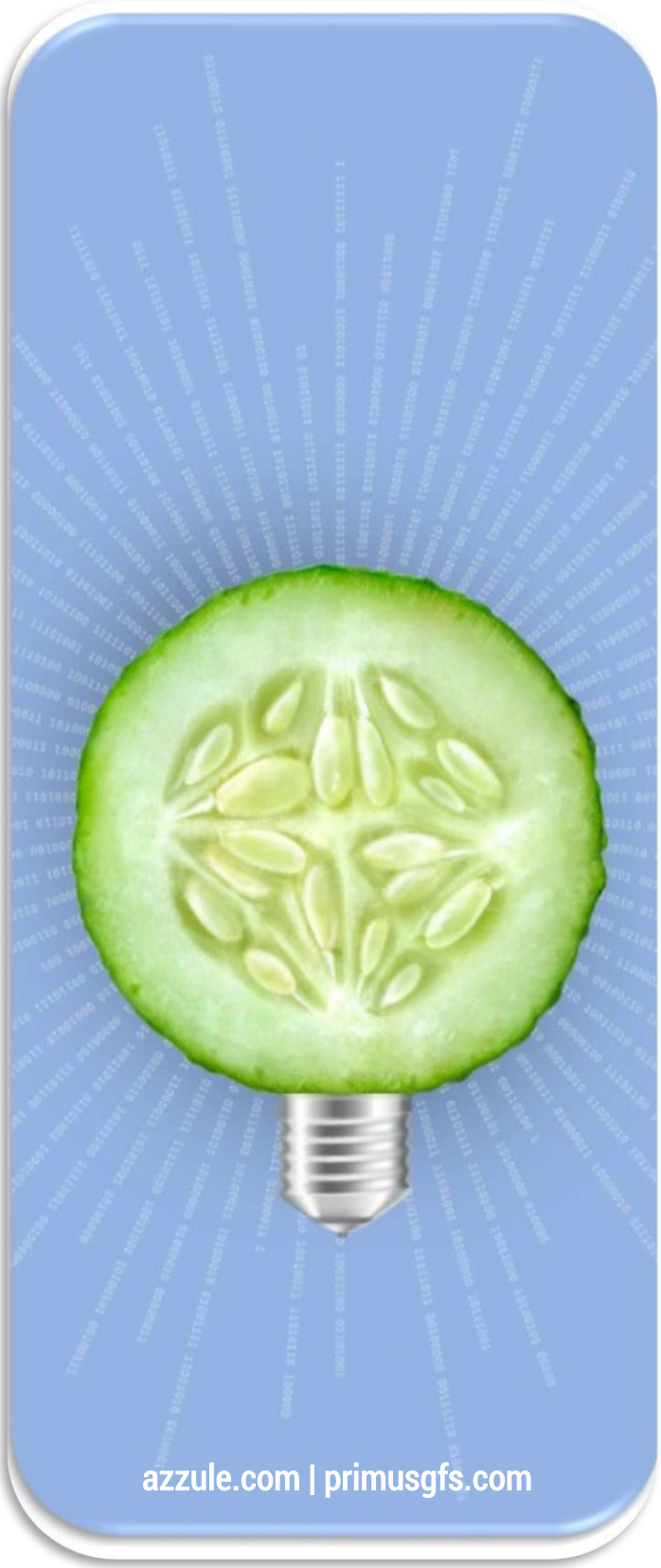
PrimusGFS v4.0

Module 1 - FSMS

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.

This Module should be completed for each one of the facility operations in the scope of the organization's application.

Module 1- FSMA – Food safety Management System

Question No.	Question	Total Points	Auditor Comments
Management System			
1.01.01	Is there a documented food safety policy detailing the company's commitment to food safety?	5	
1.01.02	Is there an established, implemented, and maintained food safety culture assessment plan that includes at least the following elements: communication, training, employee feedback, and performance measurement on food safety-related activities?	5	
1.01.03	Is there an organizational chart showing all management and workers who are involved in safety related activities and documentation (job descriptions) detailing their food safety responsibilities?	10	
1.01.04	Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?	5	
1.01.05	Is there a training management system in place that shows what types of training are required for various job roles of specific workers, including who has been trained, when they were trained, which trainings they still need to take, and a training schedule?	5	
1.01.06	Is there a documented allergen control program?	10	

