Audit Report

Global Standard for Food Safety Issue 7: July 2015

1.Audit Summary			
Company name	Valley Processing, Inc.	BRC Site Code	1156437
Site name	Valley Processing, Inc.		
Scope of audit	The grinding, filtration, pasteurization and evaporation of fruit (apples, blackberries, black raspberries, blueberries, boysenberries, marionberries, rhubarb, cranberries, cherries, grapes, pears, raspberries, strawberries) into single strength juice, concentrates, purees, puree concentrates and essences shipped out in tankers, totes, plastic pails and drums or poly lined steel drums.		
Exclusions from scope	Offsite Laboratory, Freezer Storage, Cold Storage and Dry storage		
Justification for exclusion	Offsite freezer building, offsite laboratory, offsite cold storage, offsite dry storage.		
Audit Finish Date	2017-10-19		
Re-audit due date	2018-10-17		

Voluntary modules included		
Modules	Result	Details
Choose a module	Choose an item	
Choose a module	Choose an item	
Choose a module	Choose an item	

2. Audit Results					
Audit result	Certificated	Audit grade	B	Audit type	Announced
Previous audit grade	B	Previous audit date	2016-09-22		

Number of non-conformities		
	Fundamental	0
	Critical	0

	Major	0
	Minor	13

3.Company Details

Address	108 EAST BLAINE AVENUE SUNNYSIDE, WA 98944		
Country	USA	Site Telephone Number	+15098378084
Commercial representative Name	Mary Ann Bliesner	Email	maryann@valleyprocessing.com
Technical representative Name	Margaret Sells	Email	qs@valleyprocessing.com

4.Company Profile

Plant size (metres square)	10-25K sq.m	No. of employees	51-500	No. of HACCP plans	4-8

Subcontracted processes	No
Other certificates held	Kosher, Organic
Regions exported to	North America Asia Europe
Company registration number	
Major changes since last BRC audit	Expansion project started for additional cold storage and raw apple/pear dumping station. New QS Manager and Sanitation Supervisor.

4.Company Profile

Company Description

Valley Processing is a family-owned and operated company. The processing facility is located in a semi-industrial area. It was built in 1950 and has two production lines. This facility has three main buildings which are for processing and packing. The facility is 125,000 square feet. The firm processes raw fruit into juice, juice concentrate, purees and essences. It also purchases juice concentrates and processes them into juice, juice purees and essences. The process includes fruit sorting, pasteurization, filtration, and metal detection of products packed into plastic pails and drums, poly-lined steel drums and bulk food-grade tanker trailers for further processing and ingredient use.

5.Product Characteristics

Product categories	07 - Dairy, liquid egg				
Finished product safety rationale	Pasteurization, low pH, high Brix, metal detected, filtered				
High care	No	High risk	No	Ambient high care	No
Justification for area	Mainly enclosed process, pasteurized juice, low pH, metal detected, for further processing				
Allergens handled on site	None				
Product claims made e.g. IP, organic	Organic, Kosher				
Product recalls in last 12 Months	No				

5.Product Characteristics	
Products in production at the time of the audit	Fresh Grape Juice Concentrates, Fresh Apple Juice Concentrates

6. Audit Duration Details			
On-site duration	24 man hours	Duration of production facility inspection	10 man hours
Reasons for deviation from typical or expected audit duration	Simple process, enclosed production		
Next audit type selected	Announced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2017-10-17	09:00	17:00
2	2017-10-18	08:00	16:00
3	2017-10-19	08:00	16:00

	Auditor (s) number(s)	Names and roles of others
Auditor Number	253002	Jeremiah Szabo – Lead Auditor
Second Auditor Number	N/A	

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.9) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
MaryAnn Bliesner / Owner-President	x	x		x
Margaret Sells / QS Manager	X	x	x	x
Ivette Frias / QA Lab Manager	x	x	x	X
Melanie Koch / Micro Lab Manager	x		x	X
Jeff M. – Sanitation Supervisor		x	x	x
Tim Collett / Maintenance Manager		x	x	x

Present at audit				
Ron Sellers / Production Supervisor				x

Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No.	**Clause**	**Details of non-conformity**	**Critical or Major?**	**Anticipated re-audit date**

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

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

Minor							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1	3.3.1	Some Maintenance PM records were found to be filled out in pencil. Some records reviewed did not list actual dates of the activities being completed (for example: Master	Updated paperwork to include date of the task completed. Paperwork and policies reviewed with maintenance group.	Maintenance did not know they needed to use ink to complete logs. Documentation Policy did not state that completed tasks must be dated.	Attachment Ref. NC 3.3.1 Maintenance • Maintenance and Sanitation personnel reviewed and	2017-11-17	Jeremiah Szabo

		Cleaning Schedule, internal audit records, etc.)		Maintenance and Sanitation personnel reviewed & signed Document Requirements forms.	signed these policies • Updated document requirements document date of task done and not using pencil or white out		
2	3.4.1	Internal Audit Policy is not up to date as it contained the previous Plant Manager, QS Manager and VP of Operations listed in the policy. No documented dates of actual internal audits of all BRC Standard requirements being followed as per the schedule.	Updated Quality Systems for 2017 Began using BRC Standards as IA checklist as of Nov. 2017	Quality Systems Manager position had been vacant for several months that created some gap in continued implementation.	Attached Ref. NC 3.4.1 IA Table of Content IA Table of Contents using BRC Food Standard requirements	2017-11-17	Jeremiah Szabo
3	3.5.1.2	The Supplier Approval program is not fully implemented, for example: there was an outdated GFSI certificate found for a raw red apple supplier (expired 6/23/17), no supplier questionnaire on	Supplier Approval program has been updated with ongoing Supplier Questionnaires being sent & received	Quality Systems Manager position had been vacant for several months that created some gap in continued implementation.	Attached Ref NC 3.5.1.2 Updated fruit vendor list w/required documents	2017-11-17	Jeremiah Szabo

		file for a packaging supplier).	A Questionnaire has been sent out to all Packaging Suppliers		NC 3.5.1.2 Updated Packaging vendor list w/required documents		
4	3.6.3	There is not yet a formally documented Raw Apple specification in place.	Researched and developed raw fruit specifications – including Apple	Due to oversight and also the Quality Systems Manager position had been vacant for several months that created some gap in continued implementation	Attached Ref. NC 3.6.3 Updated Apple pear raw material spec	2017-11-17	Jeremiah Szabo
5	4.4.2	There were pitted and cracked floors observed under the 20k, C1 and C2 tanks in Plant #3.	Contacted company to perform the work	Oversight and lack of follow up. Cascade Floors approved Proposal	Attached Ref. Approved work order	2017-11-17	Jeremiah Szabo
6	4.6.1	Poor utensil design and maintenance was found for two utensils (open-ended with apple pieces inside) near the raw sorting lines in plant #2, and with a broken white handled brush stored in the operators table on the mezzanine of the blending room.	Utensils were removed and either discarded or repaired. Items were added to both the Daily GMP audit and the Monthly Internal Audit Checklists	Employees had brought items into the manufacturing areas or had broken items without notifying Management	Attached Red. NC 4.6.1 Completed Daily GMP audits and Monthly IA	2017-11-17	Jeremiah Szabo

7	4.7	Broken plastic belting for the Plant #2 sorting line and incline cleat (wash) belt was observed.	Belting was repaired, and items were added to the Daily GMP & the Internal Audit	The belt was scheduled to be replaced but had not yet been completed in time by the time of audit	Attached Ref. NC 4.7 • Completed Daily GMP audit Record • Completed IA Record • Photos of repaired belt	2017-11-17	Jeremiah Szabo
8	4.9.1.1	Janitorial chemicals were not found listed on the approved chemical list.	Chemicals have been added and updated the list Task has been added to QS Manager's calendar for annual completion & Chemical List was verified on 11/9/17	Oversight and not observed during GMP audit and/or IA.	Attached Ref. NC 4.9.1.1 • Updated Janitorial Chemical List • Verification of Chemical List	2017-11-17	Jeremiah Szabo
9	4.9.3.2	The Glass & Hard Plastics List was missing the Plant #1 Cold Room and Blend room items.	Cold Room and Blend Rooms have been added for glass and brittle plastic items on the registry.	Auxiliary Areas had not been added to the Master Sanitation Schedule due to oversight	Attached Ref. NC 4.9.3.2 • Glass and Brittle Plastic registry for Pant #1 Cold Room and Blend room items.	2017-11-17	Jeremiah Szabo
10	4.11.1	There were some areas observed during the site audit that were found not be well cleaned and maintained (debris and insulation in Plant #3 Tank	Areas (Plant # 3 Tank rooms and Plant #1 boiler room) were added to Master Sanitation Schedule	Auxiliary Areas had not been added to the Master Sanitation Schedule due to oversight	Attached Ref. NC 4.11.1 • Boiler Room Cleaning Schedule	2017-11-17	Jeremiah Szabo

		rooms, dead bat, dust and debris located in the Plant #1 boiler room).			• Plant 3 weekly & Monthly Cleaning schedule • Photos showing cleaning of Tank and Boiler rooms		
11	4.16.6	There are no formal documented agreements in place for transportation carriers.	Researched & developed Carrier Expectations / Questionnaires (Doc # 102517A)	Quality Systems Manager position had been vacant for several months that created some gap in continued implementation ; and also due to oversight and/or not observed in IA	Attached Ref. NC 4.16.6 • Transport Carrier Expectations-Questionnaire. • Transport Carrier updated database with completed questionnaire	2017-11-17	Jeremiah Szabo
12	7.1.1	A bag of chips was found in an operator's toolbox located on the filter room catwalk in Plant#1 and various food items were found located in employee lockers on the 2nd floor of the Plant #1 locker room.	Signs were posted pertaining to (not) having food in processing areas and must be in designated area.	Employees failed to follow GMP rules & what's allowed in lockers had not been clarified; and also lack follow up and enforcement	Attached Ref. NC 7.1.1 • Food-Drink Not Allowed sign • Food-Drink Not Allowed photos • Not Allowed in Lockers sign	2017-11-17	Jeremiah Szabo

