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2019

An internationally recognized Global Food
Safety Initiative (GFSI) food safety audit scheme

QUESTIONS & EXPECTATIONS

PrimusGFS v3.1

MODULE 1

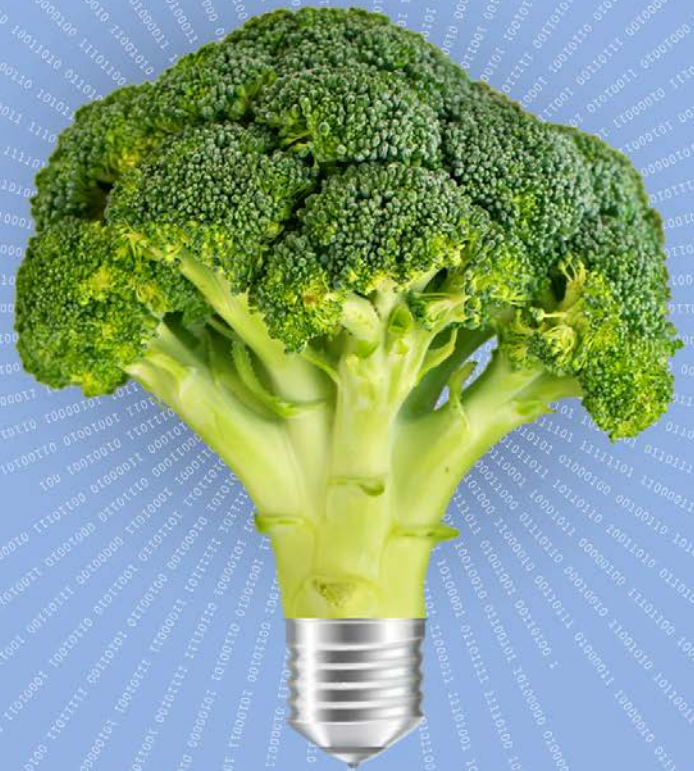**FSMS**
Food Safety Management
System Requirements

POWERED   **CONNECTED**   **SMART**

SUPPORTED   **GLOBAL**   **RECOGNIZED**

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Introduction

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Acknowledgements

Azzule Systems gained valuable feedback from several of our clients, including indoor agricultural operations in Mexico, as well as from Certification Bodies, Training Centers, and industry experts at-large during the implementation of PrimusGFS v3.0. We believe strongly in serving the needs of the various groups with which we collaborate, and in doing so worked to address all feedback and suggestions in the updated v3.1.

Version 3.1 satisfies the needs of users from a local to a global scale with flexible modules and a variety of addenda developed to ensure strength in programs, regulatory compliance, and marketability. We are grateful to those individuals and companies that provided invaluable feedback to help continually improve PrimusGFS.

Azzule would like to thank the following individuals for their contributions to v3.1: Our Certification Bodies and Training Centers, and in alphabetical order, Ashley Bell (Cloche Technical Solutions), Monica Canales (Cal-Pac Food Safety), Cailin Colwell (Pasquinelli Produce), Megan Crivelli (The Produce Nerd), Debra Garrison (Debra Garrison Consulting, LLC), Pavel Gonzalez, Elena Jimenez (Sunkist Growers, Inc.), Clarisa Molina (Ser-Ka Solutions), Hector Pedraza (Robinson Fresh), Tina Price (T. Price & Associates, LLC), Jeff Saleen (Bonipak Produce), Sarah Schlicher, Bruce Wilkins (CoActive Food Group, LLC).

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PrimusGFS integrates automatically with the supply chain, compliance, and data management features of the Azzule platform which provide food producers the tools and the knowledge necessary to take action within their food safety program. Automation and integration also allows participating operations to gain market access and visibility in promoting their food safety commitments to a large network of current and potential customers.

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Questions & Expectations

MODULE 1: FSMS

Food Safety Management System Requirements

(Sections 1.01 to 1.08)

This Module should only be completed once for all the operations in the scope of the organization's application.

