CERTIFIED QUALITY ASSURANCE

PRIMUSGFS Ver. 3.2

(Transition from Ver 3.1)

GMP's Update Training
(Facilities)

Azzule Systems has made its new version of PrimusGFS – v3.2 – available to auditees and will be the mandatory version for audits scheduled after March 1, 2022.

-Preamble -

This session includes main changes and new requirements in the PrimusGFS scheme from version 3.1 to version 3.2

- Program Regulations
- Module 1 (FSMS)
- Module 5 (GMP)
- Module 6 (HACCP)
- Module 7 (PC)

And a brief preamble of the Global Food Safety Initiative (GFSI) and the influence over PrimusGFS new version/revision

The “Global Food Safety Initiative” (GFSI)

Companies looking for food safety certification by a standard recognized by the GFSI (e.g. PrimusGFS, GlobalG.A.P, SQF, etc.), must comply with several requisites and regulations defined by the certification standard and these requisites and regulations are influenced by the Industry, stakeholders, government regulations and the GFSI

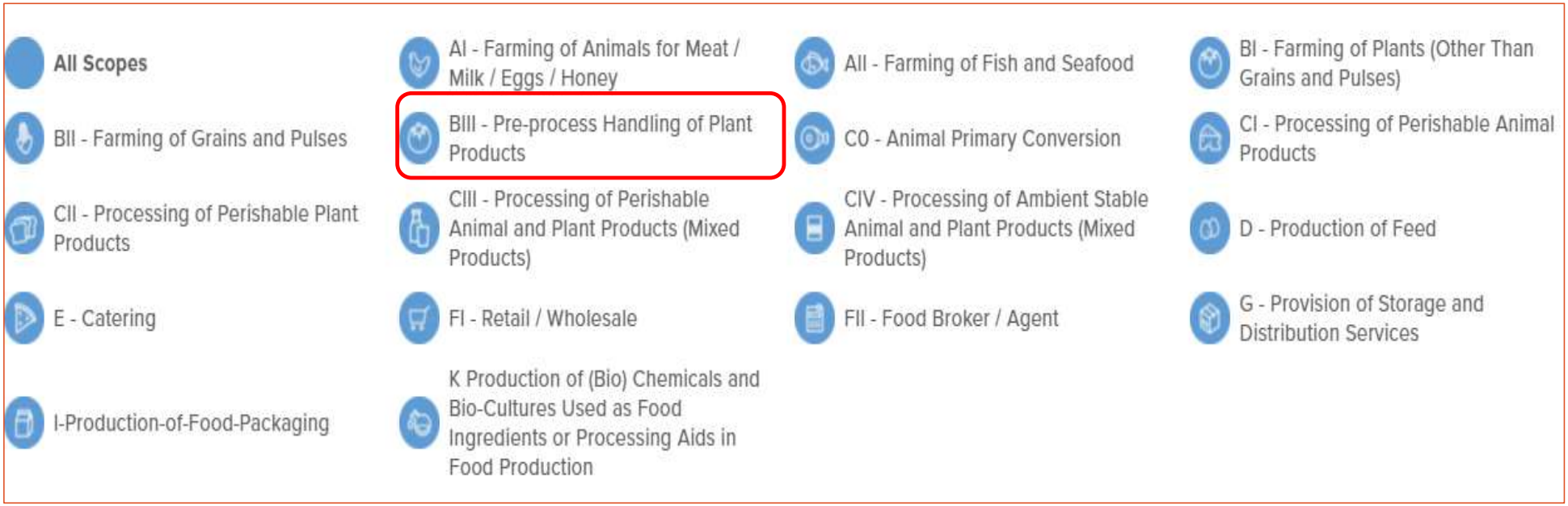
The Global Food Safety Initiative is a private organization, established and managed by “the Consumer Goods Forum”. The GFSI maintains a scheme to benchmark food safety standards for manufacturers as well as farm assurance standards.

