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CHAPTER 1: GENERAL REQUIREMENTS FOR INSPECTION AND CERTIFICATION OF PGFS Program

1.1 DEFINITIONS
Article 1 Definitions

1. This document adopts all definitions as defined by:
 - General requirements for bodies operating product certification systems (ISO 17065:2012)
 - ISO 19011
 - PrimusGFS General Regulations
 - PrimusGFS Glossary
 - *Exhibit D – Auditing and Sub-license Agreement*

This document uses the following additional definitions:

Adjacent Land	Refers to land across from or beside the growing area.
Agricultural material inputs	Materials used in the production of crops including seeds, transplants, rootstock, cuttings, compost, fertilizers, pesticides, adjuvants, growth promoters, irrigation water, soil amendments and any other material inputs into the growing process.
Agronomic inputs	For the purposes of this audit are defined as fertilizers and other soil amendments e.g. compost.
Allergen	A protein or modified protein with the potential to cause an allergic reaction in people. In the U.S. the main allergens are wheat, eggs, milk, soybeans, crustaceans (shellfish), peanuts, tree nuts (e.g. almonds, walnuts, pecans) and fish. Other countries may include other allergen listings e.g. mustard, celery and sesame. https://farrp.unl.edu/IRChart
Assessment Number	It is a number issued by Azzule to identify the producer.
Biological Hazard	Biological agents that have the capacity to cause harmful effects in humans. Common biological hazards include bacteria (pathogens), viruses and parasites.
Biosolids	Also known as sewage sludge. Semi-solids left over from municipal waste water treatment.
Chemical Hazard	Include radiological hazards, substances such as pesticide and drug residues, natural toxins (such as mycotoxins), environmental pollutants, unapproved food or color additives, and food allergens.
Clean In Place (CIP)	An equipment cleaning procedure that occurs on interior surfaces of equipment such as tanks and pipes that cannot be easily reached for cleaning. This procedure is sometimes part of larger procedure where equipment is partially cleaned in some way while still assembled and then broken down for a deeper clean before being assembled again and then “flushed” through (clean in place). CIP involves circulation of a detergent solution, water rinse and sanitizing solution through equipment by use of a spray ball or spray to create turbulence and thus remove soil. CIP does not include equipment subject to in-place manual cleaning without the use of a CIP system e.g. slicers, mixers, centrifuge dryers.
Colony forming units (CFU)	A unit of measurement used to estimate viable microorganisms (bacteria, fungus) capable of growth under the prescribed conditions (medium, atmosphere, time and temperature) that develop into visible colonies (colony forming units).

Coliform Bacteria	Gram-negative, non-spore forming, rod-shaped bacteria are frequently used as indicators of sanitary quality of water, but exist broadly in nature.
Compost	Product of microbial decomposition of organic residues into a soil amendment.
Commingling	When more than one lot/batch/GTIN is combined.
Concentrated animal feeding operation (CAFO)	A lot or facility where animals have been, are, or will be stabled or confined and fed or maintained for a total of 45 days or more in any 12-month period. The number and types of animals covered by this definition can be found in the Federal Register’s definition of medium and large CAFOs (CFR Title 40, Part 122.23).
Control measure	Any action or activity that can be used to prevent, reduce to an acceptable level, or eliminate a food safety hazard.
Cooling and Cold Storage	This type of facility operation is where they are receiving goods (either finished goods or bulk product) from fields or other facilities, to perform pre-cooling and/or cooling activities (e.g. ice injectors, top icing, hydrovac pressure cooling, etc). In this type of facility, no packing, repacking or processing activities are being performed. A Cooling and Cold Storage facility operation covers the activities involved in the Storage and Distribution Center facility type.
Cooling Techniques	<ul style="list-style-type: none"> • Forced Air Cooling - Fans in a refrigerated room (cooler) pull (force) air through the produce and cools the produce more rapidly than room cooling alone. Good air flow is essential, so produce must not be packed too closely together. • Hydrocooling - Using cascading chilled water to remove the field heat from produce. Hydro-coolers can be standalone structures or cabinet-like pieces of equipment that use a refrigerated, circulated water bath to remove field heat, increasing the shelf life. • Hydrovac cooling - Combines techniques of vacuum cooling and hydrocooling. Water is sprayed on product just before flash point of the vacuum cycle when the water evaporates from the produce additional cold water is added so cooling produce without dehydrating. • Ice - Ice is applied directly to the produce as a method of removing field heat as well as providing short-term cooling for transport or display. • Pre-cooling - Reducing temperature of product prior to storage (i.e., removing field heat). • Room cooling - Produce is placed in a refrigerated room (cooler) and allowed to naturally cool to ambient temperatures. Coolers are normally designed to regulate temperature, airflow, humidity and other environmental factors. Room cooling is used for produce that has already been pre-cooled using another method and for produce that does not need to reach its minimum cooling temperature rapidly • Vacuum cooling - Using low pressure to cool the produce through evaporative cooling. Produce is placed in a vacuum retort where the atmospheric pressure is reduced to a point where water boils and evaporates at 0 °C/32 °F.
Critical Control Point	A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
Cross-contamination	The transfer of microorganisms, such as bacteria and viruses, from a contaminated surface or substance to a previously uncontaminated surface or substance.