CONTACT:

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or by phone if you have any questions or concerns.

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MODULE 1: FSMS
FOOD SAFETY MANAGEMENT
SYSTEM REQUIREMENTS

MANAGEMENT SYSTEM

Question No.	Question	Total Points	Expectation
1.01.01	Is there a documented food safety policy detailing the company's commitment to food safety?	5	The documented policy should include a clear statement and detailed objectives of the company's commitment to meet the food safety needs of its products.
1.01.02	Is there an organizational chart showing all management and workers who are involved in food safety related activities and documentation (job descriptions) detailing their food safety responsibilities?	10	The documented organizational chart should show positions and reporting structure of workers whose activities affect food safety within the company. This document should also detail job functions and responsibilities related to food safety. Suitable alternates should be indicated in case someone can not perform the assigned responsibilities at certain moment. Document should be current and accurate.
1.01.03	Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?	5	Meetings that are either devoted to, or mention food safety issues, should be recorded as proof of company's ongoing commitment to food safety (minimum quarterly frequency). These meetings should detail Senior Management involvement in the Food Safety program.
1.01.04	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	The company has a system in place (e.g., training matrix) that shows what types of trainings are required for various job roles that affect food safety, who has been trained, when they were trained, which trainings they still need to take, and a training schedule.
1.01.05	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?	10	There should be written verification of the entire food safety management system at planned intervals (minimum every 12 months). There should be evidence that senior management is involved in the review to ensure its continuing suitability, adequacy and effectiveness and that they are continuing to support and invest in adequate food safety resources (e.g., equipment, services, supplies, personnel training, worker staffing levels, customer requirements/specifications, etc.). The review should determine the need for changes and the changes made should be documented. The documented review should meet any national or local legislative requirements.
1.01.06	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	There is a current copy of any specific industry guidelines for the crop and/or product available for review.

CONTROL OF DOCUMENTS AND RECORDS

Question No.	Question	Total Points	Expectation
1.02.01	Is there a written document control procedure (including document control register/record) describing how documents will be maintained, updated and replaced?	3	The document control procedure should show how controlled documents are to be written, coded, approved, issued and updated, and should also show how obsolete versions of documents are controlled. If using an electronic record keeping system, the procedure should cover this.
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?	5	Food safety related records should be retained for auditing purposes and in case there are legal issues, customer queries, etc. There should be a procedure in place and all monitoring and process control records should be held for a minimum of 24 months regardless of the production item's shelf life. Any records required by law to be kept longer than 24 months should be kept for the legally mandated period. Any records pertaining to long life product should be kept at least for the duration of the shelf life of the product.

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1.02.03	Are both paper and electronic food safety related documents and records created, edited, stored and handled in a secure manner?	3	Both paper and electronic documents and records that are part of the food safety program (e.g., procedures, policies, training records, testing results, monitoring records, etc.), should be stored securely and backed up in the case of electronic files. In the case of paper files, they should be generated using ink (not pencil), and if changes are made to records after initial entry, changes should be clearly legible and tracked, avoiding the use of corrective fluid. For electronic records, there should be access control and a back up of all files. When electronic records are amended, they should show what was amended, by whom and when (editing history). Records should be legible and accurate.
1.02.04	Are records maintained in an organized and retrievable manner?	3	All food safety records and documents should be stored in an organized manner, to allow for quick retrieval of records. This will aid in the detection of issues, the isolation of problems, and the identification of trends where attention is needed. Records should be accessible, even if the operation is seasonal.
1.02.05	Are all records and test results that can have an impact on the food safety program reviewed and signed off by a person responsible for the food safety program?	3	Records and test results should be reviewed and signed off by a designated person(s) responsible for the food safety program within a reasonable timeframe. The sign off should not be done by the same person who carried out the monitoring activities. If any issues are detected, corrective actions should be recorded.