Question No.	Question	Total Points	Auditor Comments
1.01.07	Is there documented management verification review of the entire food safety management system at least every 12 months, including an evaluation of resources, and are there records of changes made?	15	
1.01.08	Where specific industry guidelines or best practices exist for the crop and/or product, does the operation have a current copy of the document?	3	
Control of Documents and Records			
1.02.01	Is there a written document control procedure (including document control register/record) describing how documents will be maintained, updated and replaced?	5	
1.02.02	Is there a documented and implemented procedure that requires all records to be stored for a minimum period of 24 months (or greater if legally required) or for at least the shelf life of the product if it is greater than 24 months?	3	
1.02.03	Are both paper and electronic food safety related documents and records created, edited, stored and handled in a secure manner?	5	
1.02.04	Are records maintained in an organized and retrievable manner?	3	

Question No.	Question	Total Points	Auditor Comments
1.02.05	Are all records and test results that can have an impact on the food safety program verified by a qualified person independent of the individual(s) completing the records?	5	
Procedures and Corrective Actions			
1.03.01	Is there a written and standardized procedure for creating Standard Operating Procedures (SOPs) and their content?	5	
1.03.02	Are the written procedures available to relevant users and is a master copy maintained in a central file?	5	
1.03.03	Is there a documented corrective action procedure that describes the basic requirements for handling all non-conformances affecting food safety?	5	
1.03.04	Is there an incident reporting system, also known as a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA)?	5	
Internal and external inspections			
1.04.01	Is there a documented procedure for how internal audits are to be performed at the operations, including frequency and covering all processes impacting food safety and the related documents and records?	10	
1.04.02	Is there documented evidence of the internal audits performed, detailing findings and corrective actions?	15	
1.04.03	Are there written procedures for handling regulatory inspections?	3	
1.04.04	Are there records of regulatory inspections and/or contracted inspections, company responses and corrective actions, if any?	5	

Question No.	Question	Total Points	Auditor Comments
1.04.05	Are there documented calibration and/or accuracy verification procedures for measuring and monitoring devices used in the operations that are related to the safety of the product?	10	
1.04.06	Are calibration and/or accuracy verification records maintained and are they consistent with the requirements outlined in the SOP(s) for instruments and measuring devices requiring calibration?	5	
Release of items/product			
1.05.01	Is there a documented product release procedure available?	5	
1.05.02	Are there records of product releases kept on file?	5	
1.05.03	Is there a documented procedure for handling on hold and rejected items?	5	
1.05.04	Are there records of the handling of on hold and rejected items kept on file?	5	
1.05.05	Is there a documented procedure for dealing with customer and buyer food safety complaints/feedback along with records and company responses, including corrective actions?	10	

Question No.	Question	Total Points	Auditor Comments
Supplier/Service Provider Monitoring & Control			
1.06.01	Is there a written procedure detailing how suppliers and service providers are evaluated, approved, and include the ongoing verification activities including monitoring?	10	
1.06.02	Is there a list of approved suppliers and service providers including justification for use of any emergency (temporary) suppliers or providers?	10	
1.06.03	Are there current written food safety related specifications for all incoming products, ingredients, materials, services provided on-site, and outsourced services?	10	
1.06.04	Does the organization have documented evidence to ensure that all incoming products, ingredients, materials, services provided on-site, and outsourced service suppliers comply with the approval requirements and that all supplier verification activities (including monitoring) are being followed, as defined in the supplier approval procedure?	15	
1.06.05	Where food safety related testing is being performed by laboratory service providers,	5	

Question No.	Question	Total Points	Auditor Comments
	are these licensed and/or accredited laboratories (e.g., ISO 17025 or equivalent, national and local regulations, etc.)?		
Traceability and Recall			
1.07.01	Is there a document that indicates how the company product tracking system works, thereby enabling trace back and trace forward to occur in the event of a potential recall issue?	10	
1.07.02	Does the organization have a documented recall program including procedures, recall team roles and contact details, external contact listings, requirement for recall effectiveness checks, explanation of different recall classes and handling of recalled product?	15	
1.07.03	Is testing of recall procedures (including traceback) performed and documented at least every six months, and the company can demonstrate the ability to trace materials (one step forward, one step back) effectively?	10	
Non-Intentional Contamination			

Question No.	Question	Total Points	Auditor Comments
1.08.01	Is there a written food fraud vulnerability assessment (FFVA) and protection plan for all types of fraud, including all incoming and outgoing products?	5	
1.08.02	Is there a written food defense vulnerability assessment and food defense plan based on the risks associated with the operation?	5	
1.08.03	Are records associated with the food defense plan and its procedures being maintained, including monitoring, corrective action and verification records (where appropriate)?	5	
1.08.04	Is there a documented crisis management plan?	5	
1.08.05	Is there a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies?	3	
1.08.06	Are visitors and contractors to the company operations required to adhere to food defense procedures?	3	

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