Current Good Manufacturing Practices (cGMPs):	Regulations that are found in 21 CFR 110 (Current Good Manufacturing Practices in Manufacturing, Processing, Packing, or Holding Human Food) and enforced by the US Food and Drug Administration (FDA). cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities.
Dump Tank	Vessel used to wash produce before packing to remove soil and to improve its appearance and marketability. Water in a dump tank is reused and should be treated with an anti-microbial to maintain water quality.
Facility Operation	A production operation carried out in one or several buildings where product is being handled, manipulated and/or transformed. The types of facility operations can be classified as: “Storage & DistributionCenter”, “Cooling/Cold Storage”, “Packinghouse” or “Processing”. In these types of facilities, the focus will be on evaluation of the Good Manufacturing Practices that are in place.
Farm (Ranch)	A tract of land (not necessarily a “lot” for production purposes), under common management and common water supply, ideally contiguous (if not contiguous, similar risk is demonstrated) and used for agricultural production.
Food contact surface	Those surfaces that contact human food and those surfaces from which drainage onto the food or onto surface that contact the food ordinarily occurs during the normal course of operations; includes utensils and equipment surfaces.
Food defence	The process to ensure the security of food and drink from all forms of intentional malicious attack including ideologically motivated attack leading to contamination.
Food Fraud	A collective term encompassing the deliberate and intentional substitution, addition, tampering or misrepresentation of food, food ingredients or food packaging, labelling, product information or false or misleading statements made about a product for economic gain that could impact consumer health.
Food Grade	Term that describes equipment, tools, materials, chemicals, etc., that are of sufficient quality to be used for food production, food storage, food preparation or food contact purposes.
Food Hazard	A biological, chemical, or physical agent that is reasonably likely to cause human illness or injury in the absence of its control.
Food Safety Management System (FSMS)	A set of interrelated systems that when used in combination ensure that food is safe for human consumption. It incorporates GMPs/PRPs, GHPs, HACCP and other practices such as regulatory requirements and communication to ensure food safety is maintained.
Formal Training	A course offered by a recognized educational institution, government body or industry association/group for which a record of attendance is issued. Information about the training content is readily available from the course provider (e.g., course outline, online training materials, etc.).
Fresh-cut produce	Fresh fruits and vegetables for human consumption that have been 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.
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

