



PrimusGFS v4.0

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

Checklist 2025

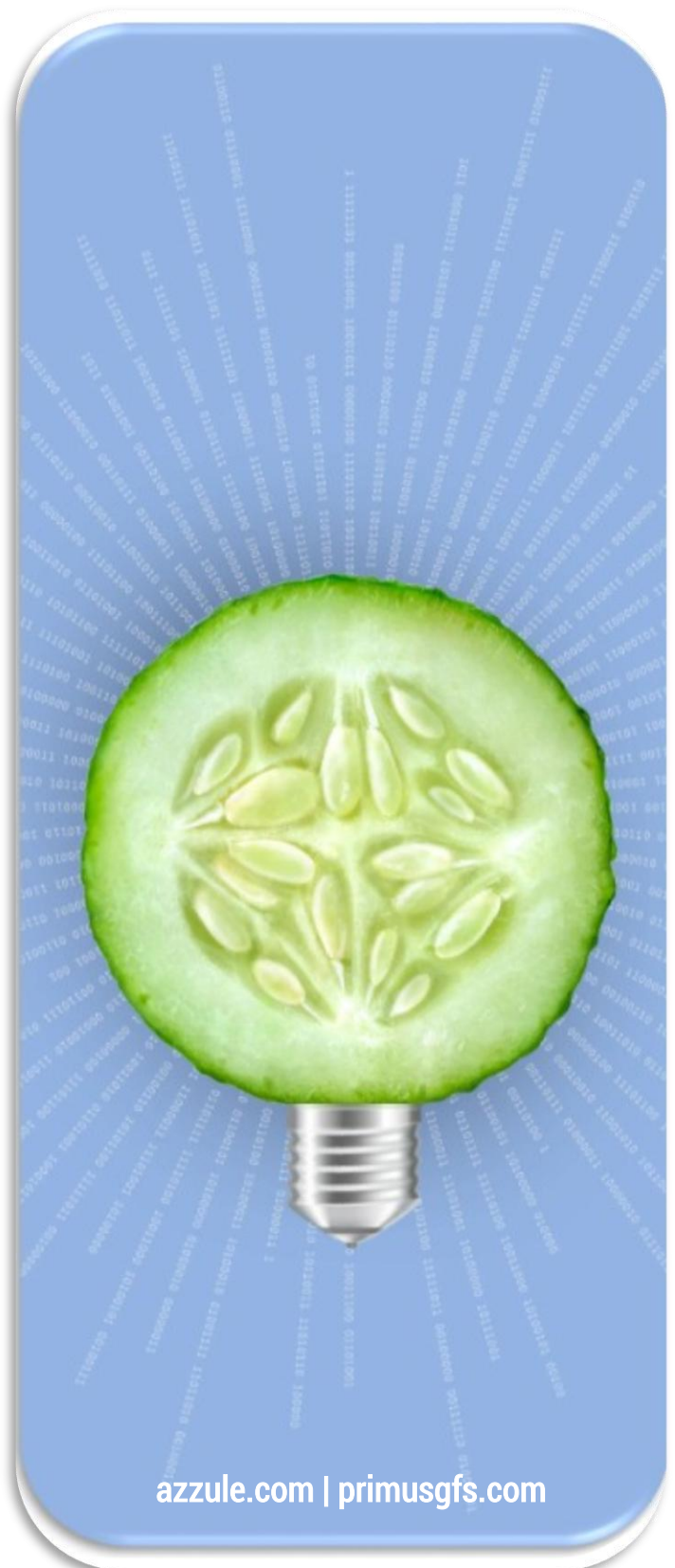
A Normative Document in the context of PrimusGFS refers to the official set of criteria that defines what requirements must be met, and how compliance is evaluated during an audit. These documents serve as the foundation for PrimusGFS audits and are essential for ensuring consistency, objectivity, and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

The PrimusGFS Checklist document is A blank audit checklist that includes all the questions from the applicable audit modules. This version does not include guidance or scoring detail and is intended to be used as a practical tool to:

- Perform internal audits or self-assessments by the auditee.
- Conduct official audits by certified auditors.
- Serve as a tracking tool to monitor ongoing compliance or improvements.

The document is designed to be a tools that provide a structured and standardized way to evaluate food safety practices during audits. They help ensure consistency in the auditing process.

PrimusGFS v4.0 updates are shown in red.



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.
- 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.
- 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	Auditor Comments
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	
7.01.02	Is there documented evidence that the food safety team members have been trained on Food Safety Plan development?	15	
7.01.03	Does a product description exist for the products produced?	10	
7.01.04	Has the process(es) been flow diagrammed in sufficient detail to completely describe the process or product handling/processing steps?	10	
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 ? This question must be scored. NA is not allowed.	15	

Question No.	Question	Total Points	Auditor Comments
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	
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	
7.02.04	Have monitoring requirements and frequencies been determined and documented for the preventive controls?	15	
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	
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	

Question No.	Question	Total Points	Auditor Comments
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	
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	
7.02.09	Have recording forms been developed for monitoring the preventive controls?	15	
7.02.10	Have verification procedures and schedules been developed for the preventive controls?	15	
7.02.11	If any preventive control has been identified, does the operation have a documented and implemented recall plan?	10	
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	

Question No.	Question	Total Points	Auditor Comments
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	
7.03.02	Are the preventive control monitoring activities and frequencies in compliance with the Food Safety Plan , charts, and procedures?	15	
7.03.03	Do workers directly involved with preventive control operations understand basic preventive control principles and their role in monitoring preventive controls?	10	
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	
7.03.05	Is there a deviation record detailing documented corrective actions when a deviation or deficiency of a preventive control occurs?	15	
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	



Question No.	Question	Total Points	Auditor Comments
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	

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