The “Global Food Safety Initiative” (GFSI)

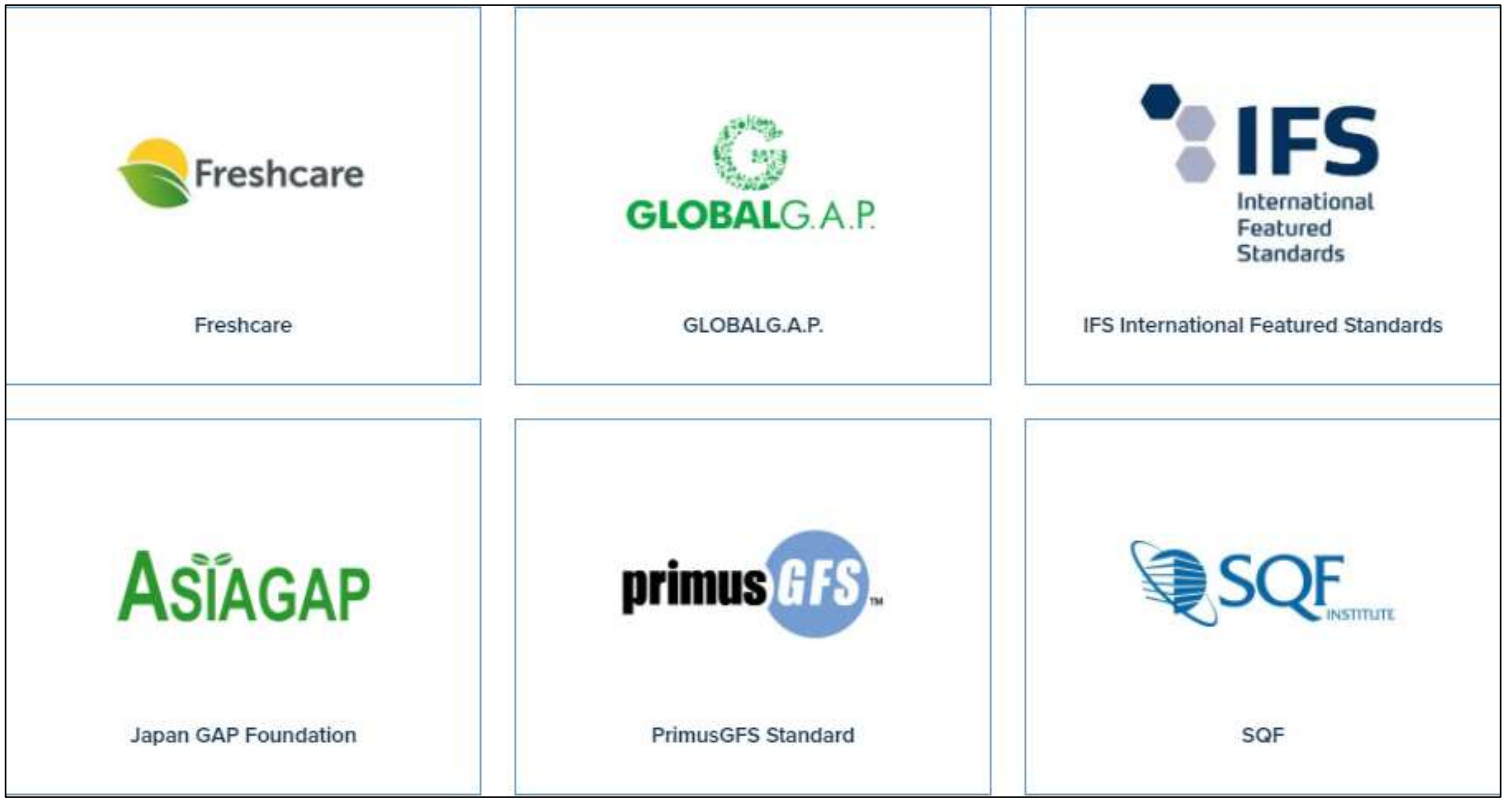
Key activities within GFSI include defining “basic” food safety requirements for food safety schemes through a benchmarking process.

GFSI Objective: To reduce food safety risks through equivalence and convergence between food safety management and audit systems and reduce the audit burden for companies looking for certification (Once GFSI certified, accepted worldwide)

The “Global Food Safety Initiative” (GFSI) Categories



The “Global Food Safety Initiative” (GFSI)
Categories & Recognized Standards (example BI & BII)



PRIMUSGFS 3.2 – NEW REGULATIONS

- ✓There are several changes to the program regulations with scope to auditors and certifications bodies (more demanding requirements).