	and construction material, water supply, plumbing and toilet facilities, equipment and utensils, raw food handling and process controls, personal hygiene, pest control, and waste disposal. See also, current Good Manufacturing Practices.
Green waste	The vegetative portion of the waste stream arising from various sources including waste from domestic and commercial premises and municipal operations.
Harvesting	This type of field operation is defined as a crew of personnel performing a harvesting process in a growing area which can include harvesting as well as washing, sorting, packing, processing or any other post-harvest activity carried out at field level.
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.
Human Pathogen	Microorganisms (bacteria, fungus, parasite, protozoa or virus) capable of causing illness or disease in people.
Indoor Agriculture (Greenhouse)	Where crops are grown in a controlled environment in a temporary or permanent enclosed structure. This does not include shade or hoop houses.
Listeria	The major human pathogen in the Listeria genus is <i>L. monocytogenes</i> . It is usually the causative agent of the relatively rare bacterial disease listeriosis, a serious infection caused by eating food contaminated with the bacteria. The disease affects pregnant women, newborns, adults with weakened immune systems, and the elderly. Listeria bacteria can grow at refrigeration temperatures and survive freezing.
Mitigation Measures	Any action or activity that can be used to prevent, reduce to an acceptable level, or eliminate a food safety risk. In order for mitigation to be effective, the risks must be identified ahead of time and a plan devised ready for implementation before or when the risk occurs
Mock Recall	A procedure to test the recall program and recall team’s ability to find and trace their product during a recall.
Multi-site operation	When an individual or one organization owns several production locations that are not separate legal entities (e.g., where an individual producer or company has several farms that all belong to them and are centrally managed). In this scenario all production areas of the certified product(s) need to be inspected and comply with the standard before a certificate can be issued.
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.
Non-synthetic crop treatments	Any crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens, e.g. compost teas, fish emulsions, fish meal, blood meal, “bio fertilizers” (commonly used for pest control, greening, disease control, fertilizing).
Organization	A legal entity that produces food in the agricultural sector and applies for PrimusGFS certification in the operations managed by the entity.

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.
Outsourcing	A firm, company or individual carrying out a process on products or service on the behalf of the auditee.
Packaging	Material or package which provides protection, tampering resistance, and special physical, chemical, or biological needs to maintain food safety,
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
Pathogen	A microorganism (fungus, bacteria, parasite, protozoa or virus) capable of causing illness or disease.
Pest	An animal, plant or other organism that is directly or indirectly injurious, noxious or troublesome, and an injurious, noxious or troublesome condition or organic function of an animal, a plant or other organism (e.g., rodents, birds, reptiles, insects, weeds, fungi, bacteria, viruses, etc.).
Potentially Ready-to-Eat/ Ready-to-Use (RTU):	Food in an edible form that has been minimally processed – cleaned/sorted, trimmed, and possibly cut before being packaged, and requires further washing and/or preparation prior to consumption.
Preventive Measures	Actions taken that are intended to reduce or prevent the severity/impact of a risk.
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).
Producer	A producer that applies for PrimusGFS certification. Once certified, the individual producer will be the certificate holder. A person (individual) or business (individual or producer group) representing the production of the products, relevant to the scope, who has the legal responsibility for the products sold by that farming business.
Product handling	Low risk post-harvest activities carried out on the produce that is still owned by the certified producer such as packing or storage. Storage, chemical treatments, trimming, washing, or any other handling where the product may have physical contact with other materials or substances is considered under produce handling.
Ready-to-Eat (RTE)	Food in an edible form without additional preparation to achieve food safety, includes raw fruits and vegetables that are thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption.
Registration	The process by which an individual producer or producer group starts the application process for certification with an approved PrimusGFS Certification Body

Repacking	Removing product from its market ready packaging, re-handling the product (e.g., re-sorting, re-grading, re-trimming, etc.), and putting it into market ready packaging materials.
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.
Revocation	<p>A type of sanction issued by a Certification Body by revoking a customer’s current certificate (s). This type of sanction should be issued based on the following circumstances or any other critical circumstance a Certification Body finds appropriate:</p> <ul style="list-style-type: none"> • Evidence of fraud is found • A suspension-related issue is not adequately resolved • The organization declares bankruptcy
Risk Assessment (GAP)	An evaluation of the growing environment food safety hazards relevant to topography, hydrology, geographical features, climatic conditions, land history, adjacent land use, water source, domestic animal and wildlife presence or any other potential sources of contamination to the crop.
Risk Assessment (GMP)	An evaluation of the facility to identify and control and food safety hazards relevant to facility location and adjacent land use e.g. animal activity, industrial activity, water source, waste water treatment sites (settling ponds, land applications, etc.) or any other potential sources of contamination.
Risk Mitigation	Actions to reduce the severity/impact of a risk.

