

# Primus Standard Audits General Regulations

Version 20.06

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## 1. Introduction

- a. The Primus Standard Audits have been developed by Azzule Systems and has been used for many years by different parties of the fresh produce industry. It is designed to be used for primary production and manufacturing sectors (including horticultural, grains, and pulses) on a global scale.
- b. Azzule Systems, which is a subsidiary of Primus Group, Inc., owns the Primus Standard Audits, functioning as its Certification Program Owner. Azzule Systems has offices worldwide, including:
  - i. Santa Maria, California, United States (Headquarters)
  - ii. Viña del Mar, Valparaíso, Chile
  - iii. Culiacán, Sinaloa, Mexico
- c. The Primus Standard Audits have been designed with a HACCP-based approach that includes measures that need to be taken, following the seven Codex Alimentarius HACCP principles. This allows the producers to assess their operation's risk and implement parameters and corrective and preventive actions to maintain their food safety program.
- d. These General Regulations explain the Primus Standard Certification System and the process to obtain certification. They also intend to establish communication mechanisms, duties and obligations of the Certification Program Owner, of Certification Bodies (CBs)/Auditing Companies, and of applicants seeking to gain certification of their operation(s).
- e. The Primus Standard website provides a public listing of certified operations and approved CBs.

## 2. Version 20.06 Update

- a. The goal of Primus Standard Audits version 20.06 was to update the audit to meet current industry practices, regulatory requirements, and customer and stakeholder compliance requirements. We took the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) rules into consideration during the development. Where the current Primus Standard requirements did not fully meet FSMA requirements, additional criteria were added for producers to comply with FSMA. An initial draft of the updated Primus Standard Audits was reviewed by stakeholders (e.g., buyers, customers, audited operations, certification bodies, etc.), and the feedback was considered in the final draft.
- b. The FDA's Produce Safety Rule is included within the Primus Standard Audits templates for Farm, Indoor Agriculture, Harvest Crew, and Facility for those operations that must meet those rule requirements.
- c. For facility operations, an updated, optional addendum covers FDA FSMA's Preventive Controls for Human Food Rule.

## 3. Standard Scope

- a. The scope of Primus Standard Audits is focused on the Food Safety of agricultural sector products (including horticultural, grains, and pulses) **designated for human**

- consumption.** Primus Standard Audits establish 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 CBs**, for the relevant food safety **practices** associated with each of their different production stages **by establishing a minimum acceptable condition for the performance of the applicants.** For this, the Primus Standard Audits have defined fundamental areas that a company in the agricultural sector **should consider (as applicable)** in the production and/or manufacturing of their products:
- i. **Good Agricultural Practices (GAP)**
    - **Farm (previous version was Ranch)**
    - **Indoor Agriculture (previous version was Greenhouse)**
    - **Harvest Crew**
  - ii. **Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Points (HACCP) System**
    - **Storage and Distribution**
    - **Cooler/Cold Storage**
    - **Cooler/Cold Storage with HACCP**
    - **Packinghouse**
    - **Packinghouse with HACCP**
    - **Processing with HACCP**
    - **Packaging**
  - iii. **Preventive Controls (PC) addendum is voluntary and applicable to GMP operations only.**
- c. An explanation of the requirements for each of these areas is provided in the current normative documents of the Primus Standard:
- i. **Primus Standard Audits - General Regulations**
  - ii. **Primus Standard Audits - Checklist**
  - iii. **Primus Standard Audits - Questions and Expectations**
  - iv. **Primus Standard Audits - Audit Scoring Guidelines**
- d. The Primus Standard may **periodically** issue additional normative documents **or updated revisions of the current normative documents (e.g., in response to factors such as significant food safety issues, new regulatory requirements, etc.).**
- e. The normative documents will be **formally reviewed** internally, and, if needed, changes will be made.
- f. **The standard review will consider all user feedback, and the changes will be sent to stakeholders for review.**
- g. English is the original language of the normative documents. Translations will be made to other languages as needed, and **will** also be issued as official normative documents. **In case any issue(s) arise(s) with the translation of the other languages, the user should refer back to the English version.**
- h. **The normative documents and their translations can be found on the Primus Standard Audits website (<https://azzule.com/primusstandardaudits/>).**

