

primus *GFS*

2018

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

GENERAL REGULATIONS

PrimusGFS v3.0



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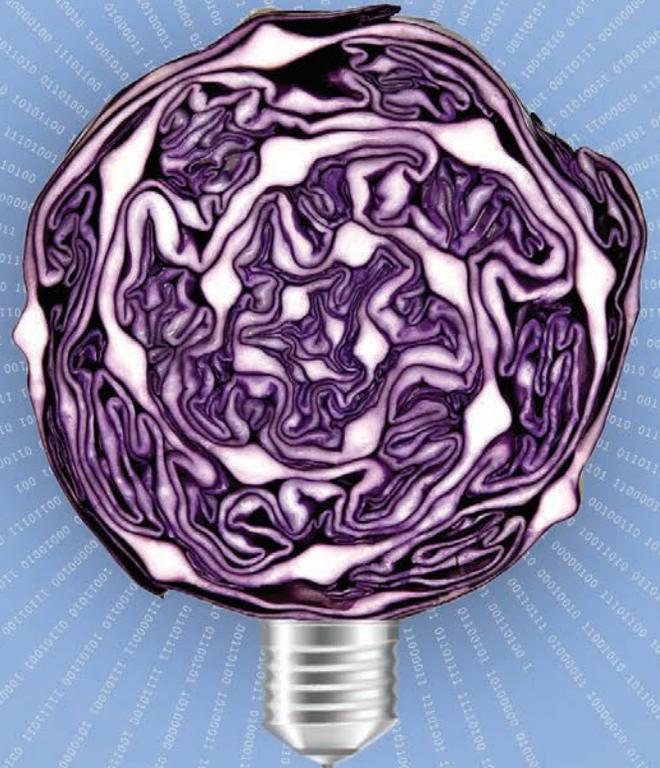
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PrimusGFS v3.0

General Regulations

Used in conjunction with the PrimusGFS v3.0 audit

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1. INTRODUCTION

- a. PrimusGFS is a Global Food Safety Initiative (GFSI) recognized audit scheme that has been developed by Azzule Systems and has been used for many years by different parties of the fresh produce industry. It is designed to be used for primary production and manufacturing sectors (including horticultural, grains, and pulses) at a world-wide level.
- b. Azzule Systems, which is a member of Primus Group, Inc., owns the PrimusGFS auditing scheme. Azzule Systems has offices worldwide, including:
 - ii. Santa Maria, California, United States (Headquarters)
 - ii. Viña del Mar, Valparaíso, Chile
 - iii. Culiacán, Sinaloa, Mexico
- c. PrimusGFS is a private **audit** scheme that establishes voluntary requirements for the certification of agricultural sector products (including horticultural, grains, and pulses) at a world-wide level.
- d. PrimusGFS has been designed with a HACCP-based approach that includes measures that need to be taken, following the 7 Codex Alimentarius HACCP principles. This allows the producers to assess their operations' risk and implement parameters and corrective and preventive actions to maintain their food safety program.
- e. These General Regulations explain the PrimusGFS Certification System and the process to obtain certification. They also intend to establish communication mechanisms, duties and obligations of the Scheme Owner, of Certification Bodies (CBs), and of applicants seeking to gain certification of their operation(s).
- f. The PrimusGFS website provides a public listing of certified operations, provisionally approved CBs, and approved CBs.

2. VERSION 3 UPDATE

- a. The goal for PrimusGFS version 3 was to update the audit to meet current industry practices, customer, and stakeholder compliance requirements. We also took the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) rules into consideration during the development. Where the current PrimusGFS requirements did not meet FSMA requirements, additional criteria was added for producers to comply with FSMA. An initial draft of version 3 was reviewed by stakeholders (e.g., buyers, customers, audited operations, certification bodies, etc.), and the feedback was considered in the final draft.
- b. The PrimusGFS audit is now divided into distinct modules that are different than previous versions of PrimusGFS. In the previous version, the ranch (now farm), harvest crew, and greenhouse (now indoor agriculture) audits were all combined into module 2: GAP. For version 3, each GAP operation type has its own distinct module. Additionally, for facility operations, there is a new, optional module that covers Preventive Controls (module 7).

3. STANDARD SCOPE

- a. The PrimusGFS **scope** is focused on the Food Safety of agricultural sector products (including horticultural, grains, and pulses) designated for human consumption. PrimusGFS establishes a series of requirements for managing the production, handling, processing and storing operations, which should be considered for consumers' safety.
- b. The main objective is to accomplish third party verification by the CBs, for the relevant food safety **practices** associated with each of their different production stages by establishing a minimum acceptable condition for the performance of the applicants. For this, **the PrimusGFS audit** has defined **seven** fundamental areas that a company in the agricultural sector **should** consider (**as applicable**) in the production and/or manufacturing of their products:
 - i. Food Safety Management System (FSMS) **applicable for all production areas.**
 - ii. Good Agricultural **Practices (GAP)**

- Farm (previous version was Ranch)
- Indoor Agriculture (previous version was Greenhouse)
- Harvest Crew
- iii. Good Manufacturing Practices (GMP)
 - Storage and Distribution
 - Cooler/Cold Storage
 - Packinghouse
 - Processing
- iv. Hazard Analysis Critical Control Points (HACCP) System is required for all GMP operations.
- v. Preventive Controls (PC) is voluntary and applicable to GMP operations only.
- c. An explanation of the requirements for each of these areas is provided in the current normative documents of the PrimusGFS Scheme:
 - i. PrimusGFS - General Regulations
 - ii. PrimusGFS - Checklist
 - iii. PrimusGFS - Questions and Expectations
- d. PrimusGFS may periodically issue additional normative documents or updated revisions of the current normative documents (e.g., in response to factors such as significant food safety issues, new regulatory requirements, significant changes made to the GFSI benchmarking requirements, etc.).
- e. The normative documents will be formally reviewed internally annually and, if needed, changes will be made. Reissuing of the normative documents will take place every four years, or more frequently, if needed (e.g., in response to factors, such as significant food safety issues, new regulatory requirements, etc.).
- f. The scheme review will take all user feedback into consideration, and the changes will be sent to stakeholders for review.
- g. English is the original language of the normative documents. Translations will be made to other languages, as needed, and will also be issued as official normative documents. In the case that any issue(s) arises with the translation of the other languages, the user should revert back to the English version.
- h. The normative documents and their translations can be found on the PrimusGFS website (www.primusgfs.com).
- i. The Scheme Owner shall carry out formal reviews of the management of the scheme and take any necessary action to ensure compliance with the current GFSI benchmarking requirements. These reviews shall be part of an internal audit program.