Sanitation Standard Operating Procedures (SSOPs):	A set of written instructions detailing all steps and activities required to perform a given cleaning and sanitation task before, during, and after production with the purpose of minimizing variation and facilitating consistency.
Sanitize	The process of reducing the number of microorganisms that are on a properly cleaned surface to a safe level. A safe level is defined as a 99.999% reduction of the number of disease microorganisms that are of public health importance. Sanitizing is accomplished by using either heat, radiation, or chemicals. Unless the item to be sanitized is effectively cleaned, it is impossible to obtain close contact between the sanitizer and the surface to be sanitized. Some chemical sanitizers, such as chlorine and iodine, react with organic matter and are less effective when the surface is not properly cleaned.
Senior Management	Person or group of people who directs and controls an organization at the highest level. Senior management has the power to delegate authority and provide resources within the organization, including the authority to authorize financial and human resource decisions
Standard Operating Procedures (SOPs):	A set of written instructions detailing all steps and activities required to perform a given routine task with the purpose minimizing variation and aiding consistency.
Self-assessment	Assessment against all applicable parts of the PrimusGFS standard by the producer, at least once per year.
Storage and Distribution Center	Facility operation where they are only receiving and storing goods (either finished goods or bulk product) for further shipment (e.g. centralized storage facilities, regional distribution warehouses, etc). In this type of facility, no cooling, packing, re-packing or processing activities are being performed.
Sub-scope of the Standard	Module covering specific production details, classified per product type
Suspension	<p>A type of sanction issued by a Certification Body by suspending an 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. • An organization is involved with an illegal activity or a serious food safety issue.
Thermotolerant coliforms	A subgroup of total coliforms. The predominant numbers of bacteria that test positive in assays for thermotolerant coliform may be E. coli, but from horticultural production and postharvest handling operations the greater numbers are often benign or non-pathogenic soil and leaf colonizers.
Water Test	For generic E. coli (unless more stringent guidelines/laws in existence)

	<126MPN (or CFU)/100mL (rolling geometric mean n=5) and <235MPN (or CFU)/100mL for any single sample. Where thresholds have been exceeded there should be recorded corrective actions including investigations, water retests and crop testing (E. coli O157:H7 and Salmonella - zero tolerance).
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1.2 Type of Assessments

Article 2 Assessments for PGFS	
1	Pre-assessment – (Optional) Before Initial Audits to identify potential gaps before a initial Audit.
2	Main Assessment – Initial Audit with Control Union.
3	Surveillance Audits – Annual Audits, to renew the scope certificate
4	Re-Audit – Additional audit to verify corrective actions for any non-conformance found during the assessment (to be determinate by the Certifier or Scheme Cordinator)
6	<p>Mandatory Unannounced Audits</p> <p>For PrimusGFS the same Checklist from the original Audit will be used. The selected organization with certified operation(s) must reach the same scoring as a certification audit to maintain their certification status. A minimum of 2% of CU projects must be selected for Unannounced audits, based on the risk (i.e. compliance history, appeals and complaints, product type(s), complexity of the process(es), or any other factors that CU determines.).</p> <p>Geographical location shall 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.</p> <p>If the CB has ≤ 10 current certified organizations, 1 organization should be chosen for the surveillance audit in their program.</p> <p>The CB will notify the organization's chosen operation(s) of the unannounced audit no sooner than 48 hours prior to the day of the audit. iii.</p> <p>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.</p>

1.3 Evaluation of Criteria – Scoring System

Article 3 Possible Answers to PGFS questions per module	
1	<p>Total Conformance</p> <p>To meet the question and/or conformance criteria in full.</p>
2	<p>Minor deficiency</p> <p>To have minor deficiencies against the question and/or conformance criteria.</p> <p>To have single or isolated non-severe deficiencies (usually up to three) against the question and/or conformance criteria.</p> <p>To have covered most of the question conformance criteria, but not all.</p>
3	<p>Major deficiency</p> <p>To have major deficiencies against the question and/or conformance criteria.</p> <p>To have numerous non-severe deficiencies (usually more than three) against the question and/or conformance criteria.</p> <p>To have single or isolated severe deficiencies against the question and/or conformance criteria.</p> <p>To have covered some of the question conformance criteria, but not most of it.</p>
4	<p>Non-conformance</p> <p>To have not met the question and/or conformance criteria requirements at all.</p>