					• Not Allowed in Lockers photos		
13	7.1.3	The methods for reviewing the effectiveness of the training have not yet been defined and implemented.	Full implementation of Alchemy training system (including verification) planned. Training scheduled on 11/21/2017	Quality Systems Manager position had been vacant for several months that created some gap in continued implementation ; and also due to oversight and/or not observed in IA	Attached Ref. NC 7.1.3 • Alchemy full implementation by December 2017 (sign off and invocie payment). • First training class for management scheduled on 11/21/17	2017-11-17	Jeremiah Szabo

Comments on non-conformities

Voluntary Modules Non-Conformity Summary Sheet

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

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

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

FSMA Module Non-Conformity Summary Sheet

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

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

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

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

Food Safety & Quality Policy is signed by the HACCP Team, which includes the Owner and President, dated 8/10/17.

There are quarterly Senior Management and HACCP Team meeting held, as coordinated by the QS Manager for review of objectives and tracking of food safety and quality items.

The company has Food Quality Objectives policy for 2017-2018 in place (9/12/17 – 9/12/18), which includes annual objectives, for example:
-20% reduction of paperwork errors
-0% Preventable HACCP Failures
-5% Reduction in Customer Complaints
-10% Negative Findings from all audits

The last Senior Management Review meeting was conducted on 10/5/17, with documented meeting minutes of inputs and outputs.

Monthly Management Staff Meetings are conducted with agenda/topics that include HACCP issues, Regulatory issues, Sanitation issues, New vendors, Vendor issues, and Food safety issues. Records of Monthly Management Staff Meetings sampled and reviewed dated: 6/13/17, 7/14/17, 8/10/17, 9/21/17, and 10/5/17.

The company's senior management team is part of the HACCP Team, and keeps informed by industry newsletters and memberships to associations, e.g., Members of the North West Food Processors Association, Juice Processors Association, Newsletters, Food Safety Magazine, and Journal of Food Science.

A genuine copy of the BRC Standard Issue 7 was available and owned by the firm

The company owner was present at the opening meeting. The company owner and President were both present during the closing meeting.

1.2 Organisational structure, responsibilities and management authority

The company has a documented Organizational Table, dated 9/22/17, with defined job positions and responsibilities for food safety and quality.
Senior Management Food Safety / HACCP and Food Defense Review Committee further defines responsibilities for food safety and quality personnel, and also lists the back-up support for coverage in the absence of any individual.

For example:
-QS Manager is back-up for QA and Lab Managers
-QA Manager is back-up for QS Manager
-President is back-up for VP of Operations
-Owner is back-up for President/Sales

Job descriptions are in place for all employees, and some examples were reviewed as follows:
-QS Manager
-VP of Operations
-Sanitation Supervisor

Details of non-applicable clauses with justification

Clause reference	Justification

2 The Food Safety Plan – HACCP

A HACCP documented procedure has been prepared (rev. #) in accordance to Juice HACCP Regulations and 21 CFR 110 and 120. Achieving a 5-log reduction and pertinent regulatory information, industry practices and scientific information is on file. The HACCP plan covers all products produced on-site (Single-Strength Juices, Concentrates and Essences, Singles Strength and Concentrated Purees).

A multidisciplinary HACCP committee includes President, Corporate VP, VP of Operations, Plant Manager, Maintenance Manager, and QA Manager (Team Leader). Last IHA-HACCP Training for the QS Manager on file (4/8-10/2008). Date of the last HACCP team meeting was held on 10/05/17; the meeting minutes have been documented.

Product Descriptions are in place for all products and are fully documented to include: Intended Use and Consumers (Fruit ingredients for bottlers and further processing/manufacturing, for general public at the consumer use level), Origin of Ingredients, Packaging materials (Plastic pails, or customer totes or poly-lined steel drums), Processing Treatments (pasteurization, patulin levels reduction, etc.), Storage and Distribution (Frozen, Refrigerated, Insulated tankers or refrigerated-vans).

Flow diagrams have been prepared, verified and signed throughout the year by a HACCP team member or multiple members (dates of verifications include 9/20/17, 9/18/17, 9/5/17, etc.). Diagrams were verified onsite by the auditor and found no issues.

Hazard analyses were papered and documented (dated September, 2017). Identified microbiological hazards: E. Coli 0157:H7; Salmonella. Cryptosporidium (apples and pears only). Identified chemical hazards included: pesticides, Patulin, Inorganic Arsenic, sanitizers, maintenance chemicals, glycol, and ammonia. Identified physical hazards included: metal, sticks, stones, wood and debris.

A likelihood and severity matrix was used to assess identified hazards for the hazard analysis portion of the HACCP plans. Justification for decisions are documented and specific control measures, e.g. Vendor approval, COAs, GMPs, LOGs, Product segregation, SSOPs, Maintenance, Foreign material control ,etc.

A CCP validation record is on file signed by the HACCP team, updated 9/9/16 to add the validation of metal detection due to a customer requirement in addition to patulin sorting (apples & pears), screens, and pasteurisation. New CCP for Inorganic Arsenic hazard has been identified (Pears and Apples), as per FDA regulatory guidance, dated 6/6/2017.

CCP Summary and Monitoring Master Plans on file:

CCP (Arsenic Control) – Plant #2 (Apple and Pear only)
Hazard: Arsenic <23 ppb (Pears), <10 ppb (Apples).
CL: Arsenic <23 ppb (Pears), <10 ppb (Apples).
Monitoring: 100% lot testing
Monitoring frequency: Every lot produced (100%, positive release).
Corrective action: Divert to fermentation product if over the CL.
Verification: Record review, test results review, and HACCP plan annual review
Records reviewed were initialed, dated and reviewed/verified. No issues noted.
Dates of records sampled and reviewed: 7/19/17 (Apple Juice), 8/14/17 (AJ Conc.), and 9/18/17 (AJ Conc.)

CCP (Patulin Control) – Plant #2 (Apple and Pear only)
Hazard: patulin >50 ppb.
CL: No visible rotten, moldy or damaged fruit.
Monitoring: Sort out fruit with visible rot or mold.
Monitoring frequency: Every bin by the fruit dump operator.
Corrective action: Filter juice with charcoal and retest as single strength juice.
Verification:, Record review, test results review, and HACCP plan annual review
Dumping records were reviewed by the auditor: dated 7/19/17, 8/14/17 and 9/18/17. Records were initialed, dated and reviewed. No issues noted.
No CCP failures have occurred for this production season.
Patulin test results sampled by the auditor were <50 ppb (meeting the CCP spec limit)

CCP (5-log reduction pasteurization), CLs have been established: Process at 186˚F for a contact time of 0.6 seconds; flow rate <80 GPM.
Monitoring procedures in place: a) Continuous chart recorders with hourly verification, b) Automatic divert valves checked 3 times a day and c) Operators responsibility.
Established Corrective action: Product re-pasteurization.
Verification activities include: Daily review of heat/temperature charts, daily HACCP monitoring records, annual verification of pump speed, review and corrective actions, and calibration.

Validation of the pasteurizer records are maintained for Plants 1 and 2 (last validated on 3/1/15 and 3/1/16). The records included measurements of maximum flow rates (GPM) compared to volume of the pasteurizer piping with the minimum total dwell time at the given critical limit temperature.
Pasteurization charts, records and any corrective actions records were sampled and reviewed by the auditor dated 7/19/17 (raspberry puree), 7/19/17 (Strawberry puree), 8/14/17 (Strawberry juice conc.), 8/14/17 (Organic Red Raspberry Puree), 8/14/17 (AJ Conc.), and 9/18/17 (AJ Conc.)

Documented root cause, corrective action and verification on file. Failures were addressed according to the documented plan and procedures. No issues noted.

