General Description of Changes to Module 1

1. Changes to earlier sections

2. Revisions

3. Certification

4. PrimusGFS Auditees

5. PrimusGFS – First-Time PrimusGFS Auditees

6. PrimusGFS - Rev. 0

7. Compliance-Related Deficiencies

8. Clarifications

9. Additional Compliance

10. References

Specify changes to system

Section 1.01.01 Changes to question numbers

1.01.02 Is there an organizational chart showing positions and responsibilities of workers within the company? This should also be indicated in case someone cannot perform the assigned responsibilities at the time required. Document should be current and accessible.

1.01.04 Is there a training management system in place that ensures that all programs required for employees are available for review? The training management system should be reviewed at least annually to determine the need for changes and the changes made should be documented. The documented review should meet any national or local legislative requirements.

1.01.06 Was a meeting of senior management convened to discuss the company's commitment to food safety? The meeting should include topics such as the company's commitment to food safety, following all food safety laws, and communicating organizational chart. The meeting should also consider the company's commitment to food safety and be attended by all those in positions to ensure its continuing suitability, adequacy, and effectiveness. The meeting should be documented. The policy may also contain a form of a "resistance statement" provided by the company's management.

1.01.08 Did an organizational chart showing positions and responsibilities of workers within the company occur in food safety-related activities and documented job descriptions, noting their food safety responsibilities?

1.01.10 Is there a documented policy for handling errors and omissions on the organizational structure chart?

1.01.12 Is there a documented policy for handling errors and omissions on the organizational structure chart?

1.01.14 Is there a documented policy for handling errors and omissions on the organizational structure chart?

1.01.16 Is there a documented policy for handling errors and omissions on the organizational structure chart?

1.01.18 Is there a documented policy for handling errors and omissions on the organizational structure chart?

1.01.20 Is there a documented policy for handling errors and omissions on the organizational structure chart?

1.01.22 Is there a documented policy for handling errors and omissions on the organizational structure chart?

1.01.24 Is there a documented policy for handling errors and omissions on the organizational structure chart?
System

1.02.01 Is there a documented and implemented process that requires all food safety related records to be kept for at least the duration of the shelf life of the product?

Minor deficiency (1 point) if:• Numerous instances of hard copy documents and records not being stored securely.
• Computerized documents and records are not being backed-up.
• Numerous instances of hard copy and/or computerized records not being stored securely.
• Electronic documents and records are not being backed-up.
Non-conformance (0 points) if:• Hard copy documents and records are not stored securely.
• Computerized documents and records are not being stored securely.

Change in v1.0.1 No Change in v3.2

All food safety records and documents should be stored following an organized and retrievable manner. This will aid in the detection of issues, the isolation of problems, and the identification of trends and retrievable of information.

Documents and records should be accessible, even if the operation is seasonal. This will aid in the detection of issues, the isolation of problems, and the identification of trends and retrievable of information.

Non-conformance (0 points) if:• Hard copy documents and records are not stored securely.
• Computerized documents and records are not being stored securely.

Change in v1.0.2

1.02.04 Are records maintained in an organized and retrievable manner?

Records should be stored on a consistent basis, to allow for quick retrieval of records. This will aid in the detection of issues, the isolation of problems, and the identification of trends and retrievable of information.

All food safety records and documents should be accessible, even if the operation is seasonal. This will aid in the detection of issues, the isolation of problems, and the identification of trends and retrievable of information.

Non-conformance (0 points) if:• Hard copy documents and records are not stored securely.
• Computerized documents and records are not being stored securely.

Change in v1.0.0

2.02.03 Are both computer and electronic records created, edited, stored and handled to a particular procedure?

Electronic records are backed-up when needed (see 1.02.04) and have secure digital signature (including date and time (where appropriate)) and audit trails. They are not editable, and the computer system is password protected. When electronic records are amended, they should show what was amended, by whom and when (see 1.02.04).


Compliance: 2 points. Both paper and electronic food safety records and documents are kept for at least the duration of the shelf life of the product (an exception is not allowed). Also, documents are accessible, consistent with the required time mandated by law for a particular product.

Change in v3.2

Compliance: 2 points. Both paper and electronic food safety records and documents are kept for at least the duration of the shelf life of the product (an exception is not allowed). Also, documents are accessible, consistent with the required time mandated by law for a particular product.