	Having systematic deficiencies against the question and/or conformance criteria (severe or non-severe issues).																																		
5	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.																																		
6	Automatic Failure There are some questions in the PrimusGFS checklist, that if down scored will lead to an automatic failure and overall score of 0% for the corresponding Modulo, These questions are identified with the phrase similar to: “ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE”																																		
7	Each question in the PrimusGFS Checklist has a possible score assigned to it. Depending on the answer given, the score obtained will be defined. Each scored question has a certain amount of points that can be obtained depending on the conformance assigned to it.																																		
8	The scoring system shows the points that an auditee can get in accordance with the possible answer. <table border="1" data-bbox="231 728 1289 1093"> <thead> <tr> <th colspan="5">SCORING SYSTEM</th> </tr> <tr> <th rowspan="2">Possible answer</th> <th colspan="4">Possible Points for the Question</th> </tr> <tr> <th>15 points</th> <th>10 points</th> <th>5 points</th> <th>3 points</th> </tr> </thead> <tbody> <tr> <td>Total conformance</td> <td>15 points</td> <td>10 points</td> <td>5 points</td> <td>3 points</td> </tr> <tr> <td>Minor deficiency</td> <td>10 points</td> <td>7 points</td> <td>3 points</td> <td>2 points</td> </tr> <tr> <td>Major deficiency</td> <td>5 points</td> <td>3 points</td> <td>1 point</td> <td>1 points</td> </tr> <tr> <td>Non-conformance</td> <td>0 points</td> <td>0 points</td> <td>0 point</td> <td>0 points</td> </tr> </tbody> </table>	SCORING SYSTEM					Possible answer	Possible Points for the Question				15 points	10 points	5 points	3 points	Total conformance	15 points	10 points	5 points	3 points	Minor deficiency	10 points	7 points	3 points	2 points	Major deficiency	5 points	3 points	1 point	1 points	Non-conformance	0 points	0 points	0 point	0 points
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1.4 CERTIFICATION

Article 4 Certification	
1	CUCNA will make the certification decision in no more than 45 calendar days from the audit date.
2	Certification decision will be based on a combination of conformance scores: the overall Total Score and the Module Scores <ul style="list-style-type: none"> - The Overall total score must be at least 90% to achieve certification - 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 ≥ 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.
3	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.
4	Certificates will have a validity of 12 months and will be issued by the PrimusGFS system. Certificate Holders must be in compliance with Scheme regulation in order to maintain certification status.

1.5 SANCTIONS

Article 5 Sanctions for Certificate Holders	
1	If the CUCNA finds a non-conformance with a certified organization’s PrimusGFS Scheme Documentation that is found to be a food safety issue and an immediate threat to the public, a sanction (suspension or revocation) will be issued.

2	Sanctions will be notified 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.
3	Only CUCNA can 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.
4	CUCNA 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.
5	<p>There are two types of possible sanctions for organizations:</p> <p>5a- Suspensions</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. - 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. - If a critical food safety issue is detected during an audit (e.g., automatic failure, special circumstance, etc.), then CUCNA 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 (unannounced) audit on the second 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. <p>5b – Revocations // Withdraw</p> <ul style="list-style-type: none"> - 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.
6	CUCNA will notify the PGFS 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.

1.6 NON-CONFORMANCES AND CORRECTIVE ACTIONS

Article 5 Guidance for NCs and Corrective Actions	
1	For all non-conformances (scored as zero points) raised during the audit, the applicant organization must submit corrective actions into the PrimusGFS database for review by the CUCNA. If no corrective action is possible, the organization should detail what they will do to control the risk. The submission of comments and/or corrective actions does not guarantee that the score will change, but should demonstrate the actions that were taken or are to be taken by the applicant organization.
2	<p>Corrective action evidence can be in the form of documents, records and/or photographs, and it must show that the non-conformance has been addressed. This evidence must be verified and accepted by the CUCNA in order to have the non-conformance closed and be considered for certification.</p> <p>Note that with an overall preliminary score of less than 85%, the auditee can submit corrective actions to the CUCNA for review but accepted corrective actions do not change the final score.</p>
3	The corrective actions from the organization should include the determination of cause(s), include any action plan(s) to address immediate issue(s) regarding the non-conformance, the corrective actions taken, and the development of preventive actions to help avoid future occurrences if necessary.