#### 4. Legislation

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

#### 5. Guidance for the Management of **Certification Bodies (CBs)**

- a. **Primus Standard certification audits can only be performed by Certification Program Owner approved CBs.** Certification activities shall be carried out by personnel who **meet the** requirements for all management, administrative, technical, and auditing functions.
- b. **The CB shall have a documented and implemented quality management system, containing all the necessary requirements to conform to the scheme. Information concerning the quality management system required for accreditation shall always be available to the Certification Program Owner.**
- c. There shall be a designated member of the CB **staff** responsible for the quality **management** system's development, implementation and maintenance. This person, the **Certification Program Manager and/or Technical Supervisor**, will be the contact person with the **Certification Program Owner regarding Certification Program management. All official communications with the Certification Program Owner must be in English.**
- d. **The CB must be accredited by a reputable accreditation body under ISO/IEC 17065 or its equivalent, for a separate food safety audit program, and must maintain such accreditation when performing audits under the Primus Standard Audits. The list of approved CBs is publicly available on the Primus Standard website: <https://azzule.com/primusstandardaudits/>**
- e. **The Certification Program Owner will define a set of indicators to analyze CB performance as part of the Primus Standard CB Integrity program, which will be monitored according to a risk-based program that will take into consideration the number of certifications issued by the CB, the size and types of audited operations, complaints received, and any other indicators that the Certification Program Owner considers necessary.**
- f. **The Certification Program Owner can execute on-site inspections of the CB offices, assess the auditors' technical skills (which can include shadowing auditors), review audit reports and corrective actions, review any materials used in the Primus Standard Audits certification process or request information and/or documentation related to the CB's accreditation, and anything pertaining to the Primus Standard. All costs associated with these activities are to be covered by the CB.**
- g. **CBs shall notify the Certification Program Owner in a timely manner regarding any relevant changes to their ownership, accreditation status, management personnel, management structure, or constitution.**
- h. **In the case of any possible conflict or problems that could bring the Primus Standard into disrepute, the Certification Program Owner and the CB shall agree on the appropriate action to take.**

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

## 6. CB Personnel Requirements

### 6.1 Conflicts of Interest

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

### 6.2 Certification Program Manager and/or Technical Supervisor

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

### 6.3 Auditor Requirements

- a. CBs are responsible for ensuring that auditors performing the inspections are in conformance with the following minimum requirements: have evidence to demonstrate their conformance, and be knowledgeable in all Primus Standard Audits documents, the General Regulations, and the training requirements.
- b. **Qualification/Education:** Auditors must have educational training 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.

#### 6.4 Work Experience

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

#### 6.5 Audit Experience

- a. Auditors must have a minimum of 10 audit days or 5 audits of practical auditing experience in performing 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 **including**: dates, audited organization, type of operation being audited, and role of the candidate auditor.

#### 6.6 Formal Auditor Training

- a. Auditors must have successfully completed **the following courses**:
  - i. HACCP training based on the Principles of Codex Alimentarius from a recognized institution with a minimum duration of 2 days or 16 hours of **formal classroom training, taken within the last 5 years.**
  - ii. **Preventive Controls/Qualified Individual Training (PCQI) is required if auditors will be performing the Preventive Controls addendum.**

#### 6.7 Auditor Assessment

- a. For an auditor's initial approval, a **witness** audit assessment must be performed by an **approved witness assessor that should be an already approved auditor or the CB's Certification Program Manager and/or Technical Supervisor** during an official Primus Standard audit. This will include an assessment of the new auditor's knowledge of the following items:
  - i. Primus Standard normative documents
  - ii. Food Safety principles, HACCP, Pre-requisite programs, access to relevant laws and regulations and **the ability to apply them when appropriate**
  - iii. **Quality Management Systems, specific audit techniques and specific scopes**
- b. The auditor assessment shall be documented. The assessment report will describe the details and outcome of the assessment. **If the auditor assessment is being completed for a newly approved CB and there are no other approved auditors, the CB's Scheme Manager and/or Technical Supervisor, or an auditor that is already approved to perform GFSI benchmarked audits or the equivalent can perform the witness assessment.**

#### 6.8 Auditor Exam

- a. All auditors must pass the Primus Standard exam to be initially approved, and subsequently when there is a new version of the audit or as required by the Certification Program Owner. **The exam includes knowledge and understanding of the following topics**:
  - i. Primus Standard normative documents
  - ii. Relevant food/agricultural-related legislation
  - iii. **Agricultural (horticultural, grains, and pulses) production/manufacturing processes**

- iv. Quality management systems, good agricultural and/or manufacturing practices, and HACCP systems.