Compliance: 2 points. Both paper and electronic food safety records and documents are kept for at least the duration of the shelf life of the product (an exception is not allowed). Also, documents are accessible, consistent with the required time mandated by law for a particular product.

No Change in v3.2

Both paper and electronic records are identified by title, date and number, lined up by date, and handled as a document system.

Compliance: 2 points. Both paper and electronic food safety records and documents are kept for at least the duration of the shelf life of the product (an exception is not allowed). Also, documents are accessible, consistent with the required time mandated by law for a particular product.

Compliance: 2 points. Both paper and electronic food safety records and documents are kept for at least the duration of the shelf life of the product (an exception is not allowed). Also, documents are accessible, consistent with the required time mandated by law for a particular product.

Change in v1.0.0

Compliance: 2 points. Both paper and electronic food safety records and documents are kept for at least the duration of the shelf life of the product (an exception is not allowed). Also, documents are accessible, consistent with the required time mandated by law for a particular product.

Compliance: 2 points. Both paper and electronic food safety records and documents are kept for at least the duration of the shelf life of the product (an exception is not allowed). Also, documents are accessible, consistent with the required time mandated by law for a particular product.

No Change in v3.2

Change in v1.0.0
### Records and Test Results

**Total compliance (5 points):** Records and test results should be reviewed, signed off and dated by a qualified person within 7 days. The verifier is independent of the individual(s) completing the record(s), corrective actions should be recorded. Ideally (not a scoring issue), there is a summary document of records reviewed and signed off as above, however, individual situations including small farming operations and contract spray services may impact how records are being reviewed and signed.

**Non-conformance (0 points):** Records and test results may include composting records, CCPs, sanitizer, pH, water turbidity, and signed off by the responsible person.

**Minor deficiency (3 points):**
- Single/isolated instance(s) of SOPs not having the required format.
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of SOPs not having the required format.
- Single/isolated instance(s) of errors and/or omissions within the document.

**Major deficiency (1 point):**
- Widespread evidence that SOPs are not written following the standardized procedure.
- Widespread evidence that SOPs are not written following the standardized procedure.
- Widespread evidence that SOPs are not written following the standardized procedure.
- Widespread evidence that SOPs are not written following the standardized procedure.

**Fundamental failure for records and/or test results to be reviewed and signed off by a qualified person within 7 days (second signatory).**

**Single/isolated instance(s) of records and/or test results not being reviewed and signed off by a qualified person.**

**Major deficiency (1 point):**
- Widespread evidence that SOPs are not written following the standardized procedure.

**Required-by-the-FSMA-PSR.pdf**

- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.

**Minor deficiency (3 points):**
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.

**Non-conformance (0 points):**
- Single/isolated instance(s) of records and/or test results not being reviewed and signed off by a qualified person within 7 days.

- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.

**Major deficiency (1 point):**
- Widespread evidence that SOPs are not written following the standardized procedure.
- Widespread evidence that SOPs are not written following the standardized procedure.
- Widespread evidence that SOPs are not written following the standardized procedure.
- Widespread evidence that SOPs are not written following the standardized procedure.

---

### Procedures and Corrective Actions

**Total conformance (5 points):** The written procedures (SOPs) should be available to the users and other interested parties. A master copy of all SOP’s should follow the organization’s document control systems, especially proper version management (see Control of Documents and Records).

**Non-conformance (0 points):** There should be a written document that describes how to create SOPs when new standard operating procedures (SOPs) for food safety activities related to good agricultural practices and/or good manufacturing procedures (SOPs) should be written following the standardized procedure. SOPs should include a date and document number or reference code and require detailing what is to be done and how it is to be done. SOPs should be reviewed, signed off by a qualified person, and dated within 7 days (second signatory).

**Minor deficiency (3 points):**
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.

**Major deficiency (1 point):**
- Single/isolated instance(s) of errors and/or omissions within the document.

**Required-by-the-FSMA-PSR.pdf**

- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.

**Non-conformance (0 points):**
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.

**Minor deficiency (3 points):**
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.

**Major deficiency (1 point):**
- Single/isolated instance(s) of errors and/or omissions within the document.

---

### Corrective Actions

**Total conformance (5 points):** The written procedures (SOPs) should be available to the users and other interested parties. A master copy of all SOP’s should follow the organization’s document control systems, especially proper version management (see Control of Documents and Records).

