

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	GENERAL GMP			
Number	Question	Expectation	Interpretation Guideline	
5.01.01	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.	
PEST COI	NTROL			
Number	Question	Expectation	Interpretation Guideline	
5.02.01	Are products or ingredients free of pests (e.g. insects,rodents,birds,reptiles, mammals) or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.	Any evidence of pest (e.g., insects, rodents, birds, reptiles or mammals, etc.) in products or ingredients are indicators of contamination, posing physical and microbiological hazards. Evidence of contamination constitutes an automatic failure of the audit.	Raw materials, work in progress, ingredients, finished goods are free from evidence or the infestation of pest (e.g., insects, rodents, birds, reptiles or mammals etc.) See 5.02.03 for reference to potential indications of pest presence.	
5.02.02	Are packaging supplies free of pest (e.g. insects, rodents,birds,reptiles,mammals) or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.	Packaging supplies are considered food-contact surfaces and therefore need to be free of pest (e.g. insects, rodents, birds, reptiles, mammals, etc.) Evidence of contamination constitutes an automatic failure of the audit.	Packaging supplies are free from evidence or the presence of pest (e.g. insects, rodents, birds, reptiles, mammals, etc.). See 5.02.03 for reference for potential indications of pest presence.	



5.02.03	Are plant and storage areas free of pest (e.g. insects, rodents, birds, reptiles, mammals) or any evidence of them?	Plant and storage areas should be free of pest (e.g. insects, rodents, birds, reptiles or mammals, etc.) to prevent possible physical or microbiological contamination.	No Change in v3.1
5.02.06	Are pest control devices located away from exposed raw materials, work-in-progress, ingredients (including water and ice), finished goods and packaging, and poisonous bait traps are not used within the facility?	Pest control devices should be located away from exposed food products, packaging materials, or equipment to prevent any physical or microbial contamination. Poisonous bait traps should not be located within the facility.	 Pest control devices should be located away from exposed food products, packaging materials, or equipment to prevent any physical or microbial contamination. Poisonous bait traps should not be located within the facility. Care should be taken to place pest control devices in such a manner that they do not pose a threat of contaminating product, packaging or raw materials. This includes the following restrictions: Poisonous bait stations and other pesticides should only be used outside the facility. There should be no domestic fly sprays used within the production and 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. Electric fly killers or insect light traps should be been to be other ital fork/lift damage) or in front of doorways (so attracting insects into the facility). Hallways or dock areas where product passes through are exempt from these distances, as long as product does not stop or is not stored in hallway or dock. If used, insect light traps should be ipaced inside a trap box and should not use allergen containing baits (e.g., peanut butter). Any snap traps inside stations. If used, insect light 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 (scored in 5.02.07
5.02.07	No Change in v3.1	All pest control devices should be maintained clean, in working order and replaced when damaged so that they will 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



STORAGE	TORAGE AREAS & PACKAGING MATERIALS			
Number	Question	Expectation	Interpretation Guideline	
5.03.04	No Change in v3.1	No Change in v3.1	All raw materials, work in progress, ingredients, finished goods or packaging that are being rejected or are awaiting final disposition (on hold) should be stored in a designated hold area, in a way that avoids accidental use of these materials in the production process (unless they have been cleared for use). Materials should be stored in a way that avoids accidental use of these materials in the production process (unless they have been cleared for use). Materials should be stored in a way that avoids accidental use of these materials in the production process (unless they have been cleared for use). The rejected or on hold items should be tagged as such, with a date showing when the product was placed on hold/rejected and the reason for being on hold/rejected and the name of the person who put the product on hold. The tagged product should not be commingled with other goods in such a way that their disposition is not clear. There should also be records of items placed on hold (e.g. an on hold/disposition log) available for review (scored in 1.05.02). N/A if rejected or on hold materials are not observed.	
OPERATI	ONAL PRACTICES			
Number	Question	Expectation	Interpretation Guideline	
5.04.02	No Change in v3.1	Ceilings and/or any overhead fixtures above storage are free from condensation or dust. Ladders or walkways (catwalks) above exposed product or packaging material have kick plates at least 3.5 inches (8 cm) high and are covered in some way that protects the product underneath. Drips or condensate (e.g., from roof, fixtures, ducts, pipes, etc.) should not contaminate food, food contact surfaces or packaging material. Adequate measures should be in place to protect from condensate.	Ceilings and/or any overhead fixtures above lines and storage are free from condensation or dust. Ladders or walkways (catwalks) above exposed product or packaging material have kick plates at least 3.5 inches (8 cm) high and are covered in some way that protects the product underneath. Drips or condensate (e.g., from roof, fixtures, ducts, pipes, etc.) should not contaminate food, food contact surfaces or packaging material. Adequate measures should be in place to protect from condensate. Condensate is scored in 5.10.05.	