CCP (Metal Detection – all products)
CL: Challenge the diversion valve function with 1.5mm Fe, 2.0mm NFe, and 2.5mm SS.
Monitoring: Challenge the diversion valve function with 1.5mm Fe, 2.0mm NFe, and 2.5mm SS, at start and end of each lot produced.
Verification by records review by QA Manager.
Corrective Actions: Recalibrate unit, rerun product and rework product that was rejected to identify source of contamination if possible. Documented as necessary.
Metal detection CCP records sampled and reviewed by the auditor dated: 7/19/17 (Apple Juice Shilling), 7/19/17 (Raspberry Puree Conc.), 7/19/17 (Red Raspberry Essence), 8/14/17 (Strawberry juice conc.), 8/14/17 (Organic Red Raspberry Puree), 8/14/17 (AJ Conc.), 8/14/17 (BBJ Conc.), 8/15/17 (Strawberry Essence), 8/15/17 (Strawberry Conc.), 9/18/17 (AJ Conc.)

Details of non-applicable clauses with justification

Clause reference	Justification

3. Food safety and quality management system

3.1 Food safety and quality manual

There is a documented food safety and quality manual available to all required personnel. The manual includes policies, procedures, SOPs, work instructions, specifications, and forms applicable to the operation.

3.2 Documentation control

Document and Record Control program is implemented and documented (dated 10/3/17). It addresses document control policies, record completion and review as well as amendments to documents. Computer security is also addressed including password protection, firewall, anti-malware, anti-virus, backups at off site daily at 2:00 AM.

A master list of system documents is kept up to date as of 10/18/17.
Changes and amendment records are kept on the footer of each document. HACCP program changes are recorded on amendment log. Change history includes reason for change, date and rev#.
Record retention and completion policies are documented and implemented for the most part. Records kept for at least three years. Records are reviewed within seven days of their creation. Product records are kept for 6 years as per policy, i.e., product shelf life plus a year.

3.3 Record completion and maintenance

Record retention and completion policies are documented and implemented for the most part. Records kept for at least three years. Records are reviewed within seven days of their creation. Product records are kept for 6 years as per policy, i.e., product shelf life plus a year.
Records are reviewed within seven days of their creation as per FSMA and Juice HACCP.

3.3.1 – MNNC**:** Some Maintenance PM records were found to be filled out in pencil. Some records reviewed did not list actual dates of the activities being completed (for example: Master Cleaning Schedule, internal audit records, etc.)

3.4 Internal audit

Internal Audit and Corrective Action Policy in place, Doc #062215, dated 3/1/16. Internal audit schedule based on risk has been prepared; last updated on 9/19/16. In-house Training for Internal Auditors procedure in place, Doc #011615, dated 1/19/15. Frequencies of audits are based on a risk assessment: low (annually), medium (semi-annually) and high (continuously).

VP of Operations and current QA Manager were trained by the previous approved QA Manager on internal auditing practices. Both have received HACCP training and are in the process of training a new internal auditor (QA Supervisor) for future additional help.

3.4.1 – MNNC: Internal Audit Policy is not up to date as it contained the previous Plant Manager, QS Manager and VP of Operations listed in the policy. No documented dates of actual internal audits of all BRC Standard requirements being followed as per the schedule.

QS Manager Internal Auditor training record on file, dated 08/3-4/2017.

Monthly GMP/Site audits are completed by the QS Manager using the Internal Audit Form, dated 8/19/17. Daily GMP audits are conducted as per the policy. A Daily GMP Audit form is used (Doc#112906A, dated 8/19/17).
Records sampled and reviewed were as follows:
Daily GMPs dated 7/19/17, 8/14/17, 8/15/17, and 9/18/17 for all areas (Plants #1, 2, and 3).
Monthly GMPs dated 7/19/17, 9/17/17, etc.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw materials and packaging

Non-Fruit Ingredient Supplier Management procedure on file (Doc#053007, dated 6-10-16).
Non-Fruit Vendor Verification Program on file (Doc#121614A, dated 10-08-15). The vendor verification program includes a risk based evaluation of each supplier. The supplier verification documents were provided to each vendor such as processing aid, packaging material and ingredients.
The company then performed a risk assessment for each of these non-fruit items (packaging supplies, processing aids and ingredients) in the HACCP plan which was last reviewed on 10/5/17.

There is also a Vendor Food Safety System Questionnaire (Doc#042803A, dated 07-06-15), in place that requires Food grade Letter of Guarantee, HACCP statement, Allergen Statement, Gluten (free) statement, GMO statement, Halal Certificate, Kosher Certificate, Organic Certificate, Specifications, FDA registration, 3rd party audit or GFSI schemes certification, Country of Origin, and SDSs.

There is a documented Fruit Vendor Management Program on file (Doc#040909, dated 09/18/16). Risk assessments are performed for each product fruit group according to HACCP plan and Vulnerability Assessment. Approved Supplier List last updated on 10/16/17.

Supplier records sampled and reviewed included:
-Enzyme Supplier- Supplier Questionnaire dated 10/20/15; COA and Specification dated 3/6/17 (rapidase); COA and Specification dated 12/12/16 (Hazyme), Kosher certificate dated 8/31/16
- Carbon Aid Supplier: Supplier Questionnaire dated 9/11/17; SQF Certificate on file (valid until 5/27/18); COA and Specification dated 1/24/17 (carbon);
-Raw Red Apple supplier- Supplier Questionnaire (sent on0 dated 10/13/17, no response yet.
-Raw Fuji Apple Supplier- 1/13/17, 3rd party audit valid 11/20/17,
-Raw Red Apple Supplier - SQF certification valid until 6/23/18,
-Packaging Supplier (Plastic Pails and Drums) - Supplier Questionnaire dated 8/29/17, COC dated 1/1/14, 3rd party audit dated 2/24/16 (no supplier questionnaire on file).

3.5.1.2 - MNNC: The Supplier Approval program is not fully implemented, for example: there was an outdated GFSI certificate found for a raw red apple supplier (expired 6/23/17), no supplier questionnaire on file for a packaging supplier).

3.5.2 Raw material and packaging acceptance and monitoring procedures

Documented Receiving Procedures in place for Fruit (Doc #101615 dated 4/12/16); Receiving and Dry Storage and Packaging, Doc #102615, dated 4/12/16. COA's or LOG's and visual inspections upon receipt are used as methods for acceptance of the raw materials, ingredients and processing aids.

Vendor Management Non-Fruit Ingredients, Doc #053007, Dated 9/26/17

3.5.3 Management of suppliers of services

Documented Supplier Services Approval and Monitoring Program on file (Doc#100614, dated 09-18-2016). Approval and monitoring included the service providers membership in a recognized trade association, historical evidence of experience, Legal registration or license of registration as appropriate, Listed service providers included: Waste management, Propane delivery, Sanitation Chemicals, outside laboratories (ISO 17025 certified), Vending machine company, Pest Control, Certification Body, Laundry Service, etc. Contracts have been put in place for each Service Provider.

Supplier Services Approval and Agreement records, for example:
3rd Party Lab – ISO 17025 certificate valid until 4/18/18
3rd Party Lab – ISO 17025 certificate valid until 10/22/18
Pest Control – Service contract/agreement dated 3/20/17
Laundry – Service Agreement dated 1/14/16
Chemical provider – Service Agreement dated 10/19/17

3.5.4 Management of outsourced processing and packing

3.5.4 - N/A. No outsourced processing and packing.

3.6 Specifications

Finished product specifications on file include these parameters: Country of origin, general requirements, physicochemical and microbiological parameters, e.g., Brix, flavour, colour, turbidity, pH, patulin, pectin, coliforms, TPC, yeast and mould.
Raw materials specifications are described on contracts, when available.
Specifications were on file for packaging materials, processing aids and non-food chemicals.
Specifications are described on letters of guarantee, technical sheets and labels. MSDS are on file for pertinent materials, for example.
Organic and Conventional, or Kosher Apple Juice Concentrate Spec dated 12/09/16. Spec compared to COAs on file for randomly selected trace exercise lot and found to be in compliance; no issues observed.

Raw Fruit Specifications on file for example:
-Blackberry – dated 4/13/16
-Raspberry – dated 4/13/16

3.6.3 - Minor NC: There is not yet a formally documented Raw Apple specification in place.

3.7 Corrective and preventive actions

Corrective and preventive action procedures are implemented according to the Internal Audit and Corrective Action Policy, Doc #062215, dated 9/2/17. Corrective actions are required for deviations within the internal audits, monthly plant audits, customer audits, 3rd party audits, customer complaints and quality and/or legality issues. A CAR form is used to document any of these findings.

HACCP Corrective actions are documented and implemented, with records maintained as appropriate throughout the process and where needed due to process variations.

Corrective action records for monthly plant audits included the observation, root cause, corrective action, completion and verification dates. Customer complaints corrective actions are reviewed quarterly in senior management meetings.

Examples of CAR's completed and tracked:
-05/17/17 (Incorrect chart placed in recorder), 07/21/17 (Verification was not performed, RC and re-training performed on 8/16/17), and 09/25/17 (divert valve check not recorded), etc.

