PrimusGFS General Regulations

Version 2.1-2

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1. Introduction

a. PrimusGFS is a private scheme that establishes voluntary requirements for the certification of Agricultural sector products (including horticultural, grains, and pulses) at a world-wide level.
b. These General Regulations explain the PrimusGFS Certification System and the process to obtain this certification. It also intends to establish communication mechanisms, duties and obligations of the Scheme Owner and of Certification Bodies and applicants who would like to gain certification of their products.

2. Standard Scope

a. The scope of PrimusGFS is focused on the Food Safety of those Agricultural sector products (including horticultural, grains, and pulses) designated for human consumption. With that intention, 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 Certification Bodies, for the relevant food safety topics associated with each of their different production stages. Additionally, it establishes a minimum acceptable condition for the performance of the applicants. For this, the Standard has defined three fundamental areas that a company in the Agricultural sector must consider in the production and/or manufacturing their products:
    i. Food Safety Management System (FSMS)
    ii. Good Agricultural and/or Manufacturing Practices (GAP and/or GMP)
    iii. Hazard Analysis Critical Control Points (HACCP) System
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 - Standard
    iii. PrimusGFS - Checklist
    iv. PrimusGFS - Questions and Expectations
d. PrimusGFS may issue additional normative documents from time to time.
e. The normative documents will be reviewed internally every year 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 review of the scheme will be carried out taking into consideration the feedback from all the users, and the changes will be sent for consultation with stakeholders.
g. English is the original language of the normative documents. Translations will be made to other languages as needed, to also be issued as official normative documents. The English version is the primary reference source.
h. The normative documents and their translations can be found in the PrimusGFS website (www.primusgfs.com).
i. The scheme owner shall carry out regular reviews of the operation of the scheme and take any necessary action to ensure compliance with GFSI requirements; these reviews shall be part of an internal audit program.

3. Legislation

a. Food Safety legislation differs from one country to another. PrimusGFS has been developed to ensure that where laws, specific guidelines for a product and/or good practices recommendations exist, these practices and parameters are used as a reference for applicant's conformance, establishing minimum acceptable criteria for food safety certification. If there are not documented laws or good practices guidelines, certification scheme users should permit certain degree of risk assessment to meet minimum criteria for food safety certification.

4. Guidance for the Management of Certification Bodies

a. The certification for PrimusGFS can only be performed by approved Certification Bodies (CBs). Certification activities shall be carried out by personnel who have the competence requirements to meet all management, administrative, technical and auditing functions.
b. The CB shall have a documented and implemented quality system that shall contain all the necessary requirements for conformance with the scheme and accreditation programs. The information of the quality system required for accreditation shall always be available to the Scheme Owner.
c. There shall be a designated member of the CB staff responsible for the quality system's development, implementation and maintenance. This person, the Scheme Manager will be the contact person with the Scheme Owner for the management of the Scheme. The CB shall maintain records regarding the qualifications, training and experience of the Scheme Manager and all staff involved in the certification process.
d. The CB must be accredited for the scope of PrimusGFS according to the ISO/IEC Guide 65, ISO/IEC 17021 or ISO/IEC 17065. The Accreditation Body must be affiliated to the International Accreditation Forum (IAF) and signatory to the Multilateral Recognition Arrangement (MLA). See Annex 1 for a flow chart of the CB approval process.
e. The list of approved and provisionally approved CBs will be made publicly available by the Scheme Owner, on the website www.primusgfs.com
f. Where the CB has a current ISO/IEC Guide 65, ISO/IEC 17021 or ISO/IEC 17065 accreditation and requests the Accreditation Body for a scope modification or extension to include PrimusGFS, the CB must provide written evidence to notify the Scheme Owner of such circumstances.
g. CBs shall be accredited within one year from the date of application to the Accreditation Body. If the accreditation is not obtained within this period the Scheme Owner shall review the situation and appropriate actions will be implemented.
h. For those CBs that provide non-accredited services, they shall make publicly available the scope of their accreditation, in order to avoid ambiguity with the accredited services offered.
i. The Scheme Owner will define a set of indicators of performance for CBs, which will be monitored according to a risk based program that will consider the number of certifications issued by the CB, products certified, the types of operation, complaints received and any other that the Scheme Owner considers representative.
j. The Scheme Owner has the faculty to execute on-site inspections at the CB office's, evaluate the auditor's regarding their technical skills (which can include shadowing auditors), review audit reports, review any materials conducted under the PrimusGFS scheme certification process or request information or documentation regarding CB's

