Audit Report

Global Standard for Food Safety Issue 7: July 2015

1.Audit Summary			
Company name	Congdon Packing LLC	BRC Site Code	2053284
Site name	Congdon Packing & Storage LLC		
Scope of audit	Washing, sorting, grading and waxing apples; packaged in plastic clam shells, poly and mesh bags and in cardboard cartons. Sorting and repackaging of pears into cartons.		
Exclusions from scope	N/A		
Justification for exclusion	N/A		
Audit Finish Date	2017-09-13		
Re-audit due date	2018-09-15		

Voluntary modules included		
Modules	Result	Details

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit type	Announced
Previous audit grade	A	Previous audit date	2016-09-07		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	4

3.Company Details

Address	10 West Mead Ave. , Yakima, Washington		
Country	United States	Site Telephone Number	5099457914
Commercial representative Name	Dani Young	Email	dyoung@congdonorchards.com
Technical representative Name	Dani Young	Email	dyoung@congdonorchards.com

4.Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	51-500	No. of HACCP plans	1-3

Subcontracted processes	No
Other certificates held	Organic
Regions exported to	Asia North America South America Europe
Company registration number	########2354
Major changes since last BRC audit	None

Company Description

Congdon Orchards, Inc. is a vertically integrated fruit growing and packing operation located in Yakima, WA- USA, founded in 1904. The facility packs fresh apples and re-packs pears under one documented HACCP Plan. The packing plant located at 10 West Mead Ave in Yakima WA currently employees 115 employees, and runs a single production shift followed by a full sanitation shift, five days a week. The 271,153 square foot facility packs an average of 6000 boxes per week and ships products to both domestic and international markets. There are no subcontracted processes

5.Product Characteristics

Product categories	05 - Fruits, vegetables and nuts				
Finished product safety rationale	Chlorine dioxide and Peroxy-acetic acid treated wash water, cold storage, no processing of fruit.				
High care	No	High risk	No	Ambient high care	No
Justification for area	BRC Decision Tree				
Allergens handled on site	None				
Product claims made e.g. IP, organic	Organic				
Product recalls in last 12 Months	No				
Products in production at the time of the audit	Granny Smith Apples, in Clamshells, bags and trays.				

6.Audit Duration Details			
On-site duration	18 man hours	Duration of production facility inspection	7 man hours
Reasons for deviation from typical or expected audit duration	Small facility with simple process		
Next audit type selected	Announced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1	2017-09-12	08:00	17:00
2	2017-09-13	06:00	14:00

	Auditor(s) number(s)	Names and roles of others
Auditor Number	233062	Parmjit Dhillon
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
Mark Blore /General Manager	x			x
Roberto Sanchez /Production Manager	x			x
Edgar Pacheco/ Assistant Technical Director	x	x	x	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	2.10.1	As per procedure CCP-Peracteic acid is monitored at start up, every hour and end of the shift. Atlest 2 CCP checks dated Sept 05, 2017 and Sept -06 were not done hourly e.g. Sept CCP was monitored at 9:51 am next check was completed at 11:04 AM, similarly Sept 05 CCP check was done at 10:36 am next check was done at 11:47.	1. The Peracetic Acid PAA 12.0, QP-2.10.1M was revised on 9/21/17 to include as part of the procedure of +/- 15 min within the 60 min testing procedure. 2. Refresher training to the Lab Tech and the Food Safety Assistant to ensure that procedure is reviewed and ensure that tests are completed within the 60 min +/- 15 min.	1. Monitoring of CCP records failed to be completed within the 60 min period as stated in the procedure 2. Lack of employee training to ensure that the tests are completed within the 60 min period 3. Lack of the procedure details ensure that the tests are completed within the 60 min time frame allowed 4. Oversight on the Technical Manager and Assistant Technical Manager to	A copy of the record Peracetic Acid PAA 12.0;Copy of the revised procedure QP-2.10.1M;Copy of Training Attendance Refresher given to employees on 9/28/17	2017-09-28	CELLERBECK