**Non-conformance (0 points):** The written procedures (SOPs) should be available to the users and other interested parties. A master copy of all SOP’s should follow the organization’s document control systems, especially proper version management (see Control of Documents and Records).

**Minor deficiency (3 points):**
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of errors and/or omissions within the document.

**Major deficiency (1 point):**
- Single/isolated instance(s) of errors and/or omissions within the document.

---

### Conclusion

The objective of this document is to provide a framework for the development of SOPs that describe the procedures for handling non-conformances and quality assurance procedures for food safety activities. This includes the identification and control of non-conformances, corrective actions, and the implementation of corrective actions in a timely and effective manner. The document is intended to be used in conjunction with relevant legal and regulatory requirements and industry best practices to ensure compliance with food safety standards. The document should be reviewed and updated as necessary to reflect changes in the organization’s procedures, regulatory requirements, or industry standards. The documentation of corrective actions and the implementation of corrective actions should be performed in accordance with the procedures outlined in this document.
### Food Safety Management System

The food safety management system is assessed according to its frequency of operation, effectiveness and the adequacy of the records kept to support these assessments. Based on the assessment results, corrective actions may be required, and/or need to be documented. The implementation of food safety system programs is assessed to ensure that they are being completed properly (e.g., using the correct log, correct frequencies, recording results correctly, recording corrective actions, etc.). This does not include the food safety management system every 12 months, see 1.01.05. The internal audit records are assessed:

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Frequency</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Food safety management system:</td>
<td>At least every 12 months.</td>
<td>-</td>
</tr>
<tr>
<td>• Food safety documentation:</td>
<td>At least quarterly.</td>
<td>-</td>
</tr>
<tr>
<td>• Farm, Indoor Agriculture and Harvest Crew:</td>
<td>At least a pre-season growing area assessment and a full GAP self-assessment during the harvest season.</td>
<td>-</td>
</tr>
<tr>
<td>• HACCP: self-audits of the HACCP program should have been done at least once within last 12 months to ensure that the process is being completed properly.</td>
<td>At least once within last 12 months.</td>
<td>-</td>
</tr>
</tbody>
</table>

### Other Audits

The internal and corrective actions (where necessary). Recording systems (documentation) for food safety related topics should be audited at least quarterly (frequency could increase or decrease depending in production seasonality.) to ensure that they are being completed properly (e.g., using the correct log, correct frequencies, recording results correctly, recording corrective actions, etc.). This does not include the food safety management system every 12 months, see 1.01.05. The internal audit records are assessed:

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Frequency</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Food safety management system:</td>
<td>At least every 12 months.</td>
<td>-</td>
</tr>
<tr>
<td>• Food safety documentation:</td>
<td>At least quarterly.</td>
<td>-</td>
</tr>
<tr>
<td>• Farm, Indoor Agriculture and Harvest Crew:</td>
<td>At least a pre-season growing area assessment and a full GAP self-assessment during the harvest season.</td>
<td>-</td>
</tr>
<tr>
<td>• HACCP: self-audits of the HACCP program should have been done at least once within last 12 months to ensure that the process is being completed properly.</td>
<td>At least once within last 12 months.</td>
<td>-</td>
</tr>
</tbody>
</table>

### Equipment Management

Scales/weight or volume measuring devices (e.g. for pesticide measurement) should have verification of accuracy and/or calibration regularly to ensure correct and accurate operation. Calibration procedures should describe the frequency of testing, the testing method and the acceptable range of variation. Calibration should be done at least quarterly (frequency could increase or decrease depending in production seasonality.). Calibration labels. Where an external service is used, procedures, licenses and/or certifications are acceptable.戴着。

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Frequency</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Food safety management system:</td>
<td>At least every 12 months.</td>
<td>-</td>
</tr>
<tr>
<td>• Food safety documentation:</td>
<td>At least quarterly.</td>
<td>-</td>
</tr>
<tr>
<td>• Farm, Indoor Agriculture and Harvest Crew:</td>
<td>At least a pre-season growing area assessment and a full GAP self-assessment during the harvest season.</td>
<td>-</td>
</tr>
<tr>
<td>• HACCP: self-audits of the HACCP program should have been done at least once within last 12 months to ensure that the process is being completed properly.</td>
<td>At least once within last 12 months.</td>
<td>-</td>
</tr>
</tbody>
</table>
Where appropriate (e.g., complaints of a repetitive nature), a trend analysis of food safety feedback should be performed to assist with the development of corrective actions.