- ✓There are few changes to the program regulations with scope to companies looking for PrimusGFS certification but two of them are very important:

  1- Corrective actions
  2- Surveillance audits

PRIMUSGFS 3.2 – NEW REGULATIONS

Non-Conformities and Corrective Actions

a) In order for the audit to move to the certification phase, all identified non-conformances must have corrective actions verified and closed out by the certification body.

b) The corrective actions must be submitted into the PrimusGFS database within 30 calendar days from the original audit date.

c) The submission of corrective actions does not guarantee that the score will increase but should demonstrate that the organization has taken or will take the corrective actions and/or preventive measures to control the identified non-conformance.

d) Note that with an overall preliminary audit score of less than 85% or an automatic failure, the organization can submit corrective actions for the CBs review, but accepted corrective actions do not change the final score.

PRIMUSGFS 3.2 – NEW REGULATIONS

Non-Conformities and Corrective Actions

e) The corrective actions from the organization should include at a minimum: the determination of cause(s) (i.e., root cause analysis), any action plan(s) to address immediate issue(s) regarding the non-conformance, the corrective actions taken, and the development of preventive actions to help avoid future occurrences if necessary.

f) If a corrective action is not able to be completed during the corrective action timeframe, the organization should submit the corrective action plan, the evidence of intent to complete, and a timeframe for completion and/or a documented risk assessment with the mitigation measures in place that shows the identified issue or non-conformance is controlled.

g) Corrective action evidence can be in the form of documents, records and/or photographs and it must show that the non-conformance has been adequately addressed.

PRIMUSGFS 3.2 – NEW REGULATIONS

Non-Conformities and Corrective Actions

h) The CB has the right to determine if an on-site assessment or remote assessment with the use of ICT is necessary to be performed to the audited organization to verify corrective actions for any non-conformance found.

What is ICT: The use of technology for gathering, storing, retrieving, processing, analyzing, and transmitting information to optimize an audit's effectiveness and efficiency, and to support and maintain the integrity of the audit process. Some acceptable technologies for conducting a remote audit are, but not limited to:

- Smartphones, Tablets, and other Handheld Devices
- Video Cameras
- Wearable Technology
- Drones
- Artificial Intelligence

PRIMUSGFS 3.2 – NEW REGULATIONS

Non-Conformities and Corrective Actions

i) The CB will have 15 calendar days to review the corrective action evidence to determine if actions taken are sufficient to control the risk(s), and notify the organization if it was accepted or rejected and close out the non-conformance(s).

j) If time allows (within the 30-calendar day corrective action timeframe), when corrective action evidence is rejected by the CB, the organization can re-submit additional evidence to close out the non-conformance.

k) Once the organization has responded to the CB regarding the non-conformances and the CB has reviewed all corrective actions submitted, the CB will close out the corrective action phase in the PrimusGFS system, which will allow for the certification decision to be made.

PRIMUSGFS 3.2 – NEW REGULATIONS

Non-Conformities and Corrective Actions

Following the issuance of the general regulations for PrimusGFS version 3.2, Azzule made a clarification regarding categories of questions and the obligation to close non-conformities:

1- Essential questions

2- General questions

3- Gathering information

This categorization is found at the document "Question & Expectations"

General	2.01.02	If the operation is growing under organic principles, is there written documentation of current certification by an accredited organic certification organization?	0	Information gathering question.Current certification by an accredited organic certification organization (national/local) should cover the audited crops, be on file and available for review. N/A if not growing under organic principles.	Information Gathering
General	2.01.03	Does the operation have a written food safety hygiene and health policy covering at least worker and visitor hygiene and health, infants and toddlers, animal presence in growing and storage areas, fecal matter, dropped product, blood and bodily fluids?	15	There should be written food safety policy rules regarding worker and visitor personal hygiene, GAPs and health requirements. The policy should cover the rules related to hygiene and health (e.g., hand washing, eating/drinking, smoking, specific clothing rules, foreign material issues, cuts/wounds, illness rules, etc.), no infants and toddlers allowed in the growing area, what to do in the case of evidence of animals and/or fecal matter in the growing and/or storage areas, and what to do in the case of dropped product, and if the product comes into contact with blood or other bodily fluids. All workers and visitors should be issued a list of rules in the relevant languages and confirm by signing they understand and agree to abide. Training provided and associated records should meet local and national regulations.	Essential
Site	2.02.01	Is there a map that accurately shows all aspects of the operation, including water sources and fixtures used to deliver water used in the operation?	5	There is a map or similar document (photograph, drawing) that accurately shows the growing area(s), adjacent land use/features, location of permanent water fixtures and the flow of the water system, including any holding tanks and water captured for re-use. Permanent fixtures include wells, gates, reservoirs, returns and other above ground features. Septic systems, effluent lagoons or ponds, surface water bodies are also identified. Document should enable location of the water sources and the production blocks they serve.	General

PRIMUSGFS 3.2 – NEW REGULATIONS

Essential Questions (Non-Conformance – Major – Minor)

Acceptable corrective actions or corrective action plans (including evidence of intent to complete and a timeline for completion and/or a documented risk assessment with mitigation measures in place demonstrating that the identified problem is controlled) must be provided to the certification body/auditor and closed to achieve certification (the question score value must be increased after corrective action is accepted).

