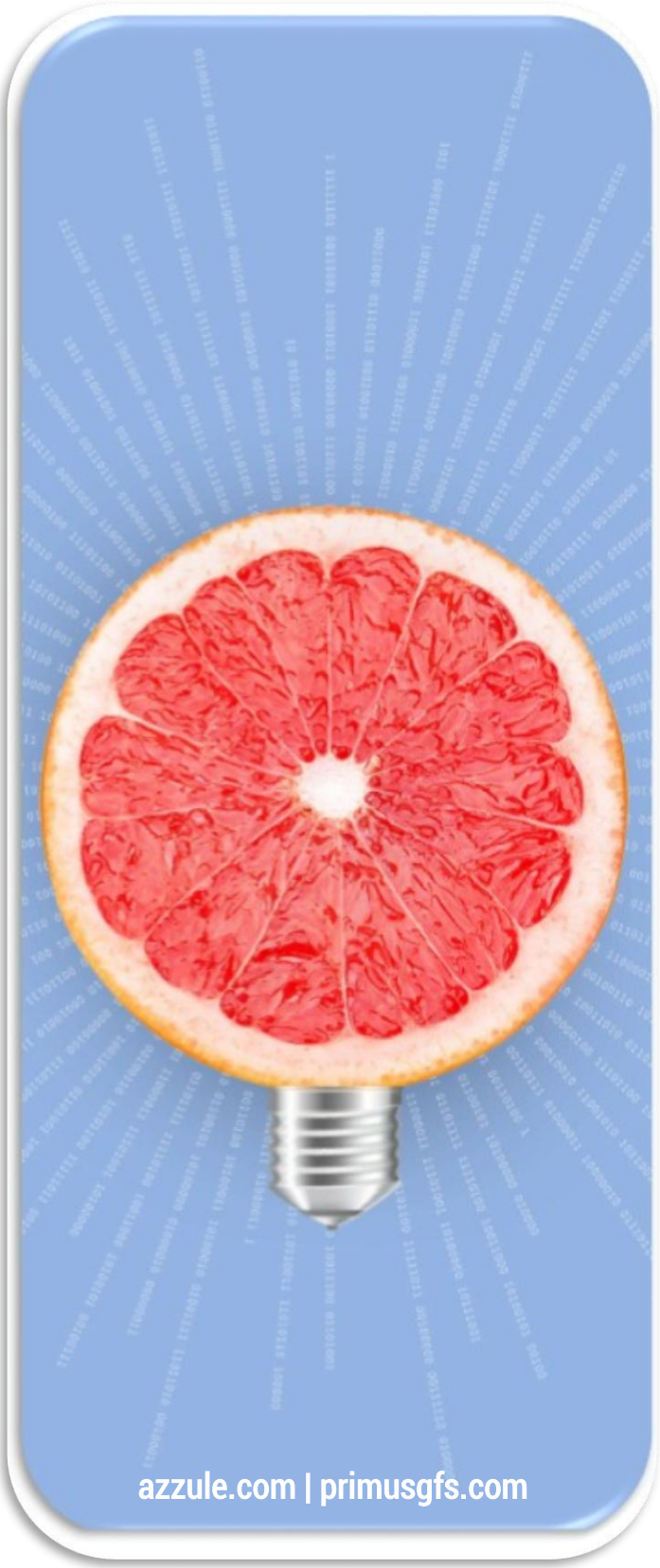
PrimusGFS v4.0

Module 7 – Food Safety Plan (*Preventive Controls*)

Questions & Expectations

2025



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

The Questions & Expectations document is the annotated version of the audit checklist. Each question is accompanied by summarized expectations, outlining: the scope of what is being evaluated; the minimum requirements or evidence needed to meet compliance and clarifications or examples of acceptable practices.

The document is designed to ensure a consistent understanding of each audit criterion and to help both auditors and auditees interpret and apply the standards effectively during audits or preparations.

PrimusGFS v4.0 updates are shown in red, along with additional considerations to be aware of for existing and new questions.

Introduction

PrimusGFS v4.0

Acknowledgements

PrimusGFS v4.0 reflects Azzule Systems' ongoing commitment to strengthening food safety systems by aligning with the Global Food Safety Initiative (GFSI) 2024 Benchmarking Requirements, evolving regulatory frameworks (including the FDA FSMA), and global industry best practices.

PrimusGFS will undergo the GFSI benchmarking process during 2025.

This version incorporates updates resulting from:

- Feedback gathered through the public stakeholder consultation process (concluded June 14, 2024).
- Regulatory developments and scientific advancements.
- Revisions to improve clarity, organization, and audit efficiency.
- Renaming and reorganization of sections.
- The addition of new requirements and questions, particularly for GFSI BMR 2024, CEA (Controlled Environment Agriculture), FSMA Pre-Harvest Agricultural Water, Harvest Crew Equipment Sanitation and traceability.
- And alignment with terminology from Codex Alimentarius and FSPCA Preventive Controls.