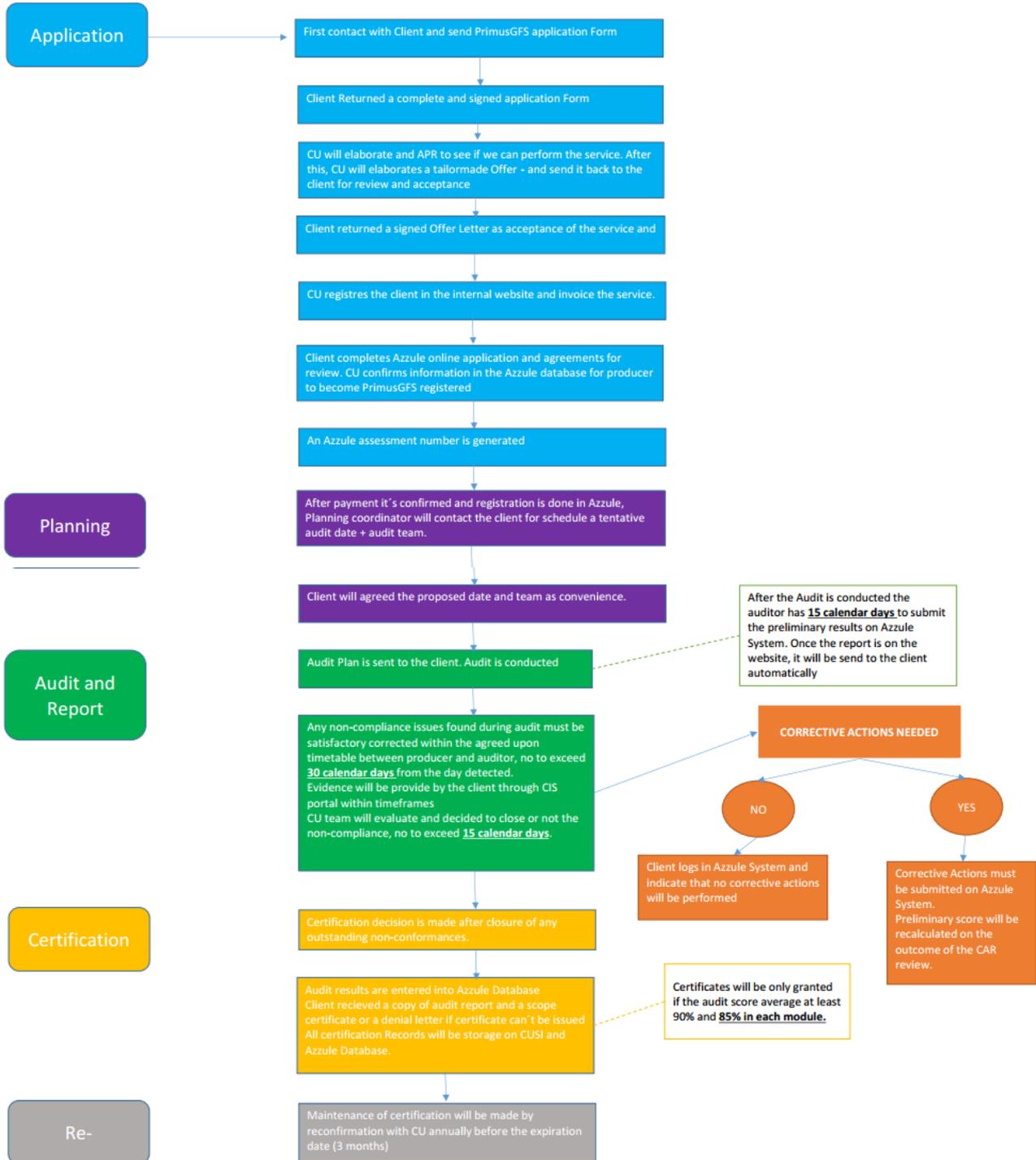
4	CUCNA has the right to determine if a re-visit to the audited organization is necessary to verify corrective actions for any non-conformance found.
5	Corrective action evidence for each non-conformance must be submitted to the CUCNA by the organization within 30 calendar days from the original audit date.
6	If corrective action is sent within the 30 calendar days, and CUCNA rejects it, the organization can re-submit additional evidence to close the non-conformance.
7	CUCNA will have 15 calendar days to review the corrective action evidence and notify the organization if it was accepted or rejected and close the non-conformance(s).