4. LEGISLATION

- a. Food Safety legislation differs from one country to another. PrimusGFS has been developed to ensure that where laws, specific industry guidelines and/or best practice recommendations exist, these practices and parameters are used as a reference for the applicant's conformance, establishing minimum acceptable criteria for food safety certification.

5. GUIDANCE FOR THE MANAGEMENT OF CERTIFICATION BODIES (CBs)

- a. PrimusGFS certification audits can only be performed by provisionally approved and approved CBs. Certification activities shall be carried out by personnel who meet the requirements for all management, administrative, technical and auditing functions.
- b. The CB shall have a documented and implemented quality management system, containing all the necessary requirements to conform to

the scheme. Examples include the rules and procedures for evaluating the applicant organizations, and their certification process for granting, maintaining, extending, suspending, and withdrawing certification. The required quality management system information for accreditation shall always be available to the Scheme Owner.

- c. There shall be a designated member of the CB **personnel** responsible for the quality **management** system's development, implementation and maintenance. This person, the Scheme Manager **and/or Technical Supervisor**, will be the contact person with the Scheme Owner **regarding** Scheme **management**. **All official communications with the Scheme Owner must be in English.**
- d. The CB must be accredited for the **PrimusGFS** scope, according to ISO/IEC 17021 or ISO/IEC 17065. The Accreditation Body must be affiliated with the International Accreditation Forum (IAF) and signatory to the Multilateral Recognition Arrangement (MLA). The list of approved and provisionally approved CBs is publicly available on the **PrimusGFS** website: <http://www.primusgfs.com/certificationBodies.aspx>.
- e. Where the CB has a current ISO/IEC 17021 or ISO/IEC 17065 accreditation and requests **a scope modification or extension from** the Accreditation Body to include PrimusGFS, the CB must provide written evidence to **the Scheme Owner** to notify of such circumstances.
- f. **Where the CB does not have a current ISO/IEC 17021 or ISO/IEC 17065 accreditation, they shall be accredited within one year of the date that the application is submitted to the Accreditation Body, with PrimusGFS being listed in their scope of accreditation. If the accreditation is not granted within this period, the Scheme Owner shall terminate the current contract and review the situation. If there is a delay in accreditation, the provisionally approved CB shall provide a plan to PrimusGFS for approval to achieve accreditation.**
- g. For those CBs that provide non-accredited services, they shall **publicize** the scope of their accreditation **on their website**, to avoid ambiguity with the accredited services offered.
- h. The Scheme Owner will define a set of indicators **to analyze CB performance as part of the PrimusGFS CB Integrity program**, which will be monitored according to a risk based program that will **be based on** the number of certifications issued by the CB, **size and** types of **audited** operations, complaints received and any other **indicator** that the Scheme Owner considers **necessary**.
- i. The Scheme Owner **can** execute on-site inspections at the CB offices, **assess** the auditors' technical skills (which can include shadowing auditors), review audit reports **and corrective actions**, review any materials conducted under the PrimusGFS scheme certification process or request information **and/or** documentation **related to the** CB's accreditation, and anything pertaining to the **PrimusGFS scheme**. All costs associated with these **activities** are to be covered by the CB.
- j. CBs shall notify the Scheme Owner in a timely manner regarding any relevant changes to their ownership, **management personnel**, management structure or constitution.
- k. In the case of any possible conflict or problems that could bring PrimusGFS into disrepute, the Scheme Owner and the CB shall agree on the appropriate action to take.
- l. **The CB shall have a procedure in place to handle complaints and appeals, which shall be made publicly available.**

6. AUDIT DURATION AND FREQUENCY

- a. The CB will be responsible for evaluating whether an **operation** meets the requirements for PrimusGFS and consequent certification. The CB will be responsible **for** defining the audit duration and frequency **for an operation**.
- b. The audit duration should be approximated by the CB when scheduling audits, and adjusted by the auditor, considering the following information:
 - i. Type of operation(s)
 - ii. Number of operation(s)
 - iii. Size of the operation(s)
 - iv. **Number of workers**
 - v. Number of products and similarity of production process(es)

- vi. Complexity of the production and/or handling process(es)
- c. The audit duration will be recorded per organization and the operations included in the certification process. The audit duration **includes** the time required to perform the **documentation review (including Module 1)** and the **visual inspection** for each operation included in the certification scope. The following guidelines **estimate** approximate audit **recording** durations:
 - i. **GAP Audits – Documentation review: 2 – 5 hours, visual inspection: 1.5 – 4 hours.**
 - ii. **GMP Audits – Documentation review: 2 – 5 hours, visual inspection: 1.5 – 6 hours.**
 - iii. **The times for both the documentation review and the visual inspection should be reflective of the size of the operation and the types of processes audited.**
- d. Audit duration **includes the time** from the opening meeting to the closing meeting (where **the non-conformances found** are **reviewed**). The **timeframes** shall be **indicated** in the audit report. CBs **must be able to** justify significant audit duration deviations.
- e. The subsequent audit **should be scheduled** 12 months from the date of the previous audit and not from the previous certificate issue date.
- f. This frequency may be modified **due to** factors, such as:
 - i. Modification of the scope and/or operation’s location during the certificate validity.
 - ii. Seasonality of the products.
 - iii. **An extension lasting an additional 3 months from** the current certificate expiration date **may be granted by the CB that made the certification decision. There must be** justifiable circumstances **that are documented.**
 - iv. Quantity and type of **non-conformances** detected at the time of the audit (e.g., a re-audit or a re-visit may be required to receive certification).
 - v. Additional visits may be required due to insufficient corrective action evidence.
- g. These or other situations must be **assessed** and documented by the CB, **who will determine** the audit frequency required for each applicant, **and document** justification for any modification.

