PrimusGFS v3.1 Rationalization of Changes:

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.

Additions made to the text will appear in red. Where no changes were made you will see "No Change in v3.1". Where text may have been removed you will see neither red text nor the phrase "No Change in v3.1". You may compare v3.0 Questions and Expectations with version 3.1 Questions and Expectations where necessary.

MANAGEMENT SYSTEM			
Number	Question	Expectation	Interpretation Guideline
1.01.01	No Change in v3.1	No Change in v3.1	There should be a dated, signed (by senior management) documented food safety policy statement reflecting the organization's ongoing commitment to providing a safe product. The policy should include statements and objectives of the company's commitment to food safety, following food safety laws, adhering to industry food safety best practices and a process of continual improvement. Everyone in the company should understand the food safety policy and be aware of their role in ensuring that it is met (e.g. by training, communicating organizational chart, etc.). The policy should be posted in a public area and in the language understood by the workers. The policy may take the form of a "mission statement" provided it meets the requirements detailed above.
1.01.04	No Change in v3.1	No Change in v3.1	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. This question is related to the training program. The training records required under specific questions will be reviewed in the applicable module(s).
1.01.06	No Change in v3.1	No Change in v3.1	There is a current copy of any specific industry guidelines for the crop and/or product available for review. Some examples include the Leafy Green Marketing Agreement (LGMA), California Cantaloupe Program, Tomato Good Agricultural Practices (T-GAP), Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Processing Unit Operations of Herbs, etc. Not applicable if no specific industry guidelines or best practices exist for the crop and/or product. Minor deficiency (2 points) if: • Missing one copy of specific industry guidelines of best practices where more than one crop or product is handled. Major deficiency (1 point) if: • There is a copy of the best practices, but it is not the current version. • Missing more than one copy of specific industry guidelines or best practices where more than one crop or product is handled. Non-compliance (0 points) if: • Specific industry guidelines or best practices exist for the crop/crop group being audited, but the operation does not have a copy • Specific industry guidelines or best practices exist for the crop/crop group being audited, but the operation does not know it exists. Reference: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm#guidance

CONTROL OF DOCUMENTS AND RECORDS			
Number	Question	Expectation	Interpretation Guideline
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?	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. The review should include that the records are complete as applicable to the monitoring activity performed, and if any issues were detected the corrective actions were addressed in a reasonable timeframe and recorded.	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. The review should include that the records are complete as applicable to the monitoring activity performed, and if any issues were detected the corrective actions were addressed in a reasonable timeframe and recorded. Examples of monitoring records may include composting records, CCPs, sanitizer, pH, water turbidity , cleaning and sanitation, etc. Reference: https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM623178.pdf#page=132 https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Records-Required-by-the-FSMA-PSR.pdf
INTERNAL AND EXTERNAL INSPECTIONS			
Number	Question	Expectation	Interpretation Guideline
1.04.01	No Change in v3.1	No Change in v3.1	Self-auditing (self-diagnostics) is a key part of an operation's food safety program. A written procedure for internal audits should be created for each operation (farm, indoor agriculture, harvest crew, or facility) in order to proactively ensure safe food production. The internal audits procedure should include the checklist used for the internal audits, cover the inspection of sites, the practices in place, the related documents required, the records generated, the frequency of the internal audits, and identification of the person(s) or position(s) responsible for conducting the internal audits. If the current PrimusGFS checklist is not utilized in the internal audit program the self-audit should still include the requirements applicable to the operation type from the PrimusGFS normative documents. Procedure should include the verification of the practices and the related documents and any corrective actions taken. Self-audits should be fully documented even if no changes are located. If issues are found, there should be detailed corrective action records. Audit records should include the date, personnel involved, areas that were checked, findings and corrective actions (where necessary). Recording systems for food safety related topics should be audited at least quarterly (frequency could increase or decrease depending in production seasonality.) to ensure that they are being completed properly (e.g., using the correct log, correct frequencies, recording results correctly, recording corrective actions, etc.). This does not include the food safety management system every 12 months, see 1.01.05. The internal audit records are assessed in each module.

1.04.02	No Change in v3.1	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.	No Change in v3.1
1.04.04	No Change in v3.1	No Change in v3.1	The equipment used should be identified (i.e. catalog, roster, list) and there are documented procedures for the calibration for measuring and monitoring devices used in the operation. Regular calibration ensures correct and accurate operation. Equipment used for measuring and monitoring processes related to food safety and/or verification of label requirements (e.g. for weight or volume). Scales/weight or volume measuring devices should have verification of accuracy and/or calibration regularly to ensure correct and accurate operation where relevant to food safety.