accreditation audit reports and corrective actions and anything pertaining to the fulfillment of this agreement. All costs associated with these supervisions are to be covered by the CB.

k. CBs shall notify the Scheme Owner in a timely manner regarding any relevant changes to their ownership, management structure or constitution.
l. 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.
m. Certification bodies are required to use PrimusGFS software.

5. Audit Duration and Frequency

a. An independent entity (approved CB) will be responsible for evaluating whether a company meets the requirements of PrimusGFS and consequent Certification. The CB will also be responsible defining the audit duration and frequency.
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) to be certified
    ii. Number of operations to be certified
    iii. Size of the operation(s)
    iv. Number of products and similarity of production process
    v. Complexity of the production and/or handling processes
    vi. Company preparation level
c. The audit duration will be recorded per organization and the operations included in the certification process. The audit duration will be composed of the time required to perform the audit of Module 1 and the time that will be required to audit each operation type included in the certification scope. The following table provides guidelines for approximate audit durations:

Operation Type	Approximate Duration (hours)		
	Module 1	Module 2	Module 3*
Ranch	3 hours	2 hours	N/A
Greenhouse		2 hours	N/A
Harvest Crew		1.5 hours	N/A
Storage & Distribution Center		3 hours	1 hour
Cooler / Cold Storage		3 hours	1 hour
Packinghouse		4 hours	2 hours
Processing		5 hours	3 hours

Estimated audit duration table

*Duration of Module 3 can vary significantly based on the number of HACCP plans, outcome of the Hazard Analysis and the number of CCPs

d. Audit duration comprises the entire audit process, from the opening meeting to the closing meeting with the organization where non-conformances are indicated. There shall be evidence in the audit report of the time taken for the audit process. Certification Bodies should justify significant audit duration deviations.
e. The due date for the subsequent audit will be 12 months from the date of the previous audit and not from the previous certificate issue date.
f. This frequency may be modified by factors such as:
    i. Modification of the scope and/or operation's location during the certificate validity.

ii. Seasonality of the products; up to 3 months extension of current certificate expiration date with justifiable circumstances.
iii. Quantity and type of non-conformities detected at the time of the audit (e.g., a re-audit or a re-visit may be required in order to receive certification).
iv. Additional visits may be required due to insufficient evidence of corrective actions.

g. These or other situations must be evaluated and documented by the CB defining the audit frequency required for each applicant, as well as justification for any modification.

6. Food Certification Categories

a. PrimusGFS is a scheme that defines the food safety requirements for production of food in the following sectors:

Scope	Category name	Operation Type(s)	Examples of product
BI	Farming of Plants (other than grains and pulses)	· Ranch · Greenhouse · Harvest Crew	Fruits; Vegetables; Any plant other than grains and pulses produced for human food consumption
BII	Farming of Grains and Pulses	· Ranch · Greenhouse · Harvest Crew	Grains and pulses produced for human food consumption
D	Pre-process handling of plant products, nuts and grains	· 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	· 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)	· 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	· 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: drying, roasting, salting, pressing, milling, etc.

Categories Table: Taken from GFSI Guidance Document: Part II, Annex 1 – GFSI Scope of Recognition.

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

7. Auditor Requirements

a. Certification Bodies are responsible for ensuring that auditors performing the inspections are in conformance with the following minimum requirements and have evidence to demonstrate their conformance.

7.1 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 GFSI Guidance, v6.2, Part II, Annex 3 or any subsequent revisions to such guidance.