				identify any deviations off the procedure as stated 1. Daily review of paperwork perform by the Food Safety Assistant will verify that the completion of all tests are being done according to the procedure and testing times shall be done accordingly.			
2	4.4.1	Damage (Hole) to South wall of cooler 7 and North wall of Cooler 8 near junction of floor and wall. Looks like damage from forklift.	1. The damaged wall by the forklift inside of cold room #7 and #8 was fixed by the refrigeration personnel.	1. Damaged cold room walls inside of cold room #7 & #8 was observed during the audit 2. These areas were observed to be damaged by the forks of one of the forklifts 3. Damaged area wasn't notified to the Production Manager and/or Supervisor 4. Lack of employee training to notify the Production Manager and/or Supervisor of damaged made to the wall 1. Refresher training to all forklift operators to	Employee Training Attendance Refresher to Forklift Operators. ;Monitoring log of Refrigeration personnel that are monitoring wall conditions;Pictures of walls inside of cold room #7 and #8.	2017-09-28	CELLERBECK

				notify immediately after an event of a damaged wall and/or piece of equipment to the Production Manager and/or Supervisor 2. Monitoring of cold room walls to ensure that any areas of concern/damages are addressed and/or replaced			
3	4.4.3	Pooling water observed by bin wash area on the floor where stage the product bins before dumped on the line. Also a pooling water observed in cooler 8 below the refrigeration units.	1. Standing water is periodically being squeegeed from the dump tank by the dump tank operator. 2. The standing water inside of the cold rooms is squeegeed out by the refrigeration personnel inside of the cold rooms.	1. Standing water observed during the BRC audit next to the dump tank and inside of cold room #8 2. Standing water is not being cleaned periodically throughout the day 3. Lack of employee training to ensure that all areas are maintained free of standing water. 4. Lack of monitoring for areas with high risk of potential standing water. 1. Refresher training to dump tank operator and refrigeration personnel to ensure	Training Attendance for Water Pooling ;Cold room cleaning logs and monitoring for excess water. ;Pictures of areas with pooling water. ;Monitoring log for Production on monitoring any excess water.	2017-09-28	CELLERBECK

				that standing water is monitored periodically throughout the day 2. Monitoring of standing water in the dump tank area and inside of the cold rooms.			
4	7.2.2	An employee at production line observed drinking water from the water fountain without removing the gloves before drinking water neither did wash hands after, before return to work, contrary to company policy.	1. Employee was reminded to ensure that gloves shall be handled properly at all times and gloves shall be changed when these have become potentially contaminated. Employee was present at the time of the refresher training given to all personnel.	1. Employee was drinking water and didn't remove gloves and didn't wash hands prior to returning to work 2. The employee failed to follow GMP procedures 3. Lack of employee training and monitoring to ensure that gloves are kept intact and free of potential contamination 1. Refresher training given to all personnel on practices and GMP procedures to follow. 2. Daily monitoring of employees to ensure that they are following procedures and changing gloves after these might have become contaminated.	Training Attendance Refresher to all personnel on GMP's. ;Daily monitoring of employee hygiene to verify GMP's.	2017-09-28	CELLERBECK

Comments on non-conformities
N/A

Voluntary Modules Non-Conformity Summary Sheet

Detailed Audit Report

1 Senior management commitment

1.1 Senior Management Commitment and continual improvement

The site has a senior management team led by the General Manager, which is fully committed to the implementation of the requirements of the standard and continual improvement of food safety and quality.

The documented policy was signed by the General Manager on June 12, 2017. The policy is communicated to all staff by being displayed in common areas such as bulletin board, front office. Additional communication is done during orientation and refresher training.

Clear objectives were set by site senior management on an annual basis and are monitored monthly.
Objectives for year include:
1. Achieve Grade A in BRC audit
2. Non Conforming product target - zero
3. Reduce Trouble Reports by 20% from previous year
Record review indicated that objectives were being achieved.

Senior manager chaired the annual, management review meeting, which includes:
• previous management review action plans and timeframes
• results of internal, second-party and/or third-party audits
• customer complaints and results of any customer feedback
• incidents, corrective actions, out-of-specification results and non-conforming materials
• review of the management of the systems for HACCP, food defense and authenticity
• resource requirements.

Records of the meeting dated Aug 29, 2017 documented the review of the site performance. Decisions and actions agreed were communicated to staff responsible for implementation and actions were implemented within agreed timescales, as observed in Management Review Meeting Agenda and Record dated Aug 29, 2017.

Food safety, legality, and quality issues are discussed during monthly, meetings. Minutes of the management review meetings dated Aug 22, 2017 and June 21, 2017 were reviewed.

The site has a designated organizational structure to provide human and financial resources to ensure compliance with requirements of the standard.

