Primus Addendum

Addendum Questions and Expectations

Primus Produce Rule Addendum - Harvest Crew v17.12

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FSMA Produce Rule Reference	**Q#**	**Question**	**Expectaction**
112.21 (b) 112.22 (c) 112.23	1.01	Is there a designated person responsible for the food safety program in the field?	There should be a person/persons assigned responsibility for the field and/or harvest crew food safety program that has been trained accordingly (including to all state and federal requirements).
112.30 (b) 112.33 (a)	1.02	Is there a food safety hygiene training program covering new and existing workers and are there records of these training events?	There should be a formal training program to inform workers of the current policies and requirements of the company regarding hygiene. Qualified trainers should lead the trainings, and training type and intensity should reflect the risks associated with the products/processes. Frequency should be at the start of the season and then some topics covered at least quarterly, but ideally monthly. These trainings should cover food safety and hygiene, the importance of detecting food safety and/or hygiene issues with co-workers and visitors, and all food safety or hygiene issues in which they are responsible. Training logs should have a clearly defined topic(s) covered, trainer(s) and material(s) used/given. Topics include, but not limited to, hand washing, protective clothing (where applicable), recognizing and reporting injury and illness, blood and bodily fluids, jewelry, dropped product, animal intrusion, food defense. There should be records of workers who have attended each session.
112.33 (a)	1.03	Does the operation have a written food safety hygiene and health policy covering at least worker and visitor hygiene and health, infants and toddlers, animal presence in growing and storage areas, fecal matter, dropped product, blood and bodily fluids?	There should be written food safety policy rules regarding worker and visitor personal hygiene/GAPs/GMPs and health requirements. All workers should be issued a list of rules in the relevant languages and confirm by signing they understand and agree to abide. Training provided and associated records should meet local and national regulations.
112.21 (d)	1.04	Is there a worker non-compliance/ disciplinary action procedure	There should be a procedure for worker non-conformance and require corrective actions be detailed. There may be a tier system, which includes re-training, verbal and written disciplinary actions and allowance for immediate termination for gross misconduct.
112.33 (a)	1.05	Are visitors and contractors to the company operations required to adhere to food defense procedures?	Visitors and contractors should be required to adhere to food defense procedures. This can be evidenced by having them sign a log when arriving to the operation, where they are agreeing to meet the company visitor and contractor food defense requirements.

Procedures and Corrective Actions | Q# 2.01

FSMA Produce Rule Reference	Q#	Question	Expectaction
112.131 (d)	2.01	Is there an incident reporting system, also known as a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA) ?	This record documents unusual and infrequent events, remedial actions and preventive actions. These might include incidents like foreign object findings, chemical spills, power outages, packaging issues, glass breakage, fires, etc., as well as any other serious incidents such as natural disasters (e.g., hurricanes, flooding, earthquakes, etc.).

Control of Documents and Records | Q# 3.01 - 3.05

FSMA Produce Rule Reference	Q#	Question	Expectaction
112.140 (a-b)	3.01	Is there a written document control procedure (including document control register/record) describing how documents will be maintained, updated and replaced?	The document control procedure should show how controlled documents are to be written, coded, approved, issued and updated, and should also show how obsolete versions of documents are controlled. If using an electronic record keeping system, the procedure should cover this.
112.140 (a-b)	3.02	Is there a documented and implemented procedure that requires all records to be stored for a minimum period of 24 months (or greater if legally required) or for at least the shelf life of the product if it is greater than 24 months?	Food safety related records should be retained for auditing purposes and in case there are legal issues, customer queries, etc. There should be a procedure in place and all monitoring and process control records should be held for a minimum of 24 months regardless of the production item's shelf life. Any records required by law to be kept longer than 24 months should be kept for the legally mandated period. Any records pertaining to long life product should be kept at least for the duration of the shelf life of the product.
112.140 (a-b)	3.03	Are both paper and electronic food safety related documents and records created, edited, stored and handled in a secure manner?	Both paper and electronic documents and records that are part of the food safety program (e.g., procedures, policies, training records, testing results, monitoring records, etc.), should be stored securely and backed up in the case of electronic files. In the case of paper files, they should be generated using ink (not pencil), and if changes are made to records after initial entry, changes should be clearly legible and tracked, avoiding the use of corrective fluid. For electronic records, there should be access control and a back up of all files. When electronic records are amended, they should show what was amended, by whom and when (editing history). Records should be legible and accurate.
112.140 (a-b)	3.04	Are records maintained in an organized and retrievable manner?	Records should be stored in an organized manner, to allow for quick retrieval of records. This will aid in the detection of issues, the isolation of problems, and the identification of trends where attention is needed. Records should be accessible, even if the operation is seasonal.

FSMA Produce Rule Reference	Q#	Question	Expectaction
112.161 (a-b)	3.05	Are all records and test results that can have an impact on the food safety program reviewed and signed off by the person responsible for the food safety program?	Records and test results should be signed off by the designated person(s) responsible for the food safety program within a reasonable timeframe. The sign off should not be done by the same person who carried out the monitoring activities. If any issues are detected, corrective actions should be recorded.

