



PrimusGFS v4.0

General Regulations 2025

A Normative Document in the context of PrimusGFS refers to the official set of criteria that defines what requirements must be met, and how compliance is evaluated during an audit. These documents serve as the foundation for PrimusGFS audits and are essential for ensuring consistency, objectivity, and transparency across all certified operations.

The **PrimusGFS General Regulations** outline the governance, operational requirements, and procedures that define how the PrimusGFS certification program functions.

These regulations serve as the foundational framework for all stakeholders involved in the scheme, Certification Bodies (CB), auditors, auditees, and Azzule Systems as the owner of the audit program.

- Ensuring consistent implementation, transparency, and integrity throughout the certification process.

The document includes key information on audit types, scoring, certification decisions, auditor qualifications, conflict of interest, use of the logo and more. Understanding and adhering to these regulations is essential for maintaining the credibility and reliability of the PrimusGFS certification program.

PrimusGFS v4.0 updates are shown in **red**.



PrimusGFS General Regulations

Version 4.0

PrimusGFS (owned by Azzule Systems, LLC)

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1. Introduction

- a. PrimusGFS is a Global Food Safety Initiative (GFSI) recognized audit standard, developed by Azzule Systems, that has been used for many years in different areas of the food industry, particularly with fresh produce. It is designed to be used for primary production (including horticultural, grains, and pulses) and manufacturing sectors at a global level.
- b. Azzule Systems, which is a member of Primus Group, Inc., owns the PrimusGFS auditing standard. Azzule Systems has offices worldwide, including:
 - i. Santa Maria, California, United States (Headquarters)
 - ii. Culiacán, Sinaloa, México
 - iii. Viña del Mar, Valparaíso, Chile
- c. 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.
- d. 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 Standard Owner, of Certification Bodies (CBs), and of applicants seeking to gain certification of their operation(s).
- e. The PrimusGFS website provides a public listing of certified operations, provisionally approved CBs, and approved CBs.

2. Version 4.0 Update

- a. Azzule Systems has expanded upon PrimusGFS version 4.0, with the help of valuable feedback from its stakeholders (customers, audited organizations, buyers, Certification Bodies, Training Centers, and industry experts at-large) to create version 4.0. On-going stakeholder input allows PrimusGFS to strengthen the audit program and ensure it meets the needs of the industry.
- b. The focus for changes made to version 4.0 was:
 - i. **PrimusGFS v4.0 updates to align with evolving food safety regulations, GFSI benchmarking requirements, and stakeholder input.** To continue to align with the Global Food Safety Initiative (GFSI) requirements, the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) rules, industry commodity guidelines, academia publications, etc. To clarify and strengthen certain sections of the audit, including updated **food safety culture and allergen control requirements in the FSMS module, expanded fertilizer and irrigation water assessments in the Farm module; new Controlled-Environment Agriculture (CEA)-specific sections in Indoor Agriculture module and terminology alignment with *Codex Alimentarius* and the Food Safety Preventive Controls Alliance, (FSPCA) in HACCP and Preventive Controls modules.**

3. Standard Scope

- a. PrimusGFS establishes a series of requirements to be used for primary production (including horticultural, grains, and pulses) and manufacturing sectors at a global level 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 food 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
 - Indoor Agriculture
 - 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 **but** applicable to GMP operations **exporting or based in the United States**.
- c. An explanation of the requirements for each of these areas is provided in the current normative documents of the PrimusGFS Standard:
 - i. PrimusGFS - General Regulations
 - ii. PrimusGFS - Checklist
 - iii. PrimusGFS - Questions and Expectations
 - iv. Appendix 6 – International Accreditation Forum's MD-4:**2023**
- 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 standard 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. Azzule Systems shall carry out formal reviews of the management of the standard 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 **and reviewing** functions.
- b. The CB shall have a documented and implemented quality management system, containing all the necessary requirements to conform to the standard. 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 Azzule Systems.
- c. There shall be a designated member of the CB personnel responsible for the quality management system's development, implementation and maintenance. This person shall also have the responsibility for reporting on the performance of the quality system for the purposes of management review and system improvement. This person, the PrimusGFS Manager (previously Scheme manager) and/or Technical Supervisor, will be the contact person with Azzule Systems regarding PrimusGFS management. All official communications with Azzule Systems must be in English.
- d. The CB must be accredited for the PrimusGFS scope, according to 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://primusgfs.com/certification/>.
- e. Where the CB has a current ISO/IEC 17065 accreditation, they need to request a scope modification or extension from the Accreditation Body to include PrimusGFS. The CB shall also inform Azzule Systems of their request to the Accreditation Body, and when notified Azzule Systems shall acknowledge the notification in writing to the CB.