The site is kept informed of new risk to authenticity, scientific and technical developments, industry codes of practice, and regulatory issues through
• membership of trade organization, such as WSU, NW Horticulture, BRC
• subscription to a service provider supplying legal updates
• information from government agencies, such as Recalls, Market Withdrawals and Safety Alerts for U.S. Food & Drug Administration (FDA), the Rapid Alert System for Food and Feed (RASFF)
• regular review of identified websites covering legislation and standards, such as FDA Guidance Documents for U.S. Food & Drug Administration (FDA),

The facility inspection report issued by Washington State Department of Agriculture from the last on-site visit

on Jan 03, 2017 was reviewed. Regulatory non-compliance was not observed.

A genuine hard copy of the current Standard is available on site and there is awareness of the change to the standard.

The audit due date was Sept 15, 2017 and was conducted on Sept 12, 2017.

The most senior production manager or operations manager on site attended the opening and closing meetings.

All non-conformances from the previous audit were effectively addressed and have not recurred at this audit.

1.2 Organisational structure, responsibilities and management authority

The company have clear organizational structure and lines of communication.

The organizational chart dated Aug 24, 2017 showed the management structure of the company and the site. Job functions and deputies for key staff with responsibility for product safety, legality, and quality are defined in Position Emergency Back Ups. Documentation indicated that the General Manager was deputized to replace the Production Manager during an absence. Documentation indicated that the position was responsible to Job descriptions for Assistant Technical Manager and Sorting Supervisor were reviewed.

Employees (Receiver, Shipper, QC, Line Operator and Maintenance) interviewed during the plant walkthrough were aware of their responsibilities. Work instructions were located at Line Supervisor office and were accessible to relevant staff. Those reviewed include Granny Smith Apple Specifications and CCP Monitoring Instructions.

Details of non-applicable clauses with justification

Clause reference	Justification

2 The Food Safety Plan – HACCP

HACCP Team:
The company has developed and implemented 1 food safety HACCP plan.

There is a multidisciplinary HACCP team led by the Technical Manager that completed HACCP training provided by International Food Protection on Oct 28, 2016. The other members of the team completed HACCP training on Aug 24, 2017.

Pre-requisite programs have been established and maintained. Control measures and monitoring procedures are included in the development and reviews of the HACCP program.

Prerequisite programs examined included: Personnel Practices, Cleaning and Sanitation, Pest Control, Premises &Equipment Maintenance and supplier approval.

Product Description:
A full description for Apples, includes:
origin of ingredients,
physical properties and chemical properties,
packaging system,
storage and distribution conditions,
target safe shelf life,
and instructions of use.
Where the product will be sold
How the product will be used
Intended use
Know alternate use

There are no allergens present at this plant.

Relevant information referenced within the HACCP study includes scientific literature, known hazards, codes of practice, guidelines, regulation, customer requirements.
Examples: Codex alimentatrious, FDA, USDA, BRC and WSDA.

The intended use of the products is direct consumption by the public and for further processing.

Process Flow Steps:
Process flow diagrams were comprehensive and available for HACCP plan reviewed.

Flow diagrams are verified annually by site inspection (challenge by 18 HACCP team members); the most recent being Aug 24, 2017. Flow diagrams for the HACCP plan processes were verified during the site inspection and included all required elements.

Hazards:
All potential hazards, reasonably expected to occur at each step in relation to product, process, and facilities were identified and recorded.

The hazard analysis, dated Aug 24, 2017 for the HACCP plan was reviewed and included all the hazards, which needs to be prevented, eliminated, or reduced to acceptable levels.
Suitable control measures for each hazard are documented in the Hazard Analysis. When their control is achievable through existing prerequisite programs, their adequacy to control specific hazards are validated.

Examples of the validation of the sanitation and Premises and Equipment Maintenance included ATP swabs, EMP Program, revised SSOP's, verification of completion of conventional & organic production daily cleaning, Daily Pre-operational checklist, Verification of Preventative maintenance documents, review of pest control inspections etc.

CCPs and Critical Limits:
Based on the hazard analysis 1 CCP were defined for the HACCP plan:

CCP 1: Peracetic acid
Establish critical limits for each CCP – Codex Alimentarius Step 8, Principle 3
The corresponding critical limits were for
CCP 1: Peracetic acid between 40 – 100 ppm. Target is 75 ppm

Validation Method of CCPs:
Validation of CCP is based in regulatory guidelines.