7.2 Experience

a. Work experience
   i. 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. Some examples of food production experience are listed in the "Categories Table: Taken from GFSI Guidance Document: Part II, Annex 1 – GFSI Scope of Recognition.
   ii. All auditors must pass the PrimusGFS exam to be initially 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:
      - PrimusGFS normative documents
      - Relevant food/agriculture related legislation
      - Agricultural production (horticultural, grains, and pulses)/manufacturing processes
      - Quality management systems, good agricultural and/or manufacturing practices and HACCP systems.
   iii. This examination should be taken by all approved auditors each time there is a new version of the scheme and before conducting audits using the new version.

b. Audit experience
   i. Auditors must have a minimum of 10 audit days or 5 audits of practical auditing experience on performing GFSI recognized audits. This experience can be as third or second party auditor or shadowing an approved auditor. Information about the audit experience shall be documented, including details like: dates, audited organization, type of operation being audited and role of the candidate auditor.

7.3 Formal Auditor Training

a. The auditors must have successfully completed the following courses:
   i. Recognized training in audit techniques based on QMS or FSMS, with 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.
   iii. Approved PrimusGFS Auditor Training as defined by the Scheme Owner.

7.4 Auditor Assessment

a. For an auditor's initial approval, a shadow audit assessment must be performed by an already approved auditor 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 be able to apply them when appropriate
   iii. Quality Systems, specific audit techniques and specific category

b. The auditor assessment shall be documented and contain all of the information found in the example template distributed by the Scheme Owner. The assessment report will describe the details and outcome of the assessment.

7.5 Technical Supervisor

a. The CB must appoint at least one person to be a Technical Supervisor (TS), with the following criteria:
   i. Meets the qualification/education and working experience of an auditor
b. The TS will have the following responsibilities:
   i. Maintain the competence of CB personnel by training them when there is a new scheme version.
   ii. Be the person who clarifies technical issues with CB personnel and audited organizations
   iii. Act as a technical contact with the Scheme Owner
   iv. Sign-off approval of new auditors for the CB

7.6 Auditing Scope

a. The assignment of scope each auditor should be defined by an analysis of the qualifications, education and experience. In order to be approved for both options of the PrimusGFS Scheme (field and facility) the auditor assessment must be performed covering both options. This can be done at the same time in one organization or as separate events. As a result, the auditor can be approved to do audits for the GAP option only (field), the GMP option only (facility) or for both options.
b. In situations where the auditor wants to extend his/her 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 complete the shadow audit assessment for the additional option (Field or Facility) and be signed-off as competent by a CB TS.

7.7 Continued training

a. To maintain the approved auditor status, there should be evidence of at least five audits or seven on-site audit working days per year against PrimusGFS to maintain the schemes and industry knowledge.
b. The Certification Body has the responsibility to ensure that their auditors are current on good practices for each option their auditors are approved for and to be able to apply relevant laws and regulations. The Certification Bodies shall maintain records of all relevant training taken by the auditors.

7.8 Attributes and Competencies

a. The Certification Bodies must have a system in place that ensures auditors are conducting and behaving in a professional manner. The assessment (include shadow audit assessment) of the auditors should cover evaluation of their personal attributes and behavior.
b. Certification Bodies must be able to demonstrate that the auditors meet the requirements for approval to maintain their competence for PrimusGFS. In the same way Certification Bodies must keep complete records of auditors qualifications, experience, training, supervised audits, assessments, sign-off, re-approval and others, while they have a work relationship and by a minimum period of two years.
c. Certification Bodies will be responsible for registering auditors in the PrimusGFS database, providing information about their qualifications, experience, training, assessment, auditing scopes, etc., and to keep this registration updated when changes occur.

8. Conflicts of Interest

a. Certification Bodies and the personnel they employ that is involved in the certification process must have a signed contract or agreement that commits them to:
   i. Avoid any conflict of interest in the certification activities, with regard 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 the CB management when 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.

