze protection, cooling, dust abatement, etc.)? What type of irrigation methods are used (e.g., micro-irrigation, drip, overhead, flood irrigation, furrow 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 source 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, these 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





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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.

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.





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Major deficiency (3 points) if:

Numerous instances of errors or omissions in the SOP.

Non-compliance (0 points) if:

- There are no sampling SOPs.
- 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* 0157: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 2.05.05.)

2.09.06e: Are there records of any anti-microbial water treatment (e.g. chlorination, U.V., ozone, etc.), and is testing current and available?

Total compliance (15 points): Any water treatment performed at the source (e.g., well, canal, holding tank) 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, ORP meter or as recommended by disinfectant supplier).

Minor deficiency (10 points) if:

• Single/isolated instance(s) of an error or omission in the records.





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Major deficiency (5 points) if:

Multiple instances of errors or omissions in the records.

Non-compliance (0 points) if:

• There are no available testing records.

2.09.06f: Are records kept for periodic visual inspection and disinfection (if occurring) 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, and any action taken. If using a disinfection injection system (e.g. chlorination), there should be monitoring logs completed on at least a daily basis. The appropriate support documentation should be available for review.

Minor deficiency (3 points) if:

• Single/isolated instance(s) of an error or omission in the records.

Major deficiency (1 point) if:

• Multiple instances of errors or omissions in the records.

Non-compliance (0 points) if:

• There are no available records.

2.09.07: Does the growing operation practice dryland farming?

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

2.09.08: Is there a documented assessment for each water source covering animal access, upstream contamination/runoff, proper well condition, water treatment, backflow, maintenance, cross contamination from leaching, recirculating water systems, etc., as applicable?

Total compliance (15 points): There should be a documented assessment for each water source used in the growing area. Prior to the first seasonal planting and at least annually and when any changes are made to the system, there should be a documented risk assessment for each water source covering potential physical, chemical and biological hazards from animal access, upstream contamination/runoff, proper well condition, water treatment, water capture, backflow, maintenance, cross contamination from leaching, cross connections, recirculating water systems, etc. If flood or furrow irrigation is used, there needs to be examples of how the operation is minimizing the risk.

Farms and indoor agriculture operations following the CA or AZ LGMA, where the risk assessments suggest a need, surface waters passing within 400 feet (121 meters) of a CAFO with more than 80,000 head, must be treated to meet microbial acceptance criteria for Generic *E.coli* of negative or < detection limit (MPN or CFU/100mL) if used in any overhead irrigation application at the field level within two weeks of scheduled harvest.

Minor deficiency (10 points) if:

• Single/isolated instance(s) of a risk assessment missing a physical, chemical and biological hazard.

Major deficiency (5 points) if:

- Numerous instances of physical, chemical and biological hazards missing from the risk assessments.
- · A single water source is not included in the risk assessment when multiple water sources are being used in the growing area.





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Non-compliance (0 points) if:

- Systematic failure to include physical, chemical and biological hazards on the risk assessments.
- Numerous water sources used in the growing area are missing risk assessments.
- No risk assessments have been performed.

2.09.09: 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/fertilize 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).

2.09.10: 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 growing 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 (or equivalent)



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registration information, active ingredient, amount applied (rate/dosage), applicator name, pre-harvest interval, restricted entry interval, type of equipment used 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 consistant.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of missing required information (e.g., a target pest that can be clearly linked to other documented information). Major deficiency (5 points) if:
- Numerous instances of missing required information (e.g., a target pest that can be clearly linked to other documented information).

Automatic Failure (0 points) if:

- Any failure to record critical required information.
- Systematic failure to record required information.

2.10.02: Do records show that pesticides and their use are in compliance with all requirements of label direction, national (e.g., EPA) registration and any federal, state or local regulations and guidelines? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.

Total compliance (15 points): All pesticides must be registered for such use, as required by prevailing regulation, and used in accordance with label directions. N/A is allowed only when registration/authorization information does not exist for pesticides to be used on target crops in the country of production.

Automatic Failure (0 points) if:

There is a single incidence of pesticides being used without complying with or following regulatory or label requirements.