SUPPLIER MONITORING / CONTROL

Number	Question	Expectation	Interpretation Guideline
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?	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.	A specification is an explicit set of food safety requirements or criteria to be met (e.g., indicating what an item is made of, contract details). Specifications are accurate, acceptable and ensure conformance with relevant customer and legislative requirements. There are 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 and/or Good Manufacturing Practices. Documented specifications are easily accessible to users and there is a documented procedure for review, amendment and approval of all specifications. Government registration and/or label information (e.g. EPA) for crop protection and processing aid products is acceptable in lieu of an actual specification provided there is evidence products are used according to label instructions. Specifications should be reviewed on at least an annual basis and there should be at least the following specifications available to review (where applicable): • seeds (e.g. lettuce or leafy greens, sprouts, microgreens) • transplants, • fertilizer/crop protection materials/adjuvants, • ingredients (e.g. product raw materials, ice), • processing aids (e.g. anti-microbials, buffers, post-harvest fungicides), • primary packaging materials (material/components manufactured with), • other materials with potential for direct product contact based on risk assessment, for example labels in direct contact with product, • On-site and outsourced services (e.g., contract crop protection sprayers, pest control, chemical suppliers, water and waste utilities, RPC rental, transport, laboratory testing, maintenance and sanitation services) provided. Note that contracted auditee operations such as co-packers, harvest crews, etc., that use materials or services that are supplied and/or selected by their customers, i.e. not purchased by the auditee should still have copies of specifications for the item provided. For example, a harvest crew that has some or all of their primary packaging provided by their contracting customer should obtain a copy of the up-to-date specification(s) from the customer.

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.	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.	There is a written procedure detailing how service providers and suppliers (e.g. raw materials, propagation materials, fertilizers, crop protection products, ingredients, processing aids, primary packaging items) are evaluated, approved and monitored. 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. U.S. Importers under the FDA's Rule Foreign Supplier Verification Programs rule should ensure requirements of rule are included in this procedure. As a minimum, the procedure should detail the following where relevant: • Agreed specifications • Letters of guarantee • Methods of evaluating approved suppliers and service providers (including second or third party audits where relevant, at least for raw materials and primary packaging) • Methods of approving approved suppliers and service providers • Methods and frequency of monitoring approved suppliers and service providers • Methods of reviewing approved supplier and service providers performance and status (including removal of approved status)
1.06.04	No Change in v3.1	No Change in v3.1	The organization has relevant information from approved suppliers/service providers to ensure that they are complying with the established approval procedures, contracts, specifications, customer and regulatory requirements and best practice guidelines. This applies to agricultural inputs, raw material, primary packaging, processing aids and other ingredient suppliers, products and services suppliers. The evidence should demonstrate the verification activities (including monitoring) detailed in 1.06.03 are being met. The evidence may include (as applicable): •Verification that packaging material is suitable for its intended purpose. e.g., current 3rd party audit certificate (ideally GFSI standard or equivalent) for all primary/food contact packaging by the manufacture. Ideally, a tests/analysis confirming no chemical migration to food contents if there is history of past occurrences. •Current (within last 12 months) second and/or third party audit certificates that includes the scope of certification for suppliers of product and ingredients. •Letters of guarantee for agricultural inputs, product raw material, processing aids, and other ingredients and service suppliers that are purchased. Letters of guarantee (also certificate of conformance) should indicate that the items supplied meet any and all legal standards, best practice guidelines and agreed specifications. Letters of guarantee should be current (within last 12 months) or indicate they are "on-going". Letters of guarantee for products are not required if own product e.g. "in-house grown" is being packed, although certificates for auditing are worth noting. •U.S. Importers under the FDA's Rule Foreign Supplier Verification Programs should have documented evidence that foreign suppliers follow requirements to verify that imported food meets U.S. safety standards. Note that contracted auditee operations such as co-packers, harvest crews, etc., that use materials or services that are supplied and/or selected by their customers, i.e. not purchased by the auditee should still have copies of the documents noted in this question, for example, third party audits. For example, in the case of a harvest crew company that has some or all of their packaging provided by their contracting customer, the harvest crew should obtain copies of the relevant packaging supplier documents such as third-party audits from their contracting customer

TRACEABILITY AND RECALL			
Number	Question	Expectation	Interpretation Guideline
1.07.03	No Change in v3.1	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.	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, percent located, time product was located and time mock recall was completed.

FOOD DEFENSE			
Number	Question	Expectation	Interpretation Guideline
1.08.01	No Change in v3.1	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. Examples of food fraud scenario may occur at operation when suppliers provide products/ materials that do not match their required specifications (e.g. unapproved chemicals, non-food grade packaging material).	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). Additional resources: https://www.pwc.com/gx/en/services/food-supply-integrity-services/food-fraud-vulnerability-assessment.html https://www.federalregister.gov/documents/2015/09/17/2015-21920/current-good-manufacturing-practicehazard-analysis-and-risk-based-preventive-controls-for-human https://www.pwc.nl/en/industries/agrifood/ssafe-food-fraud-tool.html https://www.mygfsi.com/component/k2/item/89-http-www-mygfsi-com-files-technical-documents-201805-food-fraud-technical-document-final-pdf.html https://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2018/is-that-a-beet-or-a-banana-unwrapping-food-fraud-in-the-produce-industry/ https://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2017/food-fraud-vulnerability-assessment-and-prefilter-for-fsma-gfsi-and-sox-requirements/"