- f. Where the CB does not have a current 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, Azzule Systems 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 Azzule Systems for approval to achieve accreditation.
- g. The CB shall use the PrimusGFS Certification Program in its entirety (including all modules and normative documents) for the relevant scopes.
- h. 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.
- i. Azzule Systems has defined a set of indicators to analyze CB performance as part of the PrimusGFS CB Integrity program, which is monitored according to a risk-based program that is based on the number of certifications issued by the CB, size and types of audited operations, complaints received and any other indicators considered necessary.
- j. Azzule Systems can execute on-site inspections at the CB offices, assess the auditors' technical skills (which can include shadowing auditors), access and review CB personnel competency records related to their job function, review audit reports and corrective actions, review any materials conducted under the PrimusGFS certification process or request information and/or documentation related to the CB's accreditation, and anything pertaining to PrimusGFS. All costs associated with these activities are to be covered by the CB.
- k. CBs shall notify Azzule Systems in a timely manner regarding any relevant changes to their accreditation (e.g., withdrawal or suspension), ownership, management personnel, management structure or organization.
- l. In the case of any possible conflict or problems that could bring PrimusGFS into disrepute, Azzule Systems and the CB shall agree on the appropriate action(s) to take.
- m. The CB shall have a procedure in place to handle complaints and appeals, which shall be made publicly available **on the CBs webpage**.

6. Audit Duration and Frequency

Duration

- a. The CB will be responsible for evaluating whether an operation meets the requirements for PrimusGFS and consequent certification. The CB will **also** be responsible for **calculating** the audit duration and determining the audit frequency for an operation. **The audit duration must comply with, at a minimum, the audit duration specified in Section 6c of these General regulations.**
- b. The audit duration should be **calculated** by the CB when scheduling audits **in accordance with an internal procedure**, and **may be** adjusted by the auditor **based on** 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 are provided as an estimate of expected audit durations:
 - i. GFSI scopes BI, BII, BIII – minimum of **half (0.5) days, 4 hours.**
 - ii. GFSI scopes CII, CIII, CIV – minimum of **two (2) days, 16 hours.**
 - iii. GFSI scope G – minimum of **one (1) day, 8 hours.**
 - iv. 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.
 - v. **Any deviations from the minimum expected audit duration must be properly justified, communicated to Azzule Systems and documented in the Audit Executive Summary/Scope.** Reasons for a deviation may include scope, operation size, operational process reduction on-site, a halt in the audit process by the organization, re-evaluation of the operation, etc.
- d. Audit duration includes the time from the opening meeting to the closing meeting (where the non-conformances found during the audit are reviewed). The timeframes shall be indicated in the audit report.

Frequency

- a. The subsequent audit shall be scheduled 12 months from the date of the previous audit and not from the previous certificate issue date.
- b. 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. 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).
 - iv. Additional visits may be required due to insufficient corrective action evidence.
- c. 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.

Extensions

- a. 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.

7. Certification Scopes (as defined by GFSI)

- a. PrimusGFS defines the food safety requirements for the production, handling, processing, and storage of food, in accordance with the scopes listed in Table 1.

- b. PrimusGFS covers a wide variety of processes that may be audited. Therefore, CBs must assign auditors based on their relevant knowledge and skill sets for the specific process(es) being audited, **as outlined in Appendix 4: Scope, Education, and Industry Experience**. Additionally, CBs must have qualified and experienced technical reviewers and/or certification decision-makers **who are approved to review audit reports** and make certification decisions for the applicable process(es).

