

PrimusGFS - Questions and Expectations - v3.2

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.

Module 7 - Preventive Controls Program (Sections 7.01 to 7.03)

Preventive Controls Program Requirements

Section	Q #	Question	Total Points	Expectations	Question Type
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?	10	There should be a documented list of the team carrying out the preventive control program in the operation, with one member of the team (a preventive control qualified individual), who has successfully completed recognized training in the development and application of risk-based preventive controls training (or is otherwise qualified) designated the preventive control coordinator (leader). The team should be multidisciplinary and 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.	Essential
Preliminary steps	7.01.02	Is there documented evidence that the preventive control team members have been trained on preventive control program development?	15	The preventive control coordinator should have a certificate of a formal Preventive Control Qualified Individual training from a recognized organization, institution or trainer. The rest of the team should have at least an internal training given by someone who has gone to a formal Preventive Control Qualified Individual training to make sure they are knowledgeable of the preventive control program development. These trainings should be documented.	Essential
Preliminary steps	7.01.03	Does a product description exist for the products produced?	10	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 detail the products' name and composition (ingredients), packaging used, storage conditions, shelf life, 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.	Essential
Preliminary steps	7.01.04	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 (including ingredients) going through the same process can be grouped in the same flow chart. The flow chart should indicate all raw materials, ingredients and materials used in all preparation steps, all equipment used, blending steps, processing steps, rework, by-product, returned products and products destined for further processing, packaging materials (carton and unit packaging) and packaging equipment. All inputs should be included, such as packaging, water source (e.g. city or well), ice, anti-microbials, fungicides, etc. Each step should show any holding times, temperature regimes, etc., at appropriate process steps. Diagram should show rework processes and when product is diverted to be used for other purposes. Process flows can be augmented by written process descriptions (where helpful).	Essential
Preliminary steps	7.01.05	Is there documented evidence that the flow chart(s) has been verified on-site?	10	The diagram(s) should be verified on-site and signed and dated by the preventive control team coordinator to confirm it reflects the conditions of the process at different moments in time (auditor should confirm how and when flow chart(s) were verified) and there are no missing steps.	Essential

Development of the Preventive Controls Program	7.02.01	Has a documented hazard analysis for each product been conducted, showing the various types of hazards, their likelihood of occurrence, their associated severity and their control measures?	15	There should be a detailed, documented hazard analysis for each product group (including ingredients) process flow in order to prove that a proper hazard analysis was conducted. Similar products (e.g. similar in formulation, have similar processing steps and are prepared and packaged in a similar manner) may be grouped. 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), more than one hazard may be controlled by a specified control measure and not all potential hazards require a preventive control. Preventive controls, such as process, allergens, sanitization, and supply chain should be identified for the identified hazards.	Essential
Development of the Preventive Controls Program	7.02.02	Where risk-based preventive controls are identified, have they been developed using plans and/or procedures to control identified hazard(s) are they appropriate and consistent with current scientific understanding?	15	Preventive control decisions should be properly justified with supporting documents and evidence. Preventive controls may include process preventive controls, food allergen preventive controls, sanitation preventive controls, and supply chain program as well as other preventive controls. 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. The preventive controls defined in the hazard analysis should be developed to define in detail the parameters involved and monitoring requirements, thresholds, corrective actions and verification requirements in order to control the hazard(s).	Essential
Development of the Preventive Controls Program	7.02.03	Is the preventive control program (as part of the Preventive Control Plan re-analysis) reviewed when significant changes are made (raw materials, packaging, suppliers, product, process, construction, recurring deviations, new scientific information, etc.) and at least once every 3 years?	10	The preventive controls should be reviewed by the preventive controls team when significant changes are made and at least every 3 years e.g. raw materials, packaging, suppliers, product, process, construction, new equipment, recurring deviations, new scientific information, new distribution or consumer handling practices, etc., including the hazard analysis, 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 preventive controls 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 preventive controls team should inform workers involved of the review outcomes.	Essential
Development of the Preventive Controls Program	7.02.04	Do the process preventive controls have critical limits, supported by relevant validation documentation, and do other preventive controls have parameters, values and targets (where relevant)?	15	Process preventive controls should have critical limit parameters (which are supported by validation documentation), showing that the parameters 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. Other non-process preventive controls do not control a specific processing action, and how a facility manages their system and its complexity will determine whether they are considered preventive controls or pre-requisite programs. Validation of non-process preventive controls is not required; however it may be considered under certain circumstances e.g. when major changes are made to a product or process.	Essential
Development of the Preventive Controls Program	7.02.05	Have monitoring requirements and frequencies been determined and documented for the preventive controls?	15	There should be determined and documented monitoring requirements and frequencies for the preventive controls. Monitoring applies not only to process preventive controls but also to allergen, sanitation and supply chain preventive controls as appropriate to the food safety program. The plans and/or procedures should note the frequencies of monitoring for each preventive control. Monitoring activities will vary between preventive control types.	Essential