PRIMUSGFS 3.2 – NEW REGULATIONS

Essential Questions (Non-Conformance – Major – Minor)

Corrective action must be accepted and also increase the score of the question, at least from:

- Non-conformance to Major
- Mayor to minor
- Minor to complies/yes

(if this does not happen the audit will fail).

PRIMUSGFS 3.2 – NEW REGULATIONS

General Questions

Non-Compliance:
Acceptable corrective actions or corrective action plans (including evidence of intent to complete and a timeline for completion and/or a documented risk assessment with mitigation measures in place demonstrating that the identified problem is controlled) must be provided to the certification body/auditor and closed to achieve certification (i.e., the question point value must be increased after corrective action is accepted to obtain certification).

Major and Minor:
30 calendar days to close the problem, but if the time is exceeded and there are no critical food safety issues (i.e. no concern about product/process conformity) or legality issues, the certification body can grant certification for this situation. This is ONLY for partial score values (Major and Minor)for non-critical questions.

PRIMUSGFS 3.2 – NEW REGULATIONS

Surveillance audits

Each CB must have a unannounced surveillance program in place for their certified organizations. The unannounced surveillance audits must be performed using the PrimusGFS checklist the chosen organization(s) is certified against. The selected organization with certified operation(s) must reach the required scoring as a certification audit in order to maintain their certification.

The requirement for scopes BI, BII and BIII is that a minimum of 10% per year or 1 unannounced audit be conducted every 4 years for each certified organization

- BI & BII (farming of plants, grains and pulses): Farm, indoor agriculture, harvest crew
- BII (Pre-process handling of plant products, nuts and grains): Storage and Distribution Center, Cooling / Cold storage, Packinghouse.

PRIMUSGFS 3.2 – NEW REGULATIONS

Surveillance audits

The requirement for scopes CII, CIII, CIV, G is 1 unannounced audit every 3 years for each certified organization.

CII: Processing of perishable plant products - Processor

CIII: Processing of perishable animal and plant products (mixed products) - Processor

CIV: Processing of ambient stable products – Processor

G: Storage and Distribution services for food - Storage and Distribution Center

PRIMUSGFS 3.2 – Module 1 (FSMS)

PRIMUSGFS 3.2 – Module 1 (FSMS)

There are no new questions. Changes from 3.1 to 3.2 are mainly clarifications to the guidelines, examples of compliance and/or increased scope of the requirement.

There are also multiple improvements in the wording of the guides, but without changing the scope of the requirements based on the previous version.

PRIMUSGFS 3.2 – Module 1 (FSMS)

1.01.01: Is there a documented food safety policy detailing the company's commitment to food safety?

- Promote a proactive and committed culture of food safety.

- Detailed objectives.

1.01.02: Is there an organizational chart showing all managers and workers involved in food safety activities and documentation (job descriptions) detailing their food safety responsibilities?

The organizational chart is dated and signed by management to indicate that it is correct and current.

PRIMUSGFS 3.2 – Module 1 (FSMS)

1.01.03: Is there a food safety committee and are there records of food safety meetings with topics covered and attendees?

In-person meetings must have names and signatures to indicate attendance; the auditor's discretion applies to the signature record of attendance at remote meetings.

Where the operation has less than three months of records available (new, short season operations) there should still be at least one meeting available for review – score minor deficiency; if no records score non-compliance

PRIMUSGFS 3.2 – Module 1 (FSMS)

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? - Added the following “elements” for the management verification:

- Other (official) food safety audits/visits.
- Review of incidents including unusual occurrences, foreign material issues, pest control issues, microbial testing results, food defense, food fraud, etc.
- Document control activities including updates, changes or new SOPs, customer specification issues
- Sanitation
- Pest Control
- Approved supplier/service provider program
- Worker training review
- Facility and equipment maintenance
- Recall program

PRIMUSGFS 3.2 – Module 1 (FSMS)

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? Total compliance (3 points).

