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.

GENERAL			
Number	Question	Expectation	Interpretation Guideline
4.01.01	No Change in v3.1	There should be a designated person/persons responsible for the operation's food safety program. They should have documented formal training or trained by someone that has formal credentials that is documented .This training should meet all state and federal requirements.	There should be a designated person/persons in charge of the operation's food safety program, including food safety document control and verification of food safety activities and ideally be independent of production. They should have documented formal training or trained by someone that has the documented formal credentials. This training should meet all state and federal requirements.
INSPECTION			
Number	Question	Expectation	Interpretation Guideline
4.02.01	No Change in v3.1	No Change in v3.1	There should be records of the internal audits performed at each operation, with the frequency defined in the internal audit program. Frequency depends on the type and size of the operation. The records should include the date of the audit, name of the internal auditor, justification for the answers, detail any deficiencies found and the corrective action(s) taken. An audit checklist (ideally PrimusGFS) should be used that covers all areas of the PrimusGFS audit, including growing area, storage area, worker amenities, external areas, worker practices, etc. No down score if another audit checklist is used, as long as all areas are covered. See 1.04 regarding internal audit schedule.
4.02.02	No Change in v3.1	A pre-harvest block inspection should have been performed and if harvesting is occurring, it should show if there are any harvesting restrictions, etc. (e.g. evidence of animal intrusion, changes in weather conditions or weather events, pesticide application events) The harvest crew might not have a copy of the actual inspection, but they should have a document indicating which blocks have been inspected and cleared for harvest. If there are no pre-harvest inspections, go to 4.02.03.	A pre-harvest block inspection should have been performed and if harvesting is occurring, it should show if there are any harvesting restrictions, etc. (e.g. evidence of animal intrusion, changes in weather conditions or weather events, pesticide application events) The harvest crew might not have a copy of the actual inspection, but they should have a document indicating which blocks have been inspected and cleared for harvest. If there are no pre-harvest inspections, go to 4.02.03.

HARVEST WORKER HYGIENE			
Number	Question	Expectation	Interpretation Guideline
4.05.01	English: No Change in v3.1 Spanish: ¿Las instalaciones sanitarias son adecuadas en número y ubicación? **UN PUNTO CERO DE CALIFICACIÓN EN ESTA PREGUNTA RESULTA EN UNA FALLA AUTOMÁTICA DE ESTA AUDITORIA.**	No Change in v3.1	Toilet facilities should be available to all workers and visitors. At least one toilet per 20 workers should be provided, with separate toilet facilities provided for men and women in groups larger than 5 workers, or if more stringent, as per prevailing national/ local guidelines. Toilet facility placement should be within ¼ mile or 5 minutes walking distance of where workers are located, or if more stringent, as per prevailing national/ local guidelines. A 5-minute drive is not acceptable. Reference: United States Department of Labor 1928 Title Field Sanitation https://www.osha.gov/laws-regs/regulations/standardnumber/1928/1928.110 Minor deficiency (10 points) if: • The toilet facilities are not within ¼ mile or 5 minutes walking distance. Major deficiency (5 points) if: • The operation is not meeting the 1 toilet per 20 workers criteria. Automatic failure (0 points) if: • There are insufficient or inadequate toilet facilities.
4.05.04	English: No Change in v3.1 Spanish:¿Las estaciones de lavado de manos son adecuadas en número y están ubicadas de forma adecuada para el acceso de los trabajadores y el uso de monitoreo? **UN PUNTO CERO DE CALIFICACIÓN EN ESTA PREGUNTA RESULTA EN UNA FALLA AUTOMÁTICA DE ESTA AUDITORIA.**	No Change in v3.1	An adequate number of hand washing stations, in working order, should be provided to ensure efficient worker flow (1 per 20 people on site), and be available to all workers and visitors. Hands free is an optimum system. Hand washing stations should be visible and located within close proximity of toilet facilities and 1/4 mile or 5 minutes walking distance of where workers are located. Reference: United States Department of Labor 1928 Title Field Sanitation https://www.osha.gov/laws-regs/regulations/standardnumber/1928/1928.110
4.05.05	No Change in v3.1	No Change in v3.1	Total coliforms (TC) and generic E. coli testing should occur on a routine basis. All water sources used for hand washing throughout the harvesting season should be tested. One sample per water source should be collected and tested prior to use and then at least quarterly , ideally monthly. Reference: https://extension.psu.edu/coliform-bacteria https://safewater.zendesk.com/hc/en-us/sections/202366208-Total-Coliforms https://www.govinfo.gov/content/pkg/CFR-2011-title40-vol23/pdf/CFR-2011-title40-vol23-part141.pdf https://www.epa.gov/dwstandardsregulations