Scope	Category name	Operation Type(s)	Examples of activities covered within the scope
BI	Farming of Plants (other than grains and pulses)	<ul style="list-style-type: none"> • Farm • Indoor Agriculture • Harvest Crew 	Growing, harvesting, field packing and onsite/on farm storage of plants (other than grains and pulses) including horticultural products and hydrophytes for food.
BII	Farming of Grains and Pulses	<ul style="list-style-type: none"> • Farm • Indoor Agriculture • Harvest Crew 	Growing, harvesting, transport, onsite/on farm storage of grains and pulses for food.
BIII	Pre-process handling of plant products, nuts and grains	<ul style="list-style-type: none"> • Cooling / Cold Storage • Packinghouse 	Activities on harvested plants, including horticultural products and hydrophytes for food, that keep the products whole and integral . Cleaning, shelling, de-shelling; drying; sorting, grading; onsite storage of fresh, packaged fruits, vegetables, nuts, grains and pulses, etc. 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 .
CII	Processing of perishable plant products	<ul style="list-style-type: none"> • Processing 	Production of plant products , including fruits and fresh juices, vegetables, grains, nuts, pulses and perishable pet food from plant products only. 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 .
CIII	Processing of perishable animal and plant products (mixed products)	<ul style="list-style-type: none"> • Processing 	Production of mixed animal and plant products , including ready to eat and perishable pet food. Mixing, cooking, chilling, freezing, packing in modified atmosphere, packed in vacuum packing. (e.g. ready to eat salads with grilled chicken or other meat, frozen foods with both plant and animal ingredients, etc.).
CIV	Processing of ambient stable products	<ul style="list-style-type: none"> • Processing 	Production of food products from any source that are stored and sold at ambient temperature , including canned food and ambient stable pet food. Aseptic filling, baking, bottling, brewing, canning, cooking, distilling, drying, extrusion, fermentation, freeze drying, pressing, frying, hot filling, irradiating, milling, mixing and blending, packing in modified atmosphere, packed in vacuum packing, pasteurizing, pickling, roasting, salting and refining.
G	Storage and Distribution services for food	<ul style="list-style-type: none"> • Storage and Distribution Center 	Storage, distribution, and/or logistics operations for the storage and transport of perishable or non-perishable food, feed, and packaging. Note: any packing with labelling activities are excluded.

Table 1: GFSI Scopes of Recognition (taken from GFSI v2024)

8. CB Personnel Requirements

8.1 ISO/IEC Requirements

- a. The CB shall ensure all personnel (auditors, **reviewers** and other personnel, e.g., administrative, management, technical, etc.) involved in the PrimusGFS certification process are competent for their assigned position and must document all ISO/IEC 17065 and the International Accreditation Forum's MD-4:2023 requirements **and ensure that** all personnel involved in the certification process (auditors and other personnel, e.g., administrative, management, technical, etc.), **are properly trained to understand and comply with these requirements** as they relate to their responsibility and role at the CB. In addition, the CB must include the systems and procedures in place to ensure that auditors conducting assessments meet the capabilities described in ISO/IEC 17065 and the International Accreditation Forum's MD-4:2023.

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 **audits** are in conformance with the following minimum requirements of section 8 and have evidence to demonstrate their conformance to these requirements, with specific emphasis on their knowledge of the scope assigned to audit, all PrimusGFS audit documents, the General Regulations and the education and training requirements.
- b. Examples of knowledge and skills CBs are responsible to have available to justify an auditor approval for specific scopes listed in Section 7 Certification Scopes, as defined in the Appendix 4 Scope Education and Work Experience, may include (not an exhaustive list): pasteurization, fresh or pasteurized juices, ready-to-eat salads, pet food production, growing of certain products, such as microgreens, mushrooms, or sprouts, etc. for the specific sector for which the auditor is attempting to qualify.

8.4 Qualification/Education

- a. 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 Appendix 4 Scope Education and Work Experience.

8.5 Auditor's Industry 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 **full-time work** experience in **food safety functions** as requirements defined in Appendix 4 Scope, Education and Work Experience. **Auditing experience is independent of Industry Experience and will be evaluated in the section 8.7. Consultant experience may count if the role demonstrates responsibility for food safety at the site.**

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, taken within the last 5 years.
 - iii. Approved PrimusGFS Auditor Training, as defined by Azzule Systems. CBs can require auditors to attend an additional training, based on their specific SOPs and/or Work Instructions.
 - iv. PCQI Training from a recognized institution (i.e., Food Safety Preventive Controls Alliance) is required if auditors will be performing the Preventive Control audits.

8.7 Audit Experience

- a. Auditors must have a minimum of 10 audit days with at least 2 different organizations, ideally 5, of practical auditing experience shadowing an approved auditor or performing 3rd party or 2nd Party GFSI recognized audits.
- b. Information about the audit experience shall be documented, including the following: audit date(s), audited organization, type of operation being audited, role of the potential auditor, name of GFSI standard used.