Key structural improvements include the introduction of new sections and questions, the removal or consolidation of preexisting questions, and rewording for greater clarity and simplification of requirements.

As with previous versions, PrimusGFS v4.0 has been shaped by the generous contributions of stakeholders across the food safety community, including Certification Bodies, Training Centers, industry experts, and end users. Azzule Systems is deeply grateful for their time, experience, and dedication to advancing safe and sustainable food production worldwide.

We extend our sincere appreciation to all individuals and organizations who submitted suggestions, participated in consultations, and offered expert insight during the development process of version 4.0.

Auditees have the option to present combined HACCP and Preventive Control Systems, but auditors must report/score separately.

This module applies to both domestic (U.S.) and foreign food facilities (outside the U.S.) that are required to register under Section 415 of the Food, Drug, and Cosmetic Act and comply with the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food requirements mandated by the FDA Food Safety Modernization Act (FSMA).

Question No.	Question	Total Points	Expectation
General			
7.01.01	Is there a team responsible for the Food Safety Plan at the operation, with a leader assigned for the development, implementation and on-going maintenance of the Food Safety Plan?	10	There should be a documented list of the team carrying out the Food Safety Plan in the operation, with one member of the team (a preventive control**s** qualified individual), who has successfully completed training recognized as adequate by FDA in the development and application of risk-based preventive controls (or is otherwise qualified) designated the preventive control coordinator (leader). The team should be multidisciplinary and include people from production, quality, sanitation, maintenance, shipping, procurement, sales, external consultants, etc. The size of the team will depend on the size of the operation and the processes performed.
7.01.02	Is there documented evidence that the food safety team members have been trained on Food Safety Plan development?	15	The preventive control coordinator should have a certificate of a formal Preventive Controls Qualified Individual (PCQI) training from a recognized organization, institution, or trainer. The rest of the team should have at least an internal training given by someonewho has gone to formal Preventive Control**s** Qualified Individual training to make sure they are knowledgeable of the Food Safety Plan development. These trainings should be documented.
7.01.03	Does a product description exist for the products produced?	10	Product description(s) should clearly describe the product and its distribution and be used to determine if specific controls are important throughout the distribution chain. The description should detail the products' name and composition (ingredients) including any important food safety characteristics (e.g., descriptors such as ready-to-eat (RTE), frozen, factors that can influence growth of pathogens (e.g., pH, water activity (a_w), contains preservatives), packaging used (types, material, reduced oxygen), the intended use (retail, food service, further processing), intended consumers (general public or if product is specifically intended for susceptible populations), shelf life, labeling instructions related to food safety (e.g., "keep refrigerated", cooking instructions), storage and distribution requirements (e.g., whether food is stored &/or distributed refrigerated, frozen or at ambient temperatures).
7.01.04	Has the process(es) been flow diagrammed in sufficient detail to completely describe the process or product handling/processing steps?	10	The purpose of a process flow diagram is to provide a clear, simple description of the steps in the process as they "flow" from receipt to distribution and identifies each of the steps that must be evaluated in the hazard analysis. Groups of similar products (including ingredients) going through the same process can begrouped in the same flow chart. The flow diagram should indicate all raw materials, ingredients and materials used in all preparation steps, all equipment used (e.g., pumps, tanks, hoppers, fillers), blending steps, processing steps, rework, by-product, returned products and productsdestined for further processing, packaging materials(carton and unit packaging) and packaging equipment. All inputs should be included, such as packaging, water source (e.g. city or well), ice, anti-microbials, fungicides, etc. Each step should show any holding times, temperature regimes, etc., at appropriate process steps. Flow diagram should show rework processes and when product is diverted to be used for other purposes. Process flows may be augmented by written process descriptions to explain in more detail what happens at each of the process steps.