4.05.14	Are all workers wearing protective outer garments suitable for the operation (e.g. appropriate clean clothes, smocks, aprons, sleeves and non-latex gloves)?	Workers should not wear personal clothes with sequins, pom-poms, fur, etc. No sleeveless tops without an over garment. Where dedicated protective clothing is not required/worn, it must be clear that outer street clothes are clean and not a potential source of contamination. If required, the policy should consider customer requirements, production risk, product type, etc.	If the operation has taken a decision to establish an outer garment policy based on risks this should consider the following: customer requirements, national and local legal requirements, potential cross contamination and foreign material risks, etc. Outer garments include where applicable: smocks, aprons, sleeves, gloves, etc. Suitable clothing is required for workers handling products that are potentially ready-to-eat (e.g., tomatoes, leafy greens, etc.). Items should be laundered in-house or by contract laundering agency. Individual workers should not take protective outer garments home for cleaning. Where items are laundered in-house the auditee should have documented SOP and GAP rules about how these garments are cleaned. Glove policy should be clear to workers – auditors will establish policy before making scoring decisions and note this policy for the audit report. Gloves are not allowed to replace hand-washing requirements. Gloves should be changed after break periods, using toilet facilities, any activity other than handling of food items or when gloves are soiled, torn or otherwise contaminated. If re-useable gloves are used, then they should be made of material that can be readily cleaned and sanitized, clean gloves should be issued at least daily and as needed throughout the day and stored properly in-between uses. Gloves should not be taken home for cleaning. Where gloves are used they should be non-latex (e.g. vinyl, nitrile, etc.). This includes gloves in first-aid kits. Where dedicated protective clothing is not required/worn, it must be clear that outer street clothes are clean and not a potential source of contamination. Workers should not wear personal clothes with sequins, pom-poms, fur, etc. No sleeveless tops without an over garment.
4.05.21	Have any potential foreign material issues (e.g., metal, glass, plastic) been controlled?	No Change in v3.1	No Change in v3.1

HARVEST PRACTICES

Number	Question	Expectation	Interpretation Guideline
4.06.06	Are there records of microbial testing for water used for postharvest product contact (e.g., washing, re-hydrating) and product contact surfaces (e.g., cleaning grading packing tables and harvest tools) showing that there is no detectable total coliforms and generic E. coli in the water?	All water sources should be tested that are used for postharvest product contact (e.g., washing, re-hydrating) and product contact surfaces (e.g., cleaning grading or packing tables and harvest tools) at least quarterly. Results of water testing for total coliforms and E. coli should meet the US EPA drinking water microbiological specification. For total coliforms and generic E.coli, there should be negative or < detection limit (MPN or CFU/100mL). If out of specification results are detected, then full details of corrective actions should be noted, including investigations and water retests. For commodities under the Leafy Greens Marketing Agreement, one sample per water source should be collected and tested prior to use if >60 days since the last test of the water source. Additional samples shall be collected at intervals of no less than 18 hrs. and at least monthly during use.	All water sources should be tested that are used for postharvest product contact (e.g., washing, re-hydrating) and product contact surfaces (e.g., cleaning grading or packing tables and harvest tools) at least quarterly. Results of water testing for total coliforms and E. coli should meet the US EPA drinking water microbiological specification. For total coliforms and generic E.coli, there should be negative or < detection limit (MPN or CFU/100mL). If out of specification results are detected, then full details of corrective actions should be noted, including investigations and water retests. For commodities under the Leafy Greens Marketing Agreement, one sample per water source should be collected and tested prior to use if >60 days since the last test of the water source. Additional samples shall be collected at intervals of no less than 18 hrs. and at least monthly during use. REFERENCE: https://extension.psu.edu/coliform-bacteria https://safewater.zendesk.com/hc/en-us/sections/202366208-Total-Coliforms https://www.govinfo.gov/content/pkg/CFR-2011-title40-vol23/pdf/CFR-2011-title40-vol23-part141.pdf https://www.epa.gov/dwstandardsregulations