Items/product that are rejected or put on hold. Records should show date when the item was released (if applicable), the name of the person who put the product on hold/rejected, the name of the person who authorized the release (if applicable), and any other actions taken to ensure that affected product is not commingled with other goods in such a way that their disposition is not clear. Authorized personnel should sign (with date and time) a "release" for any item placed on hold/rejected, detailing actions taken (e.g., disposition, re-work, food bank, tilled back into the ground, etc.) and any other actions taken to ensure that affected product is not commingled with other goods in such a way that their disposition is not clear. Rejected or returned food products should be maintained and available for review where applicable. Where required by law, certificates of destruction should be kept on file.

Release of Products

There should be a documented procedure detailing how to handle food safety related complaints, rejections and feedback. The procedure should require the recording (including supporting documentation) of complaints, rejections and feedback. This procedure should include monitoring requirements in order to remain approved, and methods for suspending and un-approving suppliers and service providers. The procedure should also detail how to work with a supplier in an emergency situation that has not yet been approved.

Minor deficiency (7 points) if:
• If one of the above elements of the procedure is missing.

Major deficiency (3 points) if:
• A written procedure detailing the selection, evaluation, approval and monitoring process of approved suppliers and service providers.

No Change in v3.2

Supplier Management Controls

In a written procedure describing how incoming agricultural inputs, ingredients, products, materials (including packaging) are purchased from and/or provided by approved suppliers. Where exceptions are made (e.g., market conditions), approval from management should be justified and documented. U.S. Importers under the FDA's Rule Foreign Supplier Verification Programs rule should ensure requirements of rule are included in this procedure.

Minor deficiency (7 points) if:
• If one of the above elements of the procedure is missing.

Major deficiency (3 points) if:
• A written procedure detailing the selection, evaluation, approval and monitoring process of approved suppliers and service providers.

No Change in v3.2

PGFS-R-060 Page 5 of 7 January 19, 2021
Total compliance (15 points): The organization has relevant information from approved suppliers/service providers to ensure that they are complying with the established supplier/service provider procurement procedures, specifications, regulatory requirements and best practice guidelines. Supplier verification documents should demonstrate that the supplier(s) were selected from a list of approved suppliers/service providers. This is applicable for all agricultural suppliers. Supplier verification documents should also demonstrate that the verification activities (including monitoring activities in 1.06.03 certification (ideally GFSI standard or equivalent) for suppliers of product and ingredients including primary/food past occurrences.

1.06.04 Does the organization have documented practice guidelines and agreed specifications. Letters of guarantee should be current (within last 12 months) or

Major Deficiency (1 point)
Non-compliance (points)
Control
Monitoring/

property rights and counterfeiting. An example of a food fraud scenario that may occur at an operation is when suppliers provide products/materials that do not match their required specifications (e.g. unapproved chemicals, non-food grade packaging).

A vulnerability assessment and comprehensive protection plan for all types of food fraud. This includes economically motivated food fraud, food safety hazards, adulteration, theft, computer crime, cybercrime, counterfeiting, and gray market. Intellectual property rights and counterfeiting.

Food Fraud

There should be a vulnerability assessment and comprehensive protection plan for all types of food fraud. This includes economically motivated food fraud, food safety hazards, adulteration, theft, computer crime, cybercrime, counterfeiting, and gray market. Intellectual property rights and counterfeiting. The management of a food fraud scenario that may occur at an operation is when suppliers provide products/materials that do not match their required specifications (e.g. unapproved chemicals, non-food grade packaging).

