

Addendum Checklist

Primus Preventive Controls Addendum - GMP v17.12

Preliminary steps | Q# 1.01 - 1.04

FSMA Preventive Control Reference	Q#	Question	Comments
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?	
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?	
117.126	1.03	Does a product description exist for the products produced?	
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?	

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

FSMA Preventive Control Reference	Q#	Question	Comments
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?	
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)?	
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.	
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?	
117.135 (1)	2.05	Have monitoring requirements and frequencies been determined and documented for the preventive controls?	

FSMA Preventive Control Reference	Q#	Question	Comments
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?	
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?	
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)?	
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?	
117.135	2.10	Have recording templates (recording forms) been developed for monitoring the preventive controls?	
117.165 (a)	2.11	Have verification procedures and schedules been developed for the preventive controls?	

FSMA Preventive Control Reference	Q#	Question	Comments
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?	
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?	

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

FSMA Preventive Control Reference	Q#	Question	Comments
117.135	3.01	Do all of the documents noted in the preventive control plan accurately reflect plan requirements for the preventive controls?	
117.135	3.02	Are the preventive control monitoring activities and frequencies in compliance with 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?	

FSMA Preventive Control Reference	Q#	Question	Comments
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?	
117.165 (4i)	3.05	Is there a deviation record detailing documented corrective actions when a deviation or deficiency of a preventive control occurs?	
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)?	

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/docu
ments/2017/09/13/2017-19434/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-extension](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>