7. CERTIFICATION SCOPES (AS DEFINED BY GFSI)

- a. PrimusGFS is a scheme that defines the food safety requirements for **managing the production, handling, processing and storing** of food in the following **agricultural (including horticultural, grains, and pulses) scopes**:

| CERTIFICATION SCOPES (AS DEFINED BY GFSI) | | | |
|---|--|--|--|
| Scope | Category name | Operation Type(s) | Examples of product |
| BI | Farming of Plants (other than grains and pulses) | <ul style="list-style-type: none"> • Farm • Indoor Agriculture • Harvest Crew | Growing or harvesting of plants (other than grains and pulses) for human food consumption. |
| BII | Farming of Grains and Pulses | <ul style="list-style-type: none"> • Farm • Indoor Agriculture • Harvest Crew | Growing or harvesting of grains and pulses for human food consumption. |

| CERTIFICATION SCOPES (AS DEFINED BY GFSI) | | | |
|---|---|---|---|
| Scope | Category name | Operation Type(s) | Examples of product |
| D | Pre-process handling of plant products, nuts and grains | <ul style="list-style-type: none"> • Storage and Distribution Center • Cooling / Cold Storage • Packinghouse | De-shelling of nuts; Drying of grain; Grading of fruit and vegetables; Storage; Cleaning, washing, rinsing, fluming, sorting, grading, trimming, bundling, cooling, hydro-cooling, waxing, drenching, packing, re-packing, staging, storing, loading and / or any other handling activity that does not significantly transform the product from its original harvested form. |
| EII | Processing of perishable plant products | <ul style="list-style-type: none"> • Processing | Production of plant products (including grains, nuts, and pulses). Washing, slicing, dicing, cutting, shredding, peeling, grading, pasteurization, cooking, chilling, juicing, pressing, freezing, packed in modified atmosphere, packed in vacuum packing or any other activity that significantly transforms the product from its original whole state. |
| EIII | Processing of perishable animal and plant products (mixed products) | <ul style="list-style-type: none"> • Processing | Production of plant products with ingredients from animal origin (e.g. ready to eat salads with grilled chicken or other meat, frozen foods with both plant and animal ingredients, etc.). Mixing, cooking, chilling, freezing, packed in modified atmosphere, packed in vacuum packing. |
| EIV | Processing of ambient stable products | <ul style="list-style-type: none"> • Processing | Production of food products from agricultural sources that are stored and sold at ambient temperature *Limited to agricultural products (horticultural, grains, and pulses) only. Examples are: cooking , drying, roasting, salting, pressing, milling, freeze drying , irradiating , packed in modified atmosphere , packed in vacuum packing , pasteurizing , pickling , etc. |
| J | Storage and Distribution services for food | <ul style="list-style-type: none"> • Storage and Distribution Center | Storage facilities for food for human consumption. |

Table 1: GFSI Scopes of Recognition (taken from GFSI v7.1 Guidance Document)

- b. Within PrimusGFS, there are a wide variety of processes that could be audited. Therefore, CBs should select their auditors based on their skill sets related to the process(es) being audited. CBs **also need to** have reviewers/certification decision-makers who are qualified and experienced to review and/or make the certification decisions for the process(es) being audited.

8. CB PERSONNEL REQUIREMENTS

8.1 ISO/IEC Requirements

- a. The CB must document and make known to all personnel (auditors and other personnel) involved in the certification process either the ISO/IEC 17021 or ISO/IEC 17065 requirements as they relate to their responsibility and role at the CB.

8.2 Conflicts of Interest

- a. CBs and personnel involved in the certification process must have a signed contract or agreement that ensures that they:
 - i. Avoid any conflict of interest in the certification activities, with regards to services (training and/or consultancy) provided to those applying for certification. There must be a minimum of a three-year period between providing any services and performing a PrimusGFS audit.
 - ii. Declare any potential conflicts of interest to CB management **if** assigned duties related to an applicant in the program.
 - iii. Be free from any commercial interest in the companies or products to be certified.
 - iv. Maintain the confidentiality of all client specific information, except as required by this standard or by law.

8.3 Auditor Requirements

- a. CBs are responsible for ensuring that auditors performing the inspections are in conformance with the following minimum requirements, have evidence to demonstrate their conformance, **and be knowledgeable in all PrimusGFS audit documents, the General Regulations, and the training requirements.**
- b. Qualification/Education: Auditors must have education in an agricultural/crop based, food or bio-science related discipline or, as a minimum, have successfully completed a higher education course or equivalent qualification in one of those disciplines, with a degree, diploma or a certificate from a recognized institution, as described in the GFSI Guidance, **v7.1, 2.3.2.2**, or any subsequent revisions to such guidance.

8.4 Work Experience

- a. It is preferred that an auditor have five years of experience in the agricultural and/or food industry, but as a minimum, they must have at least two years of experience in areas such as quality assurance or food safety functions in food production or manufacturing, retailing, inspection or enforcement, **or equivalent.**

8.5 Audit Experience

- a. Auditors must have a minimum of 10 audit days, **with at least 5 different organizations, of** practical auditing experience performing GFSI recognized audits. This experience can be as a third party auditor or shadowing an approved auditor. Information about the audit experience shall be documented, including **the following**: dates, audited organization, type of operation being audited and role of the **potential** auditor.

8.6 Formal Auditor Training

- a. Auditors must have successfully completed the following courses:
 - i. Recognized training in audit techniques based on QMS or FSMS, with a duration of one week/40 hours or equivalent.
 - ii. HACCP training based on the Principles of Codex Alimentarius from a recognized institution with a minimum duration of 2 days or 16 hours **of formal classroom training, taken within the last 5 years.**
 - iii. Approved PrimusGFS Auditor Training, as defined by the Scheme Owner. **CBs can require auditors to attend an additional training, based on their specific SOPs and/or Work Instructions.**
 - iv. **PCQI Training is required if auditors will be performing the Preventive Control audits.**

8.7 Auditor Assessment

- a. For an auditor's initial approval, a **witness** audit assessment must be performed by an **approved witness assessor that should be an**

already approved auditor or the CB's Scheme Manager and/or Technical Supervisor during an official PrimusGFS audit. This will include an assessment of the new auditor's knowledge of the following items:

- i. PrimusGFS normative documents
- ii. Food Safety principles, HACCP, Pre-requisite programs and access to relevant laws and regulations and can apply them when appropriate
- iii. Quality Management Systems, specific audit techniques and specific scopes
- b. The auditor assessment shall be documented and contain all the information found in the example template distributed by the Scheme Owner. The assessment report will describe the details and outcome of the assessment. If the auditor assessment is being completed for a newly approved or provisionally approved CB and there are no other approved PrimusGFS auditors, an auditor that is already approved to audit other GFSI benchmarked audits can perform the witness assessment.