3.8 Control of non-conforming product

There is a documented program to prevent the release of non-conforming product titled "Non-Conforming Product and Returned Goods" dated 09/27/17.

The non-conforming (NC) product is identified with a hold tag and is placed in a segregated section of the refrigerated or frozen area of the facility. There is also an electronic hold log “Hold Log 2016” in place for tracking non-conforming product.
The NC product is defined on procedure as not meeting internal or customer quality or safety specifications.
NC Product can be shipped to a customer whose quality spec is met.
Records are kept electronically on the COA summary Excel spread sheet. Product on hold has to be released by QA personnel.

NC product Log/records sampled and reviewed included:
-Holds logged from 1/2/17 to 9/20/17.
-Examples included: 9/20/17 (surface mold), 8/17/17 (micro hold above spec), 7/20/17 (leaking caps), etc.

3.9 Traceability

The plant has traceability program implemented. The traceability system is designed to trace finished product to the first customer and back to ingredients and primary packaging materials.
During the site inspection the auditor confirmed that the products and materials were properly identified.
Finished product labels contain packing date, lot code, net weight and product.
Traceability system is manually operated and paper based. Traceability procedure was last revised on 02/17/16. Rework products are traceable and have to be authorized by senior management for disposal decision. Traceability tests are carried out at least quarterly. The auditor reviewed records of last two traceability exercises dated 9/13/17 and 10/3/17 were on file.

The auditor asked for a random traceability exercise to be conducted while on-site. Products were found to be fully (100%) traceable within 4 hours (Traceability Start:10:12 AM, end 12:42 PM) for the following product evaluated:

-Product: SS Apple Juice
-Lot #071917-J3
-Produced on 7/19/17
-Quantity Produced: 11,800 gallons
-Quantity Shipped: 11,775 gallons (25 gallons to waste and sampling, 0 gallons left in inventory)
-2 Shipments via bulk tanker load: (SO#38284, 5,884 gallons shipped on 7/19/17, BOL#38284, Cleaning Certificate dated 7/19/17) and (SO#38285, 5,891 gallons shipped on 7/26/17, BOL#38285, Cleaning Certificate dated 7/26/17)
-Raw apples: Ticket #35977 (58 bins, received on 7/13/17), #35982 (58 bins, received on 7/14/17), #35988 (66 bins, received on 7/14/17), and #35972 (70 bins, received on 7/13/17)
-Processing aids/ingredients used, for example: Rapidase (lot #15k03V1/331, used 7/17/17), Hazyme DLL (Lot #16102V1, received 7/17/17), etc.
-COA dated 7/19/17 and 7/26/17, specifications on file, dated 12/9/16.

3.10 Complaint handling

Customer Complaint policy is implemented and documented dated 09/28/17. Complaints received via phone calls or email. They are handed over to QA department for investigation. Root cause determination is conducted and the Complaints Log (last update 6/26/18) is kept for the records. Investigations and resolutions are documented and kept on file.

Auditor reviewed complaint records and resolutions on files included, for example:
6/2/17 leaking drums at the bottom.
4/18/17 for high yeasts counts. Investigation and actions are on file.

Complaint trends are analysed on an annual basis, last date of trend analysing recorded on 9/28/17. Complaint categories include FM, Micro, Quality, and Packaging.

3.11 Management of incidents, product withdrawal and product recall

Documented procedures have been prepared for Crisis Management (Business Continuity Plan) dated 09/29/17. The procedure addresses several likely scenarios, e.g. mechanical failures, ammonia leaks, power disruption, raw material supply, fire/earthquakes, labour disputes, supply chain disruptions, etc.

Recall procedures are implemented and documented dated 9/29/17, which require annual testing of the procedures. Last mock recall was conducted on 8/29/17 on organic apple juice concentrate. Records are on file included internal contact verification, customer and regulatory verification. All traceability documentation are maintained. Senior management team has been formed to respond to recall incidents (contacts on file and listed as the Crisis Team). Files include contact information and individual responsibilities descriptions. Recall notification forms have been prepared.
Authorities and regulatory agencies emergency contact information is on file.
No recalls to date.

3.12 Customer focus and communication

Conformance to customer requests is verified by the QA department, as noted in the Conformance to Specifications procedure (dated 9/19/16). Communication comes from senior management to QA and Production Management for implementation. An example of a customer specific %TA and Brix for Apple Juice Concentrate (for fermentation) was reviewed and found to be effectively communicated using COA's and Work order instructions, with customer communicated emails dated 12/15/15.

Details of non-applicable clauses with justification

Clause reference	Justification
3.5.4	N/A - No outsourced processing and packing.

4. Site standards

4.1 External standards

The facility is located in a semi-industrial area. During the site inspection, no visible sources of contamination or adjacent activities were identified as a risk for product integrity. Parts of the facility do not have a perimeter fence and access is not controlled, e.g., apple storage area. They mitigate the risk by

using no trespassing postings and having people working on the yard 24/7. They also train employees to report any person that does not belong to that area. No grass/weeds were observed growing in any areas.

4.2 Security

Food defence program is documented dated 6/13/17.
Documented assessment are completed annually using the FDA Food Defence Self-Assessment Tool. Last assessment dated 8/10/17. Access to the three processing buildings is controlled by electronic codes.
All visitors and contractors have to report to the front office.
Visitors were present during the audit. They were accompanied by a Senior Manager and had their visitor badges on and visible.
Security checks are completed monthly during the internal GMP audits.
No external tanks or silos are present.
Training was provided to employees, last conducted on 9/11/17, 9/12/17, 9/26/17. When interviewed they were aware of their responsibility reporting the suspicious activity or unauthorized personnel in processing areas. They also mitigate the risk by having people working on the yard 24/7.
Most processing and storage areas have restricted access; except for the raw materials (fruit) outside storage where no trespassing signs are posted.
Facility FDA bioterrorism registration is current, dated 10/4/16.
The site also has State and local business approval licenses: City Business License valid through 12/31/17, USDA License valid until 3/9/18 and Washington State Food Processing License valid through 6/30/18.

4.3 Layout, product flow and segregation

The product flow and machinery layout do not seem to pose a risk to the product or materials. The flow of the process goes from the least processed to more processed product areas.
Facility layout defines risk zones. Personnel /employee rework routes, and waste flow map is prepared.
All employees have to read and sign the work flow maps. Risk designation zone maps are generated and available dated 10/16/17; Only low risk process (enclosed product) and no high risk/high-care product areas exist at the facility. Personnel routes maps/documents dated 10/16/17 are on file.
There is a site map displaying product movement routes, personnel entry points, raw materials and ingredient entry points, waste removal, etc.
Contractors and visitors are required to register at the main office, and read and agree to the food safety policies of the company. The auditor was asked to do so upon check-in.

4.3.5 - N/A. No high-care areas.
4.3.6 - N/A. No high-risk areas.

4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

At the time of the audit, walls were clean and in good condition in processing and storage areas.
Floors are made of smooth and impervious materials and kept in good repair for the most part. Doors were self-closing and properly proofed.
Drains were kept in good repair with no risk for the product as observed.
Ceilings and overhead structures (e.g. water pipes, electrical pipes, and lamp cases) were kept clean and in good repair.
Windows are made of anti-shatter materials. An inventory of glass is verified on a regular basis.
Lighting in processing, inspection and storage areas seemed to be adequate for each type of task being carried out. Light fixtures are shatter proof. Fluorescent tubes have a film coat same as ILT tubes. An inventory is carried out on a regular basis to monitor glass and brittle fixtures conditions.
Ventilation system was suitable for the process. No dust or condensation was noted in processing or storage areas.

4.4.4 - N/A. No high-risk areas.

4.4.2 – Minor NC: There were pitted and cracked floors observed under the 20k, C1 and C2 tanks in Plant #3.

4.5 Utilities – water, ice, air and other gases

Water is provided by the City. Municipal water testing results for 2017 are on file. Chemical/ Heavy Metals water testing is performed on an annual basis. Last testing report on file dated 7/13/17.
Microbiological testing is performed quarterly for coliforms, E.coli, APC, Yeast, and Mould. Records for microbial testing sampled and checked, dated 7/20/17, 9/18/17, no issues were found as the test result were within the spec limit.
Water distribution system map has been prepared, dated 10/6/17. Daily and weekly checks of the water supply for quality purposes are conducted for PH, turbidity, free chlorine, colour, and odour. Targets for quality have been established.
No ice is used.

Water back flow prevention devices are inspected annually by the maintenance department, last inspection completed on 10/3/17.

4.5.3 - N/A. Only potable water used.
4.5.4 – N/A. No air or gases used in direct contact with product.

4.6 Equipment

Processing and packing equipment is built of suitable materials. Equipment was maintained clean and in good repair. Food contact surfaces are made mostly of stainless steel (SS), e.g. screw conveyors, pipes, tanks, etc. FG compliance for sorting belt – FDA/EU compliance rating poly-propylene belt technical sheet on file.