4.06.06b	No Change in v3.1	For total coliforms and Generic E. coli, there should be negative or < detection limit (MPN or CFU/100mL). Where thresholds have been exceeded, there should be recorded corrective actions, including investigations, water retests, and if required, crop testing (E. coli O157:H7 and Salmonella < detection limits or Negative-zero tolerance).	For total coliforms and Generic E. coli, there should be negative or < detection limit (MPN or CFU/100mL). Where thresholds have been exceeded, there should be recorded corrective actions, including investigations, water retests, and if required, crop testing (E. coli O157:H7 and Salmonella < detection limits or Negative-zero tolerance).
4.06.10a	English: No Change in v3.1 Spanish only: El diseño y el estado de mesas de selección y empaque (por ejemplo, superficies lisas, costuras de soldadura lisas, materiales no tóxicos, sin madera) facilitan la limpieza y el mantenimiento efectivos?	English: No Change in v3.1 Spanish only: Mesas de selección y empaque deben estar hechas de materiales adecuados para contacto con alimentos que puedan limpiarse, desinfectarse y mantenerse fácilmente. El equipo debe estar diseñado para permitir el acceso y la limpieza fácil (incluidas las estructuras huecas en soportes, rodillos, bastidores, etc.), sin áreas difíciles de alcanzar (para escombros). Las superficies que son porosas, atrapan escombros o están muy dañadas deben reemplazarse. La madera, por ejemplo, es porosa y puede atrapar la humedad. Las soldaduras deben ser suaves y no "bobbly".	No Change in v3.1
4.06.12e	No Change in v3.1	There should be records to show that the tool dip solutions (e.g. knife dips) are being maintained on a regular basis. The strength of the sanitizers should be checked on a regular basis (e.g., hourly) and recorded, with a minimum strength for a chlorinated system of >1ppm free chlorine or >650mV. Total chlorine does not measure the "available chlorine" after the tool dip has started to be used. AUDITORS ARE INSTRUCTED TO REQUIRE A TEST AT THE TIME OF THE AUDIT.	There should be records to show that the tool dip solutions (e.g., knife dips) are being maintained on a regular basis. The strength of the sanitizers should be checked on a regular basis (e.g., hourly) and recorded, with a minimum strength for a chlorinated system of >1ppm free chlorine or >650mV. Total chlorine does not measure the "available chlorine" after the tool dip has started to be used. Auditors are instructed to require the auditee to check the strength of anti-microbial chemicals during the audit.
4.06.13	No Change in v3.1	This includes equipment with the potential to affect product (e.g., conveyor belts, mechanical harvesting units, field packing rigs, field packing buses, coring rigs and any “in-field” processing rigs). Please note that there are some more specific questions for coring rigs and any “in-field” processing rigs in a later section.	This includes equipment with the potential to affect product (e.g., conveyor belts, mechanical harvesting units, field packing rigs, field packing buses, coring rigs and any “in-field” processing rigs). Please note that there are some more specific questions for coring rigs and any “in-field” processing rigs in a later section.