#### 6.9 Auditing Scope

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

#### 6.10 Continued Training

- a. To maintain the approved auditor status, there should be evidence that the auditor has performed at least five Primus Standard audits per year at different organizations, to maintain certification program and industry knowledge.
  - i. In special circumstances that the above requirement cannot be met, there should be evidence that the auditor has performed at least five audits against another certification program (similar to the Primus Standard scopes) and at least one Primus Standard audit.
- b. The CBs have the responsibility to ensure that their auditors are current on industry best practices, food safety, and technological developments, and relevant laws and regulations for each option (Field and/or Facility) in which their auditors are approved. The CBs shall maintain records of all relevant trainings taken by the auditors.
- c. The CBs must conduct and document auditor performance evaluations.

#### 6.11 Attributes and Competencies

- a. The CBs must have a system in place that ensures auditors are conducting audits in a professional manner. The auditor assessments (including their initial witness assessment and any subsequent reviews) should also evaluate their personal attributes and behavior.
- b. CBs must be able to demonstrate that the auditors meet the approval requirements and maintain their competence as a Primus Standard auditor. In the same way,

CBs must keep complete records of auditors' qualifications, experience, training, supervised audits, assessments, sign-off, re-approval and others, **while they have a working relationship and for a minimum period of two years afterward.**

- c. **CBs will be responsible for registering auditors in the Azzule Auditing Software database. Auditors should be registered prior to their witness assessment, in order to be able to enter the report.**

## **7. Audit Duration and Frequency**

- a. **The CB will be responsible for evaluating whether an operation meets the requirements for the Primus Standard Audits and consequent certification. The CB will be responsible for defining the audit duration and frequency for an operation.**
- b. **The audit duration should be approximated by the CB when scheduling audits, and adjusted by the auditor, considering the following information:**
  - i. **Type of operation(s)**
  - ii. **Number of operation(s)**
  - iii. **Size of the operation(s)**
  - iv. **Number of workers**
  - v. **Number of products and similarity of production process(es)**
  - vi. **Complexity of the production and/or handling process(es)**
- c. **The audit duration will be recorded per organization and the operations included in the audit certification process. The audit duration includes the time required to perform the documentation review and the visual inspection for each operation included in the certification scope. The following guidelines estimate approximate audit recording durations:**
  - i. **GAP Audits – Documentation review: 2-5 hours; visual inspection: 1.5 – 4 hours.**
  - ii. **GMP Audits – Documentation review: 2-5 hours; visual inspection: 1.5 – 5 hours.**
  - iii. **The times for both the documentation review and the visual inspection should be reflective of the size of the operation and the types of processes audited.**
- d. **Audit duration spans the time from the opening meeting to the closing meeting with the organization (where the non-conformances found are reviewed). The timeframes shall be indicated in the audit report. CBs must be able to justify significant audit duration deviations.**
- e. **The subsequent audit should be scheduled 12 months from the date of the previous audit.**
- f. **This frequency may be modified due to factors, such as:**
  - i. **Modification of the scope and/or operation's location during the certificate validity.**
  - ii. **Seasonality of the products.**
  - iii. **For on-site audit certification, an extension lasting an additional 3 months from the current certificate expiration date may be granted by the CB that made the certification decision. There must be justifiable circumstances that are documented.**

- iv. Quantity and type of non-conformances detected at the time of the audit (e.g., a re-audit or a re-visit may be required to receive certification).
- v. Additional visits may be required due to insufficient corrective action evidence.
- g. These or other situations must be assessed and documented by the CB, who will determine the audit frequency required for each applicant, and document justification for any modification.
- h. Within the Primus Standard Audits, there are a wide variety of processes that could be audited. Therefore, CBs should select their auditors based on their skill sets related to the process(es) being audited. CBs also need to have reviewers/certification decision-makers who are qualified and experienced to review and/or make the certification decisions for the process(es) being audited.