4.6.1 – MNNC: Poor utensil design and maintenance was found for two utensils (open-ended with apple pieces inside) near the raw sorting lines in plant #2, and with a broken white handled brush stored in the operators table on the mezzanine of the blending room.

4.7 Maintenance

There is a maintenance program that is paper based, Preventive Maintenance Program, dated 10/9/17. It includes preventive maintenance and corrective maintenance. The critical equipment and components are listed in the program, e.g. pasteurizer, concentrator, divert valves, decanter, augers, etc.

Equipment inspection program in place that checks equipment at pre-determined frequencies, e.g. weekly checks of motors, bearings, tanks, propellers, etc.

Temporary repairs are controlled by logging and verification through maintenance request forms as is normally required, but are to be avoided if possible.

Food grade and non-food grade chemicals are kept segregated inside the Maintenance Shop. They are made of non-allergenic materials. The shops were found to be clean and organized.

Procedures are in place in case maintenance is required during production periods so that products are not affected. Records of clean-up and verification after maintenance activities were kept on all repair reports.
After maintenance activities, equipment is cleaned and an inspection is performed and documented. All records are kept at the Maintenance office in the main building.

PM and WO/Repair Records sampled and reviewed:
-Plant #1 PMs– 1/19/17 to 10/11/17
-Plant #2 PMs– 1/19/17 to 10/11/17
-Plant #3 PMs- 2/16/17 to 7/14/17
-Drain Inspection and Treatment records (monthly) – Jan-17 to Sept-17
-Repair Work Completion Records: 8/8/17 (piping connections), 10/6/17 (Removal of stickers), 9/28/17 (Plant #3 – Hole in wall), 8/28/17 (loose insulation jackets in Plant #3), Holes in wall of Plant #2etc.

4.7 – MNNC**:** Broken plastic belting for the Plant #2 sorting line and incline cleat (wash) belt was observed.

4.8 Staff facilities

Hand washing facilities are located inside the restrooms as well as in processing areas. All hand washing stations are hands-free operated. Water, liquid unscented soap and paper towels are available at every hand washing stations. Hand-washing advisory signs are posted at each facility. Warm water was readily available at hand washing stations.

Personnel are required to leave their personal belongings and food in the break room.

Clean uniforms are provided every day to personnel. Dirty garments are kept separate from clean garments.

Main restrooms are away from processing and storage areas. All restrooms are vented outside. They were found clean, in good repair and well stocked with towels, soap, and water.

Employees bring their own food. All food is kept inside the lunch room. Vendor machines are located in the lunch room as well. Refrigerators and microwave ovens are available to employees. They were found clean and in good repair conditions.

4.8.4 – N/A. No high-care areas.
4.8.5 – N/A. No high-risk areas.
4.8.10 – N/A. No catering activities.

4.9 Chemical and physical product contamination control

Raw material handling, preparation, processing, packing and storage areas

Raw material handling, preparation, processing, packing and storage area management policies are in place. Auditor reviewed the adequacy of the facilities to ensure these practices during the site audit.

4.9.1 Chemical control

There is a documented Chemical Control Policy in place, dated 10/14/16. SDSs are available to personnel at every building and for all approved chemicals. Suitability of chemicals for using in food and non-food area is documented, and letters of guarantee are on file for those chemicals listed as approved for food processing use. Chemicals names were sampled during the site inspection and cross-checked against the approved list.
All chemicals are provided with spill containment. All containers were properly labelled.

Chemical Safety Training is conducted for all site operational employees.

Training Records on file reviewed included:
SSOP Doc #082217: 8/31/17 (Day-shift), 9/1/17 (Grave-yard), 8/31/17 (Swing-shift)
BHS Chemical Safety Training – July 6, 2017 (included chemical handling, storage, labelling, MSDSs, etc.)
BHS Chemical Safety Training – July 6, 2017 (Sanitation for Cleaning Practices)
CIP SSOP Training – for all product staff (6/8/17)

Chemical records on file reviewed included:
-Evap Plus- Suitability and Tech-sheets, includes Allergen-free statement, properties, uses, etc., SDS dated 6/23/15.
-ProHD Plus – Suitability and Tech-sheets, includes Allergen-free statement, properties, uses, etc. SDS dated 2/25/15.
-Janitorial Cleaner – Jolt Degreaser– SDS dated 9/2/15, all-purpose cleaner statement included (walls, floors, etc.)
-Evaporator Tower & Boiler Chemical: POSCA-Tower Treatment – LOG, Allergen and FC statements dated 1/1/17.

4.9.1.1 – MNNC**:** Janitorial chemicals were not found listed on the approved chemical list.

4.9.2 Metal control

Filters, magnets and metal detectors are in place.

Knife and Sharp Instruments Policy, Doc #091010A, dated 01/31/17. Records are kept on file in the form of Logs located in the Plant offices, for example Plant #2 Log.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Glass and brittle plastic policy is implemented and documented dated 10/13/16. Records of inspections are on file. Inspections are conducted monthly by the Maintenance Supervisor. The inventories for the three buildings were sampled and verified during the audit. Glass inspection records are maintained in the Maintenance office and the 2017 monthly inspection records were on file. There were no records of breakage occurrences over the last year on file, and it was stated by the Maintenance Manager that this was the case. The policy does have procedures in place for if breakages would occur.

Records of Glass & Plastics audits completed were on file:
-Plant #1: Jan-17 to Sept-17
-Plant #2: Jan-17 to Sept-17
-Plant #3: Jan-17 to Sept-17

4.9.3.2 – MNNC: The Glass & Hard Plastics List was missing the Plant #1 Cold Room and Blend room items.

4.9.4 Products packed into glass or other brittle containers

4.9.4 – N/A. No products packed in glass.

4.9.5 Wood

Wood control and pallet management program is documented, dated 7/10/15. No wood utensils are allowed in processing areas. None were noted by the auditor. Pallets and bins present in process areas were clean and in good repair.
Wooden structures located in processing areas are inspected at a minimum twice a year: inspections on file for all areas dated 1/9/17, 4/18/17, and 8/17/17.

4.10 Foreign-body detection and removal equipment

4.10.1 Foreign-body detection and removal equipment

Foreign body detection and removal equipment are in place.
Magnets in use at the raw product feeding areas and items found on magnets are investigated when unusual objects are detected and found. Magnet locations are documented on process flow diagrams. Magnets are checked before cleaning and after. Bertocchi filter is monitored through visually inspecting juice. Integrity is verified before and after each run. Filter 0.03" is checked every run.

Metal detectors are in place. No X-ray technology used.

4.10.5.1 - N/A. No optical sorting equipment.
4.10.6 - N/A. No container cleanliness – glass jars, cans and other rigid containers.

4.10.2 Filters and sieves

Bertocchi screens checked as per production runs. Sock filters (finishers-100 micron) are checked every shift and after product change.
Screen Monitoring Logs reviewed dated 7/19/17 (Raspberry puree), 7/19/17 (Dark Sweet Cherries), and 8/14/17 (Organic Rasp. S/S),
Filter Audit Logs reviewed dated 7/19/17 (Organic Strawberry puree), 8/14/17 (Strawberry Juice),

4.10.3 Metal detectors and X-ray equipment

Metal detectors are in use as per customer requirements. They are validated, monitored and verified through the HACCP plan procedures (CCP-Metal Detection).

CCP (Metal Detection – all products)
CL: Challenge the diversion valve function with 1.5mm Fe, 2.0mm NFe, and 2.5mm SS.
Monitoring: Challenge the diversion valve function with 1.5mm Fe, 2.0mm NFe, and 2.5mm SS, at start and end of each lot produced.
Verification by records review by QA Manager.
Corrective Actions: Recalibrated unit, rerun product and rework product that was rejected to identify source of contamination if possible. Documented as necessary.
Metal detection CCP records sampled and reviewed by the auditor dated: 7/19/17 (Apple Juice Shilling), 7/19/17 (Raspberry Puree Conc.), 7/19/17 (Red Raspberry Essence), 8/14/17 (Strawberry juice conc.), 8/14/17 (Organic Red Raspberry Puree), 8/14/17 (AJ Conc.), 8/14/17 (AJ Conc.), 8/14/17 (BBJ Conc.), 8/15/17 (Strawberry Essence), 8/15/17 (Strawberry Conc.), 9/18/17 (AJ Conc.)

No X-ray technology used.

4.10.4 Magnets

Magnets (7) are checked at least once a day and before and after production lot runs.
Magnet pull test required at least annually. Records for magnets tests in Plant 1 and Plant 2 on file (sampled) dated 10/7/17.

4.10.5 Optical sorting equipment

4.10.5 NA. No Optical sorting equipment used

4.10.6 Container cleanliness – glass jars, cans and other rigid containers

4.10.6 – N/A. No use of glass jars, cans and other rigid containers.