2.10.03: Where products are destined for export, do records show that only pesticides approved for use in destination market(s) are used and are in compliance with all requirements of label direction, national (e.g., EPA) registration and any federal, state or local regulations and guidelines? Corrective actions are required if a non-compliance. If corrective actions are not provided and acceptable by the certification body a failure of the audit is scored.

Total compliance (15 points): All pesticides must be registered for such use in the destination market, as required by prevailing regulation, and used in accordance with label directions. (i.e. application rates, intended purpose, worker protection standards, personal protection equipment, container storage, disposal).

The grower should provide documented evidence that they are complying with the expectations regarding crop protection products of the country of origin and proof of those expectations. That evidence may be in the form of: chemical records, application methods, rates and dosage, compliance with pre-harvest intervals, or any other relevant information. This question is Not Applicable if the product is sold only in the country of production (domestic market).

Non-compliance (0 points) if:

- There is a single incidence of pesticides not being used in accordance with the country of destination regulatory or label requirements.
- Automatic failure if corrective actions are not provided and accepted by the certification body.





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2.10.04: Where products are destined for export, are there records showing that pre-harvest intervals and application rates are sufficient to meet MRL entry requirements of the country of export? Records show any non-compliant product is diverted to a market where it meets requirements. Corrective actions are required if a non-compliance. If corrective actions are not provided and acceptable by the certification body a failure of the audit is scored.

Total compliance (15 points): Maximum Residue Limits (MRL) tests should be performed. The auditor should review those to ensure it meets MRL entry requirements in the country of destination or the Codex Alimentarius Commission if the country of destination/market follows this MRL compliance. Records show that any non-compliant product is diverted to a market where it meets the requirements. This question is Not Applicable if the product is sold only in the country of production (domestic market).

Reference:

http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/en/

Non-compliance (0 points) if:

- There is a single incidence of pesticide application records not complying with the pre-harvest intervals and application rates.
- There is a single incidence of MRL testing that exceeds the country of destination requirements without corrective actions being taken.
- . Automatic failure if corrective actions are not provided and accepted by the certification body.

2.10.05: For those pesticides that are not registered for use on the target crops in the country of production or if the country does not have, or has a partial legislative framework to cover pesticides, can the grower show that they have registration information, label information, MRL tolerances, etc. for the country of destination? Corrective actions are required if a non-compliance. If corrective actions are not provided and acceptable by the certification body a failure of the audit is scored.

Total compliance (15 points): Grower should be aware of the crop protection products registered and/or authorized by a government agency for use in the target crops in the country of production. Where the country of production does not have or has partial legislation covering pesticides, and if the use of pesticides that are registered for the target crop in another country (extrapolation) is not prohibited, the grower must have information for the pesticides in the country(ies) of destination. The information must show: registration for the specific crop, product labels, Maximum Residue Limit (MRL) tolerances and may also include banned chemical lists, and any other relevant guidelines or legislation. If there is no information available for pesticides used that are not registered in the country of production, or its use based on registration, label and other legislation of the destination country, extrapolation is prohibited by the country of production, and an automatic failure will be scored. This question is Not Applicable if the product is sold only in the country of production (domestic market).

Non-compliance (0 points) if:

- There is a single incidence of missing documentation for the pesticides used for the country of destination.
- Automatic failure if corrective actions are not provided and accepted by the certification body.

2.10.06: 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): Application and harvest records show pre-harvest intervals on product labels, national (e.g., EPA) registration and any federal, state or local regulations and guidelines are being adhered to. If this is not followed, an automatic failure will be scored.





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Automatic Failure (0 points) if:

There is a single incidence of pre-harvest intervals not being followed.

2.10.07: Is there a documented procedure for the mixing/loading of pesticides?

Total compliance (5 points): There should be a documented procedure describing how to mix and load pesticides (e.g., insecticides, fungicides, herbicides, plant growth regulators, etc.). The procedure should include adhering to the product label and include: requiring activity to be in a well-ventilated, well-lit area away from unprotected people, food and other items that might be contaminated. Water used to dilute pesticides should meet the criteria noted in the Irrigation/Water Use section. This also applies to any mixes that occur off site when using contracted spraying services.

Minor deficiency (3 points) if:

• Single/isolated instance(s) of an error or omission in the procedure.

