

INSPECTION REGULATION CONTROL UNION PERU S.A.C.



CHAPTER 12

INSPECTION AND CERTIFICATION GENERAL REQUIREMENTS FOR PRIMUS GFS STANDARD



INTRODUCTION

This document contains regulations on the evaluation and certification activities of Control Unión Perú (hereinafter “CUP”) in relation to the PrimusGFS certification program. It refers to the rights and obligations of the client, as well as those of CUP.

This document is complementary to the CU IR Chapter 1 Inspection and Certification General Requirements that applies for any program certified by CUP.

This document is available on the website: [Términos y Condiciones - Control Union Perú SAC \(cuperu.com\)](https://www.cuperu.com)

Modifications to this document are highlighted in grey.

A flowchart of the certification process can be reviewed at the end of this document.

1. STANDARD SCOPE

- PGFS establishes a series of requirements to be used for primary and manufacturing sectors at a global level for consumers ‘safety.
- The main objective is to accomplish the requirements for the relevant food safety practices associated of their different production stages.
- PGFS has defined 7 fundamental areas that a company in the food sector should consider (as applicable) in the production and/or manufacturing of their products:

Production and/or Manufacturing Sector	Remark
1. Food Safety Management System (FSMS)	Applicable for all production areas.
2. Good Agricultural Practices (GAP)	<ul style="list-style-type: none"> • Farm • Indoor Agriculture • Harvest Crew
3. Good Manufacturing Practices (GMP)	<ul style="list-style-type: none"> • Storage and Distribution • Cooler / Cold Storage • Packinghouse • Processing
4. Hazard Analysis Critical Control Points (HACCP) System	Applicable for all GMP operations.
5. Preventive Controls (PC)	Voluntary and applicable for GMP operations only.

- Explanation of the requirements for each of these areas is provided in the PGFS standard documents available at the website: [PrimusGFS Version 3.2 | PrimusGFS](https://www.primusgfs.com)
- PGFS may periodically issue additional normative documents or updated versions of the current normative documents; those will be communicated by CU through our CIS system; and client is obligated to implement those changes.

2. DEFINITIONS

This document adopts the below definitions. PGFS definitions can be reviewed in the applicable normative documents.

Assessment Number	It is a number issued by Azzule to identify the producer.
Good Agricultural Practices (GAPs)	Food safety practices for farm activities related to risk mitigation of water, soil amendments, land use (previous and adjacent), animal access (domestic/wild), equipment, tools and buildings, worker health & hygiene practices.
Good Manufacturing Practices (GMPs)	Facility operation guidelines for food handlers to mitigate potential and real risks. Key categories include HACCP methods and procedures, facility design
Harvest Crew	A crew of harvest personnel under common management.

HACCP Plan	A written document that explains the formal procedures for following Hazard Analysis and Critical Control Point principles and is used to identify, prevent and control food safety hazards.
Non-conformance	Is a deficiency in compliance against the scoring criteria. For all audits, the overall total score calculated in the preliminary stage needs 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 may submit correctives actions, but they will not achieve certification. The preliminary overall total score is the combined score from all modules, not individual scores per module. If the preliminary score is $\geq 85\%$ but $<90\%$, corrective actions are required in order to become certified.
Operation	It is an individual site where food in the agricultural sector is being produced that is looking to grant certification. It could be a field operation in the case of pre-farm or a facility operation in the case of post-farm activities.
Packinghouse	This type of facility operation is where whole product is received for handling and/or manipulation without transformation taking place. Product can be for example sorted and/or sized, washed or not washed, possible post-harvest fungicide treatments applied (e.g., wax treatments), may be minimally trimmed (not altered in form), and packed for further distribution. In this type of facility, no processing activities are being performed. A Packinghouse facility covers the activities involved in the Storage & Distribution Center and Cooling and Cold Storage facility types
Preventive Controls	Controls to address hazards that occur in the products that are manufactured and significantly minimize or prevent and help ensure that the food is not adulterated. These include process, allergen, sanitation and other additional controls.
Processing facility	A facility with a controlled temperature environment where whole commodities are minimally processed and altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing, prior to being packaged for use by the consumer or a retail establishment (e.g., pre-cut, packaged, ready-to-eat salad mixes).
Report Types	<ul style="list-style-type: none"> • Preliminary Audit Report – The initial report submitted to a customer within 15 calendar days after each audit. This report type includes details about the organization and its operation, the audit duration, audit scope, product information, audit scoring summary, and answers and comments for each of the applicable questions answered. This report type does not include the customer’s evidence and/or responses to corrective action(s) or the certification body’s review response to those corrective actions. • Non-Conformance Report – An initial report submitted to a customer within 15 calendar days after each audit. This report type includes details about the organization and its operation, the audit duration, audit scope, product information, audit scoring summary, and answers and comments for each of the applicable nonconformance questions answered. This report type does not include the customer’s evidence and/or responses to corrective action(s) or the certification body’s review response to those corrective actions. • Final Audit Report – The final report submitted to a customer within 45 calendar days after each audit that includes a link to the certificate associated with the report and operation. This report type includes the customer’s evidence and/or responses to corrective action(s) and the certification body’s review response to those corrective actions. This report includes details about the organization and its operation, the audit duration, audit scope, product information, audit scoring summary, and answers and comments for each of the applicable questions answered. • Corrective Actions Report - A final report submitted to a customer within 45 calendar days after each audit. This report type includes the customer’s evidence and/or responses to corrective action(s) and the certification body’s review response to those corrective actions. This report type includes details about the organization and its operation, the audit duration, audit scope, product information, audit scoring summary, and answers and comments for each of the applicable nonconformance questions answered.
Suspension	A type of sanction issued by a Certification Body by suspending an