8.8 Auditor Assessment

- a. Auditors must undergo an assessment process on at least 3 audits to verify auditing skills and knowledge prior to receiving the final sign-off approval from the CB. Assessments should continue until the auditor is assessed as competent.
- b. The initial successful witness assessment provides an auditor a provisional approval status prior to the final sign-off approval. The CB shall ensure that the witness assessor is present on-site for parts of the audit conducted on-site.
- c. The subsequent assessments conducted after the provisional approval is granted may be conducted by additional on-site witness assessments or by remote supervision with the use of ICT. (e.g., virtual witness or review of audit report and corrective action decisions and any other applicable documents required for the assessment review, etc.)
 - i. The audit experience listed in 8.7a may include the 3 assessment audits.

- ii. If the auditor assessment(s) are conducted remotely with the use of ICT, the International Accreditation Forum's MD-4:2023 should be used as a reference.
 - d. When the assessment process is successfully completed, the CB will grant the final sign-off approval.
 - e. The assessments, including the initial on-site witness assessment, should contain a review of the new auditor's knowledge of the following items:
 - i. PrimusGFS normative documents
 - ii. Food Safety principles, HACCP, Pre-requisite programs and relevant laws and regulations and can apply them when appropriate
 - iii. Quality Management Systems
 - iv. Specific audit techniques and specific scopes
 - f. The assessments, including the initial on-site witness assessment, should also evaluate the auditor's personal attributes and behavior to confirm acceptable performance and ensure that auditors conduct themselves in a professional manner.
 - g. If an approved and qualified PrimusGFS auditor requests to work with an additional CB(s), the subsequent assessments may be exempted, as long as the new CB accepts the other CBs assessment results, conducts a witness assessment to sign-off the auditor as approved, and can justify the minimum requirements in Section 8 are met.
 - h. All assessments must be documented, and the witness assessment(s) shall contain all the information found in the example template distributed by Azzule Systems. The assessment reports should describe the details and outcome of the assessment.
 - i. The assessment must be conducted by an assessor who is already an approved PrimusGFS auditor, and it must take place during an official PrimusGFS audit. The assessor may be the CB's PrimusGFS Manager and/or Technical Supervisor, as long as they are currently or were previously approved as PrimusGFS/GFSI auditors.
 - j. 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.
- 8.9 Auditing Scope
- a. Each auditor must be assigned an audit scope(s) (refer to Section 7 Certification Scopes as defined by GFSI), based on their qualifications, education and experience as described in the Appendix 4 Scope Education and Work Experience.
 - b. In situations where the auditor wants to extend their scope to include another option of the standard, the auditor must be in compliance with all the auditor requirements mentioned in Section 8 CB Personnel Requirements and be signed-off as competent by the CB PrimusGFS Manager and/or Technical Supervisor.
- 8.10 Auditor Exam
- a. All auditors must pass the most current version of the PrimusGFS exam to be approved, and subsequently when there is a new version of the standard or as required by Azzule Systems. The exam includes knowledge and understanding of the following topics:

- i. PrimusGFS normative documents
- ii. Relevant food/agricultural related legislation
- iii. Relevant food/agricultural (horticultural, grains, and pulses) production /manufacturing processes
- iv. Quality management systems, good agricultural and/or manufacturing practices and HACCP systems.

8.11 Auditor Qualification Maintenance

- 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 standard 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 standard (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 (GAP and/or GMP) in which their auditors are approved. The CBs shall maintain records of all relevant trainings taken by the auditors.
- c. Documented performance monitoring.

8.12 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.

8.13 PrimusGFS Manager and/or Technical Supervisor

- a. The CB must appoint at least one person as the PrimusGFS Manager and/or Technical Supervisor (TS), who:
 - i. Meets the qualification/education and working experience of an auditor for all audit scopes.
- b. The PrimusGFS 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 standard is released.
 - ii. Be the person who clarifies technical issues with CB personnel and audited organizations.

- iii. Act as a technical contact with Azzule Systems. They should be responsible for the direct communication related to technical questions between the CB and Azzule Systems.
- iv. Sign-off on approval for new auditors.
- v. **Act as the Certification Decision Maker to approve the certification of all audits conducted and internally reviewed."**

8.14 Technical Reviewer

- a. **Reviewers meet the same qualification, education, and industry experience and training criteria as auditors, for all audit scopes assigned for review as described in Sections 8.4, 8.5 and 8.6 of this General regulations**
- b. The CB shall ensure the technical reviewer is knowledgeable in all PrimusGFS normative documents and any policies provided by PrimusGFS related to audit reporting.
- c. **The CB shall ensure that the technical reviewer has been trained in the audit review process and has documented approval to perform this activity.**