The documented evidence and validation supporting the control measures selected and the critical limits identified were for
CCP 1 – Washington State University validation of PAA (Peracetic acid) dated 2011 and HACCP Food Safety Report for CCP validation generated by third party lab by testing the product at different stages of production at different levels of PAA (Peracetic acid).

Monitoring and Corrective Actions:
Offline measurement monitoring systems are able to detect loss of control of CCP in time for corrective action to be taken.

CCP Operators for CCP 1 was interviewed. The Operator was aware of the critical limits and monitored the CCP per written plan. Operator was aware of procedures when the CCP critical limit was exceeded

Quality personnel are responsible for monitoring and verification of the CCPs. Records are reviewed and signed by the Food Safety Assistant. Records included date, time, and result of measurement. Records reviewed dated, e.g. Peracetic Acid 12.0 Chemical Log dated June 13, 2017 were reviewed.

Corrective actions are defined for each CCP in HACCP Critical Control Limits Validation Summary. Actions and responsibilities are defined with regards to any product manufactured when process was out of control.

The effectiveness of the site's HACCP system is verified by internal audits, review of records of deviations from acceptable limits, analysis of incidents, and customer complaints analysis. Records Management Review Meeting Agenda and Records of meeting to review information dated Aug 29, 2017 are maintained.

Review of CCP and CP records for production dated Aug 30, 2017 to Sept 12, 2017 was conducted and they were sufficient. For example, Peracetic Acid Chemical Log, dated Sept 12, 2017

Records of the HACCP and prerequisite programs review carried out by the HACCP food safety team cover:
• change in raw materials or supplier of raw materials
• or ingredients/recipe
• or in processing conditions or equipment
• or in packaging, storage or distribution conditions
• or in staff or management responsibilities
• or in consumer use
• or developments in scientific information associated with ingredients, process or product.

were documented on the HACCP review HACCP Validation Documentation dated Aug 24,2017.

Example: Annual HACCP review was done on Aug 24, 2017

N/C- 2.10.1 As per procedure CCP-Peracteic acid is monitored at start up, every hour and end of the shift. Atlest 2 CCP checks dated Sept 05, 2017 and Sept -06 were not done hourly e.g. Sept CCP was monitored at 9:51 am next check was completed at 11:04 AM, similarly Sept 05 CCP check was done at 10:36 am next check was done at 11:47.

Details of non-applicable clauses with justification

Clause reference	Justification

3 Food safety and quality management system

3.1 Food safety and quality manual

The Food Safety and Quality Management System, dated July 31, 2017 covers the scope of the Global Standard for Food Safety and contains the appropriate process and procedures.

Policies, procedures and work instructions, and other relevant document are assembled in the Food Safety and Quality Management System, dated July 31, 2017 which is available in as printed copy.

The food safety and quality manual indexes documents required for the food safety system, quality and operating procedures, the site infrastructure, product control, process control, and personnel. The food safety and quality manual is available as a hard copy to appropriate managers and/or is available to appropriate staff.

All procedures and work instructions are clearly legible, in required language and sufficiently detailed. Photographs, diagrams and / or other pictorial instructions are used where required.

3.2 Documentation control

The company operates a computer based document control system in the Technical Manager and Assistant Technical Manager computer to ensure only the correct versions of documents are available and in use.

The company has a document control procedure Document & Data Control QA-3.2.1CA dated July 31, 2017, which includes a list of all controlled documents issued indicating the latest version number, code identification, person responsible for authorization, reasons for any change or amendment. Authorization is controlled by restricted password access to create or modify documents. The Technical Manager is the only person responsible for document approval and release.

The Food Safety Assistant is responsible for replacement of obsolete documents held in hard copy.

3.3 Record completion and maintenance

Records, which demonstrate the effective control of product safety, legality and quality, are maintained.

Documentation procedure Document & Data Control QA-3.2.1CA dated July 31 , 2017 defined method for corrections to hand written errors as use of a single line through the item, initials, and rewriting the information and this was verified during audit. Exact times were required when documenting information.

The product shelf life is 9 months (CA Storage) for Apples. The record retention period is 2 years.

3.4 Internal audit

There is a program of internal audits of the food safety plan and the implementation of the requirements of the Global Standard for Food Safety to verify their effective application.
A program of internal audits is scheduled throughout the year. The scope and frequency of the audits documented in document are established in relation to the risks associated with the activity and previous audit performance. Audits are carried out enabling the whole system to be covered in a year.