	<p>organization’s current certificate(s).</p> <p>This type of sanction should be issued based on the following circumstances or any other circumstance a Certification Body finds appropriate:</p> <ul style="list-style-type: none"> • 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. <p>An organization is involved with an illegal activity or a serious food safety issue.</p>
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3. APPLICATION FOR CERTIFICATION

- a) Applicants shall provide correct information to CUP regarding the desired scope of certification. This information is provided in the Application Form (AF). Only the information declared in the AF will be used for auditing and certification purposes.
- b) Failure to declare the correct scope (incorrect information, missing sites/products) can lead in modification of the contract and extra costs (related to new visits) for your operation.
- c) All operations declared in the AF will be audited independently.
- d) **In Field Assessments:** all commodities must be present in the field at the time of audit. When the commodity is not present, 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 the commodity was not grown in the field of operation during the previous growth cycle (12 months), it cannot be considered in the audit scope. Records of production of additional products shall be available for audit.
- e) **For Harvest Crew audits,** the products need to have similar harvesting processes.
- f) **In Facility Operations:** all commodities must be present in the operation at the time of the audit. When a commodity is not present during the audit, but the operation wishes to include it in the certification scope, it may be considered if the commodity has similar production processes as to what is going to be audited, and the same personnel involved. 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 audit. If the commodity was not included in the facility’s operation during the previous production cycle (12 months), it cannot be considered in the audit scope.
- g) **Transfer of Certification Body:** if the applicant is changing to CUP, once the client is contracted, the information will need to be registered and transferred through the PGFS system. Once this process is done, NC report from prior audit(s) will be available to CUP. Auditees cannot transfer CBs with audits in progress.
- h) **Switching between Auditing Schemes:** if it becomes know that an applicant is switching form 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 by CU, applicant must complete the entire certification process for PGFS program. If CU rejects for any reason, CU will inform the applicant in writing with the reason for rejection. And CU will forward this notification to Azzule System.
- i) CU will review the AF and will prepare an Offer Letter with the fees and terms of contract. OL is sent to the applicant, if applicant returns signed then applicant becomes a client of CU for the PGFS certification program.

4. PLANNING

- a) Based on the AF, CU will plan the initial audit, and assign a qualified auditor (audit team).
- b) The client has the option to choose to schedule the audits as announced or unannounced.
- c) Per GFSI requirement, unannounced certification audits must be conducted on certified organizations participating in a GFSI recognized program following this cycle which will be managed by CU:

GFSI Scopes	Unannounced audits planned by CU
BI, BII, BIII (farm, harvest crew, indoor agriculture, cooling and cold storage and packinghouse)	To 10% of the clients. Scheduled based upon the seasonality of the production.
CII, CIII, CIV, G (Processing and Storage & Distribution)	1 unannounced audit every 3 years for each certified organization.