5.04.05	No Change in v3.1	No Change in v3.1	 Re-work includes product that has come directly from the end of the line or where possible, product that has been returned from a customer (but is still in good quality). Re-work possibilities will vary from product to product. Re-work areas in coolers should adhere to all required GMP's. In a cooler or storage and distribution center where the re-packing is routine i.e. a regular activity (more than once per week) as opposed to an occasional unscheduled event, then a packinghouse audit template should be used. All re-work should be handled correctly: Whole products undergoing re-packing should be in new final boxes and not be commingled with products from other producers and/or lots. Re-use of boxes in tomato, citrus, etc. re-pack operations is permitted only if product is re-packed into a container from the same lot of product and that the container is clean, sanitary and properly labeled. Any misuse of single use containers is scored in 5.04.15. Packaging items are opened with clean knives. Workers emptying packaging should have washed their hands and (ideally) if company policy, wear clean gloves i.e. should follow company GMP rules for hand sanitation. Re-work area is separated from the main production line. Product is collected in a clearly designated container before being transferred back to the processing line; ideally product should go through the washing step again. Outside of packaging does not touch the re-work product as it is being emptied. The traceback details are transferred correctly. Not applicable if there is no re-work/re-packing taking place.
5.04.10	No Change in v3.1	English: No Change in v3.1 Spanish: Se deben proporcionar suficientes estaciones de lavado de manos, en buen estado, para asegurar un flujo eficiente de trabajadores (1 por cada 10 personas en el lugar), y deben estar disponibles para todos los trabajadores y visitantes. Manos libres es un sistema óptimo. Las estaciones de lavado de manos deben ubicarse cerca de las instalaciones sanitarias y del área del comedor. Para las operaciones de empaque o procesamiento de artículos, las estaciones deben ser accesibles desde las áreas de producción.	To ensure efficient worker flow, there should be a minimum of one hand wash station for every ten people, and should be available to all workers and visitors. Hand washing stations should be located at access to production areas in processing and packinghouse audits and in, or immediately adjacent to toilet facilities. Within close proximity of/at toilet facilities and lunchroom is acceptable for other facility audits.



5.04.13	No Change in v3.1	No Change in v3.1	In processing, packing and repackaging areas, the use of (non-perfumed) secondary hand sanitation stations is the last activity a worker performs before taking their position on the line. Secondary hand sanitation is required for fresh-cut operations and for operations producing items that may be "ready-to-eat" (e.g., herbs, stone fruit, tomatoes, citrus, edible flowers, etc.). Note that citrus peel is often used in drinks, used for zesting, etc. Secondary hand sanitation (hand dips, gels or sprays) does not replace hand washing requirements (lack surfactant qualities). Secondary hand sanitation stations should be unscented/non-perfumed, have 60% to 95% ethanol or isopropanol and conveniently located in traffic zones but should not be obstructive. Hand dips (if used) should contain a food grade sanitizer at a determined concentration. Refer to hand sanitizer manufacturer label for dilutions. Hand dips should be regularly monitored (recorded anti-microbial strength checks) to ensure their effectiveness with corrective actions recorded (e.g. dip solution replenishment and anti-microbial additions). Hand gel and spray stations should be well stocked with a sanitizer approved for direct hand to food contact and regularly monitored (recorded checks) to ensure availability with corrective actions recorded (e.g. pack replenishment); use of a refill alert type dispenser is ideal practice. Dispensers should be located a sufficient distance from production line to prevent accidental product contamination. The auditor should check that gel pack type stations are stocked and have the auditee check the strength of anti-microbial chemicals in hand dips while touring the facility. Records are scored in 5.13.06.
5.04.14	No Change in v3.1	No Change in v3.1	Foot (boot) stations (foot dip mats, baths, sprays) should be located in areas when crossing into a "clean" zone from an area of potential contamination (e.g., from outside into the packing zone, from raw storage into packing, from bathrooms into processing, etc.). Foot dips are required in processing operations. They are not required in packinghouses, but may be considered as an additional control. Foot dips should contain a food grade sanitizer at a determined concentration. Refer to sanitizer manufacturer label for dilutions. Foot dips should be regularly monitored for volume and concentration (recorded anti-microbial strength checks) and the dip solution regularly changed to ensure their effectiveness with corrective actions recorded (e.g. dip solution replenishment and anti-microbial additions). Dry products should be EPA registered and applied as per the label instructions (label dosage directions should be followed for EPA registered floor sanitizers) and regular renewal should be monitored. The auditor should have the auditee check the strength of anti-microbial chemicals while touring the facility. Records are scored in 5.13.06. Workers should be using the foot dips as they enter the processing areas.