8.15 CB Personnel Requirements

- a. The CB shall ensure all personnel involved in the certification process have the required competency to perform activities related to their role.
- b. The CB shall record and maintain records of the qualifications, training, and experience **and approvals** 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. Training as it relates to their responsibility and role in relation to the certification process
 - v. Work experience relates to their responsibility and role in relation to the certification process per Appendix 4 Scope Education and Work Experience.
 - vi. 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" or "Indoor Agriculture" 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 growth 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, Azzule Systems 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 auditee has the option to choose to schedule their audit(s) as announced or unannounced. If choose unannounced guidelines in 9.3 b must be followed.
- 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 Azzule Systems.
Note: Applicants cannot transfer CBs with audits in progress with their current CB.
- c. Switching between Auditing Schemes: If it becomes known that an applicant is switching from another GFSI recognized certification program, the CB shall request the organization's audit history including both announced and unannounced audits and any additional information necessary to evaluate this applicant. If accepted the applicant must complete the entire process as described in Section 9.1.a above. If for any reason the CB rejects the applicant, they shall inform the applicant in writing with the reason for the rejection. The CB shall forward that notification to Azzule Systems as well.
- d. If the operation changing CBs had an unannounced audit already scheduled, or if it is a facility due for a third-year unannounced audit, this requirement will be upheld by the new 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 nine 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)
 - viii. Module 8 – Grains and Pulses
 - ix. Module 9- Integrated Pest Management (IPM) Practices
- c. Each module is divided into sections, with specific questions related to the section topics.
- d. Audits will cover the nine 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.
- viii. Module 8 is optional for operations seeking a production audit more closely aligned with the requirements for grains and pulses.
- ix. Module 9 is optional for operations that need to document their Integrated Pest Management (IPM) practices, either at the request of their clients or to voluntarily demonstrate their efforts in this area
- 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.

9.3 Unannounced Audits

- a. Per GFSI requirements, unannounced certification audits must be conducted on certified organizations participating in a GFSI recognized program following this cycle and will be managed by the CBs:
 - i. Farm, Harvest Crew, Indoor Agriculture, Cooling and Cold Storage, and Packinghouse (GFSI Scope BI, BII, BIII): Certification bodies must perform 10% unannounced per year.
 - ii. Processing and Storage and Distribution (GFSI scopes CII, CIII, CIV, G): One (1) unannounced audit is required every three (3) years for each certified organization
- b. The following rules apply to unannounced:
 - i. **The unannounced audit(s) are certification audits** and should be performed using the current PrimusGFS checklist.

- ii. The unannounced take place without prior notice, they are “no notification” audits.
- iii. The unannounced audit(s) should be scheduled based upon the seasonality of the applicant’s production following 9.1.a iv and 9.1.a v. The applicant will have a choice to select “blackout” date periods within the application.
- iv. The audit reports and certificates will display information the audit was conducted as unannounced.

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 fundamental 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 point
Non-conformance	0 points	0 points	0 points	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. Independently of the score, corrective actions must be submitted for all non-conformances marked during the audit.

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	=	<i>Total points obtained in the complete audit for the operation</i>
÷		÷		÷		÷
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	=	<i>Total points possible in the complete audit for the operation</i>
=		=		=		
<i>Module Score for Module 1</i>		<i>Module Score for applicable Modules</i>		<i>Module Score for applicable Modules</i>		<i>Overall Total Score for the operation</i>

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 Standard into disrepute **within 3 days of occurrence**.
 - ii. CBs shall ensure the integrity of certification after notification and consider the need to suspend or revoke certification. CBs **shall inform** these significant events to Azzule Systems within **48 hours of notification by the certified organization and provided regular updates**.
 - iii. **Azzule Systems shall inform the GFSI of a significant event within three business days of learning of the event via email.**
- 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. Examples of compliance issues may include potential critical nonconformities related to changes of the PrimusGFS normative documents between version changes, complaints against the certified organization, etc. The re-evaluation may include an on-site re-visit to verify that the organization is in compliance with the PrimusGFS compliance criteria.

10.6 Surveillance Audits

- a. Surveillance Audits Performed by the CBs
 - i. Each CB must have a surveillance program in place for their certified organizations. The surveillance audits must be performed using the PrimusGFS checklist the chosen organization(s) is certified against. The selected organization with certified operation(s) must reach the required scoring as a certification audit in order to maintain their certification.
 - ii. The surveillance audits should be conducted using the checklist to which the organization obtained certification, unless otherwise directed by Azzule Systems. Selection shall be based upon a risk assessment approach considering factors such as compliance history, product type(s), process complexity, appeals, complaints, or any other factors the CB determines necessary. e.g, Geographical location may also be considered

to the extent that if 50% of the certifications are from Country "A", then approximately 50% of the surveillance audits shall be conducted in Country "A" and so forth.