4.11 Housekeeping and hygiene

Specific Cleaning SSOPs are documented on each record form for each piece of equipment and each production area. For example, Doc #042507, “Main Plant #1 – Fruit Receiving Area Sanitation. There are also Master Cleaning Schedules in place for all 3 Plants. Plant Daily Sanitation Audit Records are kept for each plant and each type of process and equipment used. Records are kept for the start-up and finish of the run with what was cleaned (e.g. tank numbers, lines, pasteurizers, filters, etc.), how it was cleaned (e.g. Rinse, Caustic, Sanitize, etc.), Caustic/Sanitizer/ Rinse Water Verifications (% caustic used, sanitizer ppm, and rinse water pH), swab results (pass/fail), Spray ball cleaning & inspection, and Spot checks by supervisor.

Verification of the effectiveness of the cleaning is conducted using protein swabs and ATP swabs. The results (pass/fail) on protein and <10 rlu’s for ATP swabs, according to the manufacturer’s guidelines, are recorded on each cleaning record. Auditor verified a tanker shipment cleaning and load-out procedures for Plant #2 on 10/17/17 during the plant audit. Tanker cleaning records of certified Kosher wash was on file from the trucking company at the time of load-out dated 10/17/17. The auditor also verified cleaning records for CIP and filling lines prior to the production run of grape juice concentrate into poly-lined steel drums on 10/19/17. No issues were observed.

Records sampled and reviewed, for example, included:
SSOP CIP J-4 (dated 9/12/17)
SSOP CIP J-3 (dated 9/12/17)
MCS – Plant #1 (Jan-17 through Oct-17) – Items to be cleaned for the whole facility are listed monthly, bi-annually and annually.
MCS – Plant #2 (Jan-17 through Oct-17) – Items to be cleaned for the whole facility are listed monthly, bi-annually and annually.

Daily Cleaning Records sampled and reviewed included:
-Plant #2 Daily Cleaning Logs – 7/19/17 (3 shifts), 8/14/17 (3 shifts), 9/18/17 (3 shifts)
-Plant #1 Daily Cleaning Logs – 7/19/17 (3 shifts), 8/14/17 (3 shifts), 9/18/17 (3 shifts)
-Plant #3 Daily Cleaning Logs - 7/19/17 (3 shifts), 8/14/17 (3 shifts), 9/18/17 (3 shifts)

Environmental swabbing is completed according to the Environmental Monitoring Program (Doc#030205, dated 09/27/17). Zones 1-4 have been defined from direct food contact to non-food contact outside the processing areas. Weekly swabbing is conducted for E. coli, coliforms, and APC. Results for July-17, Sept-17, Oct-17, etc. were reviewed. Corrective actions are taken when results are unacceptable. Some high counts for APC were noted with re-cleaning and re-testing recorded until acceptable results were obtained during the month of Sept-17. Bi-annual swabbing of drains in each plant are completed for Listeria spp. Results reviewed from 7/22/17 showed acceptable (neg.) results.

4.11.1 – MNNC : There were some areas observed during the site audit that were found not be well cleaned and maintained (debris and insulation in Plant #3 Tank rooms, dead bat, dust and debris located in the Plant #1 boiler room).

4.11.7 Cleaning in place (CIP)

Specific Cleaning SSOPs are documented on each record form for each piece of equipment and each production area. Plant Daily Sanitation Audit Records are kept for each plant and each type of process and equipment used. Records are kept during the start-up and finish of the run with what was cleaned (e.g. tank numbers, lines, pasteurizers, filters, etc.), how it was cleaned (e.g. Rinse, Caustic, Sanitize, etc.), Caustic/Sanitizer/ Rinse Water Verifications (% caustic used, sanitizer ppm, and rinse water pH), swab results (pass/fail), Spray ball cleaning & inspection, and Spot checks by supervisor.

Examples of records sampled and reviewed:
SSOP CIP J-4 (dated 9/12/17)
SSOP CIP J-3 (dated 9/12/17)

Daily Cleaning Records reviewed:
-Plant #2 Daily Cleaning Logs – 7/19/17 (3 shifts), 8/14/17 (3 shifts), 9/18/17 (3 shifts)
-Plant #1 Daily Cleaning Logs – 7/19/17 (3 shifts), 8/14/17 (3 shifts), 9/18/17 (3 shifts)
-Plant #3 Daily Cleaning Logs - 7/19/17 (3 shifts), 8/14/17 (3 shifts), 9/18/17 (3 shifts)

4.12 Waste / waste disposal

Trash is collected on as weekly basis or as needed according to production activities by an approved service supplier. Waste removal services agreement is on file. Waste removal company is licensed by WA State. Solid Waste Control Plan, last updated 12/14/16.
Pick up receipts were on file for waste, for example 7/31/17 (solid waste), Jan-17 through Oct-17 (filter and pomace waste), etc.

4.12.13 – N/A. No trademarked product is sent for destruction since all products are bulk for further processing and not retail.

4.13 Management of surplus food and products for animal feed

No retail products are manufactured. Products are manufactured as per work orders and for building up inventory. No surplus is generated.
The only product that is sent to animal feed is the pomace by-product. It is intended for animal feed and is kept in sanitary conditions and removed on as needed basis.

4.14 Pest Control

Pest control procedure is documented dated 3/14/16. QS Manager oversees the program.
Pest control is contracted to a licensed company. The PC Company is licensed by the WA State Department of Agriculture. The PCO license is current, and valid until 3/28/2020 and Supervisor PCO License valid until 3/28/2020, Lic#75049.
Business License valid through 8/30/118.
Pest Control contractor service contract/agreement dated 3/20/17.
Liability Insurance valid until 1/1/2018.
Insurance policy on file dated valid until 1/1/17

Description of the service and training records are on file.
Schematics of the pest control devices layout were verified during the audit and deemed accurate. Dates of the device maps were as follows: Plant 1 (9/13/16), Plants 2&3 (10/18/17), Forklift, Shop, Dry Storage (10/18/17), etc. The devices include: ILTs, mechanical traps, exterior bait stations (NOP compliant).
Weekly inspections are performed on the inside devices.
Bait stations are inspected monthly.

Records sampled and reviewed during audit: Pesticide usage report on file dated 12/8/16, 7/6/17, etc. Mainly all for rodent bait (Contrac-Blox), and one instance of gel application (Advion Ant Gel). Service reports on file dated 10/6/17, 8/15/17, 7/19/17,
Pest trending report is updated every visit. Trends reports are on file for these: ILTs (9/14/16 – 9/14/17), Bait Stations ((9/14/16 – 9/14/17), Interior rodent traps (9/14/16 – 9/14/17).
Material usage log is kept current dated 10/5/17.
Pest program is reviewed quarterly by the PCO and annually by the area supervisor. Records on file sampled and reviewed dated 3/30/17, 4/21/17 and 10/16/17.
There is a list of approved material reported by the PC software updated as of 10/18/16 – 10/18/17.
MSDS and labels are on file, e.g. Contrac-Blox (Jan-2015), Advion Ant Gel (8/4/15), etc.
During the audit, no evidence of current, uncontrolled pest activity was observed inside the facility.
No vegetation was present around buildings.

4.15 Storage facilities

Documented Shipping and Cold Storage procedures, dated 8/7/17 and Shipping and Storage Freezer procedures dated 8/7/17, are in place.
Temperature monitoring procedures are documented for cold storage rooms and shipping.
Frozen products temperatures are kept 5 to 0˚F. Cold rooms for refrigerated products are kept at 43-50˚F
Temperature records for cold storage 45-50˚F.
The facility produces concentrate and juice to order.
FIFO for stock rotation is used for raw and packaging materials as well as processing aids.

Records sampled and reviewed for example: Freezer/Cold Room Log – October 2-6, 2017 (All areas, tanks, storage rooms) August 6-12,2017 (All areas, tanks, storage rooms), etc.

4.16 Dispatch and transport

Incoming and Outgoing Truck Inspection Approval procedures are documented, and dated 4/26/16.
Records of shipping and transportation are kept on file, on the bill of lading and the picking order.
According to work instructions, transport are inspected for cleanliness, odours, standing water, holes, and temperature. Tanker Shipping procedures and Temperature for Loading Tankers procedures (dated 2/2/15).

The transport of raw materials and packaging materials is the responsibility of the supplier.
Finished products transportation is made with qualified refrigerated carriers which are paid by the customer for the most part. The forklifts in the facility are inspected on a weekly basis.
Transport procedures are documented and implemented. Shipping records are kept.
Inspections for hygiene are conducted for all shipping and delivery vehicles. Tankers are tested for cleanliness using a rapid protein detection kit, verified by the auditor through observation of loading apple juice concentrate into an outbound tanker.
Traceability is maintained using bills of lading and invoices as well as shipping records.
There are inspection procedures in place for inbound carriers.

Examples of BOLs and shipping inspection records sampled and reviewed:

BOL's - #39225, #38284, #38285, etc.
Shipping Truck Inspection Forms: Record dated 9/5/17
Shipping Tankers dated 10/19/17, 10/6/17, 7/19/17, 7/26/17, etc.

