EN

primusGFS

2019

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

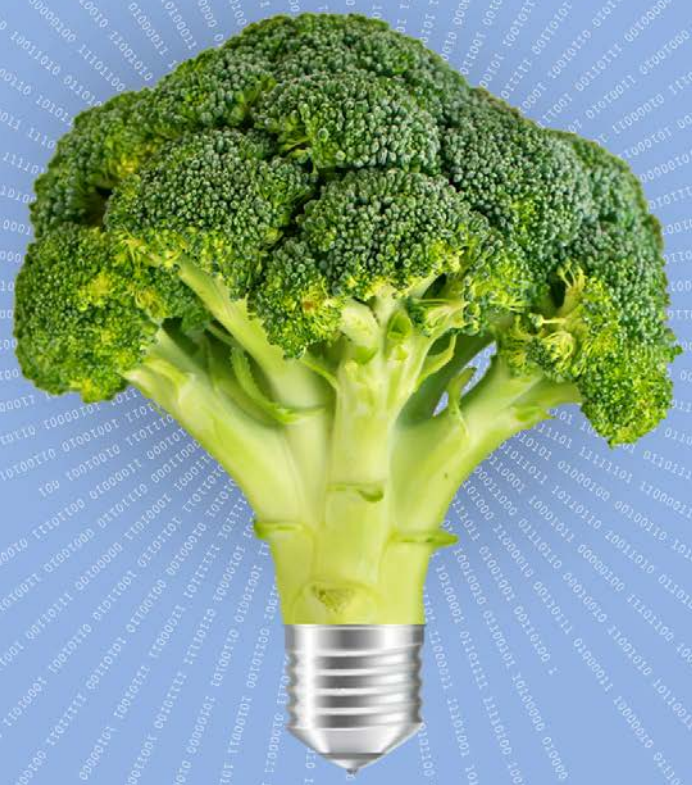
QUESTIONS & EXPECTATIONS

PrimusGFS v3.1

MODULE 6

HACCP

Hazard Analysis Critical Control Point System Requirements



POWERED

CONNECTED

SMART

SUPPORTED

GLOBAL

RECOGNIZED

primusgfs.com | azzule.com

Powered by Azzule Systems

Introduction

PrimusGFS v3.1

Acknowledgements

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

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

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

Powered by Azzule Systems

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

primusgfs.com | azzule.com

PrimusGFS v3.1

Questions & Expectations

MODULE 6: HACCP

Hazard Analysis Critical Control Point System Requirements

(Sections 6.01 to 6.03)

Auditees have the option to present combined HACCP and Preventive Control Systems, but auditors must report/score separately.

This module will always be applicable to all facility operations.

CONTACT:

Please do not hesitate to contact us via email at **PrimusGFS@azzule.com** or by phone if you have any questions or concerns.