Supplier Monitoring / Control | Q# 4.01 - 4.02

FSMA Produce Rule Reference	Q#	Question	Expectaction
112.60 (b)	4.01	Are there current written food safety related specifications for all incoming products, ingredients, materials (including packaging), services provided on-site, and outsourced services?	There should be written, detailed, up to date specifications for all incoming products, ingredients, materials (including packaging), services provided on-site, and outsourced services (including when exceptions will be allowed) that have an effect on food safety, addressing the required Good Agricultural Practices and/or Good Manufacturing Practices. Documented specifications should be easily accessible to workers. The specifications should be reviewed at least annually.
112.60 (b)	4.02	Does the organization have documented evidence to ensure that all incoming products, ingredients, materials, services provided on-site and outsourced service suppliers comply with the approval requirements and that all supplier verification activies (including monitoring) are being followed, as defined in the supplier approval procedure?	The organization should have the required documentation for approved suppliers to ensure that they are complying with the established supplier/service provider approval procedures, contracts, specifications, regulatory requirements and best practice guidelines. Supplier verification documents should demonstrate that the ongoing approval requirements are being met (e.g., third party audits, certificates of analysis, reviews of supplier records, etc.).

Harvest Practices | Q# 5.01 - 5.05

FSMA Produce Rule Reference	Q#	Question	Expectaction
112.44 (a3)	5.01	Are there records of microbial testing for water used for postharvest product contact (e.g., washing, re-hydrating) and product contact surfaces (e.g., cleaning grading packing tables and harvest tools) showing that there is no detectable *E.coli* in the water?	For Generic *E.coli,* there should be negative or < detection limit (MPN or CFU/100mL). Where thresholds have been exceeded, there should be recorded corrective actions, including investigations and water retests (E.coli O157:H7 < detection limits or Negative-zero tolerance).

FSMA Produce Rule Reference	Q#	Question	Expectaction
112.44 (a3)	5.02	Do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?	Written procedures (SOPs) should exist covering corrective measures not only for the discovery of unsuitable or abnormal water results, but also as a preparation on how to handle such findings.
112.44 (a3)	5.03	If unsuitable or abnormal results have been detected, have documented corrective measures been performed?	For Generic E.coli, there should be negative or < detection limit (MPN or CFU/100mL). Where thresholds have been exceeded, there should be recorded corrective actions, including investigations, water retests and crop testing (E.coli O157:H7 and Salmonella < detection limits or Negative-zero tolerance).
112.48 (b)	5.04	Are there specific Standard Operating Procedures (SOPs) for the monitoring, testing and changing of recirculated and batch water systems (e.g., dump tanks) and for monitoring water temperature?	There should be specific SOPs describing the process of changing the water systems and monitoring the water temperature. The water temperature should be appropriate for the products and processes being performed.
112.48 (b)	5.05	Are there records of visual monitoring, testing and changing of recirculated and batch water systems (e.g., dump tanks) and water temperature checks (where relevant)?	There should be records of visual monitoring, testing and changing of recirculated and batch water systems and water temperature checks (where relevant).

Harvest Worker Hygiene | Q# 6.01 - 6.04

FSMA Produce Rule Reference	Q#	Question	Expectaction
112.44 (a4)	6.01	Are total coliforms (TC) and generic *E.coli* tests conducted on the water used for hand washing at the required and/or expected frequency?	Total coliforms (TC) and generic *E.coli* testing should occur on a routine basis. All water sources used for hand washing throughout the harvesting season should be tested. One sample per water source should be collected and tested prior to use and then ideally monthly.
112.44 (a4)	6.02	Do written procedures (SOPs) exist covering proper sampling protocols, which include where samples should be taken and how samples should be identified?	There should be a documented procedure in place detailing how water samples are to be taken, including stating how samples should be identified i.e. clearly naming the location that the sample was taken, identifying the hand wash station, the water source and the date.
112.44 (a4)	6.03	Do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?	Written procedures (SOPs) should exist covering corrective measures, not only for the discovery of unsuitable or abnormal water results, but also as a preparation on how to handle such findings.

FSMA Produce Rule Reference	Q#	Question	Expectaction
112.44 (a4)	6.04	If unsuitable or abnormal results have been detected, have documented corrective measures been performed?	For TC and generic E.coli, there should be negative or < detection limit (MPN or CFU/100mL). Where thresholds have been exceeded, there should be recorded corrective actions, including investigations and water retests.

*Where laws, commodity specific guidelines and/or best practice recommendations exist and are derived from a reputable source, th*en 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/GuidanceRegula-tion/FSMA/ucm378628.htm
- FSMA Final Rule on Sanitary Transportation of Human and Animal Food: https://www.fda.gov/Food/GuidanceRegula-tion/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
- 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