4.16.6 – MNNC: There are no formal documented agreements in place for transportation carriers.

Details of non-applicable clauses with justification

Clause reference	Justification
4.3.5	N/A. No high-care areas.
4.3.6	N/A. No high-risk areas.
4.4.4	N/A. No high-risk areas.
4.5.3	N/A. Only potable water used.
4.5.4	N/A. No air or gases used in direct contact with product.
4.8.4	N/A. No high-care areas.
4.8.5	N/A. No high-risk areas.
4.8.10	N/A. No catering activities.
4.9.4	N/A. No use of glass jars, cans and other rigid containers.
4.10.5.1	N/A. No optical sorting equipment.
4.10.6	N/A. No container cleanliness – glass jars, cans and other rigid containers.
4.10.5	N/A. No Optical sorting equipment used.
4.10.6	N/A. No use of glass jars, cans and other rigid containers.

4.12.13	N/A. No trademarked product is sent for destruction since all products are bulk for further processing and not retail.

5. Product control

5.1 Product design/development

The company has procedures in place for controlling changes in the process or equipment (form dated 01/18/16). HACCP Procedures address changes.
Sanitary equipment designs procedures are in place with required new equipment evaluation records to be kept (e.g. Sanitary Equipment design records for Plant #2 Belt Hopper (4/1/16), Metal Detector install (6/8/16), etc.).
Supplier approval and monitoring procedures are in place for any new fruit items.
It is stated that the process is to prevent unauthorized changes that may impact the safety or quality of the product. It is stated that no changes are to be made to the process.
Changes have to be reviewed by Plant Manager and VP of Operations.
No new products have been developed in the last 12 months.

5.2 Product labelling

Supplier approval and monitoring procedure dated 2017. Label Approval Policy, Doc #041406, dated 10/07/17.
Changes on labels are verified by the Corp VP and communicated by means of sales orders and enforced by QA Lab Personnel. Labels are issued by the QA Lab only.
LOG is issued to customers every year.
PDF label art work is sent by the customer and reviewed by Lab Manager when a customer specific labelling requirement is needed.
No product labelling claims are made.

5.3 Management of allergens

Allergen/Sensitizer Policy, Doc #70501E, dated 1/31/17. No allergens are used in production and no products require labelling for allergens. Allergen awareness training is provided during employee orientation and annual refreshing training, last conducted on 9/26/17.
Sulphites are naturally present in grape juice. A total of 4 composite samples are tested annually for each crop year, Concord, Niagara, and Organic for each product (last tested in 11/30/16 (2016 crop), All sulphites results <10 ppm as per tested and evident by an outside lab COAs) to verify this.

5.4 Product authenticity, claims and chain of custody

The company is a member of the NWFPA, Juice Processors Association, and subscribe to Food Safety and Food Quality Magazines to stay abreast of historical and emerging threats or issues. The firm has a documented Vulnerability Assessment (Doc#082115 and dated 09/26/2017) signed by the HACCP team, including the company President. The assessment takes into account fraudulent activity that could occur in all raw materials, historical events of adulteration, economic factors for risk of adulteration, access to raw materials in the supply chain, and the nature of the raw materials. The company has used a risk matrix based on likelihood and severity, and has conducted a vulnerability assessment using the following format for each raw materials, ingredients, packaging and processing aids, e.g. “Whole Fruit” – Historical

Evidence (unauthorized pesticides), Economic Gain (cheaper products and fabricated test results), Supply Chain access/nature of materials (Whole, sound fruit), Origin (US, Canada, Chile, Mexico).
A record with the date of the last review was 9/26/17.

Domestic Origin Policy for All USDA Products in place, dated 5/2/2017. Organic claims are verified through the site's organic certification program and audited by a licensed certification body. Where specific varietal claims have been made, such as "Concord Grapes", letters of verification of varieties from growers are in place.
Domestic claims such as "100% Domestic" are verified by a "QA Audit for USDA Orders" to meet customer requirements for every shipment where this claim is made, e.g. QA Audit for USDA Orders records for SO #38944, dated 9/16/17.
Non-GMO Claims at customer requests – supported by supplier approval documentation, for example Non-GMO organism statement for Amylase Enzyme dated 5/7/15.

Kosher Certificate on file valid until 6/30/18.
Organic Certificate on file dated 7/18/17.

5.5 Product packaging

Packaging supplier provided certificate of conformity for sampled packaging materials.
Packaging in use includes liners, 5 gallon pails, 55 gallon drums and food-grade insulated tankers.
The pails and drum liners are stored in suitable conditions. There was no obsolete packaging observed during the audit at the facility. The packaging materials are suitable for food contact and intended use.
Letter of guarantee for liners states bags meet US FDA regulations.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Procedure titled "how to check a new production lot" on file dated 2/3/15. The procedure addresses sample collection and testing during production and finished product for COA creation.

There is a QA manual containing SOPs for testing procedures (Physicochemical and organoleptic). The manual also addresses verification and calibration procedures for lab equipment. Examples included: Microbial testing of finished product (dated 1/15/15), Total Acidity SOP (dated 1/28/15), Bostwick Procedures (dated 2/04/15), etc.

Retention samples is up to 3-5 years depending on product and shelf-life statements.
Conformance to internal and customer Specs procedure is implemented and documented dated 9/14/12.
Testing is performed for each batch. Organoleptic testing includes taste and odour.
Physicochemical testing includes pH, TA, turbidity, ˚Brix, colour, and specific gravity.

Microbiological testing includes total coliforms, E. Coli, TPC and Y&M, performed at off-site.
Product testing is performed at the start of packaging, at the end of production run and at the end of packaging to monitor product quality consistency.

On-going shelf life testing is completed and records are maintained in the Shelf-life Validation Log. Shelf-life Validation Program, Doc #102114, dated 10/05/15 on file. For example, testing records present for Raspberry Puree dated 7/10/15 (2 years), produced 07/09/15, DS Cherry Essence, dated 9/15/17 (5 years), etc.

5.6.2 Laboratory testing

Microbiological and pathogen testing is now completed off-site at a separate location. ISO certifications are on file for outside contracted labs, for example ISO 17025 Certificate valid through 12/14/16. No on-site microbiological or pathogen testing labs are used.

5.7 Product release

Product Release and Lot Allocation program is implemented and documented dated 9/12/16. Procedure is based on positive release principles.
Product is released after successful execution of all planned controls provided including micro testing. COAs are verified against specifications prior to release. QA releases product into the computerized system to make it available for shipping inventory.

Details of non-applicable clauses with justification

Clause reference	Justification
5.6.2.2	N/A. No on-site microbiological or pathogen testing labs on-site.

6. Process control

6.1 Control of operations

The company has a documented Process Manual, (Doc #032306, Rev #9 dated 9/15/16) in place that includes work instructions and procedures with step by step batching instructions for “All Juice and Concentrates, Puree Concentrates, Single Strength Purees”.
Each of the processing procedures has flow diagrams and instructions for conventional, organic and kosher products. Instructions for clean-up, batching/mixing of enzymes and pectinase, heat/cooking controls, flow rates, filter controls, regulatory Brix and product identity instructions and volume controls area listed. Process monitoring of mixes, volumes, time and temperatures are recorded by chart recording and verified by operators. The main regulatory process monitoring is in regard to product identity and the minimum FDA allowance for Brix, which is verified by the laboratory.
CIP cleaning instructions are in place for each piece of equipment that has operational controls and panels for adjusting times, temperature, flow rates, etc.
The firm uses in-line chart recording of time (flow rate in Gallons per minute) and temperature, as well as volume controls present, which has an automated diversion valve for when process specifications are not met. The operators verify the functionality of the diversion valve at the start of every production run.

Examples of Process Control SOPs on file, sampled and reviewed:
Apple or Pear juice and concentrate DOC#040706, 6/9/15.

Rhubarb juice and concentrate DOC#012715, 03/10/16.
Apple and pear single strength puree DOC#022306A, 9/14/16.
Receiving Processed Fruit procedures, dated 1/31/17.
Fruit Dumping and Fruit Culling SOP, and 10/4/17.
Metal Detector SOP, dated 10/2/17.
Pasteurization-Decant and Schmitt Operations SOP, dated 10/2/17.

6.2 Labelling and pack control

The firm has a documented Labelling Approval Policy (Doc #041406, dated 010/7/17) which contains instructions for coding and labelling. There is also a Lot Coding Procedure, dated 12/6/16, define finished product labelling and coding.

Records are kept on Packaging & Label Audit Traceability forms (Doc #121603) for regulatory compliance, organic labelling, Kosher labelling, lot coding, weight control, product parameters, and expiration dates are part of the procedures.
Copies of the product labels are kept in production records.
Packaging, container type, weight control, and process parameters are all verified prior to changing production runs.
Label control on a record as follows, # labels issued, # labels used plus partials drums, # labels returned.

