FSMA Preventive Controls Preparedness Module Assessment Report

BRC Global Standard for Food Safety Issue 7

Item No.	Clause	Module item	Conforms (Y/N)	Comments
1	CD	Company Description and major changes since the BRC audit		
2	PROD	Products being produced at the time of the audit		
3	FI	Overview of facility inspection		
4	117.20	Handwashing areas, dressing and locker rooms, and bathrooms must have adequate lighting.	Y	Light intensity inspection are completed on monthly basis and adequate lighting was observed during audit.
5	117.37	The water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.	Y	A water distribution map was reviewed, check valves at present in the facility.
6	117.40	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.	Y	Seams on food contact surface observed to be smooth. All equipment are designed for packing of cherries.
7	117.80	Ice used in contact with food must be manufactured in accordance with the good manufacturing practice (GMP) requirements of 21 CFR § 117.	N/A	Ice is not used in the facility.
8	117.110	Where defect action levels (DALs) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.	Y	QC Inspections are conducted throughout the day to ensure minimum quality standards are met. WSDA inspectors are at the site and any product does not meet the quality requirements is rewashed and regraded until product is within specifications.
9	117.130 (a)	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • economic adulterants which affect food safety • environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • radiological hazards • unintentional adulterants that affect food safety.	Y	Facility had performed hazard analysis which includes biological, chemical, physical and radiological hazards. Vulnerability assessment is performed on suppliers. Environment is monitored monthly for Listeria, Salmonella and E coli.
10	117.130 (b)	All identified, known, or reasonably foreseeable hazards must be evaluated to determine 'hazards that require a preventive control' (i.e., significant hazards).	Y	Preventive controls are developed for all significant hazards.
11	117.135	Establish one or more preventive control(s) for each identified 'hazard that require a preventive control' (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.	Y	
12	117.139	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: • notifying consignees of how to return or dispose of recalled product • conducting effectiveness checks to verify recall is carried out • appropriate disposal of recalled product (i.e., destroy,	Y	Facility had developed product withdrawal and recall procedure Incident Traceability for Recall dated May 01, 2018 meets requirements for disposal of recalled product..

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		divert, repurpose).		
13	117.145	Establish monitoring activities and a written procedure for each preventive control in a manner consistent with the requirements of BRC section 2.10.	Y	Facility had developed monitoring activities for all preventive controls.
14	117.150	Establish corrective action procedures when preventive controls are not implemented in a manner consistent with the requirements of BRC sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).	Y	Corrective actions are developed for all preventive controls and documented in Preventive Controls Process Steps dated June 0, 2017
15	117.160	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring revalidation or within 90 calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.	N	Facility validated the process control before implementation of food safety plan. There is no procedure to re validate the preventive control after a change is made or within 90 calendar days of first food production.
16	117.165 (a)	The PCQI (or authorized designee) reviews the monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or their authorized designee) reviews the verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record has been created.	Y	All records are verified within 48 hours as reviewed during the audit. Reviewed Chemical Concentration Log dated June 12, 2018 which was reviewed on June 13, 20188
17	117.165 (b)	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • sampling procedure to include method, quantity, frequency, and number of samples • analytical method • laboratory conducting an analysis • corrective action procedure where a pathogen is detected.	N/A	Product testing is not used as verification activity.
18	117.165 (c)	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • adequate number and location of sample sites • timing and frequency of sampling • analytical method • laboratory conducting the analysis • corrective action procedure where a pathogen is detected.	Y	Facility had developed and implemented Environmental Sampling Plan dated Mar 22, 2018. Facility takes about 30 samples from all 4 zones on monthly basis as described in the procedure.
19	117.165	Devices used to verify preventive controls must be calibrated.	Y	All devices and equipment used to monitor preventive controls are calibrated on predetermined frequency. Thermometer are calibrated monthly, scales are calibrated annually.
20	117.180	Identify a PCQI responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training or qualifications via job	Y	Assistant Technical Manager is responsible for implementation of food safety plan and had completed the PCQI training on Oct 28, 2016 and have 7 years of experience developing and implementing food safety

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		experience.		programs..
21	117.305	All records required by 21 CFR § 117 must include: • the date and time of the activity being documented • signature/initials of individual performing the activity or conducting the record review • information to identify the facility (e.g., name and location) • the identity of the product and lot code where applicable	Y	All records include date, real time and signature of person performing monitoring activity and initial of verifier, including facility name, product name and lot code information..
22	117.310	The owner, operator or agent in charge of the facility must sign and date the written food safety plan initially and again upon any changes following reanalysis.	Y	Food safety plan is signed by General Manager reviewed dated June 28, 2018
23	117.315	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours, with the exception of the food safety plan, which must remain onsite	Y	Records are kept for 2 years in the facility.
24	117.405	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified and the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.	Y	Facility had Approved Supplier Program, verification activities are performed at the facility level by conducting lab analysis and record verification.
25	117.420	Supplier approval must be documented before receiving and using raw materials and ingredients. Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.	Y	All suppliers are approved before product is brought into the facility.
26	117.430	One or more supplier verification activities (as defined in 21 CFR § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients and periodically thereafter at an adequate frequency.	Y	Verification activities are performed before product is purchased as reviewed in procedure Supplier Evaluation & Management dated April 10, 2016.

Voluntary Modules Non-Conformity Summary Sheet

Critical			
No.	**Clause**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Clause**	**Details of non-conformity**	**Corrective action taken**	**Proposed action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Clause**	**Details of non-conformity**	**Corrective action taken**	**Proposed action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1	117.160	Facility validated the process control before implementation of food safety plan. There is no procedure to re validate the preventive control after a change is made or within 90 calendar days of first food production.	1. The BRC/FSMA Assessment Tool was revised on 7/12/18 to include that no changes were made to the food safety pre-requisites /PC's and that no changes have been made to the PC's.	1. Validation of the process controls didn't include that any changes are validated within 90 calendar days of the first food production 2. The Pre-Requisites/Preventive Controls are validated annually 3. The procedure didn't include that in the event of any changes of the PC's that shall be validated within 90 days 4. Missed by the Assistant Technical Manager that the assessment will need	The revised FSMA Self Assessment Tool (pg. 11);The revised policy to reflect the procedure to verify PC's.	07/31/2018	Parmjit Dhillon

Minor							
				to be completed within 90 calendar days of any changes or updates made to the PC's.			