PROCEDURES AND CORRECTIVE ACTIONS

Question No.	Question	Total Points	Expectation
1.03.01	Is there a written and standardized procedure for creating Standard Operating Procedures (SOPs) and their content?	5	There should be a written document that describes how to create SOPs when required to cover any food safety related activities. SOPs should include a date and document number or reference code and require detailing what is to be done, how it is done, how often, by whom, what recordings are required and any immediate corrective action to perform when deficiencies occur. There should be clear evidence that this system is being followed, based on SOPs reviewed.
1.03.02	Are the written procedures available to relevant users and is a master copy maintained in a central file?	5	The written procedures should be available to the users and other interested parties involved in performing the activities described in the procedures. A master copy of all SOPs and associated recording forms should be assembled and stored as a reference.
1.03.03	Is there a documented corrective action procedure that describes the required processes for handling non-conformances affecting food safety?	5	The corrective action procedure should outline how the operation manages corrective actions. Specifically, the determination of cause, establishment of an action plan(s) to address immediate issue(s) regarding non-conformance(s) (including any actions taken regarding affected product), corrective actions taken and the development of preventive actions to help avoid future occurrences. Records of the corrective action activities and their follow-up should be kept on file.
1.03.04	Is there an incident reporting system, also known as a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA) ?	5	This record documents unusual and infrequent events, remedial actions and preventive actions. These might include incidents like foreign object findings, chemical spills, power outages, packaging issues, glass breakage, fires, etc., as well as any other serious incidents such as natural disasters (e.g., hurricanes, flooding, earthquakes, etc.).

INTERNAL AND EXTERNAL INSPECTIONS

Question No.	Question	Total Points	Expectation
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	A written procedure for internal audits should be created covering each operation. The procedure should cover the inspection of the sites, the practices in place, the related documents required, the records generated, the recording system to be used for the audits, the frequency of the internal audits and identification of the person(s) responsible for conducting the internal audits. The internal audit records are assessed in each module.
1.04.02	Are there written procedures for handling regulatory inspections?	3	Written procedures for handling regulatory inspections allow workers to be aware of how to handle the inspection appropriately. For example, documenting the inspector's credentials, contact information to facilitate open actions after the inspection, ensuring that the inspector is always accompanied, identified meeting space, rules on taking samples and photographs, how to follow-up after the inspection, etc.
1.04.03	Are there records of regulatory inspections and/or contracted inspections, company responses and corrective actions, if any?	5	Reports of previous inspections are on file and any deficiencies noted have been responded to (date of response, action taken, and signature). Inspections include regulatory (e.g., Federal and State) and third-party audits.
1.04.04	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	Equipment used for measuring and monitoring processes related to food safety and/or verification of label requirements (e.g., for weight or volume) should be identified (i.e., catalog, roster, list) and SOPs should be available. Scales/weight or volume measuring devices should have verification of accuracy and/or calibration regularly to ensure correct and accurate operation. Calibration procedures should describe the frequency of testing, the testing method and the acceptable range of variation. Corrective actions should be detailed when applicable. Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency.
1.04.05	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	Calibration and/or accuracy verification records should be available for all applicable equipment and show frequency of testing, the testing method and the acceptable range of variation. Corrective actions should be recorded.

RELEASE OF ITEMS / PRODUCT

Question No.	Question	Total Points	Expectation
1.05.01	Is there a written procedure for handling on hold and rejected items?	5	There should be a documented procedure that explains how items (raw materials, packaging, work in progress, finished product, etc.) that have either been rejected or placed on hold should be handled, including the release of the on hold/rejected items. The procedure should identify who (position/title) is authorized to determine the disposition of materials that are placed on hold and include details on how the affected items are separated in terms of identification system (e.g., when, why, who), and any other physical separation needed to ensure that affected items are not commingled with other goods in such a way that their disposition is not clear.