Development of the Preventive Controls Program	7.02.06	Are there documents that show validation work for the process preventive controls and was this validation work performed by or overseen by a Preventive Control Qualified Individual?	10	Validation is applying scientific concepts and demonstrating that following the plan will control the identified hazards. Process preventive controls should document validation work performed or overseen by a qualified individual. Validation is required for most process controls when hazards requiring a preventive control are identified. Validation is ideally done before the plan is implemented. Where relevant, other preventive controls types e.g. sanitation-related preventive controls (e.g. how long processing line can run between cleaning, allergen controls) should be supported by validation work and all validation work dated within 90 days of starting production.	Essential
Development of the Preventive Controls Program	7.02.07	Do the preventive control plans, charts and/or procedures indicate that specific responsibilities have been assigned for the monitoring, recording and corrective action implementation?	10	Specific responsibilities should be assigned for the monitoring, recording and corrective action implementation of each preventive control to ensure compliance.	Essential
Development of the Preventive Controls Program	7.02.08	Have standard operating procedures (SOPs) been created for the monitoring process(es) of the preventive controls, including those in plan or chart format (e.g., process preventive controls)?	10	Clear and simple standard operating procedures (SOPs) should be written for each monitoring process(es) of the preventive controls, even those that are documented in plan or chart formats (e.g., process preventive controls). These SOPs should expand the monitoring activities in detail in the form of work instructions, and match what is written in the preventive controls program.	General
Development of the Preventive Controls Program	7.02.09	Have corrective action procedures been established for the preventive controls, including a detailed action plan for operators to follow if out of specification situations are observed (loss of control/deviation) and plans to adjust process back into control?	15	Corrective actions are procedures that must be taken if preventive controls are not properly implemented (e.g. there is a deviation from a critical limit) and unsafe product may have been produced. There should be a documented, detailed plan with procedures to follow when there is a loss of control (deviation) of a preventive control appropriate to the **nature** of the hazard and preventive control. Requirements vary for process, food allergen, sanitation and supply chain program preventive controls. Corrective action details for a process preventive control should note the critical limit issue that has occurred, what corrective actions were carried out, including what happened to potentially affected product and also how the process was "repaired" or "amended" in order to get the process back to the required control level. Preventive measures and root cause analysis may be appropriate.	Essential
Development of the Preventive Controls Program	7.02.10	Have recording forms been developed for monitoring the preventive controls?	15	Defined record templates are required for recording preventive control monitoring. The parameters on the records should reflect those in the preventive control program. These templates should be managed under the document control program. Monitoring recording requirements vary depending on preventive control type.	General
Development of the Preventive Controls Program	7.02.11	Have verification procedures and schedules been developed for the preventive controls?	15	Preventive controls should have documented verification activities associated with the monitoring that verifies the correct implementation of the preventive controls. Examples of verification include preventive control monitoring and corrective action record reviews, testing associated with preventive controls, equipment inspection associated with preventive controls, 2nd & 3rd party supplier audits, testing related to raw materials, internal audits, equipment calibration and accuracy, etc. Some verification activities should be performed or overseen by a preventive controls qualified individual. Also some of the verification activities, such as testing and auditing benefit from record reviews and trend analysis. Where verification activities have found that preventive controls were not performing as required, there should be records that show that this prompted a review of the relevant part of the preventive control program.	Essential

Execution of the Preventive Controls Program	7.03.01	Is there documented evidence that all plant workers have attended a preventive control training, including specific training for workers directly involved with preventive controls?	10	Preventive control training is important in ensuring that all workers are knowledgeable regarding the basics of preventive controls. This training is especially important for workers directly involved with preventive control operations, and for those workers, the training should cover the explanation of the procedures in which they are responsible and be included in the training management program (see 1.01.04). All training activities should be documented.	General
Execution of the Preventive Controls Program	7.03.02	Are the preventive control monitoring activities and frequencies in compliance with the preventive control plans, charts, and procedures?	15	The monitoring records should show that testing frequency, parameters and any other details match what is written in the preventive control plans, charts, and procedures. The records should show actual values or observations, be accurate and legible, be real-time recording and have adequate detail.	Essential
Execution of the Preventive Controls Program	7.03.03	Do workers directly involved with preventive control operations understand basic preventive control principles and their role in monitoring preventive controls?	10	Individuals should understand the basics of a preventive control program and how it applies to their operations. Individuals should have a good understanding of the details of the preventive controls that they are directly involved with, including procedures, parameters, critical limits in the case of process preventive controls and corrective action procedures. Auditor should interview operators to verify.	Essential
Execution of the Preventive Controls Program	7.03.04	Are preventive control associated records signed off (or initialed) by the workers who are carrying out and recording the preventive control activities?	15	Records should be legibly signed off in order to show who actually performed the preventive control monitoring activities. If initials are used, there should be a way to easily determine who the initials refer to.	Essential
Execution of the Preventive Controls Program	7.03.05	Is there a deviation record detailing documented corrective actions when a deviation or deficiency of a preventive control occurs?	15	When a monitoring or verification step shows a deviation or deficiency against a preventive control (including when a critical 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 future similar issues in the future. This may include root cause analysis.	Essential
Execution of the Preventive Controls Program	7.03.06	Are the records associated with preventive controls reviewed and signed off by a preventive controls qualified individual or trained designate (second signatory)?	10	Preventive control records should be reviewed, dated and signed off by the designated person(s) responsible i.e. preventive controls qualified individual-PCQI or trained designate within 7 working days of the original preventive control 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. 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.	Essential

Where laws, commodity specific guidelines and/or best practice recommendations exist and are derived from a reputable source, then th 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.

Caution symbol questions are of essential importance to food safety due to potential concern(s) regarding the conformity of the product/processes or there are legal concerns if not in total compliance. Please refer **PrimusGFS General Regulations - Appendix 3 Guidance for Closure of Deficiencies and Corrective Actions** for details.

Document Revision History		
Date	Rev.#	Description
1/19/21	0	Initial
7/20/21	1	No changes to Module 7
8/27/21	2	No changes to Module 7
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