9. Certification Process

9.1. Application

a. Applicants must provide the CB with the information defining the scope of the certification they want to achieve for their operations. This information should include as a minimum the following:

i. Organization details;
ii. Contact information;
iii. Details about the operation(s) to be included in the scope of the certification. In case of field operations, each site is called either "Ranch" or "Greenhouse" and the application should detail the different sites to be certified. In case of 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 the 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.
    - 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 detail in the scope of the audit 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 the certification.
  - The operation must be running and the commodities must be present in the operation at during 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 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 detail in the scope of the audit 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 or flow chart, 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 validity of the current audit certificate.
vii. Language for the audit to be performed in and language to be used for the audit report.

b. Transferring Certification Bodies: In the case that the organization is changing Certification Bodies, the information will need to be recorded and transferred through the PrimusGFS system. While doing that, the system will make the Non-Conformance Report(s) from the prior audit(s) available to the new Certification Body. Auditees cannot transfer CB's with audits in progress.

9.2. Audit execution

a. The audit should be performed using the most recent version of the PrimusGFS normative documents.
b. The PrimusGFS Standard is divided in three Modules:
   i. Module 1 - Food Safety Management System (FSMS)
   ii. Module 2 - GAP and GMP options
   iii. Module 3 – Hazard Analysis Critical Control Point (HACCP)
c. Each Module is divided into sections related to the specific Module and each section includes questions detailing the specific section. The following table (Table 1) describes the structure of the Standard, showing the division in Modules and Sections:

Module 1	Module 2		Module 3
Food Safety Management System	GAP Option	GMP Option	HACCP
1.01 Management System 1.02 Control of Documents and Records 1.03 Procedures and Corrective Actions 1.04 Internal and external inspections 1.05 Rejection and release of product 1.06 Supplier Control 1.07 Traceability and Recall 1.08 Food Defense	2.01 General GAP 2.02 Site Identification 2.03 Ground History 2.04 Adjacent Land Use 2.05 Pest and Foreign Material Controls - *Applicable for greenhouses only* 2.06 Growing Media (Substrate) Use - *Applicable for greenhouses only* 2.07 Fertilizer/Crop Nutrition 2.08 Irrigation / Water Use 2.09 Crop Protection 2.10 Field Employee Hygiene *(Applies to on-the-farm or greenhouse workers not the harvesting workers)* 2.11 Harvesting Inspections, Policies and Training 2.12 Harvesting Employee Activities & Sanitary Facilities *(Applies to harvesting workers)* 2.13 Harvest Practices 2.14 Transportation and Tracking 2.15 On site storage	2.16 General GMP 2.17 Pest Control 2.18 Storage Areas & Packaging Materials 2.19 Operational Practices 2.20 Employee Practices 2.21 Equipment 2.22 Equipment Cleaning 2.23 General Cleaning 2.24 Buildings and Grounds 2.25 Chemicals Files 2.26 Pest Control Documentation 2.27 Operation Monitoring Records 2.28 Maintenance & Sanitation Files 2.29 Employee Documentation 2.30 Testing/ Analyses Records 2.31 Temperature Controlled Storage & Distribution Logs 2.32 Allergen Control	3.01 Preliminary steps 3.02 Development of the Written HACCP Plan 3.03 Execution of the HACCP plan on the Plant Floor

Table 1. PrimusGFS Standard Structure

d. Audits will cover the three Modules for certification.
   i. Module 1 will always be applicable to all certifications.
   ii. Module 2 is divided in two options, GAP and GMP and at least one of them will always be applicable, depending on the type of operation. The GAP Option is applicable for Field operations and the GMP Option is applicable to Facility operations.