3 auditors who are independent from the audited department carry out internal audits. An example of the Internal auditor receiving training on course: Internal Auditor Training Course dated Mar 18-19, 2014.

There were Internal audits throughout the year. The internal audit report for Management Commitment, completed on July 26, 2017 and Quality Management System on Aug 24, 2017 was reviewed. The report contained details of conformity and non-conformity with requirements. A report contained details of corrective action, assigned responsibility, time scales and verification of effective action was reviewed.

There is a program of monthly documented inspections to ensure that the factory environment, processing equipment, and tools, are maintained in a suitable condition for food production. Records of inspections of Facility Inspection Monitoring Reports dated May 23, 2017 and Aug 24, 2017 were reviewed. Inspections are conducted by Food Safety Assistant and Assistant Technical Manager.

3.5.1 Management of suppliers of raw materials and packaging

The supplier approval and monitoring system ensures that any potential risks from raw materials and packaging to the safety, authenticity, legality, and quality of the final product are understood and managed. Suppliers of cherries and packaging material were identified as low-risk. There is not risk ingredient in the facility as per risk assessment
Risk assessments of raw materials, packaging materials, and other products to identify potential risk to product safety, authenticity, legality, and quality were reviewed on Aug 24, 2017. The hazard analysis, the risk or substitution of fraud, and the business impact form the basis for raw materials acceptance and testing and for supplier approval and monitoring.

The supplier approval procedure Supplier Evaluation & Management QP-3.5.1 dated July 31, 2017 is on site.

All suppliers are required a GFSI recognized certificate or supplier audit performed by an auditor to ensure suppliers effective manage safety and quality risks of raw materials, and are operating effective traceability process.

GFSI recognized certificate for Apples- SQF dated Oct 18, 2017, was reviewed and the low risk supplier letter of commitment to food reviewed and MRL testing by third party was for Apples and they were found satisfactory.

The approved supplier list was updated on Aug 22, 2017. All suppliers are accounted for and approved.

A Receiver was interviewed regarding knowledge of approved suppliers at receipt and was able to demonstrate access to the current list.

N/A – 3.5.1.4. According to the procedures, exceptions are not permitted.

3.5.2 Raw material and packaging acceptance and monitoring procedures

Controls on the acceptance of raw materials do not compromise the safety legality or quality of products
The documented procedure for the acceptance of raw materials and packaging Receiving QP3.5.2.1. dated July 31, 2017 is on site. Raw material acceptance and its release are based on one or a combination of:
• product sampling and testing.
• visual inspection on receipt
•
The parameters for acceptance and frequency of testing are defined on Receiving QP 3.5.2.1. dated July 31, 2017 for a list of raw materials and packaging.
Records for acceptance of each batch of raw material and packaging reviewed during the plant walkthrough were Brix, Pressure in Weights dated Sept 06. 2017 and September 07, 2017.

3.5.3 Management of suppliers of services

There is an effective program in place to manage Suppliers of Services.

A documented procedure for the approval and monitoring of suppliers of services Contract Services Provider in Management QP 3.5.3.1.CA, dated July 27, 2016 was reviewed and has been applied to
• pest control
• transport and distribution
• laboratory testing
• waste management.
Calibration services

Vending machine service

Contracts or formal agreements exist with the suppliers of services that clearly define service expectations and ensure potential food safety risks associated with the service have been addressed.
Examples of contracts reviewed: PCO and labelling

3.5.4 Management of outsourced processing

N/A – 3.5.4 There is no outsourced production.

3.6 Specifications

Specifications for raw materials, packaging materials, finished products that could affect the integrity of the finished product are available.
Specifications for raw materials and packaging materials ensure compliance with relevant safety and legislative requirement; and include defined limits for relevant attributes that may affect the quality or safety of the final products (chemical, radiological, microbiological, or physical standards).
Example of a raw material randomly selected for review Organic Gala Apples and Granny Smith Premium Domestic WXFP.

Specifications are available for all finished products in register. They include key data to meet legal requirements and assist customer in the safe usage of product. Finished product specification for Apple Golden Delicious, dated Oct 29, 2016 was reviewed and successfully compared with process specifications and customer requirements.
Finished product specification reviewed and approved by customer was Organic Gala (6-14 and 6-12) #969425, dated May 13, 2016

Specifications are reviewed whenever products change (e.g. ingredients, processing method) or at least every three years. Red Cherries 4 lb, dated Mar 22, 2017 Cherries Sweet & Organic Red Sweet Cherries reviewed included the date of the review and the date of approved changes.