Major deficiency (1 point) if:

· Numerous instances of an error or omission in the procedure.

Non-compliance (0 points) if:

- Systematic errors or omissions in the procedure.
- There is no procedure.

2.10.08: Is there a documented procedure for the application of pesticides?

Total compliance (5 points): There should be a documented procedure describing how to apply pesticides (e.g., insecticides, fungicides, herbicides, plant growth regulators, etc.). The procedure should include adhering to the pesticide label and include the use of Personal Protective Equipment (PPE), re-entry intervals, excessive winds, posting of treated areas, etc.

Minor deficiency (3 points) if:

• Single/isolated instance(s) of an error or omission in the procedure.

Major deficiency (1 point) if:

Numerous instances of an error or omission in the procedure.

Non-compliance (0 points) if:

- Systematic errors or omissions in the procedure.
- There is no procedure.

2.10.09: Is there a documented procedure for the rinsing and cleaning of pesticide equipment?

Total compliance (5 points): There should be a documented procedure describing how to rinse and clean pesticide equipment. Pesticide equipment includes measuring containers and devices, mixing containers, application equipment, rinseable pesticide containers, etc. The procedure should include adhering to the product label, to country, federal, state or local laws and regulations, and should include: rinsing empty equipment immediately to prevent residues from drying and becoming difficult to remove, and adding a rinsate (water from rinsing containers or equipment) to spray tanks as part of the pesticide mixing process.





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Minor deficiency (3 points) if:

• Single/isolated instance(s) of an error or omission in the procedure.

Major deficiency (1 point) if:

• Numerous instances of an error or omission in the procedure.

Non-compliance (0 points) if:

- · Systematic errors or omissions in the procedure.
- There is no procedure.

2.10.10: Is there documentation that shows the individual(s) making decisions for pesticide applications are competent?

Total compliance (15 points): Current valid certificates, licenses, 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.

2.10.11: 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): Current valid certificates, licenses, or another form of proof of training recognized by prevailing national/local standards and guidelines should be available for individuals handling, mixing/loading/and applying pesticide materials.

Minor deficiency (10 points) if:

• Single/isolated instance(s) of missing training documentation.

Major deficiency (5 points) if:

· Numerous instances of missing training documentation.

Non-compliance (0 points) if:

- There is no documentation showing training for individuals handling pesticide materials.
- There is no documentation for the supervising person.





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2.10.12: Are pesticides stored without risk of contamination, in a locked, dedicated area with legible labels, and are empty pesticide containers held and disposed of according to their label and/or regulatory instructions?

Total compliance (10 points): Pesticide containers should be stored securely: away from other materials, locked, signs posted, away from water source, off floor, well-ventilated, and inventory kept.

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.

Minor deficiency (7 points) if:

Single/isolated instance(s) of pesticides stored improperly.

Major deficiency (3 points) if:

· Numerous instances of pesticides stored improperly.

Non-compliance (0 points) if:

• Systematic failure to store pesticides properly.

2.10.13: Is it evident that the equipment used for pesticide applications is in good working order?

Total compliance (10 points): All equipment used in pesticide applications should be in good working order so that correct applications can be made, thus reducing potential crop contamination or drift issues.

Minor deficiency (7 points) if:

• Single/isolated instance(s) of equipment not in good working order.

Major deficiency (3 points) if:

• Numerous instances of equipment not in good working order.

Non-compliance (0 points) if:

• Systematic failure to maintain equipment in good working order.

2.10.14: Are restricted entry interval (REI) signs posted in the area(s) where pesticide applications occur?

Total compliance (10 points): All agricultural pesticide labeling provides a specific REI. Some regulations provide REIs for certain pesticide/crop combinations. Whenever there is a labeling REI and a regulatory REI for an application, the longer REI must be followed.

Warning signs should be posted before an application when required by the pesticide label, regulations or restricted material permit. Auditors should view signage used to post and posting areas.

All indoor applications require warning signs.

Minor deficiency (7 points) if:

• Single/isolated instance(s) of REI signs not being posted.





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Major deficiency (3 points) if:

• Numerous instances of REI signs not being posted.

Non-compliance (0 points) if:

- Systematic failure to post REI signs.
- Signage is required but is not available.