- Within Module 2, GAP option, the applicability of each section depends on the operation to be certified, with the following sections applicable for each operation:
    - Ranch: sections 2.01 to 2.10 will be applicable, except for section 2.05 and 2.06 that apply only to "Greenhouse" operations.
    - Greenhouse: sections 2.01 to 2.10 will be applicable
    - Harvesting: sections 2.11 to 2.15 will be applicable (harvest crew audits can be linked to growing areas).
- Within Module 2, GMP option, sections from 2.16 to 2.32 will be applicable, although there will be some individual questions that may be not applicable in some types of operations as determined when doing the inspection, based on each facility.

iii. Module 3

- This module will not be applicable to field operations, i.e. for activities carried out only in the growing area at farm level.
- This module will always be applicable to all facility operations.
- For those facility operations where there are no steps that meet the definition of a Critical Control Point
  Some sections of the Module 3 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 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.

e. The scope of certification should be defined clearly to decide how the audit will be structured for each applicant organization. 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.

10. Evaluation

10.1. Conformance by individual questions

a. Each Module of the PrimusGFS Standard is composed of several sections and each section includes several requirements. To verify conformance to the PrimusGFS Standard requirements, the PrimusGFS Checklist and the PrimusGFS Questions and Expectations shall be used.
b. 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.
d. The possible answers to the questions in each Module are listed in the following table (Table 2):

Module 1	Module 2		Module 3
Food Safety Management System	GAP Option	GMP Option	HACCP

Possible answers:	Possible answers:	Possible answers:	Possible answers:
· Total Conformance · Minor Deficiency · Major Deficiency · Non Conformance · Non Applicable	· Yes · No · Non Applicable	· Total Conformance · Minor Deficiency · Major Deficiency · Non Conformance · Non Applicable	· Total Conformance · Minor Deficiency · Major Deficiency · Non Conformance · Non Applicable

Table 2. PrimusGFS - Possible answers to questions in each Module

e. Each question in the PrimusGFS Checklist has to be looked at individually and answered according to the observations during the audit.
f. In case of finding deficiencies to one question and/or its expectations, the following considerations shall be made when noting the issue(s) in the audit report:
   i. For questions in Module 1, Module 2 – GMP option and Module 3, the amount of deficiencies and the associated risks have to be considered to assign the severity of the finding, which can be Minor Deficiency, Major Deficiency and Non 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 decision are described in the table below (Table 3). 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.

Conformance for questions in Module 1, Module 2 – GMP option and Module 3	
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 3. PrimusGFS – Statements of conformance for questions in Module 1, Module 2 – GMP option and Module 3

   ii. For questions in Module 2 – GAP option, in case of finding deficiencies for the question and/or the expectations for that question, assign the answer to each question as described below in the general statement of the table (Table 4). When the requirement is not applicable for the operation being audited, Non-applicable answer is given. These statements are superseded by the criteria described in the question's expectations and applicants and users should be aware that some questions do not follow these general statements e.g. automatic failure questions.

Conformance for questions in Module 2 – GAP option	
Answer	**Criteria used**
Total conformance *(can be Yes or No, depending on the question)*	To meet the question and/or conformance criteria in full. This is when the answer Yes or No is the same as the "earning points answer".
Non-conformance *(can be Yes or No, depending on the question)*	The question or conformance criteria have not been fully met. This is when the answer Yes or No is **NOT** the same as the "earning points answer".
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 4. PrimusGFS – Statements of conformance for questions in Module 2 – GAP option

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. For questions in Module 1, Module 2 – GMP option and Module 3, each question has certain possible points that can be obtained depending on the conformance assigned to it. The score system for each question is described in the table below (Table 5):

Scoring system for questions in Module 1, Module 2 – GMP option and Module 3				
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 points	1 points
Non-conformance	0 points	0 points	0 points	0 points

Table 5. Scoring System for questions in Module 1, Module 2 – GMP option and Module 3

c. For questions in Module 2 – GAP option, each question has certain possible points that can be obtained depending on the conformance assigned to it. The score system for each question is described in the table below (Table 6):

Scoring system for questions in Module 2 – GAP option								
Possible answer	***Possible Points for the question***							
	20 points	**15 points**	**10 points**	**7 points**	**5 points**	**3 points**	**2 points**	**0 points**
Total conformance (may be Yes or No)	20 points	15 points	10 points	7 points	5 points	3 points	2 points	0 points
Non-conformance (may be Yes or No)	0 points	0 points	0 points	0 points	0 points	0 points	0 points	0 points