Question No.	Question	Total Points	Expectation
Development of the Food Safety Plan			
7.02.01	Has a documented hazard analysis for each product (or product group) been conducted, showing the various types of hazards, their likelihood of occurrence, their associated severity and their preventive controls?	15	There should be a detailed, documented hazard analysis for each product or product group (including ingredients) process flow in order to prove that a proper hazard analysis was conducted. Similar products (e.g. similar in formulation, have similar processing steps and are prepared and packaged in a similar manner, etc.) may be grouped. Each step identified in the process flow diagram should be assessed in the hazard analysis. Justifications should be documented when identifying hazards that require a preventive control. Consideration should be given to what preventive controls, if any exist, can be applied to each known or reasonably foreseeable (i.e., potential) food safety hazard. More than one preventive control may be required to control a specific reasonably foreseeable food safety hazard(s), more than one hazard may be controlledby a specified preventive control and not all potential hazards require a preventive control. Preventive controls, such as process, allergens, sanitization, and supply chain should be identified for the identified potential hazards.
7.02.02	Where risk-based preventive controls are identified, have reasonably appropriate procedures, practices, and processes been developed to control identified hazard(s) are they appropriate and consistent with current scientific understanding?	15	Preventive control decisions should be properly justified with supporting documents and evidence. Preventive controls may include process preventivecontrols, food allergen preventive controls, sanitation preventive controls, and supply chain program as well as other preventive controls. Preventive controls should be created from the documented hazard analyses, i.e. there should be a logical documented approach showing why the process was deemed a preventive control or not. The preventive controls identified in the hazard analysis should be described, defining in detail the parameters involved and monitoring requirements, thresholds, corrective actions and verification requirements in order to control the hazard(s).
7.02.03	Do the process preventive controls have critical limits, supported by relevant validation documentation, and do allergen, sanitation, supply chain or other preventive controls have parameters, values and targets (where relevant)?	15	Process preventive controls should have critical limitparameters (which are supported by validation documentation), that are scientifically derived and meet any relevant legal requirements. Validation approaches could take the form of scientific principles and data, expert opinion, plant observations, testing, etc. (i.e., publicly available legislative documents, industry best practice documents, peer reviewed research papers, on site validation studies, etc.), or a mix of different validation sources. Validation of allergen, sanitation, supply chain or other preventive controls is not required but the operation could consider under certain circumstances or for certain preventive controls such as sanitation related controls.
7.02.04	Have monitoring requirements and frequencies been determined and documented for the preventive controls?	15	There should be determined and documented monitoring requirements and frequencies for the preventive controls. Monitoring applies not only to process preventive controls but also to identified allergen, sanitation and supply chain preventive controls as appropriate to the food safety program. The plans and/or procedures should note the responsibility and frequencies of monitoring for each preventive control. Monitoring activities will vary between preventive control types.

Question No.	Question	Total Points	Expectation
7.02.05	Are there documents that show validation work for the process preventive controls and was this validation work performed by or overseen by a Preventive Controls Qualified Individual?	10	Validation is applying scientific concepts and demonstrating that following the plan will control the identified hazards. Process preventive controls should document validation work performed or overseen by a qualified individual. Validation is required for most process controls when hazards requiring a preventive control are identified. Validation is ideally done before the plan is implemented. Where relevant, other preventive controls types e.g. sanitation-related preventive controls (e.g. how long processing line can run between cleaning, allergen controls) should be supported by validation work and all validation work dated within 90 days of starting production, or within a reasonable timeframe with written justification of the PCQI, when a control measure, product or process change.
7.02.06	Do the Food Safety Plan, charts and/or procedures indicate that specific responsibilities have been assigned for the monitoring, recording, verification, and corrective action implementation?	10	Specific responsibilities should be assigned for the monitoring, recording, verification, and corrective action implementation of each preventive control to ensure compliance.
7.02.07	Have standard operating procedures (SOPs) been created for the monitoring process(es) of the preventive controls, including those in plan or chart format (e.g., process preventive controls)?	10	Clear and simple standard operating procedures (SOPs) should be written for each monitoring process(es) of the preventive controls, even those that are documented in plan or chart formats (e.g., process preventive controls). These SOPs should expand the monitoring activities in detail in the form of work instructions, and match what is written in the preventive controls plan.
7.02.08	Have corrective action procedures been established for the preventive controls, including a detailed action plan for operators to follow if out of specification situations are observed (loss of control/deviation) and plans to adjust process back into control?	15	Corrective actions are procedures that must be taken if preventive controls are not properly implemented (e.g. there is a deviation from a critical limit) and unsafe product may have been produced. There should be a documented, detailed plan with procedures to follow when there is a loss of control (deviation) of a preventive control appropriate to the nature of the hazard and preventive control. Requirements vary for process, food allergen, sanitation and supply chain program preventive controls. Corrective action details for a process preventive control should note the critical limit issue that has occurred, what corrective actions were carried out, including what happened to potentially affected product and also how the process was "repaired" or "amended" in order to get the process back to the required control level. Preventive measures and root cause analysis may be appropriate.
7.02.09	Have recording forms been developed for monitoring the preventive controls?	15	Defined record templates are required for recording preventive control monitoring. The parameters on the records should reflect those in the Food Safety Plan. These templates should be managed under the document control program. Monitoring recording requirements vary depending on preventive control type.