4.06.13f	No Change in v3.1	There should be evidence that a sanitation program is in place for harvesting equipment, with records to verify. The program should state the frequency of cleaning and sanitizing and the procedures. Frequency should reflect the type of machinery, type of harvesting practice and the risk associated with the crop involved. This includes water tanks used for post-harvest water use. For "in-field" processing, clean and core, etc., at least daily cleaning should be performed.	There should be evidence that a sanitation program is in place for harvesting equipment, with records to verify. The program should state the frequency of cleaning and sanitizing and the procedures. Frequency should reflect the type of machinery, type of harvesting practice and the risk associated with the crop involved. This includes water tanks used for post-harvest water use. For "in-field" processing, clean and core, etc., at least daily cleaning should be performed.
4.06.14a	Are there specific Standard Operating Procedures (SOPs) for the monitoring and changing of recirculated and batch water systems (e.g., dump tanks) and for monitoring water temperature?	There should be specific SOPs describing the process of changing the water systems and monitoring the water temperature. The water temperature should be appropriate for the products and processes being performed.	There should be specific SOPs describing the process of changing the water systems and monitoring the water temperature. There should be documentation that validates the water changing frequency. Minimum frequency for water changing is at least daily; records of changes are kept. Water may be used for longer if a validated regeneration system (e.g., a water pasteurization/filtration system) is being used. The water temperature should be appropriate for the products and processes being performed. Minor deficiency (7 points) if: • Single/isolated instance(s) of errors or omissions within the SOPs for water changing. • Single/isolated instance(s) of errors or omissions in the validation documentation for water changing Major deficiency (3 points) if: • Numerous instances of errors or omissions within the SOP's for water changing. • Numerous instances of errors or omissions in the validation documentation for water changing. Non-compliance (0 points) if: • SOPs for water changing do not exist. • SOPs do not address the frequency of water changing/ • There is no validation documentation for water changing frequency.

4.06.14d	No Change in v3.1	No Change in v3.1	Water systems using anti-microbial agents should have records showing that the strength of the solution is within stated parameters. For ""single pass"" systems, this should be every batch of anti-microbial solution that is mixed. Recirculated/batch water systems should be checked hourly by measuring the ""free anti-microbial"" as opposed to bound microbial (e.g., testing for free chlorine (or ORP) as opposed total chlorine). Where out of specification results are recorded, there should be corrective action records, including root cause analysis and preventive actions (where relevant). Non-compliance (0 points) if: • Water testing and changes are not being recorded. • Recorded solution strengths systematically out of parameters i.e. an unstable system (even if documented corrective actions exist). • Systematic errors and omissions in the records. • Total chlorine has been recorded throughout the system, when free chlorine or ORP should have been recorded e.g. in chlorinated recycled water systems. • Frequencies of checks systematically do not meet requirements of prior to start up and throughout the production runs. • Single pass water system is in use without anti-microbial being used. The auditor should consider whether to apply Q4.06.09 and score an automatic failure in view of the risk of cross contamination. • Recycled/reused water system is in use without an anti-microbial being used. The auditor should consider whether to apply Q 4.06.09 and score an automatic failure in view of the risk of cross contamination.
4.06.14e	No Change in v3.1	No Change in v3.1	The strength (concentration, pH, etc.) of anti-microbial chemicals should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction-based test, test probe, ORP meter or as recommended by the disinfectant supplier). Any water treatment at the source (e.g., well, canal) should be monitored. Solutions that are too weak will be ineffective, while those too strong may be harmful to workers or product. Where necessary, pH of solutions should also be checked. Methods include dip sticks, test strip papers, conductivity meters, titration, color comparison methods (e.g., tintometers, etc.). All test solutions/strips should be within date code, appropriate for the concentrations used and stored correctly (especially light and temperature sensitive materials). If the ORP meter controls the pumps that are injecting the anti-microbial and/or buffer, there should be an independent calibrated ORP probe or other method (e.g., test trip papers, titration) in order to verify injector readings. Probe sensors need periodic cleaning and calibration and may become temporarily saturated by over-injection of anti-microbial or buffer. The auditor should have the auditee check the strength of anti-microbial chemicals while touring the operation.