8.8 Auditor Exam

- a. All auditors must pass the PrimusGFS exam to be approved, and subsequently when there is a new version of the scheme or as required by the Scheme Owner. The exam includes knowledge and understanding of the following topics:
 - i. PrimusGFS normative documents
 - ii. Relevant food/agricultural related legislation
 - iii. Agricultural (horticultural, grains, and pulses) production /manufacturing processes
 - iv. Quality management systems, good agricultural and/or manufacturing practices and HACCP systems.
- b. Each time there is a new version of the scheme, the updated exam should be taken by all approved auditors before conducting audits using the new version.

8.9 Auditing Scope

- a. Each auditor should be assigned an audit scope, based on their qualifications, education and experience. In order to be approved for both options of the PrimusGFS Scheme (field and facility), the auditor assessment(s) must be performed for both field and facility audits. The assessment(s) can be performed at the same time for one organization or as separate events. As a result, the auditor can be approved to do audits for the GAP option only (field), for the GMP option only (facility) or for both options.
 - i. For GMP auditor approval, the auditor should be approved based on the audit scope of their witness assessment. For example, if the auditor is assessed and approved during a packinghouse audit, then they should only be approved for packinghouse, cooling and cold storage, and storage and distribution audits. To be approved to audit processing facilities, the auditor should be assessed during a processing audit and subsequently approved for all PrimusGFS facility scopes.
 - ii. For GAP auditor approval, the auditor should be approved based on the audit scope of their witness assessment.
- b. In situations where the auditor wants to extend their scope to include another option of the Scheme, the auditor must be in compliance with all the auditor requirements mentioned in this section and undergone and successfully completed the witness audit assessment for the additional option (field or facility) and be signed-off as competent by the CB Scheme Manager and/or Technical Supervisor.

8.10 Continued Training

- a. To maintain the approved auditor status, there should be evidence that the auditor performed at least five PrimusGFS on-site audits per year at different organizations, to maintain scheme and industry knowledge.
 - i. In special circumstances that the above requirement cannot be met, there should be evidence that the auditor performed at least five audits against another GFSI scheme (similar to the PrimusGFS scope) and at least one PrimusGFS audit.
- b. It is the CB's responsibility to ensure that their auditors are current on industry best practices, food safety, and technological developments, and relevant laws and regulations for each option (Field and/or Facility) in which their auditors are approved. The

CBs shall maintain records of all relevant trainings taken by the auditors.

- c. Documented performance monitoring.

8.11 Attributes and Competencies

- a. The CBs must have a system in place that ensures auditors are conducting audits in a professional manner. The auditor assessments (including their initial witness assessment and any subsequent reviews) should also evaluate their personal attributes and behavior.
- b. CBs must be able to demonstrate that the auditors meet the approval requirements and maintain their competence as a PrimusGFS auditor. In the same way, CBs must keep complete records of auditors' qualifications, experience, training, supervised audits, assessments, sign-off, re-approval and others, while they have a working relationship and for a minimum period of two years afterward.
- c. CBs will be responsible for registering auditors in the PrimusGFS database, providing evidence of their qualifications, experience, training, assessment, auditing scopes, etc., and to keep this registration updated when changes occur. Auditors should be registered prior to their witness assessment, in order to be able to enter the report into the PrimusGFS system.

8.12 Scheme Manager and/or Technical Supervisor

- a. The CB must appoint at least one person as the Scheme Manager and/or Technical Supervisor (TS), who:
 - i. Meets the qualification/education and working experience of an auditor for all audit scopes.
- b. The Scheme Manager and/or Technical supervisor will have the following responsibilities:
 - i. Maintain the competence of CB personnel and auditors by ensuring they are trained when a new version of the scheme is released.
 - ii. Be the person who clarifies technical issues with CB personnel and audited organizations.
 - iii. Act as a technical contact with the Scheme Owner. They should be responsible for the direct communication related to technical questions between the CB and the Scheme Owner.
 - iv. Sign-off on approval for new auditors.

8.13 Other Personnel Requirements

- a. The CB shall record and maintain records of the qualifications, training, and experience of all personnel that are involved in the certification process. These records shall be dated and include as a minimum:
 - i. Name and address
 - ii. Employer(s) and position held
 - iii. Educational qualifications and professional status
 - iv. Experience or training as it relates to their responsibility and role in relation to the certification process
 - v. Details on performance monitoring

9. CERTIFICATION PROCESS

9.1 Application

- a. Applicants must provide the CB with the scope of their operations that they want certified. This information should at least include:
 - i. Organization details;
 - ii. Contact information;