Santa Maria, California | United States of America | **+1-805-862-4219**

Culiacán, Sinaloa | Mexico | **+52-667-716-5037**

Viña del Mar | Chile | **+56-32-332-5045**

primusgfs.com | azzule.com

PRELIMINARY STEPS			
Question No.	Question	Total Points	Expectation
6.01.01	Is there a team responsible for the HACCP program at the operation, with a leader assigned, if applicable, for the development, implementation and on-going maintenance of the HACCP system?	10	There should be a documented list of the team carrying out the HACCP program in the operation, with one leader or coordinator assigned as responsible. The team should be multidisciplinary and may include people from production, quality, sanitation, maintenance, shipping, procurement, sales, external consultants, etc. The size of the team will depend on the size of the operation and the processes performed.
6.01.02	Is there documented evidence that the HACCP team members have been trained on HACCP principles?	15	At least one member of the HACCP team, should have a certificate of a formal HACCP training from a recognized organization, institution or trainer with a minimum duration of 2 days or 16 hours, taken within the last 5 years. The rest of the team should have at least an internal training to make sure they are knowledgeable of the HACCP principles. These trainings should be documented.
6.01.03	Does a product description exist for the products produced?	10	The description should detail the products' composition (ingredients), packaging used, storage conditions, distribution requirements, important food safety characteristics (if any) (e.g., pH, water activity), label instructions, the intended use, statement on whether the product is RTE and who the intended consumer is.
6.01.04	Has the process(es) been flow charted in sufficient detail to completely describe the process or product handling/ processing steps?	10	The information (from receiving through to shipping) on the flow diagram is used to evaluate whether or not hazards exist associated with each step of the process. Groups of similar products going through the same process can be grouped in the same flow chart. Diagram should show re-work processes and when product is diverted to be used for other purposes. Process flows can be augmented by written process descriptions (where helpful).
6.01.05	Is there documented evidence that the flow chart(s) been verified on-site?	10	The diagram(s) should be verified on-site and signed and dated by the HACCP team coordinator to confirm it reflects the conditions of the process at different moments and there are no missing steps.
DEVELOPMENT OF THE HACCP PLAN			
Question No.	Question	Total Points	Expectation
6.02.01	Has a documented hazard analysis for the processes been conducted, showing the various types of hazards, their likelihood of occurrence, their associated severity and their control measures? **A ZERO POINT (NON-COMPLIANCE) DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.**	15	Hazard analyses are required to identify each hazard (biological, chemical and physical) at each stage of the production process. The analyses should evaluate the likelihood of hazard occurrence and potential hazard severity. The hazard analysis document(s) should show the control measures. Each step identified in the process flow diagram should be assessed in the hazard analysis. The hazard analysis should be reviewed when changes occur affecting the product description and/or the process flow. **A ZERO POINT (NON-COMPLIANCE) DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.**
6.02.02	Have CCP decisions been made with documented justification and where CCPs are implemented in a specific processing step, have they been developed to control the identified hazard(s)?	15	The CCPs should be created from the documented hazard analyses, i.e. there should be a logical documented approach (such as utilizing a CCP decision tree) showing why the process was deemed a CCP or not. CCP decisions should be properly justified with supporting documents and evidence. The CCPs defined in the hazard analysis should be developed in detail to define the parameters involved and the monitoring requirements needed in order to control the hazard.

6.02.03	Have critical control point (CCP) processing steps been identified that eliminate or reduce food safety hazards to an acceptable level? Informational gathering. If the answer is YES, continue with the next question. If the answer is NO, the rest of "Module 6 HACCP" is not applicable.	0	The identification of CCPs in the process will require the development of the criteria for managing it and the execution of the necessary activities in the production line.
6.02.04	Have CCP critical control limits been established and supported by relevant validation documentation?	15	A critical control limit (CCL) represents the dividing line used to judge whether a CCP is under control or not. Each Critical Control Point should have one or more critical control limits for each identified hazard. All CCPs should be supported by validation documentation showing that the critical control limits (CCL) are scientifically derived and meet any relevant legal requirements. Validation could take the form of publicly available legislative documents, industry best practice documents, peer reviewed research papers, on site validation studies, etc., or a mix of different validation sources.
6.02.05	Have monitoring requirements and frequencies been determined and documented for the CCPs?	15	Monitoring requirements should detail the actions necessary (observations or measurements) to ensure whether a CCP is under control. Frequencies of monitoring should also be defined and documented for each CCP.
6.02.06	Have specific responsibilities been assigned for the monitoring, recording and corrective action implementation of each CCP?	10	Specific responsibilities should be assigned for the monitoring, recording and corrective action implementation of each CCP to ensure compliance.
6.02.07	Have standard operating procedures (SOPs) been created for the monitoring process(es) of the CCPs, which would include how to carry out the monitoring activities?	5	Clear and simple standard operating procedures (SOPs) should be written for each monitoring process(es) of the CCPs. These SOPs should the monitoring activities in detail in the form of work instructions, and match what is written in the HACCP Plan.
6.02.08	Have corrective action procedures been established for the CCPs, including a detailed action plan for operators to follow if the critical control limit(s) of a CCP are not met (loss of control/deviation) and plans to adjust the process back into control?	15	There should be a documented, detailed plan with procedures to follow when there is a loss of control (deviation) of a CCP so that adjustments can be made in a timely manner and to assure that the process is back under control. The procedures include details regarding how to handle affected products (if necessary). Corrective action procedures should also include requirements to review the CCP to try and avoid a repeat of the loss of control.
6.02.09	Have recording templates (recording forms) been developed for monitoring the CCPs?	15	Defined record templates are required for recording CCP monitoring. The parameters on the records should reflect those used in the HACCP Plan. These templates should be managed under the document control program.
6.02.10	Have verification plans and schedules been developed for each CCP?	10	Each CCP should have documented verification activities associated with the monitoring that verifies the correct implementation of the HACCP plan (e.g., CCP documentation checks, specific testing associated with the CCP, customer feedback, equipment calibration, etc.). Where verification activities have found that CCPs were not performing as required, there should be records that show that this prompted a review of the relevant part of the HACCP Plan.
6.02.11	Is the HACCP system verified when operational changes are made and at least once every 12 months?	10	The HACCP system should be reviewed by the HACCP team when operational changes are made and at least every 12 months, including the product descriptions, process flows, hazard analyses, CCP decisions, CCP recording and worker training to ensure that the program is up to date and working properly. Where emerging issues, such as recalls, an outbreak, new research, etc., are relevant to the products and processes at hand, consideration of a HACCP review should occur. Documented re-training or educational sessions may be necessary. The review should include a written record which demonstrates each of the elements of the plan have been reviewed, verified as being accurate/appropriate and there should be a change record included in the plan to track changes over time. The HACCP team should inform workers involved of the review outcomes.