Records reviewed by auditor: Concord Grape Juice Concentrate (Lot#101917), Apple Juice Concentrate (Lot#071917).

6.3 Quantity, weight, volume and number control

Weight Control Policy, dated 9/25/17, defines instructions for weighing pails, drums, etc. Accuracy check procedures are included. Calibration methods are identified, with each piece of equipment and location listed.
Pails and Drums are weighed three times per lot number for verification checks.
Tankers are filled and then weighed on the truck scale.
Drums are weighed individually.

Weight records sampled and reviewed dated 10/19/17

6.4 Calibration and control of measuring and monitoring devices

The production, truck and laboratory scales/balances are required to be calibrated on an annual basis. Acceptability versus unacceptability and corrective actions procedure are documented. The scales/balances are all calibrated by an outside authorized contractor who uses NIST traceable weights for calibration.
The firm maintains two NIST traceable thermometers for use as a standard to check all temperature measuring equipment within the facility.
The outside contractor used for scale/balance calibration provides certificates of calibration stating that NIST traceable weights are used.
Screens used for filtration have been purchased from an outside manufacturer and are verified to be in compliance with the correct size by purchase, but also validated through CCP monitoring for foreign materials directly after the filter steps as recorded on CCP monitoring records.

Out of Tolerance measuring devices are addressed with an acceptable vs. unacceptable result documented. Adjustments and/or replacement is required as per the procedure when unacceptable results are found. A Backup systems procedure for re-pasteurizing juices is in place to be followed if measuring devices are found to be inaccurate.
Corrective actions for scales/balances and the use of back-up devices are documented with the procedures.

Examples of calibration records reviewed on file sampled and reviewed:
Plant #3 Evaporator temperature and flow rate meters – last calibrated on 5/31/17
Plant #1 (east) pasteurizer temperature and flow rate meters – last calibrated on 5/27/17
Plant #1 (west) pasteurizer temperature and flow rate meters – last calibrated on 5/31/17
Thermometers-
Tank Room #1 – last calibrated on 7/28/17
Tank Room #2 – last calibrated on 7/28/17
Cold Barrel Room – last calibrated on 7/28/17

Details of non-applicable clauses with justification

Clause reference	Justification

7. Personnel

7.1 Training: raw material handling, preparation, processing, packing and storage areas

Training programs are implemented and documented titled “Employee Training”, Doc #072611B, dated 09/15/16.
All employees are trained upon hiring using orientation materials.

Ongoing training is implemented as well as annual refreshing training. Employees’ names and signatures appear on records. The following training records were sampled and reviewed by the auditor:

Annual refreshing training dated 9/11/17. It was provided by QA Manager, Maintenance Manager and VP of Operations. Training includes topics of the firm’s policies, programs and procedures related to food safety and quality such as: Allergen Awareness and Policy, Bandage and Open Sores, Clean Hands policy, communicable diseases policy, Doors and door program, HACCP, Food Defence, etc.
Quizzes are given after the training sessions to all employees and records are kept.

Specific job related training is given to each employee depending on the nature of the job duties/title, for example, CCP operators:
-CCP training for the Metal Detection CCP operators last given on 10/10/17, 10/9/17, and 10/5/17.

-CCP training for the Pasteurization Decant and Schmidt Operators last given on 10/10/17, and 10/9/17.
-Fruit Culling and Dumping procedures last given on 10/10/17

Training is performed in English and translators are used for Spanish speakers.
Employee GMP training for all employees was conducted on 2/23/17, 9/11/17, 9/12/17, 9/26/17, 10/5/17 and 10/12/17.
New hires and temporary employees are given an orientation training which includes.
Annual Food Safety Refresher Training for all employees took place on 9/11/17, with records kept. Topics included for example, Food defence, Mission Statement, GMP, Allergens, Documentation/records, Drum & Pail Movement, Disease policy, knife and sharps, hand washing, etc.
Examples of new hire training records sampled and reviewed dated 9/11/17 10/9/17, 10/13/17, 10/11/17, etc.

7.1.1 – MNNC: A bag of chips was found in an operator's toolbox located on the filter room catwalk in Plant#1 and various food items were found located in employee lockers on the 2nd floor of the Plant #1 locker room.

7.1.3 – MNNC**:** The methods for reviewing the effectiveness of the training have not yet been defined and implemented.

The methods for reviewing the effectiveness of the training have not yet been defined and implemented.

GMP Procedure, dated 9/26/17, addresses prohibited items in production area, employee practices and hygiene. Employees were observed washing and sanitizing hands upon entering processing areas. No prohibited items were carried by employees in production areas.
Employees with exposed wounds were not observed during the site tour.
Illness control policy provides instructions for staff and policies are in place to control the usage and storage of personal medicines, as stated in the Medication Policy, dated 8/5/17. It states that medication has to be stored in lockers but medicines for life-threatening conditions are permitted with the employees at all times when a supervisor is notified.
Metal detectable bandages are in use and storage in accessible areas (QA labs), with check-out logs kept. Logs of metal detectable bandages checked through functioning metal detectors on-site are kept.

7.3 Medical screening

Communicable diseases, GMPs and Food security procedures address that any illnesses are to be reported to the supervisor. Policies in place and communicated during the new hire and refresher employee training sessions, for example Communicable Diseases Policy, Doc #081110A, dated 01/30/17.

Visitors and contractors are managed through a Contractor and Visitors HACCP/GMP Training sign-in policy, dated 1013/17. The same medical screening pre-cautions and prohibition against communicable diseases are enforced for contractors and visitor as stated in the policy. The auditor was asked to read and sign the policy upon checking in at the main office.

7.4 Protective clothing: employees or visitors to production areas

GMP Procedure, dated 9/26/17, that addresses prohibited items in production area, employee practices and hygiene, and addresses the clothing requirements, including uniforms (company provided protective shirts).
Hair restraint is implemented in all open product areas, and includes hairnets and beard nets to be worn as necessary. Employees were observed following this policy during the site audit.

Laundry is provided by an approved 3rd party service, with agreements and specifications for cleaning in place, dated 1/14/16.

Clean Hands Policy, Doc #072211, dated 8/29/16. Clean uniforms, hair restraint, and clean personal clothing and shoes are required. Clean uniforms are supplied daily. They are kept separate from dirty uniforms. A laundry service delivers clean uniforms on a regular basis. Protective clothing is supplied in sufficient quantities to staff.

A documented Glove Policy is in place, dated 1/31/17, which defines glove use practices for maintenance (non-disposable), chemical handling gloves (neoprene), laboratory disposable gloves and production disposable non-latex, nitrile gloves. Disposable polyethylene arm sleeves and aprons are used for the barrelling/filling crew and packaging employees.

7.4.4 NA. No high-risk or high-care areas as per BRC definitions.
7.4.5 NA. No high-risk or high-care areas as per BRC definitions.

Details of non-applicable clauses with justification

Clause reference	Justification
7.4.4	N/A. No high-risk or high-care areas as per BRC definitions.
7.4.5	N/A. No high-risk or high-care areas as per BRC definitions.

Module 8 - Traded Goods	
Scope	
8.1 Approval and performance monitoring of manufacturers/packers of traded food products	
8.2 Specifications	
8.3 Product inspection and laboratory testing	
8.4 Product legality	

8.5 Traceability

Module 9: Management of Food Materials for Animal Feed

Scope	
9.1 Management Commitment	
9.2 HACCP	
9.3 Outsourced Production	
9.4 Specifications	

9.5 Traceability
9.6 Chemical and Physical Product Contamination Control
9.7 Labelling
9.8 Training

Module 11: Meat supply chain assurance

Scope	
11.1 Traceability	

11.2 Approval of meat supply chain
11.3 Raw material receipt and inspection
11.4 Management of cross-contamination between species
11.5 Product testing
11.6 Training

Module 12: AOECS Gluten-free Foods	
Scope	
12.1 Senior management	
12.2 Management of suppliers of raw materials and packaging	
12.3 Outsourced production	
12.4 Specifications	
12.5 Management of gluten cross-contamination	
12.6 Management of incidents, product withdrawal and product recall	

12.7 Labelling
12.8 Product inspection and laboratory testing

Module 15 FSMA Preventive Controls Preparedness Module

Item no.	Clause	Module item	Conforms (Y/N)	Comments
1	117.20	Handwashing areas, dressing and locker rooms, and bathrooms must have adequate lighting.		
2	117.37	The water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
3	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.		
4	117.80	Ice used in contact with food must be manufactured in accordance with the good manufacturing practice (GMP) requirements of 21 CFR § 117.		
5	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.		
6	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.		
7	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).		
8	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.		
9	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, divert, repurpose).		
10	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.		
11	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).		
12	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.		

13	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.		
14	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.		
15	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.		
16	117.165	Devices used to **verify** preventive controls must be calibrated.		
17	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 experience.		
18	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.		
19	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.		
20	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.		
21	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.		

22	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.		
23	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.		