5. AUDIT

5.1 AUDIT TYPES

Audit type	Remark
Pre-assessment	(Optional) To identify potential gaps before an initial audit. A schedule pre-assessment audit cannot be converted into a certification audit once the audit has begun or post audit.
Initial audit	Client's first audit. Can be announced ⁽¹⁾ or unannounced ⁽²⁾ following what is set in section 4.
Recertification audit	Audit to renew the certification. Can be announced ⁽¹⁾ or unannounced ⁽²⁾ following what is set in section 4.
Surveillance unannounced audit	Special audit type to evaluate maintenance of the certification by the client. CU will use the latest PGFS checklist to confirm requirements implementation. Client must reach the required scoring as a certification audit to maintain its certification. Selection for this audit type is based on a risk assessment considering factors such as compliance history, product types, process complexity, appeals, complaints or any other factor. This audit type is notified no sooner than 48 hours prior to the day of the audit. Client can only reject this audit one time with a justifiable reason. If rejected a second attempt, this will result in a suspension of all current audit certificates. This audit does not substitute a recertification audit.
Surveillance audits performed by Azzule Systems	As part of PrimusGFS Integrity Program, Azzule will perform 2 assessment types: <ol style="list-style-type: none"> Auditor assessment: sporadic auditor assessments to ensure that qualified auditors are performing the audits properly according to the PGFS Standard. Client will be required to accept the PGFS representative on-site during the audit, which is set in the ToC. PGFS representative conducting the audit will have no say during the audit nor will they point out any deficiencies to the auditor at the time of the audit. Auditee assessment: Consists in Azzule performing an on-site audit for a certified operation. These audits will be performed using the current PGFS checklist or the version the certified operation is certified against, and the client must reach the same scoring as a certification audit to maintain their certification. By 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 on-site during the audit.
Re-evaluation audits	Additional audit to verify implementation of corrective actions for NCs found during the audit (to be determined by certifier).
⁽¹⁾ Considerations for Announced audits	<ul style="list-style-type: none"> Can be performed in 2 phases: Phase 1: document review audit Phase 2: on-site audit Same auditor will perform both phases. No greater than 30 days between each.
⁽²⁾ Consideration for Unannounced audits	<ul style="list-style-type: none"> Are performed using the current PGFS checklist. Are scheduled based upon the seasonality of the client production following considerations set for field/harvest crew/facility operations.

	<ul style="list-style-type: none"> • The client has the choice to select “blackout” date periods within the application. • Audit report and certificate will display information that the audit was conducted as unannounced.
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5.2 CONDITIONS FOR AUDIT

- Audit will be planned to meet the conditions set in section 3.
- CU reserves the right to fail the audit due to special circumstances. Some examples include deliberate illegal activities, physical acts/threats to an auditor, attempt bribery, falsified records, etc., or finding serious food safety issues during the audit.

5.3 AUDIT EXECUTION

- Audit is performed using the most recent version of the PGFS normative documents.
- PGFS Standard is divided into seven Modules; and each module into sections, with specific questions related to the section topics.
- Audits will cover the seven modules for certification:

Module	Module name	Requirement
Module 1	Food Safety Management System (FSMA)	Required for all certifications.
Module 2	Farm	Required for farm operations.
Module 3	Indoor Agriculture	Required for indoor agriculture operations.
Module 4	Harvest Crew	Required for harvest crew operations. HC can be audited as stand-alone or in conjunction with a farm, indoor agriculture, or facility operation.
Module 5	Facility	Required for all facility operations. Depending on the type of facility, there may be individual questions in the module that are not applicable.
Module 6	Hazard Analysis Critical Control Point (HACCP)	Required for all facility operations. Some sections may be not applicable. Applicability shall be determined based on the outcome of document hazard analysis of all steps of each process. HACCP process and system must be in conformance with all existing legal requirements.
Module 7	Preventive Controls (PC)	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.

- The scope of certification should be clearly defined at the application, to determine the modules to be audited and the time of the audit.
- Ownership of different areas, locations, activities, or crops of the company applying for certification are elements to consider when deciding what type of operation(s) will be included in the scope. This decision is made by the client during the application.
- Auditor must perform the audit based on the defined scope.
- Preventing Conflict of Interest:** an auditor is not assigned to audit the same client for more than 3 consecutive years at a maximum.