There is a current copy of any specific industry guidelines for the crop and/or product available for review (electronic copies are accepted). Some examples include the Produce Safety Rule, FSMA Seven Rules including Foreign Supplier Verification Programs, Sanitary Transportation of Human and Animal Food, 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 or activity.

PRIMUSGFS 3.2 – Module 1 (FSMS)

1.02.05: Are all records and test results that can have an impact on the food safety program verified by a qualified person independent of the individual(s) completing the records? Total compliance (5 points):

Records and test results should be reviewed, signed off and dated by a qualified person within 7 days. The verifier is independent of the individual completing the record(s), understands the purpose of the verification and understands what they need to review on the record(s) before they sign (i.e. PCQI qualification, evidence of training, etc.). Examples of records may include composting records, pre-harvest records, pre-operational inspections, anti-microbial, water turbidity, cleaning and sanitation, etc.

If any issues are detected, corrective actions should be recorded. Ideally (not a scoring issue), there is a summary document of records reviewed, who reviewed (position) and who verified the summary document (position). Pesticide application records are ideally reviewed and signed off on as above, however, individual situations including small farming operations and contract spray services may impact how records are being reviewed and signed.

PRIMUSGFS 3.2 – Module 1 (FSMS)

1.03.03: Is there a documented corrective action procedure that describes the basic requirements for handling all non-conformances affecting food safety? Total compliance (5 points):

There should be a documented corrective action procedure that outlines how the company manages corrective actions including preventative actions and follow-up validation to ensure corrective action taken has solved the problem. Specific corrective action procedures and records are assessed in each module. The procedure should require that records of the corrective action activities and their follow-up are completed using the same format with the required information (see below) detailed.

- Review of the NC
- Determination of the cause
- Action Plan
- Implementation of corrective actions
- Validation (follow-up)
-

PRIMUSGFS 3.2 – Module 1 (FSMS)

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? Frecuencias:

- FSMS: every 12 months
- Food Safety Documentation: Quarterly
- GAP (farm, greenhouse): at least one pre-season assessment of the growing area and a full self-assessment of GAP (module 2 or 3) during the harvest season
- GAP (Harvest crew): at least one in season (attention with products in the scope, + 1 could be needed).
- GMP (facilities – module 5): monthly processors, other quarterly operations
- HACCP (Facilities): every 12 months

PRIMUSGFS 3.2 – Module 1 (FSMS)

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? Total compliance (10 points):

For GAP, this covers items such as fertilizer and pesticide application equipment, pesticide measuring equipment (e.g. scales), ORP and pH meters, and other equipment related to the safety of the product. Pesticide application equipment (e.g. sprayers), and corresponding measuring equipment (e.g. scales, cups) should be verified and when required calibrated (or replaced) regularly to ensure correct and accurate operation. Calibration and/or verification procedures should describe frequency, method and the acceptable range of variation (when applicable). Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency.

For GMP, this includes equipment used for measuring and monitoring processes (handheld and automated) related to food safety e.g. ATP testing systems, thermometers, scales for weighing ingredients (e.g. in juice operations), metal detectors, ORP meters, flow meters and pH meters. Scales used to check final product weight are exempt (unless relevant to food safety).

PRIMUSGFS 3.2 – Module 1 (FSMS)

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? Total compliance (5 points).

Calibration and/or accuracy verification records should be available for all applicable equipment and should consider at least equipment identification, date, frequency of testing, testing method, result (variation), and corrective actions. Both internal (where the company checks the equipment for themselves) and external (where equipment is sent away, or an outside specialist company comes on site and checks the equipment in situ) calibrations should be documented and on file. Proof of calibration includes records, invoices and on machines labels. Where an external service is used, procedures, licenses and/or certifications are acceptable.

PRIMUSGFS 3.2 – Module 1 (FSMS)

1.08.02: Is there a written food defense vulnerability assessment and food defense plan based on the risks associated with the operation? Total compliance (5 points):

The operation should have a documented food defense plan that outlines the organization's security controls based on a written food defense vulnerability assessment of risks associated with the operations. This plan should include Good Agricultural Practices and/or Good Manufacturing Practices, as well as a written risk/vulnerability assessment, and controls for the identified risks.

