

Addendum Checklist

Primus Produce Rule Addendum - Harvest Crew v17.12

Food Safety Hygiene | Q# 1.01 - 1.05

FSMA Produce Rule Reference	Q#	Question	Comments
112.21 (b) 112.22 (c) 112.23	1.01	Is there a designated person responsible for the food safety program in the field?	
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?	
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?	
112.21 (d)	1.04	Is there a worker non-compliance/disciplinary action procedure	
112.33 (a)	1.05	Are visitors and contractors to the company operations required to adhere to food defense procedures?	

Procedures and Corrective Actions | Q# 2.01

FSMA Produce Rule Reference	Q#	Question	Comments
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) ?	

Control of Documents and Records | Q# 3.01 - 3.05

FSMA Produce Rule Reference	Q#	Question	Comments
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?	
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?	
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?	
112.140 (a-b)	3.04	Are records maintained in an organized and retrievable manner?	

FSMA Produce Rule Reference	Q#	Question	Comments
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?	

Supplier Monitoring / Control | Q# 4.01 - 4.02

FSMA Produce Rule Reference	Q#	Question	Comments
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?	
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 activities (including monitoring) are being followed, as defined in the supplier approval procedure?	

Harvest Practices | Q# 5.01 - 5.05

FSMA Produce Rule Reference	Q#	Question	Comments
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 <i>E.coli</i> in the water?	

FSMA Produce Rule Reference	Q#	Question	Comments
112.44 (a3)	5.02	Do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?	
112.44 (a3)	5.03	If unsuitable or abnormal results have been detected, have documented corrective measures been performed?	
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?	
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)?	

Harvest Worker Hygiene | Q# 6.01 - 6.04

FSMA Produce Rule Reference	Q#	Question	Comments
112.44 (a4)	6.01	Are total coliforms (TC) and generic <i>E.coli</i> tests conducted on the water used for hand washing at the required and/or expected frequency?	
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?	
112.44 (a4)	6.03	Do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?	

FSMA Produce Rule Reference	Q#	Question	Comments
112.44 (a4)	6.04	If unsuitable or abnormal results have been detected, have documented corrective measures been performed?	

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>