WORKER	VORKER PRACTICES			
Number	Question	Expectation	Interpretation Guideline	
5.05.06	Are all workers wearing protective outer garments suitable for the operation (e.g., appropriate clean clothes, smocks, aprons, sleeves, 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. Suitable protective outer garments are required for workers handling processed products, washed packinghouse products (after the washing step) that are potentially ready-to-eat (e.g., tomatoes, leafy greens, etc.), and in packinghouses that overwrap product (e.g., washed whole potatoes). Outer garments include where applicable: smocks, aprons, sleeves, gloves, etc. For example, smocks worn in processing operations, aprons (minimum) in packinghouses after wash step and where potentially ready-to-eat product is being overwrapped. Sleeves are required to prevent product contact with clothing. Items should be laundered in-house or by contract laundering agency. Individual workers should not take garments home for cleaning. Where items are laundered in-house the auditee should have documented SOP and GMP rules about how these garments are cleaned. If workers sleeves come into contact with washed ready-to-eat products, then protective waterproof sleeve covers should be used. 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 handwashing 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 not be taken home for cleaning. Where gloves are used they should be more lawed 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.) – see 5.05.03. This includes gloves in	
5.05.13	No Change in v3.1	The operation must have a worker access security system in place that could include ID cards (with photo), biometrics, unique assigned passcodes or key fobs (not an exhaustive list). The system employed must provide a unique link between the worker and site/facility access, be revocable upon termination from the company with controls to limit duplication. Agency labor should also have ID cards (such as agency ID's that are checked on arrival). The ID cards, if worn on the outer garments, should be firmly attached so as not to be a food safety hazard. If stored on one's person, this is also acceptable i.e. the ID card can be provided if challenged (if stored in pockets, etc., hand sanitation would be required after showing the ID card, prior to handling product). Companies with less than 20 workers are not expected to have an ID system.	The operation must have a worker access security system in place that could include ID cards (with photo), biometrics, unique assigned passcodes or key fobs (not an exhaustive list). The system employed must provide a unique link between the worker and site/facility access, be revocable upon termination from the company with controls to limit duplication. Agency labor should also have ID cards (such as agency ID's that are checked on arrival). The ID cards, if worn on the outer garments, should be firmly attached so as not to be a food safety hazard. If stored on one's person, this is also acceptable i.e. the ID card can be provided if challenged (if stored in pockets, etc., hand sanitation would be required after showing the ID card, prior to handling product). Companies with less than 20 workers are not expected to have an ID system.	



GENERA	GENERAL CLEANING			
Number	Question	Expectation	Interpretation Guideline	
5.08.07	No Change in v3.1	No Change in v3.1	There should be an adequate supply of cleaning equipment (per procedures employed). Cleaning equipment should be free of debris, cleaned and stored correctly between uses. Cleaning equipment should be stored away from the food and operational areas in a designated storage area. Cleaning equipment is stored to prevent it becoming a source of cross contamination for the product, materials, packing equipment, and in general, for the complete operation. Brooms, mops, etc., should be stored off the floor and "head down" in order to avoid them being contaminated by any accidental spills and prevent them from being harborage areas for pests and ensure debris does not contaminate the handle. Squeegees used for condensate control and in processing operations should be stored in dedicated sanitizer solutions and these solutions should be at the correct dilution and part of the sanitizer monitoring system. Auditors should spot check solution strength during the audit. Equipment used for different types of cleaning should not be stored touching each other (see next question).	
BUILDIN	G AND GROUNDS			
Number	Question	Expectation	Interpretation Guideline	
5.10.09	No Change in v3.1	No Change in v3.1	 In cold stores, coolers and packinghouses this question is only applicable if the facility is fitted with raised dock doors, levelers and buffers. This question should be scored for operations who are handling temperature-controlled items. Where goods are not temperature controlled, then this question is only scored if the raised dock doors, levelers and buffers are fitted. Minor deficiency (2 points) if: Operation handling temperature-controlled goods that do not use a dock buffer system (or equivalent temperature management system). Counter measures in place. Major deficiency (1 point) if: Operation handling temperature-controlled goods that do not use a dock buffer system (or equivalent temperature management system). Limited counter measure in place. Non-compliance (0 points) if: Operation handling temperature-controlled goods that do not use a dock buffer system (or equivalent temperature management system). Limited counter measure in place. 	