- iii. Details about the operation(s) to be included in the scope of certification. For field operations, each site is called either a “Farm” (previously Ranch) or “Indoor Agriculture” (previously Greenhouse) and the application should detail the different sites to be certified. There is also the “Harvest Crew” option if that is to be audited, in addition to a field operation, facility operation, or as a stand-alone audit. For facility operations, each site can either be called a “Storage & Distribution Center”, “Cooling/Cold Storage”, “Packinghouse” or “Processing”.
- iv. Field operation products covered in the scope of certification.
 - The commodities must be present in the field at the time of the audit.
 - Where a commodity is not present at the time of the audit but the operation wishes to include it in the certification scope of their audit, it may be considered if the commodity is considered to have similar growing processes as to what is going to be audited, and the same personnel involved. **If it is a Harvest Crew audit, the products need to have similar harvesting processes.**
 - The auditor will indicate on the audit report what products were observed at the time of the audit, similar products not observed at the time of the audit and products that were not similar and not seen at the time of the audit. The auditor is to include specific details in the audit scope and throughout the audit report related to which products were observed at the time of the audit, as well as which records were reviewed.
 - If the commodity was not grown by the field operation during the previous growing cycle (12 months), they cannot be considered in the audit scope. Records of production of the additional products should be available for review.
- v. Facility operation products covered in the scope of certification.
 - The operation must be running and the commodities included in the scope of certification must be present in the operation at the time of the audit. The auditor must review all operational steps at the time of the audit. If certain steps are not taking place at the time of the audit, the operation will not be able to be certified. If there is any doubt as to whether all operational steps are included in the audit, the auditor should consult with the CB technical team. If there is any doubt regarding this, the Scheme Owner should be contacted.
 - Where a commodity is not present at the time of the audit but the operation wishes to include it in the certification scope of their audit, it may be considered if the products have similar production processes as to the products that are going to be audited, and the same personnel is involved.
 - The auditor will indicate on the audit report what products were observed at the time of the audit, similar products not observed at the time of the audit and products that were not similar and not seen at the time of the audit. The auditor is to include specific details in the audit scope and throughout the audit report related to which products were observed at the time of the audit, as well as which records were reviewed.
 - Process description(s) or flow chart(s), with step-by-step details of the production process and the equipment used needs to be available for review at the time of the audit. If the commodity was not included in the facility’s operation during the previous production cycle (12 months), they cannot be considered in the audit scope.
- vi. Desired audit period based on the seasonality of the crop and the validity of the current audit certificate.
- vii. Language for the audit to be performed in and the language to be used for the audit report.
- viii. **Country of destination per commodity (if known, should be included on the application).**
- ix. **The choice to schedule the audit(s) as announced or unannounced. If the applicant chooses the preferred option as unannounced the following rules apply:**
 - **The unannounced audit(s) should be performed using the current PrimusGFS checklist.**
 - **The unannounced audit(s) should be scheduled following the rules described in 10.6 Surveillance Audits (a) ii. If the applicant does not accept the first attempt of the unannounced audit the CB should conduct the audit as announced.**
 - **The audit reports and certificates will display information the audit was conducted as unannounced.**

- b. Transferring CBs: In the case that the organization is changing CBs, the applicant is responsible for submitting the request to switch CBs in the PrimusGFS system. Once the transfer is complete, the Corrective Action Report(s) from the prior audit(s) will be provided to the new CB via email from the Scheme Owner. Note: Applicants cannot transfer CBs with audits in progress with their current CB.

9.2 Audit Execution

- a. The audit shall be performed using the most recent version of the PrimusGFS normative documents.
- b. The PrimusGFS Standard is divided into seven Modules:
 - i. Module 1 – Food Safety Management System (FSMS)
 - ii. Module 2 – Farm
 - iii. Module 3 – Indoor Agriculture
 - iv. Module 4 – Harvest Crew
 - v. Module 5 – Facility
 - vi. Module 6 – Hazard Analysis Critical Control Point (HACCP)
 - vii. Module 7 – Preventive Control (PC)
- c. Each module is divided into sections, with specific questions related to the section topics.
- d. Audits will cover the seven modules for certification.
 - i. Module 1 is required for all certifications.
 - ii. Module 2 is required for farm operations.
 - iii. Module 3 is required for indoor agriculture operations.
 - iv. Module 4 is required for harvest crew operations. Harvest crews can be audited as stand-alone or in conjunction with a farm, indoor agriculture, or facility operation.
 - v. Module 5 is required for all facility operations. Depending on the type of facility, there may be individual questions in the Module that are not applicable.
 - vi. Module 6 is required for all facility operations. Some sections of module 6 may not be applicable. Applicability should be determined based on the outcome of the documented hazard analysis of all steps of each process. This HACCP Module is based on the 7 Codex Alimentarius HACCP principles and the 12 HACCP implementation steps. In all cases, the HACCP process and system must be in conformance with all existing legal requirements.
 - vii. Module 7 is optional to all facility operations. This module includes specific language found in the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) Preventive Controls for Human Food Rule and is included to serve as a guide for Preventive Controls for Human Food compliance.
- e. The scope of certification should be clearly defined prior to the audit to determine the modules to be audited at the time of the audit. Ownership of the different areas, locations, activities or crops of the company applying for certification are elements to consider when deciding what types of operation(s) will be included in the scope. That decision should be made by the applicant organization. The auditor must perform the audit based on the defined scope. A scheduled Pre-Assessment audit cannot be converted into a certification audit once the audit has begun or post audit, i.e. during on-site documentation review or visual inspection.
- f. An auditor should not be assigned to audit the same organization for more than three consecutive years at a maximum. The fourth consecutive audit should only occur with justifiable reasons, i.e. auditor availability, auditee location.

10. EVALUATION

10.1 Individual Question Conformance

- a. To verify conformance, the PrimusGFS Checklist and the PrimusGFS Questions and Expectations shall be used.
- b. **There are information gathering questions included throughout the audit that are worth zero points each. For scored questions, each question of the PrimusGFS Checklist has a possible score assigned to it.**
- c. The auditor must evaluate and answer each one of the questions **that applies to the operation being audited.**

| THE POSSIBLE ANSWERS TO THE QUESTIONS IN EACH MODULE ARE LISTED BELOW: | |
|--|--|
| Answer | Criteria used |
| Total conformance | To meet the question and/or conformance criteria in full. |
| Minor deficiency | To have minor deficiencies against the question and/or conformance criteria. To have single or isolated non-severe deficiencies (usually up to three) against the question and/or conformance criteria. To have covered most of the question conformance criteria, but not all. |
| Major deficiency | To have major deficiencies against the question and/or conformance criteria. To have numerous non-severe deficiencies (usually more than three) against the question and/or conformance criteria. To have single or isolated severe deficiencies against the question and/or conformance criteria. To have covered some of the question conformance criteria, but not most of it. |
| Non-conformance | To have not met the question and/or conformance criteria requirements at all. Having systematic deficiencies against the question and/or conformance criteria (severe or non-severe issues). |
| Non-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 answering Non-applicable. |

Table 2: PrimusGFS Scoring Criteria

- d. Each question in the PrimusGFS Checklist should be looked at individually and answered according to the auditor’s observations during the audit.
- i. The amount of deficiencies and the risks associated should be considered when assigning the severity of the finding, which can be a Minor Deficiency, Major Deficiency or Non-Conformance. When no deficiencies are found, a Total Conformance is given. When the requirement is not applicable for the operation being audited, a Non-applicable answer is given. Some general statements for the scoring decisions are described in the table above (Table 2). These statements are superseded by the criteria described in the question’s expectations and users should be aware that some questions do not follow these general statements (e.g., automatic failure questions).

