PrimusGFS - Checklist - v 1.6

This Module should be completed only once for the entire audit. It is common for all the operations in the scope of the application done by the organization.

Module 1 - FSMS (Sections 1.01 to 1.08)

Food Safety Management System Requirements

Available Answers: TC - Total Compliance, Mi - Minor Deficiency, Ma - Major Deficiency, NC - Non Compliance and N/A - Not Applicable

Section	Q #	Question	Total Points	Given Answer	Auditor Notes
Management System	1.01.01	Is there a documented food safety policy detailing the company's commitment to food safety?	5		
Management System	1.01.02	Is there a Food Safety Manual or other documented food safety management system covering the scope of business included in this audit and procedures/instructions for all food safety processes?	5		
Management System	1.01.03	Is there a detailed organizational structure chart of all employees whose activities affect food safety?	3		
Management System	1.01.04	Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?	5		
Management System	1.01.05	Is there documented management verification of the entire food safety management system on at least an annual basis?	5		
Management System	1.01.06	Is there a documented analysis detailing resources required to implement and improve the food safety management system processes with documented commitment from senior management to provide these resources?	5		
Records Requirements	1.02.01	Are all records free of “correction fluid” (white out), pencil text and erasable ink text? If using computerized records, is there a system that shows record amendments (data history) if the records are changed after initial entry?	3		
Records Requirements	1.02.02	Are all monitoring and process control records stored for a minimum period of a year or for at least the shelf life of product if greater than a year?	3		
Records Requirements	1.02.02	Are the written procedures available to relevant users and is a master copy maintained in a central file?	5		
Procedures and Corrective Actions	1.03.01	Are there written Standard Operating Procedures (SOPs) that detail work instructions for food safety related activities performed in the field operations?	5		
Procedures and Corrective Actions	1.03.02	Are there written Standard Operating Procedures (SOPs) that detail work instructions for food safety related activities in the facility operations?	5		

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Procedures and Corrective Actions	1.03.03	Is there a corrective action procedure that describes the requirements for follow up and prevention of future occurrences?	5		
Internal and external inspections	1.04.01	Is there a program for periodic self-inspections of the field operations covering any process impacting food safety and are records maintained detailing corrective actions? For Field (GAP option) this includes the growing and harvesting practices and all the related documentation and records generated.	10		
Internal and external inspections	1.04.02	Is there a program for periodic self-inspections of the facility operations covering any process impacting food safety and are records maintained detailing corrective actions? For Facility (GMP option) includes the observation of the facility practices and all the relate documentation and records generated.	10		
Internal and external inspections	1.04.03	Are there written procedures for handling regulatory inspections?	3		
Internal and external inspections	1.04.04	Are there records of regulatory inspections and/or contracted inspections, company responses and corrective actions, if any?	5		
Internal and external inspections	1.04.05	Are there documented policies and/or procedures for the calibration for measuring and monitoring devices used in the field operations such as fertilizer and crop protection application equipment, and other equipment related to the safety of the product?	10		
Internal and external inspections	1.04.06	Are there documented policies and/or procedures for the calibration for measuring and monitoring devices used in the facility operations such as chemical application equipment, thermometers, metal detectors, ORP meters, pH meters and other equipment related to the safety of the product?	10		
Rejection and release of product	1.05.01	Is there a written procedure for handling on hold or rejected products?	10		

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Rejection and release of product	1.05.02	Are product release procedures implemented (e.g. lot signed out, when a product lot sample is undergoing an analysis, etc.) and are records available for review?	5		
Rejection and release of product	1.05.03	Is there a documented system for dealing with customer complaints and buyer food safety complaints and are those on file, along with company responses, including corrective actions?	10		
Supplier Monitoring	1.06.01	Are there current written specifications for all ingredients, materials, products and services purchased &/or provided that relate to product safety, are they easily accessed and there is a review process in place for the specifications?	5		
Supplier Monitoring	1.06.02	Is there a list of approved suppliers?	5		
Supplier Monitoring	1.06.03	Is there a written procedure detailing the selection, evaluation, approval and monitoring process of approved suppliers?	5		
Supplier Monitoring	1.06.04	Does the organization have documented evidence to ensure that raw material, processing aids and ingredients suppliers comply with specifications, regulatory requirements and best practice guidelines?	15		
Supplier Monitoring	1.06.05	Does the organization have documented evidence to ensure that packaging, materials and services suppliers comply with specifications, regulatory requirements and best practice guidelines?	15		
Supplier Monitoring	1.06.06	Are appropriate supplier controls in place (e.g. results of pesticide multi-residue analysis) to ensure product pesticide residues of raw material/ingredients do not exceed published MRLs?	5		
Traceability and Recall	1.07.01	Is there is a documented account that indicates how the company product tracking system works, thereby enabling trace back and trace forward to occur in the event of a potential recall issue?	10		
Traceability and Recall	1.07.02	Does the organization have a documented recall program including: procedures, recall team roles and contact details, external contact listings, explanation of different types (classes) of recalls?	15		
Traceability and Recall	1.07.03	Is testing of recall procedures (including trace back) performed and documented annually? Can the company identify where affected product was sent?	10		
Traceability and Recall	1.07.04	Is there a daily incidents report, sometimes called a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA) ?	5		

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Product testing	1.08.01	Based on risk assessment, is there scheduled testing program for raw materials, work in progress, packaging and finished goods?	5		
Product testing	1.08.02	If test are necessary from the risk assessment, is there evidence of the test results for raw materials, work in progress, packaging and finished goods, at the scheduled frequencies and with follow-up for identified deviations?	5		
Product testing	1.08.03	Are testing and analysis performed by licensed/accredited laboratories (e.g. ISO 17025 or equivalent, National Regulations, State Department, etc.)?	5		