## 8. Certification Process

### 8.1 Application

- a. Applicants must provide the CB with the scope of their operations that they want certified. **At a minimum**, this information should include:
  - i. Organization details;
  - ii. Contact information;
  - iii. Details about the operation(s) to be included in the scope of certification. **For** field operations, each site is called either a **"Farm"** (previously **Ranch**) or **"Indoor Agriculture"** (previously **Greenhouse**) or **"Harvest Crew"** and the application should detail the different sites to be certified. **For** facility operations, each site can either be called a **"Storage & Distribution Center," "Cooling/Cold Storage Facility," "Packinghouse," "Processing Center" or "Packaging Center."**
  - iv. Field operation products covered in the scope of certification.
    - The commodities must be present in the field at the time of the audit.
    - Where a commodity is not present at the time of the audit but the operation wishes to include it in the certification scope of their audit, it may be considered as long as the commodity is considered to have similar growing processes as to what is going to be audited, and the same personnel involved. **If it is a Harvest Crew audit, the products need to have similar harvesting processes.**
      - The auditor will indicate on the audit report what products were observed at the time of the audit, similar products not observed at the time of the audit, and products that were not similar and not seen at the time of the audit. The auditor is to include specific details in the audit scope and throughout the audit report related to which products were observed at the time of the audit, as well as which records were reviewed.
      - If the commodity was not grown by the field operation during the previous growing cycle (12 months), they cannot

- be considered in the audit scope. Records of production of the additional products should be available for review.
- v. Facility operation products covered in the scope of certification.
    - The operation must be running and the commodities **included in the scope of certification** must be present in the operation at **the time of the audit**. **The auditor must review all operational steps at the time of the audit**. **If certain steps are not taking place at the time of the audit, the operation will not be able to be certified**. **If there is any doubt as to whether all operational steps are included in the audit, the auditor should consult with the CB technical team**. **If there is any doubt regarding this, the Scheme Owner should be contacted**.
    - Where a commodity is not present at the time of the audit but the operation wishes to include it in the certification scope of their audit, it may be considered if the products have similar production processes compared to the products that are going to be audited, and the same personnel is involved in the process(es).
      - The auditor will indicate on the audit report what products were observed at the time of the audit, **similar products not observed at the time of the audit**, and products that were not similar and not seen at the time of the audit. The auditor is to include specific details in the audit scope and throughout the audit report related to which products were observed at the time of the audit, as well as which records were reviewed.
      - Process description(s) or flow chart(s), with step-by-step details of the production process and the equipment used needs to be available for review at the time of the audit. If the commodity was not included in the facility's operation during the previous production cycle (12 months), they cannot be considered in the audit scope.
  - vi. Desired audit period based on the seasonality of the crop and **the** validity of the current audit certificate.
  - vii. **Language that the auditor would use during the course of the audit.**
  - viii. **The choice to schedule the audit(s) as announced or unannounced.**

## 8.2 Desk Review

- a. **Desk Review, also referred as remote activities, is an off-site review of required documents submitted by an organization that is in the process of certification. This audit approach allows an auditor to review all applicable documents related to the organization's Primus Standard audit program prior to on-site/remote auditing. The use of the desk review should be used in accordance to the International Accreditation Forum's MD-4:2018-IAF "Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes.**
- b. **A desk review option can only be chosen for announced and pre-assessment audits.**

- c. The desk documentation review is optional for an organization when the organization is applying for an on-site auditing option. The desk review is mandatory for an organization when the organization is applying for a remote auditing option.
- d. The CB has the responsibility to review an organization's desk review request depending upon the specific risks associated with that organization. Risks may include complaints or recalls related to the organization; history and maturity of the organization's Primus Standard Audit food safety management system; pending compliance or legal issues; significant changes to their management or operation system, for example, a change of physical location, a change in the scope of activities, etc.
- e. The CB must verify that the organization and the auditor have an agreed audit plan to ensure the desk review will be finalized prior to the on-site/remote audit.
- f. The CB and the organization shall use the compliance grid tool developed by Azzule, i.e. the Certification Program Owner, or another secure data sharing methods to perform the desk review process.
- g. The desk documentation review, including non-conformances, should not be discussed with the organization until completion of the on-site/remote audit process.