Table 6. Scoring System for questions in Module 2 – GAP option

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

10.3. Score calculation per module and per operation

a. There will be two types of score calculations done in each audit:
   i. Module Score, which will be calculated for each one of the three Modules in an audit and in Module 2 for each one of the options.
   ii. Overall Total Score, which will be calculated for each operation audited.
b. The Module Score is calculated for each one of the modules of the audit, considering the total sum of points obtained in each Module and/or option divided by the total possible points of the corresponding Module and/or option, represented in a percentage. See Table 7 below for a diagram of the scoring calculation structure.
c. The Overall Total Score will be calculated for each operation, considering the total sum of points obtained in the entire audit, divided by the total possible points in the entire audit, represented as a percentage. See Table 7 below for a diagram of the scoring calculation structure.
d. For GMP audits, the Overall Total Score calculated in the preliminary stage will need to be ≥ 85% in order to proceed to corrective action and subsequent certification decision phase. If the GMP preliminary overall total score is <85% then the audit is "not certified. If the GMP preliminary score is ≥ 85% but <90% then corrective actions will be required in order to become certified.

Module 1		Module 2				Module 3		|OPERATION
Food Safety Management System		GAP Option		GMP Option		HACCP		
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 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 sum of possible points for each applicable question in this module	=	*Total points possible in the complete audit for the operation*
=		=		=		=		
Module Score for Module 1		*Module Score for Module 2 – GAP*		*Module Score for Module 2 – GMP*		*Module Score for Module 3*		*Overall Total Score for the operation*

Table 7. Scoring calculation structure

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

10.4. Automatic failure

a. There are some questions in the PrimusGFS checklist, that if down scored will lead to 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 for example, 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 evidence of corrective action to affect other questions in the audit in addition to the one being evaluated.
c. Certification Decision
   i. The CB reserves the right to consider all information gathered during the certification process to make the decision for granting certification for each specific operation or a whole organization.
d. Suspension /Revocation of Certification
   i. The CB reserves the right to consider all information regarding the certified organizations and operations to suspend or revoke current certificates if they represent a serious food safety issue or there is discovery of illegal activities (see GR 10.5.e.i).
e. Significant Food Safety Events For Certified Organizations & their Operations
   i. All certified organizations shall inform their corresponding CB 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. CB's should correspond these significant events to the Scheme Owner.
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, changes to the requirement of the certification scheme standard, changes of ownership and/or management.
   ii. If the CB has any reason to believe 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 has the option to perform surveillance audits. Surveillance audits will be performed using the current PrimusGFS checklist, and the selected organization with certified processes will need to pass the audit as if it were a regular audit in order to maintain certified.

- This is currently an option for CBs that will later be mandated by the Scheme Owner with an allotted percentage of the certified operations that will need to receive Surveillance audits.

ii. The CB will notify the operation in writing of the surveillance audit no sooner than 48 hours prior to the day of the audit.

iii. The operation can only reject a surveillance audit one time. If rejected on the second offer, this will result in a suspension of the certificate.

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 a second person on-site during the audit.
- The additional person on-site during the auditor assessments 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, and the selected organization with certified processes will need to pass the audit as if it were a regular audit in order to maintain certified.

- 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 Surveillance audit.
- The audited operations will be required to accept a second person 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). Any language used by the CB to generate the audit reports is acceptable by the Scheme Owner, but the information inputted to the PrimusGFS database shall be also provided in English.

d. Every audit report shall include as a minimum the following information:

i. Name of the CB
ii. Name of the applicant organization
iii. Details about the operation under certification
iv. Date and time of the audit (start and finish of module 1 and module 2/3)
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.
xii. Shippers (customers of the auditee) designated during the application process (if applicable)