The document should include relevant food defense risks such as site/building access, personnel, visitors, contractors, computers, raw material receipt (raw materials, product and packaging), trucks (incoming and outbound), water sources, storage areas for product, materials, chemicals, production areas, shipping areas, etc. There may also be a requirement to ensure that suppliers have proper food defense programs. The food defense plan creation should also meet any national or local regulations (including management oversight and approval). Documented operational risk management (ORM) systems are acceptable if they show the controls that have been implemented for the food defense risks that have been identified. The plan should be reviewed at least once every 12 months e.g. as part of management verification review process.

PRIMUSGFS 3.2 – Module 5 (Good Manufacturing Practices)

PRIMUSGFS 3.2 – Module 5 (GMP) – section “Storage Areas and Packaging Materials"

5.03.09: Is any packaging stored outside being protected?

Packaging material must:

- Store indoors.
- Store off the ground/floor.
- Be protected from dust, leaks and other contaminants.
- If stored outdoors, it should be covered with a waterproof, dustproof cover and included in a pest control program.

(applies to contact and non-contact material)

PRIMUSGFS 3.2 – Module 5 (GMP) – section "Operational Practices"

5.04.04: Where facilities are not completely enclosed, are there measures in place to mitigate potential hazards? Total compliance (15 points):

Production areas should all be enclosed (walls and roof) with doors either closed or pest protected in some way (e.g., strip curtains, air curtains, speed doors, etc.) or other mitigating measures (e.g. equipment cleaned prior to use, covering equipment, no product storage, etc.); auditor discretion applies.

Walls can be solid, fine mesh or any other pest proof material, with openings that should be no greater than 1/8 inch (3 mm).

Dust and pest proof wall materials are required for processing operations.

It does not apply if the facilities are completely enclosed.

PRIMUSGFS 3.2 – Module 5 (BPM) – section "Operational Practices"

5.4.09 - Does the facility use appropriate test strips, test equipment or test probes to verify the concentrations of antimicrobial chemicals (product contact water, terminal disinfectants, immersion stations, etc.) that are used, are in operational condition and are being used correctly?

Water samples for testing should be taken from, and/or probes located in, areas farther away from the antimicrobial injection/addition site.

If an ORP meter controls the pumps that inject the antimicrobial and/or buffer, free chlorine levels should be checked using an independent method (e.g. titration, appropriate test strips)

Probe sensors must be properly located

PRIMUSGFS 3.2 – Modulo 5 (BPM) – sección “Practicas Operacionales”

5.05.11: Is fresh drinking water easily accessible to workers?

If there is evidence (i.e., visual observation or documentation) that the water is coming from a questionable source, the auditor should review the results of the water quality tests.

PRIMUSGFS 3.2 – Module 5 (BPM) – "Chemical Files" section

5.11.03: Are there specific Standard Operating Procedures (SOPs) for monitoring antimicrobial parameters in single-pass and/or recirculated/batch water systems, for changing recirculated/batch water systems (e.g. discharge tanks, canals, hydraulic vacuum cleaners, hydraulic coolers, etc.) and for monitoring water pH and temperature (if applicable)?

The water temperature should be appropriate for the products and processes being performed. Measuring total chlorine is not viewed as acceptable for recycled water systems. Single pass systems must have a stated anti-microbial level. For chlorine, the criteria should be ≥10 ppm free chlorine. Lower concentrations should be properly justified with supporting documents, rationale and evidence. Note, US (NOP) regulations allow for chlorine use in wash water at levels sufficient to control microbial contaminants and higher than 4 ppm free chlorine, where there is a final rinse with potable water to meet their ≤4 ppm free chlorine product contact requirement. Other anti-microbials include peracetic acid, chlorine dioxide, etc.

PRIMUSGFS 3.2 – Module 5 (BPM) – section "Maintenance and Sanitization Files"

.14.07: Are there records showing verification of cleaning and sanitizing chemical concentrations? Total compliance (5 points).

Where cleaning and sanitizing chemicals are mixed on-site, there should be records of verification of the anti-microbial concentrations. The strength of cleaning chemicals should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction-based test, test probe, or as recommended by disinfectant supplier). Refer to 5.04.09 for actual method used. Solutions that are too weak will be ineffective, while those too strong may be harmful to employees, product or equipment. Methods include, dip sticks, test strip papers, conductivity meters, titration, color comparison methods (e.g., tintometers, etc.).