6.02.12	Is there documented evidence that all plant workers have attended a HACCP training, including training for CCP operators?	10	HACCP training is important in ensuring that all workers are knowledgeable regarding the basics of HACCP. This training is especially important for CCP operators, and for those workers, the training should cover the explanation of the procedures in which they are responsible. All training activities should be documented.

EXECUTION OF THE HACCP PLAN ON THE PLANT FLOOR

Question No.	Question	Total Points	Expectation
6.03.01	Do all of the documents noted in the HACCP Plan accurately reflect plan requirements for the CCPs?	15	Documents noted in the HACCP Plan should be in place for each CCP, and records should reflect the plan requirements. Using document version control helps ensure that the documents on the production floor match those in the plan.
6.03.02	Are the CCP monitoring activities and frequencies in compliance with the HACCP Plan and CCP SOPs?	15	The monitoring records should show that testing frequency, parameters and any other details match what is written in the HACCP Plan and CCP SOPs.
6.03.03	Do CCP operators understand basic HACCP principles and their role in monitoring CCPs?	10	CCP operators should understand basic HACCP principles and have a good understanding of the details of the CCPs that they have been assigned to monitor, including monitoring procedures, critical controls and corrective action requirements. Auditor should interview operators to verify.
6.03.04	Are CCP monitoring records signed off (or initialed) by the operator(s) who are carrying out and recording the CCP check?	15	Legibly signed off records should be recorded in order to show who actually performed the CCP monitoring tests. If initials are used, there should be a way to easily determine who the initials refer to.
6.03.05	Is there a deviation record detailing documented corrective actions when a deviation/loss of control of a CCP occurs (a critical control limit is exceeded)?	15	When a monitoring or verification step shows a deviation/loss of control against a CCP in the HACCP Plan (including when a critical control limit is exceeded), the incident should be recorded on a deviation record (or similar form), along with actions taken. This includes recording what happened to the affected product, how the situation was rectified and any preventative actions taken to avoid similar issues in the future.
6.03.06	Are the CCP records reviewed and signed off by the quality control supervisor and/or management (second signatory)?	10	Records should be signed off by the designated person(s) responsible for internal verification of the company's HACCP plan within 36 hours of the original CCP monitoring activity occurring. The sign off should not be done by the same person who carried out the monitoring activities. If any issues are detected, corrective actions should be recorded.

Where laws, commodity specific guidelines and/or best practice recommendations exist and are derived from a reputable source, then these practices and parameters should be used. Audit users should allow a degree of risk association if laws, guidelines, best practices, etc., have not been documented.