Question No.	Question	Total Points	Expectation
7.02.10	Have verification procedures and schedules been developed for the preventive controls?	15	Preventive controls should have documented verification activities associated with the monitoring that verifies the correct implementation of the preventive controls. Examples of verification include preventive control monitoring and corrective action record reviews, testing associated with preventive controls, equipment inspection associated with preventive controls, 2nd & 3rd party supplier audits, testing related to raw materials, internal audits, equipment calibration and accuracy, etc. Some verification activities should be performed or overseen by a preventive controls qualified individual. Also, some of the verification activities, such as testing and auditing, benefit from record reviews and trend analysis. Where verification activities have found that preventive controls were not performing as required, there should be records that show that this prompted a review of the relevant part of the Food Safety Plan.
7.02.11	If any preventive control has been identified, does the operation have a documented and implemented recall plan?	10	A recall plan is required when a hazard requiring a preventive control is identified as a result of conducting the hazard analysis. A pre-defined recall plan is required to define who and how to notify direct customers and consignees, notify the public (when appropriate), how to conduct the investigation, define responsibilities, coordinate actions, etc. Cross reference with 1.07.02.
7.02.12	Is there documented evidence that the food safety plan (primary documents in the preventive controls food safety system) has been verified on-site?	10	The Food Safety Plan (FSP) should be verified on- site and signed and dated by the owner, operator or agent in charge of the facility whenever it is first completed and whenever the plan is modified. This may be a signed and dated cover page or table of contents of grouped documents or of individual documents making up the FSP.
Execution of the Food Safety Plan			
7.03.01	Is there documented evidence that all plant workers have attended a preventive control training, including specific training for workers directly involved with preventive controls?	10	Preventive control training is important in ensuring that all workers are knowledgeable regarding the basics of preventive controls. This training is especially important for workers directly involved with preventive control operations, and for those workers, the training should cover the explanation of the procedures in which they are responsible and be included in the training management program (see 1.01.04). All training activities should be documented.
7.03.02	Are the preventive control monitoring activities and frequencies in compliance with the Food Safety Plan, charts, and procedures?	15	The monitoring records should show that testing frequency, parameters and any other details match what is written in the Food Safety Plan, charts, and procedures. The records should show actual values or observations, be accurate and legible, be real-time recording and have adequate detail.
7.03.03	Do workers directly involved with preventive control operations understand basic preventive control principles and their role in monitoring preventive controls?	10	Individuals should understand the basics of a Food Safety Plan and how it applies to their operations. Individuals should have a good understanding of the details of the preventive controls that they are directly involved with, including procedures, parameters, critical limits in the case of process preventive controls and corrective action procedures. Auditor should interview operators to verify.

Question No.	Question	Total Points	Expectation
7.03.04	Are preventive control associated records signed off (or initialed) by the workers who are carrying out and recording the preventive control activities?	15	Records should be legibly signed off in order to show who actually performed the preventive control monitoring activities. If initials are used, there should be a way to easily determine who the initials refer to.
7.03.05	Is there a deviation record detailing documented corrective actions when a deviation or deficiency of a preventive control occurs?	15	When a monitoring or verification step shows a deviation or deficiency against a preventive control (including when a critical limit is exceeded), the incident should be recorded on a deviation record (or similar form), along with actions taken. This includes recording what happened to the affected product, how the situation was rectified and any preventative actions taken to avoid future similar issues in the future. This may include root cause analysis.
7.03.06	Are the records associated with preventive controls verified and signed off by a preventive controls qualified individual or trained designate (second signatory)?	10	Preventive control records should be reviewed, verified, dated and signed off by the designated person(s) responsible i.e. preventive controls qualified individual-PCQI or trained designate within 7 working days of the original preventive control monitoring activity occurring. Ideally records are reviewed prior to release of product to prevent potential recall and unintended consequences should a deviation be found during record review. The sign off should not be done by the same person who carried out the preventive control monitoring activities. If any issues are detected, corrective actions should be recorded.
Re-analysis of the Food Safety Plan			
7.04.01	Is there documented evidence that there is a re-analysis of the Food Safety Plan at least once every 3 years and when significant changes are made?	10	At least every 3 years there should be a documented re-analysis of the preventive controls plan and when any significant change occurs (e.g. changes in raw materials, packaging, suppliers, product, process, construction, new equipment, recurring deviations, new scientific information, new distribution or consumer handling practices, etc.). Where emerging issues,such as recalls, an outbreak, new research, etc., are relevant to the products and processes at hand, consideration of a preventive controls re-analysis should occur. This should include a written record which demonstrates each of the of the elements of the preventive controls plan (including but not limited to the hazard analysis, review of records and trends e.g., monitoring, corrective actions) have been verified and that the system is operating according to the plan. There should be a change record included in the plan to track changes over time. Documented re-training or educational sessions may be necessary as a result of the re-analysis.

Where laws, commodity specific guidelines and/or best practice recommendations exist and are derived from a reputable source, then these practices and parameters should be used. Audit users should allow a degree of risk association if laws, guidelines, best practices, etc., have not been documented.

Document Revision History		
Date	Rev.#	Description
31/07/2025	0	Initial