CHEMICA	CHEMICAL FILES			
Number	Question	Expectation	Interpretation Guideline	
5.11.04	No Change in v3.1	No Change in v3.1	Water systems should have specific SOPs that describe the process of changing the water, performing and recording anti-microbial sanitizer strength testing (including parameters, testing frequency, methodology and corrective action requirements), and methods and monitoring procedures for measuring build-up of organic material (turbidity) in recirculated and batch water systems. There should be documentation that validates the water changing frequency and water testing 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. For single pass water systems, there should be a specific SOP that describe the performing and recording anti-microbial sanitizer strength testing (including parameters, testing frequency, methodology and corrective action requirements). This question is not asked in the Storage and Distribution Audits. REFERENCE: https://www.canr.msu.edu/news/turbidity_in_post_harvest_wash_water_monitor_and_change_when_needed	
OPERATI	ON MONITORING RECORDS			
Number	Question	Expectation	Interpretation Guideline	
5.13.02	No Change in v3.1	Incoming trailer (and other forms of transport, e.g., rail cargo carriages) checks for product and packaging should ensure that the trailer was clean, odor free, pest free and in good repair (e.g., no damaged insulation). Inspection records when receiving food materials that are temperature controlled for safety reasons should show that the transport temperature control equipment was working properly, temperature settings were set correctly, product was received at the required temperature and that were no signs of temperature abuse in transit. The receivers should be aware and follow any special documented instructions and specifications communicated by the shipper/supplier of the materials.	No Change in v3.1	



5.13.03	Are there records for the necessary process monitoring activities (e.g., pH, water temperature vs. product temperature, metal detection, X-ray, labeling, heating processes, reduction/kill step processes, postharvest pesticides (i.e. fungicides, wax, etc.), control of water activity, drying, etc.), showing, for example, monitoring frequencies, results and where necessary the corrective actions?	Records should show process control parameters are being met and detail corrective actions (where necessary). Processes include sterilizing, irradiating, pasteurizing, cooking, blanching, freezing, refrigerating, controlling pH, or controlling aw. Corrective actions to also include root cause analysis and preventive actions (where relevant). Any processes and/or chemicals used should meet existing legal requirements (including residue levels), used as per label requirements, and meet export requirements (as applicable). See 5.13.04 regarding anti-microbial use. There may be some overlap with preventive controls and/or HACCP topics, see modules 6 & 7.	There should be appropriate logs in use for all process monitoring activities, including postharvest treatments (i.e. fungicides, wax, etc.). Processes include sterilizing, irradiating, pasteurizing, cooking, blanching, freezing, refrigerating, controlling pH, or controlling aw. Any processes and/or chemicals used should meet existing legal requirements (including residue levels), used as per label requirements and meet export requirements (as applicable). These may be combined on a single log or on multiple logs. The records should show process control parameters are being met and detail corrective actions when the process is outside the established limits. Corrective actions to also include root cause analysis and preventive actions (where relevant). If monitoring is not continuous, then the amount or frequency of monitoring should be sufficient to verify the process is in control; auditee should be able to support monitoring frequency being used. Any issues with monitoring frequency should be scored in Q 5.04.08. Where produce is immersed in water and has been shown to be susceptible to microbial infiltration from water, the water temperature differentials during immersion should be controlled in accordance with current regulation, industry guidelines or best practices. For example, for tomatoes FDACS, USDA and the University of FloridaGAPs require postharvest water to be maintained at temperatures 10°F (5.6°C) or higher above the fruit pulp temperature, and water temperature should be monitored at least hourly.
5.13.06	No Change in v3.1	No Change in v3.1	The company should have a log sheet for evaluating the hand and/or foot and/or tool dip (where appropriate) stations solution strength. The log sheet should include target antimicrobial concentration (ppm) and frequency of verification. The figures recorded must match the type and graduation of the testing system being used. An omission would include where an out of spec concentration is recorded but there is no record of corrective actions. Foot dips are required in processing audits operations (see 5.04.14). Any operation with hand, foot or tool dips is required to keep monitoring records (uncontrolled dips are a hazard). Where hand gel or spray stations using prepared solutions are used, there should be monitoring logs indicating stations are regularly checked to confirm units are stocked and operational.