5.4 EVALUACION OF COMPLIANCE

- Auditor will verify compliance of each requirement from the PGFS checklist and the PGFS Question and expectations.

- b) There are information gathering questions included throughout the audit that are worth zero points each. For scored questions, each question of PGFS 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.
- d) The possible answers to the question are listed below:

Answer	Criteria used
Total conformance	To meet the question and/or conformance criteria in full.
Minor deficiency	To have a minor deficiency 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 comment.
Automatic failure	Certain questions do not follow these general statements. These are identified with a phrase: "ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE" Client will be immediately informed during the audit if this automatic failure is reached. When automatic failure occurs an overall score of 0% for the corresponding module is calculated.

5.5 SCORING SYSTEM AND CALCULATION PER MODULE PER OPERATION

- a) Each question in the PGFS 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 number of points that can be obtained depending on the conformance assigned to it. The table below describes the scoring system:

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	2 points
Non-conformance	0 points	0 points	0 points	0 points

- c) The PGFS checklist calculates automatically the results according to the findings.
- d) There are 2 types of scoring calculations for each audit:
 - Module Score, which is calculated for each one of the modules audited.
 - Overall Total Score, which is calculated for each audited operation.

5.6 NON-CONFORMITIES AND CORRECTIVE ACTIONS

- a) When NCs (minor or major deficiencies) have been found during the audit; client has 30 calendar days from the last audit date to submit into the PGFS database a root cause analysis, which includes: correction, root cause and corrective action. See a detailed explanation in Annex A16 Inspection Regulation chapter 1.
- b) Corrective evidence can be in the form of documents, records, and/or photographs and it must show that the NC has been adequately addressed.
- c) Auditor will evaluate the root cause analysis, within 15 calendar days, and will determine if it is sufficient to close the NC or if additional clarification is needed. Client will be informed about the NC status. In case of rejection, if time allows (within 30 calendar days for corrective action, client can re-submit additional evidence to close NC.
- d) CU has the right to determine if a re-evaluation audit (on-site or remote) is necessary to be performed to verify implementation of corrective actions.
- e) Once the client has responded and CU has reviewed all the corrective actions submitted, CU will close the NCs in PGFS System, this will allow for the certification decision to be made.
- f) The submission of the corrective actions does not guarantee that the score will increase but demonstrates that the client has taken measures to control the identified NCs and prevent they occurred again.
- g) **NOTE:** with an overall preliminary audit score of less than 85% or an automatic failure, the client can submit corrective actions for review, but the accepted corrective actions do not change the final score.
- h) If the corrective action is not able to be completed within the deadline given, the client shall submit a 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.

6. CERTIFICATION DECISION

- a) CU will take a certification decision and issue a final audit report in no more than 45 calendar days from the last audit date.
- b) Certification decision is based on a combination of conformance scores: the overall Total Score and the Module Scores.
- c) **To grant a certification:** (applies for initial and recertification audits)
 - Overall Total Score – must be at least 90% to achieve certification.
 - Module Score – each module of the operation must be a minimum of 85% to be certified.
- d) All overall scores for all audits must be $\geq 85\%$ in the preliminary stage to be certified.
- e) **Certification Denial:** If the preliminary score is less than 85% a negative certification decision will be made. New audit will be necessary to obtain a certification. This applies also for recertification decision.
- f) Certification will be issued to each operation individually that complies with the minimum scoring criteria. In case the client has 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.
- g) Certificates have a validity of 12 months and will be issued in the Primus GFS system.

6.1 MAINTENANCE OF CERTIFICATION

- a) Clients must follow PGFS standard to maintain its certification status.
- b) When surveillance unannounced audits are performed, clients shall reach at least the same score obtained during its regular audit to maintain its certification.
- c) A recertification audit is scheduled for next year within the period of 12 months after the last audit date of the certified operation.

6.2 SUSPENSION/REVOCATION OF CERTIFICATION

6.2.1 Suspension: A client can be suspended if:

- a) If during a surveillance unannounced audit client does not reach the same score obtained in its certification audit, the certificate will be suspended for no more than 6 months.
- b) A non-conformance is found to be a food safety issue and an immediate threat to the public.