10.2 Scoring System

- a. Each question in the PrimusGFS Checklist has a possible score assigned to it. Depending on the answer given, the score obtained will be defined.
- b. Each **scored** question has a certain **amount of** points that can be obtained depending on the conformance assigned to it. The scoring system for each question is described in the table below (Table 3):

| SCORING SYSTEM | | | | |
|-------------------|----------------------------------|-----------|----------|----------|
| Possible answer | Possible Points for the Question | | | |
| | 15 points | 10 points | 5 points | 3 points |
| Total conformance | 15 points | 10 points | 5 points | 3 points |
| Minor deficiency | 10 points | 7 points | 3 points | 2 points |
| Major deficiency | 5 points | 3 points | 1 point | 1 points |
| Non-conformance | 0 points | 0 points | 0 point | 0 points |

Table 3: Scoring System

- c. It is important to note that for all questions answered Non-applicable, the points assigned to that question will be taken out of the total possible score, so calculations are not affected by those answers.

10.3 Scoring Calculation per Module and per Operation

- a. There will be two types of scoring calculations for each audit:
 - i. Module Score, which is calculated for each one of the modules audited.
 - ii. Overall Total Score, which is calculated for each audited operation.
- b. The Module Score is calculated for each one of the modules included in the audit, considering the total sum of points obtained in each module divided by the total points possible, represented in a percentage. See Table 4 below for a diagram of the scoring calculation structure.
- c. The Overall Total Score is calculated for each operation considering the total sum of points obtained in the entire audit, divided by the total points possible for the entire audit, represented as a percentage. See Table 4 below for a diagram of the scoring calculation structure.
- d. For all audits, the Overall Total Score calculated in the preliminary stage will need to be $\geq 85\%$ in order to proceed to the subsequent certification decision phase. If the preliminary overall total score is $<85\%$ then the audit is "not certified." The applicant organization will still have the availability to submit correctives actions, but they will not be calculated to achieve certification. If the preliminary score is $\geq 85\%$ but $<90\%$, corrective actions will be required in order to become certified.

| SCORING CALCULATION STRUCTURE | | | | | | |
|--|---|--|----|--|---|---|
| Module 1 | | Farm Modules | | Facility Modules | | Operation |
| Food Safety Management System | | Farm (2) / Indoor Farming (3) / Harvest Crew (4) | | Facility (5) / HACCP (6) / Preventive Control (7) | | |
| Total sum of the points obtained for each one of the questions applicable in this module | + | Total sum of the points obtained for each one of the questions applicable in this module | or | Total sum of the points obtained for each one of the questions applicable in this module | = | Total points obtained in the complete audit for the operation |
| ÷ | | ÷ | | ÷ | | |
| Total sum of possible points for each applicable question in this module | + | Total sum of possible points for each applicable question in this option | or | Total sum of possible points for each applicable question in this option | = | Total points possible in the complete audit for the operation |
| = | | = | | = | | |
| Module Score for Module 1 | | Module Score for applicable Modules | | Module Score for applicable Modules | | Overall Total Score for the operation |

Table 4: Scoring Calculation Structure

- e. The scores shall be displayed in rounded down **whole number** percentages.
- f. This calculation should be repeated for each operation included in the certification scope.

10.4 Automatic Failure

- a. There are **certain** questions in the PrimusGFS checklist that if down scored will **result in** an automatic failure and an overall score of 0% for the corresponding module.
- b. These questions are identified with a phrase similar to: "ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE".
- c. Applicant should be immediately informed of the automatic failure by the auditor during the audit.

10.5 Special Circumstances

- a. Automatic Failure
 - i. The CB reserves the right to fail the audit due to special circumstances. Some examples include deliberate illegal activities, physical acts/threats to an auditor, attempted bribery, falsified records, etc., or finding serious food safety issues during the audit.
- b. Corrective Actions
 - i. The CB reserves the right to consider all information provided by the organization, as corrective action **evidence**, to affect other questions in the audit in addition to the one being **reviewed**.

- c. Certification Decision
 - i. The CB reserves the right to consider all information gathered during the certification process to make the decision **as to whether they will** grant certification for each specific operation or a whole organization.
- d. Suspension/Revocation of Certification
 - i. The CB reserves the right to consider all information **related to** the certified organizations and operations to suspend or revoke current certificates, if they represent a serious food safety issue or **if illegal activities are detected**.
- e. Significant Events for Certified Organizations and their Operations
 - i. All certified organizations shall inform their corresponding CB **and PrimusGFS at PrimusGFS@azzule.com** about any food safety related prosecution, significant regulatory food safety non-conformity, product recall related to food safety or any other issues that could bring the Scheme into disrepute. CBs shall ensure the integrity of certification after notification and consider the need to suspend or revoke certification. CBs should correspond these significant events to the Scheme Owner **within seven days of the occurrence**.
- f. Cause for Early Re-evaluation of a Certified Organization
 - i. The certified organization shall inform the CB of any significant changes, which could affect the safety of product. **This includes** any ownership and/or management changes, **and any changes made to the process, machines or production practices**.
 - ii. If the CB has any reason to believe that there could be compliance issues in relation to the certification requirements, a re-evaluation shall be performed to verify conformance with the PrimusGFS normative documents or the license agreement. This can include an on-site re-visit to verify that the organization is in compliance with the PrimusGFS compliance criteria prior to certifying the organization.