1.05.02	Are there records of the handling of on hold and rejected items kept on file?	5	Records should be kept to provide information about of any item (raw materials, packaging, work in progress, finished product, etc.) that is rejected or put on hold, including at least: date and time, amount of product affected, reason for being on hold/rejected, name of the person who rejected the product or put it on hold, details of product disposition, date, time, the actions taken, and the signature of an authorized person to release the product.
1.05.03	Is there a documented product release procedure available?	5	Product release procedures are needed when the product is approved for shipment or harvest (they do not indicate the release of a product that has been placed on hold). Product release procedures assure that a lot is only released for shipment (sale) when lot meets agreed standards (e.g. specification) or meets agreed testing requirements (e.g. results confirmed negative or within limits results from testing, etc.). This includes crops approved for harvest and crop harvest where harvested product is direct picked into packaging during harvest (e.g., mushrooms, berries, individually wrapped lettuce) or there is in-field processing/semi-processing. Products should not be released for harvest or shipment without assuring that necessary evaluations have been performed. N/A for organization's that only have authority over the growing activities and operation(s), and not the harvesting activities.
1.05.04	Are there records of product releases kept on file?	5	Product release records are needed to document when the product is approved for shipment or harvest (they do not indicate the release of a product that has been placed on hold). Product release records should show documented evidence that all product that is shipped and harvested is released only when the release procedure has been completed and the product has been "signed off" for by authorized personnel. Records should be available demonstrating the sign off for the "release" of all product shipped. N/A for organization's that only have authority over the growing activities and operation(s), and not the harvesting activities.
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	There should be a documented procedure detailing how to handle food safety related complaints, rejections and feedback. The procedure should require the recording to include (where applicable): • Date/Time of complaint/rejection/feedback • Who made the complaint/gave feedback, • Contact information, • Product description, • Where the product was purchased, • Amount of product, • Product code/date, • Nature of complaint/rejection/feedback, • Corrective actions (including details of cause if known) • Corrective actions taken to prevent reoccurrence. Where appropriate, a trend analysis of food safety feedback should be performed to assist with the development of corrective actions.

SUPPLIER MONITORING / CONTROL

Question No.	Question	Total Points	Expectation
1.06.01	Is there a list of approved suppliers and service providers?	5	There should be a list of approved suppliers and service providers. All incoming products, ingredients, materials (including packaging) and services that relate to food safety should be sourced from approved entities. Where exceptions are made (e.g., market conditions), approval from management should be justified and documented.

1.06.02	Are there current written food safety related specifications for all incoming products, ingredients, materials (including primary packaging), services provided on-site, and outsourced services?	5	There should be written, detailed, up-to-date specifications for all incoming products, ingredients, materials (including primary packaging), services provided on-site, and outsourced services (including when exceptions will be allowed) that have an effect on food safety, addressing the required Good Agricultural Practices and/or Good Manufacturing Practices. Documented specifications should be easily accessible to workers. The specifications should be reviewed at least annually.
1.06.03	Is there a written procedure detailing how suppliers and service providers are evaluated, approved, and include the ongoing verification activities including monitoring? *Note that supply chain preventive controls and supply-chain-applied controls are also mentioned in Module 7.*	5	The procedure for evaluation, approval and on-going verification, including monitoring of suppliers, on-site service providers and outsourced service providers should include the indicators to be considered for decision making (including food safety hazards), exceptions and the elements the providers should comply with to make sure they meet the defined specifications. This procedure should include monitoring requirements in order to remain approved, and methods for suspending and un-approving suppliers and service providers. The procedure should also detail what is needed (minimum requirements) in the case of working with a supplier in an emergency situation that has not yet been approved.
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	The organization should have the required documentation for approved suppliers to ensure that they are complying with the established supplier/service provider approval procedures, contracts, specifications, regulatory requirements and best practice guidelines. Supplier verification documents should demonstrate that the ongoing approval requirements detailed in 1.06.03 are being met (e.g., third party audits, certificates of analysis, reviews of supplier records, etc.).
1.06.05	Where food safety related testing is being performed by external laboratory service providers, are these licensed and/or accredited laboratories (e.g., ISO 17025 or equivalent, national and local regulations, etc.)?	5	Food safety related testing that is performed by external laboratory service providers should be done by currently permitted, licensed and/or accredited laboratories for the scope(s) of work being carried out. Examples of these licenses and accreditations include ISO 17025 accreditations or equivalent, national and local regulations in the country of production, etc. Documented evidence of these licenses and/or accreditations should be available.