TESTING	ESTING			
Number	Question	Expectation	Interpretation Guideline	
5.16.01	No Change in v3.1	No Change in v3.1	A written risk-based, scientifically valid microbiological testing program has been developed and is used to verify the effectiveness of cleaning and sanitization programs and/or meet customer or other specific requirements. The objective of environmental monitoring is to serve as an early warning system to target sanitation efforts and avoid product contamination. The operations program should be recorded and include: • design such as the zonal approach, food or nonfood contact, spent irrigation water, test & hold, water, ice, product, ingredients, etc. • rationale for the organisms chosen in the testing • procedures for the sampling and testing (i.e. surfaces, water, product, ingredients, etc.) • timing and frequency of testing • the testing methodology, • lab that performs the tests • the acceptable results/threshold levels for each organism tested • any hold and release (test and hold) activities The "Environmental Monitoring Program Sampling & Testing Guide" outlines the minimum sampling and testing frequency based on product and processes. Rational for sampling and testing frequency: The testing should be performed on sample sites that are chosen based upon microbial risk to the facility's environment and potential sources of contamination. Each process should be evaluated in order to identify the actual and potential sources of contamination. Each process should be evaluated in order to identify the actual and potential sources of contamination. The number of samples routinely taken in each site location will vary depending on the classification of the area's risk (i.e., raw or processed product area), design, amount and complexity of equipment and process, and the layout of the handling environment. Site locations should be reassessed and updated based on test results obtained. The records should be recorded, including the organism tested for, the testing methodology, lab that performed the test, details of the sampling sites, when the test occurred and the results (including units	



devices.

MODULE 5: FACILITY SUMMARY OF CHANGES FROM VERSION 3.0 TO VERSION 3.1

5.16.02	No Change in v3.1	Testing should be recorded, including organism tested for, the testing methodology, lab that performed the test, details of the sampling sites, when the test occurred and the results (including units of measure). If any issues are detected, corrective actions should be recorded. (see 5.16.08) Testing should meet written program requirements, including zonal approach, food contact/non-food contact surfaces, spent sprout irrigation water, test & hold, water, ice, etc.	Testing should be recorded, including organism tested for, the testing methodology, lab that performed the test, details of the sampling sites, when the test occurred and the results (including units of measure). If any issues are detected, corrective actions should be recorded. (see 5.16.08) Testing should meet written program requirements, including zonal approach, food contact/non-food contact surfaces, spent sprout irrigation water, test & hold, water, ice, etc.
5.16.05	No Change in v3.1	No Change in v3.1	Compressed air or other mechanically introduced gases (e.g., nitrogen, carbon dioxide) used in direct contact with product, product food contact areas and the interior surface of packaging should be free of contaminants (e.g. microorganisms, particulates, water, oil, etc.). Oil used in compressors should be food grade (see 5.01.03). Compressors should have high efficiency filters at the compressor inlet and as close as possible to the point of use to protect against contamination (included as part of the equipment preventative maintenance, see 5.14.01) Verification testing should be based on a documented risk assessment and controls in place (e.g., use of the air/gas, risk to the product/food contact surfaces and type of process/product). At a minimum, testing should occur once every 12 months. Testing may include microbiological (e.g., total plate count, indicator organisms appropriate to operation) and moisture content (where moisture is a risk to the product e.g., dry operations). Testing should meet written program requirements and be based on risk the produce and process.
TEMPER	ATURE CONTROLLED STORAGE	AND DISTRIBUTION LOGS	
Number	Question	Expectation	Interpretation Guideline
5.17.04	No Change in v3.1	There should be a documented procedure to check truck trailer (or other transportation system, e.g., railway carriages) temperature prior to shipment. Where relevant, requirements from the organization that has contracted the carrier should	There should be a documented procedure to check truck trailer (or other transportation system, e.g., railway carriages) temperature prior to shipment. Where relevant, requirements from the organization that has contracted the carrier should be followed, including the use of time temperature recording devices.

be followed, including the use of time temperature recording