Frequency of checks should correspond with the SSOP, but at least at mixing and then at a frequency that ensures the availability of the anti-microbial is adequate while the cleaning operation is being done. Corrective actions should also be recorded.

N/A if no mixing is taking place on-site e.g. where pre-mixed chemicals are bought and used.

PRIMUSGFS 3.2 – Module 5 (BPM) – "testing" section

5.16.01: Is there a written risk-based, scientifically valid microbiological testing program that may include pathogen testing, and details program design (zonal approach, food contact/non-food contact surfaces, spent sprout irrigation water, test & hold, water, ice, etc.), rationale for organisms tested for, procedures for sampling and testing (surfaces, water, product, ingredients, etc.), timing and frequency of testing, the testing methodology, the lab that performs the tests, and acceptable results/threshold levels for each organism?

A written risk-based, scientifically valid microbiological testing program has been developed and is used to verify the effectiveness of cleaning and sanitization programs, monitor the facility environment for microorganisms of human health concern and/or meet customer or other specific requirements. A microbiological testing program can be used to verify that appropriate controls such as GMPs and sanitation programs are in place and working properly.

PRIMUSGFS 3.2 – Module 5 (BPM) – "testing" section

The program must be documented and include:

- design and scope such as the zonal (1-4) approach, food or nonfood contact equipment, spent irrigation water, test & hold, water, ice, product, ingredients, etc.
- rationale for the organisms chosen to be tested for
- Procedures for the sampling and testing (i.e., surfaces, water, product, ingredients, etc.)
- rationale for 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

GFSI Scope V7	GFSI Scope 2020	Type of Operation	Product(s) or Process Characteristics	Minimum EMP Sampling & Testing Frequency	Minimum Sampling Zones	Minimum Water Sampling & Testing Frequency	Minimum Ice Sampling & Testing Frequency (if ice is used)	Minimum Post-sanitation checks (e.g. ATP)
		Storage & Distribution						
D	BIII		Perishable goods (produce) - ambient temperatures	Quarterly	Zone 3 & 4	Every 12 months	N/A	N/A
D	BIII		Perishable goods (produce) - received with ice (no ice made or added on-site), high humidity storage	Monthly	Zones 3 & 4	Every 12 months	N/A	N/A
J	G		Dry non-perishable goods (ambient temperatures)	Not required		Every 12 months	N/A	N/A
J	G		Temperature controlled (≥ 32°F/0°C) goods (refrigeration)	Monthly	Zones 3 & 4	Every 12 months	N/A	N/A
J	G		Temperature controlled (< 32°F/0°C) goods (frozen)	Not required		Every 12 months	N/A	N/A
		Cooling & Cold Storage						
D	BIII		All products/commodities (dry-evaporators/condensors, forced-air cooled, vaccum cooled)	Monthly	Zones 1-4	Every 12 months	N/A	N/A
D	BIII		All products/commodities (wet-hydrocoolers, hydrovacs, ice making, ice injection, top icing)	Monthly	Zones 1-4	Quarterly	Quarterly	Weekly
		Packinghouse						
D	BIII		Potentially RTE, wet process and/or with high humidity storage	Monthly	Zones 1-4	Quarterly	Quarterly	Weekly
D	BIII		Potentially RTE, dry pack only	Monthly	Zones 1-4	Every 12 months	N/A	Weekly
D	BIII		Non-RTE (i.e. potatoes, hard squash, dry beans, pulses, grains)	Not required		Every 12 months	N/A	N/A
		Processing						
EII	CII		Cut fruit &/or vegetables	Weekly	Zones 1-4	Monthly	Monthly	Daily
EII	CII/CIII		IQF products	Weekly	Zones 1-4	Monthly	Monthly	Daily
EII	CII		Mushrooms (sliced)	Weekly	Zones 1-4	Monthly	N/A	Daily
EII	CII		Sprouts	Weekly	Zones 1-4	Monthly	N/A	Daily
EII	CIII		Mixed plant & animal perishable products	Weekly	Zones 1-4	Monthly	N/A	Daily
EII	CIV		Non-perishable products	Monthly	Zones 1-4	Monthly	N/A	Daily
EIV	CII/CIV		Juice (pH <4.5)	Quarterly	Zones 1-4	Monthly	N/A	Daily
EIV	CII/CIV		Juice (pH ≥4.5)	Monthly	Zones 1-4	Monthly	N/A	Daily

PRIMUSGFS 3.2 – Module 5 (BPM) – "testing" section

5.16.09 - Is there a documented training program with records of training for sampling workers, including aseptic sample collection techniques, sampling protocols and sample handling?