### 8.3 Audit Execution

- a. The audit **shall** be performed using the most recent version of the Primus Standard Audits Normative Documents.
- b. The Primus Standard **consist of five audit types:**
  - i. **Farm**
  - ii. **Indoor Agriculture**
  - iii. **Harvest Crew**
  - iv. **Facility** with or without Hazard Analysis Critical Control Point (HACCP) Option.
    - **Processing audit type must be performed with HACCP.**
    - **Facility templates should be performed with HACCP if a customer requirement.**
  - v. **Primus Preventive Controls Addendum - GMP v20.06 is optional to the facility.**
- c. The scope of certification should be **clearly defined prior to the audit**. Ownership of the different areas, locations, activities or crops of the company applying for certification are elements to consider when deciding what types of operation(s) will be included in the scope. That decision should be made by the applicant organization. The auditor must perform the audit based on the defined scope. **A scheduled Pre-Assessment audit cannot be converted into a certification audit once the audit has begun or post audit, i.e. during on-site documentation review or visual inspection.**
- d. The maximum number of times that an auditor can be assigned consecutively to audit the same organization is three. The fourth consecutive audit should only occur with justifiable reasons, e.g. auditor availability, auditee location, etc.

## 9. Evaluation

### 9.1 Individual Question Conformance

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

The possible answers to the questions in each Option are listed below:	
Answer	Criteria used
Total conformance	To meet the question and/or conformance criteria in full.
Minor deficiency	To have minor deficiencies against the question and/or conformance criteria. To have single or isolated non-severe deficiencies (usually up to three) against the question and/or conformance criteria. To have covered most of the question conformance criteria, but not all.
Major deficiency	To have major deficiencies against the question and/or conformance criteria. To have numerous non-severe deficiencies (usually more than three) against the question and/or conformance criteria. To have a 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, there are some questions that do not allow for Non-applicable answers.

- d. Each question in the Primus Standard Audits Checklist should be looked at individually and answered according to the auditor's observations during the audit.
  - i. The number of deficiencies and the risks associated with them should be considered when assigning the severity of the finding, which can be a Minor Deficiency, Major Deficiency, or Non-Conformance. When no deficiencies are found, a Total Conformance is given. When the requirement is not applicable for the operation being audited, a Non-applicable answer is given. Some general statements for the scoring decisions are described in the table above. 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, etc.).

### 9.2 Scoring System

- a. Each question in the Primus Standard Audits 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 scoring system for each question is described in the table below.

Scoring System				
<i>Possible answer</i>	<i>Possible Points for the question</i>			
	<b>15 points</b>	<b>10 points</b>	<b>5 points</b>	<b>3 points</b>
<b>Total conformance</b>	15 points	10 points	5 points	3 points
<b>Minor deficiency</b>	10 points	7 points	3 points	2 points
<b>Major deficiency</b>	5 points	3 points	1 points	1 points
<b>Non-conformance</b>	0 points	0 points	0 points	0 points
<b>Not applicable</b>	0 points	0 points	0 points	0 points

- c. It is important to note that for all questions answered Non-applicable, the points assigned to that question will be taken out of the total possible score, so calculations are not affected by those answers.
- d. The section titled *Additional Questions (Not Part of the Overall Food Safety Percentage)* in each audit type is required but the scoring will not be used in the calculation of Overall Total Score. These questions are to will help assess the organization’s readiness to achieve certification against a GFSI recognized certification programs.

9.3 Scoring

- a. For all audits, the Overall Total Score calculated will need to be  $\geq 85\%$  in order to achieve certification.
- b. The scores shall be displayed in rounded down whole number percentages.
- c. Although corrective actions can be submitted, they will not be considered in the calculation in the Overall Total Score.

9.4 Automatic Failure

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

9.5 Special Circumstances

- a. Automatic Failure
  - i. The CB reserves the right to fail the audit due to special circumstances. Some examples include deliberate illegal activities, physical acts/threats to an auditor, attempted bribery, falsified records, etc., or finding serious food safety issues during the audit.