1.7 Extension of Certificates

Article 6 Extension of existing Certificates	
1	<p>An organization’s certified operation can apply for an extension of scope to their current certification for:</p> <ul style="list-style-type: none"> 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. <ul style="list-style-type: none"> 1. Similar product 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.
2	<p>Justifiable circumstances will be reviewed By CUCNA 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. CUCNA 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. To add a commodity, the client should send a new AF requesting the extension of the scope, the justification and all relevant information needed. This will be uploaded in the last APR with a remark declaring the addition or the extension of the scope.</p>
3	<p>Adding similar products:</p> <ul style="list-style-type: none"> 1.-CU certifier will notify to scheme owner about the addition of the product to the scope. 3.-Once approved, CU certifier will re-open the final report to add the new product. The certificate validity will not change, considering the initial certification date. <p>Adding not similar products</p> <p>In case it is needed a new visit, the new inspection will generate additional costs, so the customer must know the costs and be aware that the validity of the certificate will not change.</p> <ul style="list-style-type: none"> 1.-The scheme owner will be notified about an addition to the scope. 2.- Once approved, CU certifier will re-open the final report to add the new product. 3.-The auditors will inspect the added commodity on site. 4-. If there are Non-compliances, the auditee will just have 7 days to submit corrective actions. 5.-If it is granted the addition of the product, the certificate validity will not change, considering the initial certification date.
4	<p>CUCNA 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.).</p>
5	<p>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.</p>
6	<p>An extension lasting an additional 3 months from the current certificate expiration date may be granted, thereby a total certification life of 15 months. There must be justifiable circumstances that are documented. All justifications and new certification dates must be recorded in CUSI and Azzule</p>

system.

2.PGFS CERTIFICATION PROCESS



2.1 PrimusGFS General Conditions

Article 1 Standard Scope													
1	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.												
Article 2 Audit Frequency													
1	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.												
2	This frequency may be modified by factors such as: a.Modification of the scope and/or operation’s location during the certificate validity. b.Seasonality of the products; up to 3 months extension of current certificate expiration date with justifiable circumstances. c.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). d.Additional visits may be required due to insufficient evidence of corrective actions.												
Article 3 Application													
1	It is Applicants responsibility to provide the correct information to Control Union in regards the scope of the certification they want to achieve for their operations. In order to accept a certification, request a complete and signed Application Form (AF) will be required. Only the information declared in the application form, will be used for auditing/certification purposes. A failure declaring the correct scope (Incorrect information, missing sites/products) can lead in extra costs (related to new visits) for your operation.												
2	In Field assessments, all 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.												
3	In Facility Operations, all commodities must be present in the operation 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 production processes as to what is going to be audited, and the same personnel involved.												
4	<u>Transferring Certification Bodies:</u> 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.												
Article 4 Audit													
1	PGFS Audit can be divided in two options. <table border="1" data-bbox="226 1780 1428 2072"> <tr> <th colspan="2">Applicability of PrimusGFS Audit</th> </tr> <tr> <td colspan="2">1.- Food Safety Management System (FSMS). Applicable to all certifications.</td> </tr> <tr> <th>GAP OPTION</th> <th>GMP OPTION</th> </tr> <tr> <td>Applicability of each section depends on the operation to be certified, with the following sections applicable for each operation:</td> <td>For Facility, HACCP (module 6) will always be applicable. *Module 7 is an optional module.</td> </tr> <tr> <td>2. Ranch</td> <td>5.Facility</td> </tr> <tr> <td>3. Greenhouse</td> <td>6.HACCP</td> </tr> </table>	Applicability of PrimusGFS Audit		1.- Food Safety Management System (FSMS). Applicable to all certifications.		GAP OPTION	GMP OPTION	Applicability of each section depends on the operation to be certified, with the following sections applicable for each operation:	For Facility, HACCP (module 6) will always be applicable. *Module 7 is an optional module.	2. Ranch	5.Facility	3. Greenhouse	6.HACCP
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2. Ranch	5.Facility												
3. Greenhouse	6.HACCP												