1.06.07 Is the company in compliance with all applicable federal, state and local laws and regulations (e.g., USDA, FDA, state, local, etc.)? Yes

Major Deficiency (Points)
Single instance of an omission or incorrect data in the documentation:
Non-compliance (points)

Compliance (10 points): Testing of recall procedures should be performed at least every six months. (For short season crops the mock recall was initiated, the product or material chosen, the scenario, amount of product produced, affected lot ID's (date code(s), lot code(s), etc.), amount located, percent located, time product was located and time mock recall was completed. Documentation should also include any "lessons learned" from the mock recall process. GAP related organizations (for example customers. GAP related organizations (for example (farm and crew)) operations may create a mock scenario where they receive information from a client indicating there is a problem that warrants a recall. An alternate GAP mock scenario is that the grower is informed of a problem with an input that may properly tested. This mock recall would only cover the relationship between the Organization and the customer who has provided

Non-compliance (0 points): Three or less elements of the mock recall are missing (e.g., supporting documentation, packaging material)

Microbial random sampling and testing of recalled product(s) has been performed at least every six months. This includes quantitative and qualitative analysis of the recalled material(s). The number of samples to be tested should be determined based on the type, size and nature of the recall, as well as the number of recalls conducted in the past year. The number of samples to be tested should be determined based on the type, size and nature of the recall, as well as the number of recalls conducted in the past year.

Measurable Expected Outcomes

• The organization should have documented (ideally GFSI standard or equivalent) for suppliers of product and ingredients including primary/food past occurrences.

There should be a vulnerability assessment and comprehensive protection plan for all types of food fraud. This includes economically motivated food fraud, food safety hazards, adulteration, theft, computer crime, cybercrime, counterfeiting, and gray market. Intellectual property rights and counterfeiting. An example of a food fraud scenario that may occur at an operation is when suppliers provide products/materials that do not match their required specifications (e.g. unapproved chemicals, non-food grade packaging).

Food Fraud

Compliance (10 points): Testing of recall procedures should be performed at least every six months. (For short season crops

Major Deficiency (Points)
Single instance of an omission or incorrect data in the documentation:
Non-compliance (points)

Compliance (10 points): Testing of recall procedures should be performed at least every six months. (For short season crops

Non-compliance (0 points): Three or less elements of the mock recall are missing (e.g., supporting documentation, packaging material)

Microbial random sampling and testing of recalled product(s) has been performed at least every six months. This includes quantitative and qualitative analysis of the recalled material(s). The number of samples to be tested should be determined based on the type, size and nature of the recall, as well as the number of recalls conducted in the past year. The number of samples to be tested should be determined based on the type, size and nature of the recall, as well as the number of recalls conducted in the past year.

Measurable Expected Outcomes

• The organization should have documented (ideally GFSI standard or equivalent) for suppliers of product and ingredients including primary/food past occurrences.

There should be a vulnerability assessment and comprehensive protection plan for all types of food fraud. This includes economically motivated food fraud, food safety hazards, adulteration, theft, computer crime, cybercrime, counterfeiting, and gray market. Intellectual property rights and counterfeiting. An example of a food fraud scenario that may occur at an operation is when suppliers provide products/materials that do not match their required specifications (e.g. unapproved chemicals, non-food grade packaging).
**Food Defense 1.08.02**

Total conformance (5 points): The operation should have a documented food defense plan that outlines the organization’s security controls based on a written food defense vulnerability assessment, and controls for the identified risks. The plan should also meet any national or local regulations (including management oversight and approval). Based on this assessment, the operation should create monitoring, corrective action and verification procedures (if appropriate). These procedures should note the recording requirements of the food defense plan. The plan should be reviewed at least once every 12 months.

The food defense plan creation should also meet any national or local regulations (including management oversight and approval). Documented operational risk management (ORM) systems are acceptable if they show the controls that have been implemented for the food defense risks that have been identified. Risk/vulnerability assessment templates can be found at: [https://www.fsis.usda.gov/shared/PDF/Self_Assessment_Checklist_Food_Security.pdf](https://www.fsis.usda.gov/shared/PDF/Self_Assessment_Checklist_Food_Security.pdf?MOD=AJPERES)

Additional resources:
- [Minor deficiency (3 points) if: Single/isolated instance(s) of errors or omissions in the risk assessment or food defense plan.]
- [Major deficiency (1 point) if: Numerous instances of errors or omissions in the risk assessment or food defense plan.]
- [Non-conformance (0 points) if: Food defense plan has not been documented.]

---

**Food Defense 1.08.03**

Are records associated with the food defense plan and its procedures being maintained, including monitoring, corrective action and verification records (where appropriate)?

No change in v3.2

- Change in v2.0

Other comments (1 point): The records maintained in the food defense plan should be maintained in accordance with the details of the plan and any associated procedures. These records are also subject to the documented control and records requirements of this module.