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. The applicant organization must analyze the non-conformances raised during the audit and address the deficiencies detailed in the audit report. In order to have the corrective actions evaluated by the CB, the applicant organization must submit evidence of the actions taken.
b. The evidence of corrective actions can be in the form of documents, records and/or photographs and it must be appropriate to show 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 for GMP audits with an overall preliminary score less than 85%, the auditee can send corrective action details to the CB's for review, but accepted corrective actions do not change the final score.
c. Corrective action evidence for each non-conformance must be submitted to the CB by the organization in a period of time not exceeding 30 calendar days from the original audit date.
d. The CB will have 15 calendar days to review the corrective action evidence and notify the organization if it was accepted or not and to close the non-conformance(s).
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. 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.
g. The applicant organization should be aware that some non-conformances may not be able to be corrected due to the issue that has been detected and any other circumstances.
h. Once the applicant organization has responded to the CB about all 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 (see section 13).

13. Certification Decision

a. The CB shall make the certification decision no more than 45 calendar days from the audit date.
b. The audit report shall be evaluated by the authorized representatives of the CB in order to make the decision of whether or not certification is granted. These CB representatives shall be impartial and technically capable of evaluating the outcome of the audit reports, including but not limited to:
   i. The scope of the certification (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

13.1. Evaluation 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% Module and/or option in order to be certified. All Overall Scores for GMP audits must be 85% in the preliminary stage in order to receive certification. If the preliminary score is less than 85%, a not certified decision is made. Another audit will be necessary to receive certification.
c. See the following table below (Table 8) for details of minimum scores for certification on different scenarios:

<table>
<tr><th colspan="4">Scenario 1 : One Field operation as Ranch or Greenhouse and/or Harvesting</th></tr>
<tr><td>Module 1</td><td>Module 2</td><td>Module 3</td><td rowspan="3">Overall Final Score</td></tr>
<tr><td>FSMS</td><td>GAP Option</td><td>HACCP (not applicable)</td></tr>
<tr><td>Final Module Score for Module 1</td><td>Final Module Score for Module 2 – GAP</td><td>Module is not considered for calculation of the overall audit score.</td></tr>
<tr><td>≥ 85%</td><td>≥ 85%</td><td>N/A</td><td>≥ 90%</td></tr>
<tr><th colspan="4">Scenario 2 : One Facility operation, any type</th></tr>
<tr><td>Module 1</td><td>Module 2</td><td>Module 3</td><td rowspan="3">Overall Final Score</td></tr>
<tr><td>FSMS</td><td>GMP Option</td><td>HACCP</td></tr>
<tr><td>Module Score for Module 1</td><td>Module Score for Module 2 – GMP</td><td>Module Score for Module 3</td></tr>
<tr><td>≥ 85%</td><td>≥ 85%</td><td>≥ 85%</td><td>≥ 85% Preliminary & ≥ 90% Final</td></tr>
<tr><th colspan="4">Scenario 3 : One Field and one Facility operation, any type</th></tr>
<tr><td>Module 1</td><td>Module 2</td><td>Module 3</td><td rowspan="3">Overall Final Score</td></tr>
<tr><td>FSMS</td><td>GAP Option</td><td>HACCP (not applicable)</td></tr>
<tr><td>Final Module Score for Module 1</td><td>Final Module Score for Module 2 – GAP</td><td>Module is not considered for calculation of the overall audit score.</td></tr>
<tr><td>≥ 85%</td><td>≥ 85%</td><td>N/A</td><td>≥ 90%</td></tr>
<tr><td>FSMS</td><td>GMP Option</td><td>HACCP</td><td rowspan="2">Overall Final Score</td></tr>
<tr><td>Module Score for Module 1</td><td>Module Score for Module 2 – GMP</td><td>Module Score for Module 3</td></tr>
<tr><td>≥ 85%</td><td>≥ 85%</td><td>≥ 85%</td><td>≥ 85% Preliminary & ≥ 90% Final</td></tr>
</table>