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

## 9.6 Surveillance Audits

- a. Surveillance Audits Performed by the CBs
  - i. Each CB must have a surveillance program and conduct unannounced audits on their certified organizations that received an announced or unannounced certificate following 8.1 Application (a) viii. The unannounced audits will be performed using the current Primus Standard checklist (if mandated for all audits at the time of the unannounced audit) or the version the chosen organization(s) is certified against (in the case of a surveillance audit). The selected organization with certified operation(s) must reach the scoring mentioned in Section 9.3 Scoring in order to maintain their certification.
    - Ideally, the surveillance program should include 2% of a CB's current certified organizations, based on a risk assessment approach, considering factors such as compliance history, appeals and complaints, product type (s), complexity of the process(es), or any other factors the CB determines. If the CB has  $\leq 10$  current certified organizations, one organization should be chosen for the surveillance audit in their program.

- ii. The CB will notify the organization's chosen operation(s) (using the Azzule Auditing Software) of the unannounced audit no sooner than 48 hours prior to the day of the audit.
  - iii. The organization can only reject a surveillance audit one time with justifiable reasons. If rejected on the second attempt, this will result in a suspension of all current audit certificates.
- b. Surveillance Audits Performed by the Certification Program Owner
- i. As part of the Primus Standard Integrity Program, the Certification Program Owner will perform sporadic auditor assessments. The purpose is to ensure that qualified auditors are performing the audits properly according to the Primus Standard Audits program.
    - The audited operations will be required to accept the Certification Program Owner representative(s) on-site during the audit.
    - The Certification Program Owner representative conducting the auditor assessment on-site will have no say during the audit nor will they point out any deficiencies to the auditor at the time of the audit.
  - ii. The Certification Program Owner will also have the option to perform auditee assessments, which will consist of the Certification Program Owner performing an on-site audit for a certified operation. These surveillance audits will be performed using the current Primus Standard checklist or the version the certified organization is certified against, and the selected organization with certified processes must reach the same scoring as a certification audit (mentioned in the Evaluation section of this document) in order to maintain its certification.
    - By performing these audits, the Certification Program Owner will be able to verify auditor performance (based on the prior audit report) at the time of the certification audit.
    - The audited operations will be required to accept a second person on-site during the audit.

## 10. Requirements for Audit Reports

- a. The audit report will be always issued from the Azzule Auditing Software database.
- b. After each audit, the auditor must enter the information into the Azzule Auditing Software database to generate an audit report within 15 calendar days.
- c. The audit report will be written in the language that the applicant requests (English and Spanish are current languages available in the Azzule Auditing Software database).
- d. Minimally, every audit report shall include:
  - i. Name of the CB
  - ii. Name of the applicant organization
  - iii. Details about the operation under certification
  - iv. Audit Duration (date and time of the audit: start and finish of the documentation review and of the visual inspection/walkthrough)
  - v. Name and version of the Primus Standard Audits normative documents used for certification

- vi. Audit scope – details of the process under certification
  - vii. Product(s) observed during audit; Product(s) not overserved but of a similar risk type to what was observed; Product(s) not observed and not of a similar risk type to what was observed.
  - 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 Primus Standard Audits checklist. These will be responded to base on guidance from the Certification Program Owner.
  - xii. Any other additional information required by the Certification Program Owner (e.g., GPS points, etc.).
- e. Additionally, every audit will generate a non-conformance report that will give a summary of all the non-conformances found in the audit, with the corresponding comments and details for each non-conformance.

## 11. Non-conformances and Corrective Actions

- a. For all non-conformances (scored as zero points) raised during the audit, the applicant organization should submit corrective actions into the Azzule Auditing Software database. The submission of comments and/or corrective actions does not change the audit score, but should demonstrate that actions were taken or are to be taken by the applicant organization.
- b. 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.
- c. The corrective actions from the organization should include the determination of cause(s), including 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.