Staff should be trained in applicable microbiological sampling techniques, as well as ATP bioluminescence and allergen sampling (where relevant).

Training should ensure that sampling personnel have been educated on the concepts of aseptic sampling using aseptic techniques, sampling protocols and sample handling.

Training may include a formal training course, directly from laboratory personnel or through an online resource.

N/A if all sampling is handled by the laboratory service provider.

PRIMUSGFS 3.2 – Module 6 (HACCP)
similar changes in preventive controls section (module 7) in corresponding questions

PRIMUSGFS 3.2 – Module 6 (HACCP) – section "Preliminary Steps"

6.01.03: Does a product description exist for the products produced?

Product description(s) should clearly describe the product and its distribution and be used to determine if specific controls are important throughout the distribution chain. The description should indicate the product(s) name, composition (ingredients), type(s) of packaging, shelf-life and method of storage and distribution. Information should include intended use i.e. does it need washing, peeling, cooking prior to consumption, is it RTE, etc., by the consumer, and reflect the label of the product (unit packed product). Intended use should include any potential for abuse or misuse of the produce (e.g. eating raw when product is intended to be cooked). Product description(s) should list all ingredients including allergens, define and indicate details regarding whether the item is perishable or long life, if there are any special storage and distribution requirements and any important food safety characteristics that can influence the growth of pathogens (e.g., pH, water activity), and labeling requirements including allergen information and any other legal requirements. Product description(s) should define the potential risk associated with the product, materials used and also who the intended customers are (general public, restricted to certain sectors, e.g. people not suffering from a certain allergy, diabetic issues, other at-risk groups, etc.)

PRIMUSGFS 3.2 – Modulo 6 (HACCP) – sección “Desarrollo del Plan HACCP”

6.02.03: Is the HACCP system reviewed when significant changes are made and at least once every 12 months?

The review should include a written record demonstrating that each of the elements of the plan, including product descriptions, process flows, hazard analyses, PCC decisions, PCC registration, customer complaints, equipment calibration, log review, trend analysis data, etc., have been reviewed, verified as accurate/appropriate, and a record of changes to the plan should be included to track changes over time.

PRIMUSGFS 3.2 – Module 6 (HACCP) – section "Execution of the HACCP Plan in the Plant"

.03.05: Are the CCP records reviewed and signed off by the quality control supervisor and/or management (second signatory)? Total compliance (10 points):

CCP records should be reviewed, dated and signed off by a trained, designated person within 36 hours of the original CCP monitoring activity occurring.

Ideally records are reviewed prior to release of product to prevent potential recall and unintended consequences should a deviation be found during record review.

Allowance may be made for operations that are not running daily (auditor discretion applies). The sign offs should be done by the quality control supervisor or manager (second signatory). This should be a separate signature to that of the CCP operator. The individual signing off should check the records (e.g. dates, production lines, monitoring results, frequencies, corrective actions, use of correct forms, etc.), since their signature is basically stating that everything is in order relative to the written HACCP plan and associated documents. If discrepancies are found during the record review corrective actions must be taken and documented (6.03.06).

PRIMUSGFS 3.2 – Module 7 (Preventive Controls)

PRIMUSGFS 3.2 – Module 7 (CP) – section "Preliminary Steps"

7.01.01: Is there a team responsible for the preventive control program at the operation, with a leader assigned, if applicable, for the development, implementation and on-going maintenance of the preventive control program?

here should be a formally identified group of people in charge of development and maintenance of the preventive control program along with their corresponding responsibilities.

One member of the team (a preventive control qualified individual - PCQI), who has successfully completed recognized training in the development and application of risk-based preventive controls training (or is otherwise qualified) should be designated the preventive control coordinator (leader).

The team must be multidisciplinary.

Lastly a Message from AZZULE - PrimusGFS

Lastly, if would be great if you could mention that PrimusGFS v3.2 is available and can be used by anyone.

We are currently waiving v3.2 certification fees, promoting all operations certified against v3.2, and the operation can even conduct v3.1 & v3.2 at the same time.

We are working to ensure we (Azzule) receives copies of v3.2 certificates to provide GFSI evidence of v3.2 implementation to close our recognition process. They are mandating to see v3.2 in use by the industry to achieve successful benchmark.

THANKS!