TRACEABILITY AND RECALL

Question No.	Question	Total Points	Expectation
1.07.01	Is there is 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	The tracking system should be shown in writing or in the form of a flow diagram and demonstrates the product tracking system that is used by the operation. The system should be able to show that it can trace back to the supplier(s) of materials including commodities, packaging, ingredients, processing aids, work in progress, etc., and also show that the system can trace forward and indicate which customer(s) received products. This is usually accomplished by lot coding materials throughout a process and recording these lot codes at different points in the process. The traceability system should be in evidence when touring the operation and also when checking paperwork, and should also include any product that goes through an outsourced process. For facilities only, the auditor should choose a finished product lot code to test the traceability system and have the auditee demonstrate how the code traces back to raw material supplier(s) and traces forward to the customer(s).
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	There should be a written procedure describing how to perform a product recall, a list of recall team members and their contact details, responsibilities and alternates, a referral to customer and supplier contact details, handling of recalled product, explanations of relevant laws (e.g., product withdrawal, recalls classes if USA is involved as a country of production or destination, etc.).

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| 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 | Testing of recall procedures should be performed at least every six months. (For short season crops where the operation runs 6 months or less throughout the year, only one mock recall is required.) Where two mock recalls per year are required, one of the mock recalls should include the primary packaging as part of the exercise. The steps taken to conduct the mock recall as well, as the records utilized to demonstrate the program, is effective and should be consistent with the scenario identified. Documentation should indicate the date and time the mock recall was initiated, the product or material chosen, the scenario, amount of product produced, affected lot ID's (date code(s), lot code(s), etc.), amount located, and percent located. Mock recall documentation should include copies of documentation that support the trace (forward and back depending on the scenario) from the affected finished good lot through to the production run(s) affected, and therefore, showing if other lots are affected and which other customers might have received affected lot(s). Checks should be carried out to ensure that contact details exist for the affected customers. Documentation should also include any "lessons learned" from the process. |

FOOD DEFENSE

Question No.	Question	Total Points	Expectation
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	There should be a vulnerability assessment and comprehensive protection plan for all types of food fraud. This includes economically motivated hazards, economically motivated food safety hazards, adulterant substances, mislabeling, theft, tampering, simulation, diversion or gray market, intellectual property rights and counterfeiting. An example of a food fraud scenario that may occur at an operation is when suppliers provide products/materials that do not match their required specifications (e.g. unapproved chemicals, non-food grade packaging material).
1.08.02	Does the company have a documented food defense plan based on the risks associated with the operation?	5	The company should have a documented food defense plan that includes a written vulnerability assessment, and controls for the identified risks. The food defense plan creation should also meet any national or local regulations (including management oversight and approval). Based on this assessment, the operation should create monitoring, corrective action and verification procedures (where appropriate). These procedures should note the recording requirements of the food defense plan. The plan should be reviewed at least once every 12 months.
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	The records required in the food defense plan should be maintained, in accordance with the details of the plan and its associated procedures. These records are also subject to the document control and records requirements of this module.
1.08.04	Is there a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies?	3	The company should have a current list of emergency contact phone numbers available for company management, law enforcement and appropriate regulatory agencies.
1.08.05	Are visitors and contractors to the company operations required to adhere to food defense procedures?	3	Visitors and contractors should be required to adhere to food defense procedures. This can be evidenced by having them sign a log when arriving to the operation, where they are agreeing to meet the company visitor and contractor food defense requirements.

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.