## 12. Certification Decision

### 12.1 Certification Process

- a. If the Overall Total Score is  $\geq 85\%$ , the certification decision will automatically be made in the Azzule Auditing Software.
- b. The audit report may be reviewed by the authorized CB personnel to make the decision of whether or not to grant certification. These CB personnel shall be impartial and technically capable of reviewing the outcome of the audit reports, including but not limited to:
  - i. The certification scope (operation, products, etc.)
  - ii. Percentage Scores by module and for the entire audit
  - iii. Evidence that the appropriate corrective actions have been taken to resolve any outstanding non-conformances

## 12.2 Issuing Certification

- a. The **Primus Standard Audits** certification will be issued individually to each operation that complies with the minimum scoring criteria.
- b. Primus Standard is valid for a maximum period of 12 months from the audit date.
- c. The certificate must be issued from Azzule **Auditing Software**.

## 13. Sanctions

### 13.1 Sanctioning of CBs

- a. Suspension of an approved Primus Standard CB - A CB shall be suspended if:
  - i. The CB's ISO/IEC 17065 or its equivalent accreditation for a separate food safety audit certification program has been suspended so that the CB cannot maintain such accreditation when performing audits and certification under the Primus Standard Audits program.
  - ii. The CB does not pay the agreed upon fees.
  - iii. The CB improperly uses the Primus Standard logo or trademark.
  - iv. An issue is discovered by the Primus Standard Integrity Program.
  - v. The CB does not abide by the requirements of the General Regulations, License Agreement, or other **Certification Program** requirements.
- b. **Revocation of an approved Primus Standard CB** - A CB shall have its approval revoked if:
  - i. Evidence of fraud is found
  - ii. The CB declares bankruptcy
  - iii. A suspension related issue is not adequately resolved
- c. **Any change in the status of the CB will be reflected on the Primus Standard Audits website.**

### 13.2 Sanctioning of Certified Organizations

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

- 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 the new observation(s).
  - An organization does not pay the agreed fees.
  - An organization rejects a surveillance audit on the second CB notification.
  - The organization improperly uses the Primus Standard Logo or trademark.
  - An organization is involved with an illegal activity or a critical food safety violation.
- ii. Revocations - an organization's certification shall be revoked if:
- Evidence of fraud is found
  - A suspension related issue is not adequately resolved
  - The organization declares bankruptcy
  - An organization that has had its certification revoked shall not be accepted for certification in the Primus Standard Audits program for a period of six months after the date of revocation.
- f. The CB shall always notify the Certification Program 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.

#### 14. 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 Certification Program Owner by using the Azzule Auditing Software or by any other means established by the Certification Program Owner.
- b. The documented audit reports generated by the CB during the certification process for each operation, including those submitted through the Azzule Auditing Software, should be provided to the applicant, the CB and the Certification Program 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 except where required by law and the normative documents; the CB shall not release any applicant certification activity information to any outside party without the applicant's authorization. The CB shall document all communications between the CB and applicant, whereby the applicant authorizes the release of certification information to an outside party.

#### 15. Extension of Scope Certification

- a. An organization's certified operation can apply for an extension of scope to their current certification for:

- i. Increased growing area of an already certified operation, if the operation has “like commodities” in terms of risk, along with justifiable circumstances.
  - ii. Adding products to already certified operations, with justifiable circumstances.
  - iii. If products are approved and added to the current report, the product(s) will be added to the “Product(s) not observed but of a similar risk type to what was observed;” or “product(s) applied for but not observed” categories.
- b. Justifiable circumstances will be reviewed at the CB level and include all relevant information, such as: similarity (risks, processes, location and personnel) between new products and already certified products, and any additional information the CB considers as part of their risk assessment. The CB will have to review all information before a decision regarding a request for extension of scope of increased growing area and/or adding new commodities is granted.
- c. The CB will determine if there is a need to visit to the organization that requests a scope extension due to the increased 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.).

## 16. Use of Logo and Trademark

- a. The Primus Standard trademark and logo may only be used with the Certification Program Owner’s permission.
- b. The CB must always obtain the Primus Standard logo from the Certification Program Owner. This will ensure that it contains the exact corporate color and format.
- c. The CB is responsible for controlling certified operations’ use of the Primus Standard trademark and logo. The rules for the use of the logo and trademark will be defined in the License Agreement signed between the Certification Program 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 Primus Standard Audits certificate linked to that organization, and when the organization makes it clear which operations are certified. The logo can only be used for business-to-business communications.
- e. Primus Standard approved CBs can use the trademark and/or logo for promotion of their Primus Standard Audits certification activities in business-to-business communications.