- c) If the re-certification audit results in an automatic failure, while the client still has a valid certificate.
- d) If a critical food safety issue is detected during an audit (e.g., automatic failure, special circumstance, etc.), then CU will consider suspending existing certificates related to this new observation.
- e) Client does not pay the agreed fees.
- f) If a client rejects a surveillance audit on a second notification.
- g) The client improperly used the PrimusGFS or GFSI logo or trademark.
- h) The client is involved with an illegal activity or a serious food safety issue.
- i) When applicable, during suspension period client shall take appropriate remedial actions to close the NCs found. Client shall send CU an appropriate action plan and implementation measures for closing the NCs
- j) CU will perform a re-evaluation audit to evaluate implementation of corrective actions.
- k) If measures are enough, suspension is lifted. If no actions were sent or measures are not sufficient to close the NCs, then the certificate will be revoke.
- l) In any of both cases, client will receive a formal letter indicating the certification status and conditions set.
- m) CU will inform Azzule Systems in a timely manner and in writing of any sanction applied to a client, as well as update the system to reflect those changes.

6.2.2 Revoke of certifications: a certification will be revoked if:

- a) There is evidence of fraud found.
- b) A suspension related issue is not adequately resolved.
- c) The client is declared in bankruptcy.
- d) Client will receive a formal letter indicating the certification status and conditions set.
- e) CU will inform Azzule Systems in a timely manner and in writing of any sanction applied to a client, as well as update the system to reflect those changes.
- f) An operation with a revoked certificate shall not be accepted for certification under PrimusGFS standard for a period of 6 months after the date of revocation.

6.3 SIGNIFICANT EVENTS FOR CLIENTS AND THEIR OPERATIONS

- a) Clients are obliged to inform CU 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.
- b) CU will take appropriate measures to ensure the integrity of the certification after notification (this may include on site audits), after the evaluation CU will decided whether to suspend or revoke the certification.
- c) CU will inform Azzule System within 7 days of the occurrence.

6.4 CAUSE FOR EARLY RE-EVALUATIONS OF A CERTIFIED ORGANIZATION

- a) Clients shall inform CU 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.
- b) If CU has any reason to believe that there could be compliance issues in relation to the certification requirements, a re-evaluation will be performed to verify conformance with the PrimusGFS standard. Examples of compliance issues: potential critical nonconformities related to changes, complaints against the client, etc.
- c) The re-evaluation may include an on-site visit.

6.5 DISTRIBUTION OF AUDIT REPORTS

- a) Documented audit reports generated by CU during the certification process of each operation, including those submitted through the PrimusGFS database, are provide to the client.
- b) Client is the ownership of the audit report and authorizes the availability of the report for access. CU will ensure appropriate confidentiality except where required, upon request by GFSI, law and the normative documents.
- c) CU will document all communications with the client, in relation to the authorization of release of certification information to an outside party.

6.6 EXTENSION OF SCOPE CERTIFICATION

- a) A certified client can apply for an extension of scope to their current certification for:
 - Increased growing area of an already certified operation, if the operation has “like commodities” in terms of risk, along with justifiable circumstances.
 - Adding products to already certified operations, with justifiable circumstances.
 - 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 products not observed” will be included on the certificate.
- b) CU will evaluate the justifiable circumstances and include all relevant information such as: similarity (risk, processes, location, and personnel) between new products and already certified products, and any additional information required by CU that considers as part of the risk assessment. CU will review all the information before a decision regarding a request for extension of scope of increased growing area and/or adding new commodities is granted.
- c) CU will determine if there is a need to visit the client to increase the growing area, adding commodities to already certified operations and/or adding a new process to the certificate (e.g., new packing line, automated chopper, etc.).
- d) In the case of adding a new operation to an already certified organization, the client will be required to have a full new audit including the FSMS and all relevant modules for that operation (if the audit for the new operation takes place greater than 30 days after the original audit date).

6.7 USE OF LOGO AND TRADEMARK

- a) Use of PrimusGFS trademark and logo are authorized by Azzule system.
- b) During audits, CU will evaluate the use of PrimusGFS trademark and logo. The rules for the use of logo and trademark will be defined in the sublicense agreement signed between CU and each client.
- c) Infringement of the rules could lead into sanctions.
- d) Clients 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.
- e) The logo can only be used for business-to-business communications.

7. CHANGE CONTROL

No. version and date	Description
Version 1.0; 09/03/2022	Initial version

PRIMUSGFS CERTIFICATION PROCESS FLOWCHART