<table>
<tr><th colspan="4">Scenario 4 : Two Field and one Facility operations, any type</th></tr>
<tr><td>Module 1</td><td>Module 2</td><td>Module 3</td><td rowspan="2">Overall Final Score</td></tr>
<tr><td>FSMS</td><td>GAP Option</td><td>HACCP (not applicable)</td></tr>
<tr><td rowspan="4">Final Module Score for Module 1</td><td>Final Module Score for Module 2 – GAP</td><td>Module is not considered for calculation of the overall audit score.</td><td rowspan="2">Overall Final Score</td></tr>
<tr><td>≥ 85%</td><td>N/A</td><td>≥ 90%</td></tr>
<tr><td>GAP Option</td><td>HACCP (not applicable)</td><td rowspan="2">Overall Final Score</td></tr>
<tr><td>Final Module Score for Module 2 – GAP</td><td>Module is not considered for calculation of the overall audit score.</td></tr>
<tr><td>≥ 85%</td><td>≥ 85%</td><td>N/A</td><td>≥ 90%</td></tr>
<tr><td>FSMS</td><td>GMP Option</td><td>HACCP</td><td rowspan="2">Overall Final Score</td></tr>
<tr><td>Module Score for Module 1
≥ 85%</td><td>Module Score for Module 2 – GMP
≥ 85%</td><td>Module Score for Module 3
≥ 85%</td></tr>
<tr><td colspan="3"></td><td>≥ 85% Preliminary & ≥ 90% Final</td></tr>
<tr><td colspan="4">Table 8. Minimum score for certification on different scenarios</td></tr>
</table>

13.2. Issuing certification

a. Certification will be issued individually to each operation that complies with the minimum scoring criteria. In case of having more than one Field and/or more than one Facility operation of any type from 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 valid only for certified operations.
c. PrimusGFS is valid for maximum period of 12 months from the Certification date.
d. The certificate must be issued from the PrimusGFS system.

13.3. Complaints and Appeals

a. The CB shall have in place a procedure to handle complaints and appeals, which shall be publicly available.

14. Sanctions

14.1. Sanctioning of Certification Bodies

a. Suspension of an approved PrimusGFS CB - A CB shall be suspended if:
   i. The CB's accreditation has been suspended
   ii. The CB does not pay the agreed 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 requirement.

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

14.2. Sanctioning of Certified Organizations

a. If upon inspection of a certified organization the CB finds a non-conformance with the PrimusGFS Scheme Documentation, a sanction (suspension or revocation) shall be issued.
b. All sanctions shall be in writing, and shall 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. Note, the CB can issue the sanction to an entire certified organization or narrow it to a specific certified product(s) or specific operation(s) within the scope of the current certification.
e. There are two types of possible sanctions to 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.
      - An inspection results in an automatic failure.
      - 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).
         - The organization improperly uses the PrimusGFS or GFSI logo or trademark
         - An organization is involved with an illegal activity or serious food safety issue.
   ii. Revocations - an organization's certification shall be revoked if:
      - An organization does not pay the agreed to fees
      - 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. There is 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 in 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 17065 Guidelines. Except where required by law, the CB shall not release any certification activity information of applicant to any outside party without applicant's authorization. The CB shall document any and all communications between CB and applicant whereby applicant authorizes the release of certification information to an outside party.

16. Extension of Scope of 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 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 will have to be evaluated 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 the need for a visit to the organization in order 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 organization and/or the implementation of FSMS procedures may be different relative previous operation audits.

17. Use of Logo and Trademark

a. The PrimusGFS trademark and logo may only be used with the permission from the Scheme Owner.
b. The PrimusGFS logo must always be obtained by the CB from the Scheme Owner. This will ensure that it contains the exact corporate color and format.
c. The CB is responsible for the control of the use of the PrimusGFS trademark and logo on certified operations. 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 organizations and making clear reference to the certified operations. The logo can only be used for business to business communications.
e. PrimusGFS approved Certification Bodies, can use the trademark and/or logo for promotion of their accredited PrimusGFS certification activities in business-to-business communication and on their accredited PrimusGFS certificates.