3.7 Corrective action

The site is able to demonstrate the use of information from identified failures in the food safety and quality management system to make necessary corrections and prevent recurrence.

The procedure for the management of corrective action is Corrective Action and Preventative Action QP 3.7.1. CA, dated July 31, 2017.
Identified non-conformities that place the safety, legality, or quality of product at risk could arise from customer complaints, process analyses, internal and external audits, senior manager revisions, organizational issues, process measurements, and auto-assessment. CCP failures, out of specification product, unsatisfactory pre-operational inspections. Unsatisfactory environmental test results, coding errors. Corrective actions include:

• clear documentation of the non-conformity
• assessment of consequences by a suitably competent and authorized person
• identification of the corrective action to address the immediate issue
• identification of an appropriate timescale for correction
• the person responsible for corrective action
• verification that the corrective action has been implemented and is effective
• identification of the root cause of the non-conformity and implementation of any necessary preventative action.

Records of Finding of monthly Inspection were completed dated Aug 31, 2017 & Aug 15, 2017 were reviewed.

3.8 Control of non-conforming product

The site has a system in place to effectively prevent the release of any out-of-specification product.

The procedure for the management of nonconforming product is Non Conforming Product and Equipment QP3.8.1.CA., dated July 31, 2017. The procedure includes the requirement to staff to identify and report

potentially nonconforming product; direct labelling of packed product defined responsibilities for decision making; personnel have been trained; activities are registered; nonconforming product is effectively managed to control release; and records of destruction are maintained. No product was placed on hold or destroyed this year, it was one of the company objective.

3.9 Traceability

The plant has a system that enables the traceability of raw materials and in process and final product packaging from source through processes and distribution and vice versa. During the audit a vertical traceability challenge was set involving Organic Gala Apples, manufactured on Aug 28, 2017, batch code 17G1017165, and 4081 of cases manufactured. Dispatch details of the product manufactured were that 160 cases were shipped on Aug 31,2017 to Hammonton NJ , shipment# 121490-1, 196 cases were shipped on Aug 31, 2017 to Portland shipment number 121527-7, 350 case were shipped on Aug 31, 2017 to Wilmer, TX on shipment number 121657-7 and so on. Traceability involved raw materials and packaging materials usage. The exercise performed on 21 minutes, achieved a number 100% forward traceability and a satisfactory mass balance check, where yield was number 99.9%, within standard yield range.

Production, quality and CCP records; raw material, packaging, and finished product specification were reviewed. Raw material and packaging material inspection records, manufacturing specifications, dispatch records, and relevant records of prerequisite programs were also reviewed.

When materials arrive at the site, they are identified with internal traceability code.

Traceability of raw materials and packaging used is achieved using physical labeling of materials/products, by recording systems identifying the allocation of materials using computerized bar-coding systems.

Finished goods are stored on pallets identified by pallet tag that is also detailed in dispatch information to enable traceability when product leaves the site.

Identification of part-used packs in production and storage areas is by pallet tag.

Identification of finished product and materials pending investigations is by hold for disposition label.

Traceability is supported with FAMOUS inventory management system.

Traceability undertaken by the site for raw material to finished products was conducted on Aug 29, 2017, 2017, using raw material Gala, lot G737, processed on Aug 23, 2017. Full traceability was achieved on 18 minutes, including a satisfactory mass balance check.

Traceability undertaken by the site for finished product back to raw materials was conducted on date using finished product Organic Gala 6-14 CT, lot number G737, manufactured on Aug 28, 2017. Full traceability was achieved on 18 minutes, including a satisfactory mass balance check.

All raw materials have been accessed for traceability.

N/A – 3.9.4. Rework is not used.

3.10 Complaint handling

A procedure Product /Customer Complaints QP3.10.1CA is on site to handle Customer and consumer complaints effectively and information is used to reduce recurring complaints.

Complaints are addressed by Technical Manager and sales department.
Complaints are recorded and records are made of investigation in database where sufficient information is provided. Appropriate action is carried out promptly and effectively.
Example complaint that demonstrated adequate investigation, resolution and corrective action: Decay Bruising dated May 22, 2017.

