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.

DEVELOPMENT OF THE PREVENTIVE CONTROLS PROGRAM			
Number	Question	Expectation	Interpretation Guideline
7.02.01	No Change in v3.1	The hazard analysis is required to identify biological, chemical (including radiological), physical, and economically motivated hazards for food safety at each stage of the production process. The analyses must evaluate if the risk requires a preventive control and evaluate the severity and likelihood of occurrence in the absence of control. All decisions must be justified in a documented manner. Preventive controls, such as process, allergens, sanitization, and supply chain should be identified for the identified hazards. 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 hazard analysis identifies and evaluates hazards, and determines if control measures are in place to prevent, eliminate or reduce the food safety hazard to an acceptable level. There should be a detailed, documented hazard analysis for each process flow in order to prove that a proper hazard analysis was conducted. Note, if there are errors in the process flow, it is likely there will also be errors in the hazard analysis. At each step of the process, from raw material receipt and storage, through processing and packing, storage and distribution, the hazard analysis should look at the severity and likelihood of all potential food safety hazards that may be reasonably expected to occur in terms of specific biological, chemical (including radiological), physical, and economically motivated hazards, as well as the control measures for each. Preventive controls, such as process, allergens, sanitization, and supply chain should be identified for the identified hazards. Examples of specific biological hazards include Listeria monocytogenes, Salmonella spp., Enterohaemorrhagic E. coli (EHEC), Shiga toxin-producing E. coli (STEC), Cryptosporidium parvum, Cyclospora cayetanensis; chemical hazards include mycotoxins, pesticide residues, sanitation chemicals, lubricants, allergens; physical hazards include stones, metal, glass, and brittle plastic. Evaluation should include all ingredients, equipment, processing steps (e.g., receiving, dump tanks, brush bed systems, recycled wash systems including hydro-vacuum coolers, ice injectors, flume washers, etc., single line wash systems, ice manufacturing), and inputs including packaging materials and post-harvest treatments, etc. Each step identified in the process flow diagram should be assessed in the hazard analysis. Justifications should be documented when identifying significant and non-significant hazards. Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure. The hazard analysis should indicate if an adequate control step for this potential risk exists further down the process. The hazard analysis should be reviewed when changes occur affecting the product description and/or the process flow.

7.02.02	Have preventive control decisions been made with documented relevant validation justifications and where preventive control(s) are implemented in a specific processing step, have they been developed using plans and/ or procedures to control the identified hazard(s)?	The preventive control decisions should be created from the documented hazard analyses, i.e. there should be a logical documented approach showing why the process was deemed a preventive control or not. Preventive control decisions should be properly justified with supporting documents and evidence. The preventive controls defined in the hazard analysis should be developed to define in detail the plans/charts and procedures involved, including monitoring requirements, thresholds, corrective actions and verification parameters in order to control the hazard.	The preventive control decisions should be properly justified with supporting documents and evidence. The preventive controls defined in the hazard analysis should be developed to define, in detail, the parameters involved, and monitoring requirements to control the hazard(s). Types of preventive controls: process, allergen, sanitation, and supply chain. The process preventive controls should be created from the documented hazard analysis i.e. there should be a logical documented approach (such as utilizing a decision tree) showing why the process was deemed a preventive control or not. Minor deficiency (10 points) if: • Single fault in the logic or justification of one preventive control decision. • Single preventive control developed that does not meet the criteria for a preventive control. Major deficiency (5 points) if: • More than one fault in the logic or justification of the preventive control decisions. • More than one preventive control developed does not meet the criteria for a preventive control. • One (where there are multiple) preventive control has been omitted. Non-compliance (0 points) if: • No preventive controls have been developed in the hazard analysis step even though clearly preventive controls did exist. • More than one preventive control has been omitted in a plan where there should be multiple preventive controls. • A single preventive control has been omitted in a plan where there is a single preventive control.
7.02.04	Do the process preventive controls have critical limits, supported by relevant validation documentation, and other preventive controls have parameters, values and targets (where relevant) supported by relevant validation documentation?	No Change in v3.1	No Change in v3.1

EXECUTION OF THE PREVENTIVE CONTROLS PROGRAM			
Number	Question	Expectation	Interpretation Guideline
7.03.06	No Change in v3.1	Records should be signed off by the designated person(s) responsible (i.e. qualified individual for preventive controls) for internal verification of the company's preventive control program. The sign off should not be done by the same person who carried out the preventive control monitoring activities. If any issues are detected, corrective actions should be recorded.	Preventive control records should be reviewed and signed off off by the designated person(s) responsible (i.e. qualified individual for preventive controls) within 7 calendar days of the original preventive control monitoring activity occurring. 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 preventive control 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 preventive control program and associated documents. If discrepancies are found, then the sign off signatory should note the issues and corrective actions that are then taken. Minor deficiency (7 points) if: • Single/isolated instance(s) of preventive control records not reviewed and signed off within 7 days by the quality control supervisor or manager (second signatory). • Single/isolated instance(s) of the preventive control records being signed off by the second signatory but there are issues with the records that have not been highlighted. Major deficiency (3 points) if: • Numerous instances of preventive control records not reviewed and signed off within 7 days by the quality control supervisor or manager (second signatory). • Numerous instances of the preventive control records being signed off by the second signatory but there are issues with the records that have not been highlighted.