10.6 Surveillance Audits

- a. Surveillance Audits Performed by the CBs
 - i. Each CB **must have a surveillance program and conduct unannounced audits on their certified organizations that received an announced or unannounced certificate following 9.1 Application (a) ix**. The unannounced audits will be performed using the current PrimusGFS checklist (if mandated for all audits at the time of the unannounced audit) or the version the chosen organization(s) is certified against (in the case of a surveillance audit). The selected organization with certified operation(s) **must reach the same scoring as a certification audit mentioned in the Evaluation section of this document** in order to maintain their certification.
 - Ideally, the surveillance program should include 2% of a CBs current certified organizations, based on a risk assessment approach, considering factors such as compliance history, appeals and complaints, product type(s), complexity of the process(es), or any other factors the CB determines. If the CB has ≤ 10 current certified organizations, 1 organization should be chosen for the surveillance audit in their program.
 - ii. The CB will notify the **organization's chosen operation(s) (using the PrimusGFS software)** of the **unannounced** audit no sooner than 48 hours prior to the day of the audit.
 - iii. The **organization** can only reject a surveillance audit one time **with justifiable reasons**. If rejected on the second **attempt**, this will result in a suspension of **all current audit** certificates.
- b. Surveillance Audits Performed by the Scheme Owner
 - i. As part of the PrimusGFS Integrity Program, the Scheme Owner will perform sporadic auditor assessments. The purpose is to ensure that qualified auditors are performing the audits properly according to the PrimusGFS scheme.
 - The audited operations will be required to accept **the PrimusGFS representative(s)** on-site during the audit.
 - The **PrimusGFS representative conducting the auditor assessment** on-site will have no say during the audit nor will

they point out any deficiencies to the auditor at the time of the audit.

- ii. The Scheme Owner will also have the option to perform auditee assessments, which will consist of the Scheme Owner performing an on-site audit for a certified operation. These surveillance audits will be performed using the current PrimusGFS checklist **or the version the certified organization is certified against**, and the selected organization with certified processes **must reach the same scoring as a certification audit (mentioned in the Evaluation section of this document) in order to maintain their certification.**
 - By performing these audits, the Scheme Owner will be able to verify auditor performance (based on the prior audit report) to what was observed at the time of the **certification** audit.
 - The audited operations will be required to accept a second person(s) on-site during the audit.

11. REQUIREMENTS FOR AUDIT REPORTS

- a. The audit report will be always issued from the PrimusGFS database.
- b. After each audit, the auditor must enter the information into the PrimusGFS database to generate a preliminary audit report within 15 calendar days.
- c. The audit report will be written in the language that the applicant requests (English and Spanish are currently the only languages available in the PrimusGFS database).
- d. Every audit report shall **at least** include:
 - i. Name of the CB
 - ii. Name of the applicant organization
 - iii. Details about the operation under certification
 - iv. **Audit Duration (date and time)** (start and finish of **the documentation review and of the visual inspection/walkthrough**)
 - v. Name and version of the PrimusGFS normative documents used for certification
 - vi. Audit scope – details of the process under certification
 - vii. Product(s) observed during audit, similar product(s) not observed and product(s) applied for but not observed. The GFSI scope code is also recorded, although not currently included on the published version of the report
 - viii. Names of personnel involved in the audit from the applicant organization
 - ix. Auditor name
 - x. Audit scoring summary
 - xi. Answers and comments for each of the questions in the PrimusGFS checklist. These will be responded to based on guidance from the Scheme Owner**
 - xii. Shippers (customers of the auditee) designated during the application process (if applicable)
 - xiii. Any other additional information required by the Scheme Owner (e.g., GPS points, GFSI scope, etc.)**
- e. Additionally, every audit will generate a non-conformance report that will give a summary of all the non-conformances found in the audit, with the corresponding comments and details for each non-conformance.

12. NON-CONFORMANCES AND CORRECTIVE ACTIONS

- a. For all non-conformances (scored as zero points) raised during the audit, the applicant organization must submit corrective actions into the PrimusGFS database for review by the CB. If no corrective action is possible, the organization should detail what they will do to control the risk. The submission of comments and/or corrective actions does not guarantee that the score will change, but should demonstrate the actions that were taken or are to be taken by the applicant organization.
- b. In order to potentially increase the audit score, the applicant organization must submit evidence of the corrective actions taken into the PrimusGFS database for review by the CB.
- c. Corrective action evidence can be in the form of documents, records and/or photographs and it must show that the non-conformance has been addressed. This evidence must be verified and accepted by the CB in order to have the non-conformance closed and be considered for certification. Note that with an overall preliminary score of less than 85%, the auditee can submit corrective actions to the CB for review, but accepted corrective actions do not change the final score. (See Section 13 for further information on the certification requirements.)
- d. The corrective actions from the organization should include the determination of cause(s), include any action plan(s) to address immediate issue(s) regarding the non-conformance, the corrective actions taken, and the development of preventive actions to help avoid future occurrences if necessary.
- e. The CB has the right to determine if a re-visit to the audited organization is necessary to verify corrective actions for any non-conformance found.
- f. Corrective action evidence for each non-conformance must be submitted to the CB by the organization within 30 calendar days from the original audit date.
- g. The CB will have 15 calendar days to review the corrective action evidence and notify the organization if it was accepted or rejected and close the non-conformance(s).
- h. If time allows (within the 30 calendar day corrective action timeframe), when corrective action evidence is rejected by the CB, the organization can re-submit additional evidence to close the non-conformance.
- i. Once the applicant organization has responded to the CB regarding the non-conformances and the CB has reviewed all corrective actions submitted, the CB will close the corrective action phase in the PrimusGFS system, which will allow for the certification decision to be made.

13. CERTIFICATION DECISION

13.1 Certification Body

- a. The CB shall make the certification decision no more than 45 calendar days from the audit date.
- b. The audit report shall be reviewed by the authorized CB representatives to make the decision of whether or not to grant certification. These CB representatives shall be impartial and technically capable of reviewing the outcome of the audit reports, including but not limited to:
 - i. The certification scope (operation, products, etc.)
 - ii. Percentage Scores by module and for the entire audit
 - iii. The appropriate corrective actions have been taken to resolve any outstanding non-conformances

13.2 Calculation of Scores

- a. Based on the outcome of the final audit report, the scores should be calculated and analyzed for each operation to determine if they comply with the minimum score for certification.
- b. The certification decision shall be based on a combination of conformance scores: the Overall Total Score and the Module Scores.
 - i. The Overall Total Score must be at least 90% to achieve certification.

- ii. Each one of the Module Scores for the operation must be a minimum of 85% to be certified. All Overall Scores for **all** audits must be $\geq 85\%$ in the preliminary stage in order to **be certified**. If the preliminary score is less than 85%, a not certified decision is made. Another audit will be necessary to receive certification.

13.3 Issuing Certification

- a. Certification will be issued to each operation individually that complies with the minimum scoring criteria. In the case of **an organization** having more than one operation **included in** the same application, the calculations should be made separately for each operation and one certificate should be issued to each operation that complies with the scoring requirements.
- b. The PrimusGFS certification is **only** valid for certified **audited** operations.
- c. PrimusGFS is valid for a maximum period of 12 months from the certification date.
- d. The certificate must be issued from the PrimusGFS system.