- iii. The CB will notify the organization's chosen operation(s) of the surveillance audit no sooner than 48 hours prior to the day of the audit.
- iv. 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.
- v. Surveillance audits are not an approved substitute for the unannounced audits required in Section 9.3 above.

b. Surveillance Audits Performed by Azzule Systems

- i. As part of the PrimusGFS Integrity Program, Azzule Systems will perform sporadic auditor assessments. The purpose is to ensure that qualified auditors are performing the audits properly according to the PrimusGFS standard.
 - 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. Azzule Systems will also have the option to perform auditee assessments, which will consist of Azzule Systems 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, Azzule Systems 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 executive summary/ scope – details of the process under certification. The executive summary should reflect what is observed at the time of the audit including a description of the growing/harvesting/packing/processing process. This executive summary is mandatory even in the absence of non-conformances. If there are additional products that an operation produces during other times of the year, it can be acknowledged in the executive summary/scope, but the auditor should mention the process was not observed at the time of the audit.
- vii. Product(s) observed during audit, product(s) not observed but of similar risk type to the products observed, and product(s) not observed and not of a similar risk type to the product(s) observed. The GFSI scope code, following Section 7 Certification Scopes as defined by GFSI, should also be 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's 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 Azzule Systems.
- xii. Labeled as unannounced, if the audit was performed as unannounced.
- xiii. Shippers (customers of the auditee) designated during the application process (if applicable)
- xiv. Any other additional information required by Azzule Systems (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 & Corrective Actions

- a. In order for the audit to move to the certification phase, all identified non-conformances must have corrective actions verified and closed out by the certification body.
 - Note: Non-conformances in this section also includes Major and Minor deficiencies.
- b. The corrective actions must be submitted into the PrimusGFS database within 30 calendar days from the original audit date.
- c. The submission of corrective actions does not guarantee that the score will increase, but should demonstrate that the organization has taken or will take the corrective actions and/or preventive measures to control the identified non-conformance.
- d. Note that with an overall preliminary audit score of less than 85% or an automatic failure, the organization can submit corrective actions for the CBs

review, but accepted corrective actions do not change the final score. (See Section 13 for further information on the certification requirements.)

- e. The corrective actions from the organization should include at a minimum: the determination of cause(s) (i.e., root cause analysis), 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.
- f. If a corrective action is not able to be completed during the corrective action timeframe, the organization should submit the corrective action plan, the evidence of intent to complete, and a timeframe for completion and/or a documented risk assessment with the mitigation measures in place that shows the identified issue or non-conformance is controlled.
- g. Corrective action evidence can be in the form of documents, records and/or photographs and it must show that the non-conformance has been adequately addressed.
- h. The CB has the right to determine if an on-site assessment or remote assessment with the use of ICT is necessary to be performed to the audited organization to verify corrective actions for any non-conformance found.
- i. The CB will have 15 calendar days to review the corrective action evidence to determine if actions taken are sufficient to control the risk(s), and notify the organization if it was accepted or rejected and close out the non-conformance(s).
- j. 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 out the non-conformance.
- k. Once the organization has responded to the CB regarding the non-conformances and the CB has reviewed all corrective actions submitted, the CB will close out 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 and issue the final audit report no more than 45 calendar days from the audit date.
- b. The audit report shall be technically 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 to ensure compliance with the PrimusGFS requirements, including (but not limited to):
 - i. Certification scope in the application matches the report scope and has been thoroughly evaluated by the auditor (operation, products, etc.)
 - ii. Percentage Scores by module and for overall total score
 - 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 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 PrimusGFS 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 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 Azzule Systems 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. Azzule Systems 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 Azzule Systems by using the PrimusGFS system or by any other means established by Azzule Systems.
- 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 Azzule Systems.

- 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 17065 Guidelines. Except where required, upon request, by GFSI, 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 **and documented** 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.
- e. **Azzule will review all extension of scope requests properly documented by the CB and will inform them whether the request is accepted or not.**

17. Use of Logo and Trademark

- a. The PrimusGFS trademark and logo may only be used with Azzule Systems permission.

- b. The CB must always obtain the PrimusGFS logo from Azzule Systems. 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 Azzule Systems 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. **The logo is not permitted on product packaging under any circumstances.**
- 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.

Document Revision History

Date	Rev. No.	Description
July 2025	0.	Initial