4.06.17b	Do records show that pesticides applied postharvest and their use are in compliance with all requirements of label direction, national (e.g., EPA) registration and any federal, state or local regulations and guidelines? **A ZERO POINT (NON-COMPLIANCE) DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE.**	Grower should have information for the registered and/ or authorized by governmental agencies in the country of production for the target crops in the postharvest period, in accordance with label directions. Information should at least detail: ingredients, target pest(s)/ organism(s) or diseases, application methods that are required or preferred, how much chemical should be applied, rate of application, whether there are any restrictions on use (such as temperature, time of day, season of the year, contamination of sensitive areas, exposure of non-target species, application methods that are prohibited, how often the pesticide should or may be applied, all restricted entry intervals (REIs) pertaining to existing uses (as applicable), maximum application rates per treatment and per year, pre-planting intervals (PPIs), pre-harvest intervals(PHIs) and storage and disposal guidelines. N/A is only allowed when registration/authorization information does not exists for pesticides to be used in the postharvest period for the target crops in the country of production. Where registration information exists, and it is not available at the growing operation, then an automatic failure of the audit will result. **A ZERO POINT (NON-COMPLIANCE) DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE.**	Grower should have information for the pesticides registered and/or authorized by government agencies in the country of production for the target crops in the post-harvest period, in accordance with label directions. Information should at least detail: ingredients, target pest(s)/organism(s) or disease(s), application methods that are required or preferred, how much chemical should be applied, rate of application, whether there are any restrictions on use (such as temperature, time of day, season of the year, contamination of sensitive areas, exposure of non-target species, application methods that are prohibited, how often the pesticide should or may be applied, all restricted entry intervals (REIs) pertaining to existing uses, as applicable), maximum application rates per treatment and per year, pre-planting intervals (PPI's), pre-harvest intervals (PHI's) and storage and disposal guidelines. N/A is only allowed when registration/authorization information does not exist for pesticides to be used in the post- harvest period for the target crops in the country of production. Where registration information exists, and it is not available at the growing operation, then an automatic failure of the audit will result. **A ZERO POINT (NON-COMPLIANCE) DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE.**

TRANSPORTATION AND TRACKING

Number	Question	Expectation	Interpretation Guideline
4.07.02b	No Change in v3.1	No Change in v3.1	For finished goods packed in the field, there should be date coding on each individual unit package, as clamshells, bags, baskets or others. The information should be enough to identify the date of harvest and the exact location of where the product was grown. This question is not applicable for raw material/bulk product destined for further handling in a packinghouse or processing facility. Reference: https://www.producetraceability.org/documents/Best_Practices_Case_Label-_010312_FINAL.pdf

ON-SITE STORAGE			
Number	Question	Expectation	Interpretation Guideline
4.08.04a	Are pest control devices located away from items and/or equipment used in the harvesting process (e.g., packing material, cartons, clamshells, re-usable containers, disinfectants, grading/packing tables, RPCs, harvesting equipment, etc.), and poisonous bait traps are not used inside the storage areas?	Pest control devices should be located away from items or equipment with food contact surfaces to prevent any physical or microbial contamination. Poisonous bait traps should not be used inside any storage areas.	Pest control devices should be located away from items or equipment with food contact surfaces to prevent any physical or microbial contamination. Poisonous bait traps should not be used inside any storage areas. Care should be taken to place pest control devices in such a manner that they do not pose a threat of contaminating product, packing or raw materials. This includes the following restrictions: • There should be no domestic fly sprays used within the storage areas. • Block bait as opposed to grain and pellet bait should be used (except for the external use of National Organic Program approved materials). • If used, insect light traps (ILTs), electrical fly killers (EFKs) or pheromone traps should be regularly cleaned out (kept free from a build-up of insects and debris). Sticky type ILTs should be monitored at least monthly and the sticky board replaced if ineffective. ILTs that use sticking as opposed to zapping methods (EFKs) are preferred. • If used, insect light traps or electric fly killers should not be placed above or in close proximity (10 feet, 3 meters) to product, food contact surfaces, equipment, or packaging material. • If used, insect light trap bulbs should be replaced at least every 12 months (this should be recorded), or as more frequently if directed by manufacturers. • No fly swatters should be evident in the storage areas. • No bait should be found outside of bait stations. If used, snap traps should be placed inside a trap box and should not use allergen containing baits (e.g., peanut butter). Any snap traps inside stations should be checked at least weekly and checks recorded.
4.08.04b	No Change in v3.1	All pest control devices should be maintained clean, in working condition and replaced when damaged in order to accomplish their intended use. Date of inspections should be posted on the devices as well as kept on file (unless barcode scanned).	No Change in v3.1