14. SANCTIONS

14.1 Sanctioning of CBs

- a. Suspension of an approved PrimusGFS CB - A CB shall be suspended if:
 - i. The CB's **ISO/IEC 17021 or ISO/IEC 17065** accreditation has been suspended
 - ii. The CB does not pay the agreed upon fees
 - iii. The CB improperly uses the PrimusGFS or GFSI logo or trademark
 - iv. An issue is discovered by the PrimusGFS Integrity Program
 - v. The CB does not abide by the requirements of the General Regulations, License Agreement or other Scheme requirements.
- b. Revocation of an approved PrimusGFS CB - A CB shall have its approval revoked if:
 - i. Evidence of fraud is found
 - ii. The CB declares bankruptcy
 - iii. A suspension related issue is not adequately resolved
- c. **Any change in the status of the CB will be reflected on the PrimusGFS website.**

14.2 Sanctioning of Certified Organizations

- a. If the CB finds a non-conformance with a certified organization's PrimusGFS Scheme Documentation **that is found to be a food safety issue and an immediate threat to the public**, a sanction (suspension or revocation) shall be issued.
- b. All sanctions shall be in writing, and include the nature of the non-conformance, the time frame for resolution (if applicable) and provisions for escalation of sanctions if the non-conformance is not corrected within the specified period.
- c. Only the CB may lift a suspension sanction after sufficient corrective actions have been submitted, with verification either through written or visual evidence and/or an on-site visit.
- d. The CB can issue the sanction to an entire certified organization or narrow it to down to a specific operation(s) within the scope of the current certification.
- e. There are two types of possible sanctions for organizations:
 - i. Suspensions - an organization's certification shall be suspended if:
 - A non-conformance is found to be a food safety issue and an immediate threat to the public.

- If the re-certification audit results in an automatic failure, while the organization still has a valid certificate.
 - If a critical food safety issue is detected during an audit (e.g., automatic failure, special circumstance, etc.), then the CB should consider suspending existing certificates related to this new observation(s).
 - An organization does not pay the agreed to fees.
 - If an organization rejects a surveillance audit on the second CB notification.
 - The organization improperly uses the PrimusGFS or GFSI logo or trademark.
 - An organization is involved with an illegal activity or a serious food safety issue.
- ii. Revocations - an organization's certification shall be revoked if:
- Evidence of fraud is found
 - A suspension related issue is not adequately resolved
 - The organization declares bankruptcy
 - An organization that has had its certification revoked shall not be accepted for certification in the PrimusGFS program for a period of six months after the date of revocation.
- f. The CB shall always notify the Scheme Owner in a timely manner and in writing of any sanction applied to a certified organization, as well as update the system to reflect those changes.
- g. The **Scheme Owner** has a list that contains all suspended operations (those suspended after receiving certification), and those operations "not certified due to special circumstances" where the operation was "not certified" based on reasons other than score, which is available to CBs.

15. DISTRIBUTION OF AUDIT REPORTS

- a. CBs must provide and make available the information for each certification process, including but not limited to, audit details, outcome and the certification status to the Scheme Owner by using the PrimusGFS system or by any other means established by the Scheme Owner.
- b. The documented audit reports generated by the CB during the certification process for each operation, including those submitted through the PrimusGFS database, should be provided to the applicant, the CB and the Scheme Owner.
- c. Ownership of the audit report, determination of details made available and authorization for access shall remain with the applicant. The CB shall ensure appropriate confidentiality is in place and in conformance with all GFSI and ISO/IEC 17021 or ISO/IEC 17065 Guidelines. Except where required by law and the normative documents, the CB shall not release any applicant certification activity information to any outside party without the applicant's authorization. The CB shall document all communications between the CB and applicant, whereby the applicant authorizes the release of certification information to an outside party.

16. EXTENSION OF SCOPE CERTIFICATION

- a. An organization's certified operation can apply for an extension of scope to their current certification for:
 - i. Increased growing area of an already certified operation, if the operation has "like commodities" in terms of risk, along with justifiable circumstances.
 - ii. Adding products to already certified operations, with justifiable circumstances.
 - iii. If products are approved and added to the current report, the product(s) will be added to the "similar product(s) not observed" or "product(s) applied for but not observed" categories. Only the "similar product(s) not observed" will be included on the certificate.
- b. Justifiable circumstances will be reviewed at the CB level and include all relevant information, such as: similarity (risks, processes,

location and personnel) between new products and already certified products, and any additional information the CB considers as part of their risk assessment. The CB will have to **review** all information before a decision regarding a request for extension of scope of increased growing area and/or adding new commodities is granted.

- c. The CB will determine if there is a need to visit to the organization to increase the growing area, adding of commodities to already certified operations and/or adding a new process to the certificate (e.g., a new packing line, automated chopper, etc.).
- d. In the case of adding a new operation to an already certified organization, the organization may be required to have a full new audit including the FSMS and all relevant modules for that particular operation (if the audit for the new operation takes place greater than 30 days after the original audit date). This is required because the FSMS procedures may have changed since the original **audit** and/or the implementation of FSMS procedures may be different relative to previous operation audits.

17. USE OF LOGO AND TRADEMARK

- a. The PrimusGFS trademark and logo may only be used with the Scheme Owner's permission.
- b. The CB must always obtain the PrimusGFS logo from the Scheme Owner. This will ensure that it contains the exact corporate color and format.
- c. The CB is responsible for controlling **certified operations'** use of the PrimusGFS trademark and logo. The rules for the use of the logo and trademark will be defined in the License Agreement signed between the Scheme Owner and the CB (exhibit C of the CB license agreement) and in the Sub-License Agreement signed between the CB and each organization. Infringement of the rules by either CBs or organizations could lead to sanctions.
- d. Organizations can only use the trademark and/or logo when there is a valid PrimusGFS certificate linked to that organization, and **when the organization** makes it clear **which operations are certified**. The logo can only be used for business to business communications.
- e. PrimusGFS approved CBs can use the trademark and/or logo for promotion of their accredited PrimusGFS certification activities in business-to-business communications and on their accredited PrimusGFS certificates.