	4. Harvesting	*7. Preventive Controls
Article 5 Special Circumstances		
1	Automatic Failure, is a special circumstance where CU 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	
2	Suspension/Revocation of Certification CU 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	
3	Significant Food Safety Events for Certified Organizations & their Operations All certified organizations shall inform CU 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. CU shall ensure the integrity of certification after notification and consider the need to suspend or revoke certification. CU will notify these significant events to Azzule Systems.	
4	Cause For Early Re-evaluation of a Certified Organization The certified organization shall inform CU 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. If the CU 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.	

Annex 1: Use of the PrimusGFS Logo and Trademark

This chapter describes the conditions concerning publication and use of certification mark, regarding the PrimusGFS logo. *The PrimusGFS logo and trademark (collectively, the “Logo”) is owned by Azzule*

General Conditions

- a) The logo may only be used with the permission from the Scheme Owner (Azzule Systems).
- b) The logo must always be obtained by CU from the Scheme Owner. This will ensure that it contains the exact corporate color and format. *Certificate Holders (CHs) must obtain the electronic data file or hardcopy of the Logo, from their respective CU.*
- c) CU is responsible for the control of the use of the logo on certified operations (valid certificate issued by CU).
- d) Organizations can only use the logo when there is a valid PrimusGFS certificate linked to that organizations and making clear reference to the certified operations and scope. *CHs are not entitled to grant sublicenses to any third party for the use of PrimusGFS trademark and logo.*
- e) *CHs do not acquire any physical or intellectual proprietary rights in the Logo beyond the license granted herein*
- f) PrimusGFS approved Certification Bodies can use the logo for promotion of their accredited PrimusGFS certification activities in business-to-business communication and on their accredited PrimusGFS Certificates.

Obligations of Certificate Holders (CHs).

- a) *Not use Logo as a product certification mark and shall never use it on their products or packaging of product.*
- b) *Only use the logo in business to business communications such as website, invoices, letterhead, promotional material, etc.*
- c) *Only use Logo in a manner consistent with the registered scope of your certification. Operations and/or products not included in your registered scope are not certified and you are prohibited from using the logo in any way that would indicate or imply otherwise.*
- d) *Pay all fees and costs set by Azzule and/or as agreed to with CU.*
- e) *Cooperate with Azzule and its agents to allow reasonable access to verify compliance with these rules*

Sanctions

- a) When the CHs does not respect the conditions mentioned in this annex *and it's notified in written by CU*, the CHs will stop immediately, without delay, *the use of the Logo* against which CU and the Scheme Owner has objected. *The use might include (but not limited) to any promotional materials, websites, or communications on which the Logo may be published.*
- b) In the event that the CHs does not comply the considerations mentioned in previous articles and/or PrimusGFS regulations, CU will apply any of the following measurements:
 - Suspension or withdrawal of the certificate
 - Publication of the non-compliance on CU website
 - Juridical procedures
- c) *Azzule or CU may withdraw CHs license for use of Logo if:*
 - *CHs uses the Logo in a manner that is intended to be detrimental to Azzule or the PrimusGFS program.*
 - *CHs fails to correct the issues or conditions that led to the suspension of the use of the logo within the time frame agreed to with CU; or*
 - *The CHs ceases operation or declares bankruptcy*

Actions taken will depend on the severity of the non-compliances, that will be evaluated by CU.

Additional to the faculty to early terminated the agreement between CU and it's client without the requirement of a court order and without any cause imputable to CU, the client is bind to repair the damages, as required in written by CU or by Azzule within a term that shall not exceed of 15 (fifteen) calendar days counting since the mentioned notification. Likewise the Certification documents granted to the CLIENT as result of the audit shall be consider as definitively withdrawn.

Appeal of Suspension or Revocation of License to use the Azzule Logo

*CHs may appeal a decision to suspend or withdraw the use of the Logo by notifying Azzule and CU, in writing, **within 14 days** of the date of the notice of suspension. The appeal will be handled in accordance with the appeals process of the CU or Azzule, whichever is applicable, but under no circumstances in a way that contravenes GFSI rules, regulations, or the governing documents.*