Primus Addendum

Addendum Questions and Expectations

Primus Preventive Controls Addendum - GMP v17.12

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Preliminary steps | Q# 1.01 - 1.04

FSMA Preventive Control Reference	Q#	Question	Expectaction
117.126 (2)	1.01	Is there a team responsible for the preventive control program at the operation, with a leader assigned and for the development, implementation and on-going maintenance of the preventive control program?	There should be a documented list of the team carrying out the preventive control 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.
117.190 (6) 117.180 (8 c1)	1.02	Is there documented evidence that the preventive control team members have been trained on preventive control program development?	At least one member of the preventive control team should have a formal Preventive Control Qualified Individual training.The rest of the team should have at least an internal training to make sure they are knowledgeable of the preventive control program development. These trainings should be documented.
117.126	1.03	Does a product description exist for the products produced?	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.
117.130	1.04	Has the process(es) been flow charted in sufficient detail to completely describe the process or product handling/processing steps and has the flow chart(s) been verified on-site?	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. The diagram(s) should be verified on-site and signed by the preventive control team coordinator to confirm it reflects the conditions of the process at different moments and there are no missing 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).

Development of the Preventive Controls Program | Q# 2.01 - 2.13

FSMA Preventive Control Reference	Q#	Question	Expectaction
117.130	2.01	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?	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.
117.135	2.02	Have process 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 process preventive controls 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 paremeters in order to control the hazard.
117.135 (a)	2.03	Have processing steps that are deemed preventive controls been identified i.e. steps that significantly minimize or prevent food safety hazards? Informational gathering. If answer is YES, continue with next question. If answer is NO, the rest of the addendum is not applicable.	The identification of preventive controls in the process will require the development of the criteria for managing it and the execution of the necessary activities in the production line. Types of preventive controls: process, allergen, sanitation and supply-chain.
117.135 (1)	2.04	Do the process preventive controls have critical limits, and other preventive controls have parameters, values and targets (where relevant) supported by relevant validation documentation?	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. Ideally, other preventive control types (e.g., sanitation controls) should have validation documentation (where useful).
117.135 (1)	2.05	Have monitoring requirements and frequencies been determined and documented for the preventive controls?	The plans/charts and/or procedures should document the monitoring requirements including detailing the actions necessary (observations or measurements) to ensure whether a preventive control is under control. The plans and/or procedures should note the frequencies of monitoring for each preventive control. Monitoring activities will vary between preventive control types.

FSMA Preventive Control Reference	Q#	Question	Expectaction
117.160	2.06	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?	Process preventive controls should document validation work performed or overseen by a qualified individual. The validation work could include peer reviewed scientific literature, legislative documentation, trade association guidance, in-plant observations and testing, etc. Where useful and relevant, other preventive controls types e.g. sanitation preventive controls should be support by validation work dated within 90 days of starting production.
117.135	2.07	Do the preventive control plans, charts and/or procedures indicate that specific responsibilities been assigned for the monitoring, recording and corrective action implementation?	Specific responsibilities should be assigned for the monitoring, recording and corrective action implementation of each preventive control to ensure compliance.
117.135 (1)	2.08	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)?	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.
117.150 117.165 (b)	2.09	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?	There should be a documented, detailed plan with procedures to follow when there is a loss of control (deviation) of a preventive control 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 preventive controls to try and avoid a repeat of the loss of control.
117.135	2.10	Have recording templates (recording forms) been developed for monitoring the preventive controls?	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.
117.165 (a)	2.11	Have verification procedures and schedules been developed for the preventive controls?	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 indidvidual. 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.

FSMA Preventive Control Reference	Q#	Question	Expectaction
117.170	2.12	Are the preventive controls (as part of the Food Safety Plan re-analysis) reviewed when operational changes are made (facility, process, equipment, ingredients, packaging etc.) and at least once every 3 years?	The preventive controls should be reviewed by the preventive controls team when operational changes are made and at least every 3 years, including the product descriptions, process flows, hazard analyses, preventive control decisions, preventive control 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 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.
117.135	2.13	Is there documented evidence that all plant workers have attended a preventive control training, including training for workers directly involved with preventive controls?	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. All training activities should be documented.

Execution of the Preventive Controls Program | Q# 3.01 - 3.06

FSMA Preventive Control Reference	Q#	Question	Expectaction
117.135	3.01	Do all of the documents noted in the preventive control plan accurately reflect plan requirements for the preventive controls?	Documents noted in the preventive control plans, charts, and procedures should be in place for preventive controls (where relevant), for example process preventive controls. Records should reflect the plan requirements. Using document version control helps ensure that the documents on the production floor match those in the plans, charts, and procedures.
117.135	3.02	Are the preventive control monitoring activities and frequencies in compliance with the preventive control plans, charts, and procedures?	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.
117.135	3.03	Do workers directly involved with preventive control operations understand basic preventive control principles and their role in monitoring preventive controls?	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, critical limits in the case of process preventive controls and corrective action procedures. Auditor should interview operators to verify.

FSMA Preventive Control Reference	Q#	Question	Expectaction
117.135	3.04	Are preventive control associated records signed off (or initialed) by the workers who are carrying out and recording the preventive control activities?	Legiliby signed off records should be recorded 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.
117.165 (4i)	3.05	Is there a deviation record detailing documented corrective actions when a deviation or deficiency of a preventive control occurs?	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.
117.165 (4)	3.06	Are the records associated with preventive controls reviewed and signed off by the quality control supervisor and/or management (second signatory)?	Records should be signed off by the designated person(s) responsi ble 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.

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. This includes the U.S. FDA FSMA guidelines, and where any FSMA guidelines are stricter than the audit guidelines, the FSMA guidelines prevail, including compost produced in-house. Audit users should allow a degree of risk association if laws, guidelines, best practices, etc., have not been documented.

Resources

- Produce Safety Alliance: https://producesafetyalliance.cornell.edu
- Food Safety Preventive Controls Alliance: https://www.ifsh.iit.edu/fspca
- FDA Food Safety Modernization Act (FSMA): https://www.fda.gov/Food/GuidanceRegulation/FSMA/
- California Leafy Greens Marketing Agreement (LGMA) http://www.caleafygreens.ca.gov/food-safety-program/food-safety-practices/
- *FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals: https://www.fda.gov/-*Food/GuidanceRegulation/FSMA/ucm361902.htm
- FSMA Final Rule for Preventive Controls for Human Food: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm
- FSMA Final Rule on Produce Safety: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm
- FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm
- FSMA Final Rule on Sanitary Transportation of Human and Animal Food: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm
- FSMA Final Rule Amendments to Registration of Food Facilities: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm440988.htm

- *FSMA; Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules: https://www.federalregister.gov /documents/2016/08/24/2016-20176/the-food-and-drug-administration-food-safety-modernization-act-extension-and-clarification-of*
- Extension of Compliance Dates for Subpart E in the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: https://www.federalregister.gov/documents/2017/09/13/2017-19434/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-extension
- FDA Food Code: https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/
- United Fresh Produce Association: https://www.unitedfresh.org
- Produce Marketing Association: https://www.pma.com