Complaint data and trends are reviewed at the monthly management meetings. Complaint trend of 2016 was reviewed. Records of complaints 21 related with quality defect (decaying) a complaint included a root cause analysis and corrective actions to improve complaint level and prevent recurrence were reviewed.

3.11 Management of incidents, product withdrawal and product recall

The company has a plan and system in place to manage incidents and a product withdrawal and recall procedure that includes requirements of the Standard.

The company has a documented procedure Crisis Management, dated July 31, 2017 on site to report and manage incidents and potential emergencies to maintain product safety, quality, and legality included are the withdraw and product recall, if needed.

The company has developed a product withdrawal and recall procedure Incident Traceability for Recall dated July 31, 2017. The procedure includes identification of the recall management team and written guidance provided to key staff. A list of key contacts is available, maintained and updated; a communication plan; details of external agencies; and the accountability for all stock, recovery, storage, and disposal.

The recall procedure is scheduled to be tested twice a year and the most recent test was carried out on Aug 29, 2017. Results included records of the timings of key activities, which were used to review the procedure and implement improvements as necessary.

Requirement to notify the certification body in event of a product recall is detailed in the product withdrawal and recall procedure.

3.12 Customer Focus and Communication

Customer specific policies and requirements are understood and implemented.

Customer specific requirements, codes of practice, working methods have been incorporated into the following work instructions / procedures and product specifications.

Records of communications of specific customer requirement to suppliers of Pink Lady Apples dated May 29, 2016 were reviewed.

Details of non-applicable clauses with justification

Clause reference	Justification
3.5.1.3	N/A – 3.5.1.3 Raw material is not purchased from an agent or broker.
3.5.1.4	N/A – 3.5.1.4. According to the procedures, exceptions are not permitted.
3.5.4	N/A – 3.5.4 There is no outsourced production.
3.5.4.1	N/A– 3.5.4.1 There is no outsourced production.
3.5.4.2	N/A – 3.5.4.2 There is no outsourced production.
3.5.4.3	N/A – 3.5.4.3 There is no outsourced production.
3.5.4.4	N/A – 3.5.4.4 There is no outsourced production.
3.9.4	N/A – 3.9.4. Rework is not used.
3.12.2	N/A-3.12.2. No is no specific requirements for the raw materials

4 Site standards

4.1 External standards

The site is of suitable size, location, and construction to allow the production of safe and legal products. The buildings are in good repair and maintained.

An assessment was completed and there are no local activities that could affect production by introducing contaminants to products.

Neighboring business and activities include. CA warehouse, Foods Manufacturing facility and train track and hwy.

The perimeter of the site is in good order.

External traffic routes in the premises are maintained in good repair to avoid contamination of product.

The building fabric was noted to be in a good condition and the factory was well proofed. GMP audits and planned maintenance inspections monitor the building.

4.2 Security

Security systems in place protect products from theft or malicious product contamination while on site.

A security based on risk is documented in Food Defence and Security Policy dated May 05, 2017 . Areas have been assessed according to risk; sensitive or restricted areas are defined, clearly marked, monitored and controlled.

There are measures in place to maintain site security and prevent entry to production areas:
• All visitors and contractors report and sign a log recording their arrival, read and sign agreement to comply with site personal hygiene rules and other GMP.
• Plant personnel are trained in security procedures during their orientation training.
• Plant personnel are responsible for challenging unaccompanied and unauthorized people.
• Visitor, driver and contractor reporting system
• Secure fences and locked gates
• Locked external doors
• CCTV are located in sensible points
• Access to production areas is restricted to staff authorized to work in those areas
• All materials are stored within their designated storage areas inside the buildings.
• Finished goods are stored in a secure area.
• The secure storage of finished products is included in procedures.
• Vehicle trailers are locked before leaving the site

The site is a registered food business. Ref XXXXXXXX2354.

N/A-4.2.3. Facility does not have storage tanks, silos or intake pipes with external opening.

4.3 Layout, Product Flow and Segregation

Factory layout, flow of process, and movements of personnel is sufficient to prevent the risk of product contamination and to comply with all relevant legislation.

A site plan dated Aug 29, 2016 showing the processing and handling areas depicts low risk areas, enclosed product areas, and non-product areas, was verified on site.

The site map dated Aug 07, 2017 defines access points for personnel and raw material (including packaging), routes for personnel, raw materials, removal of waste, movement, and movement of rework, location of staff

facilities and production process flow, which were verified on site.

Contractors and visitors are all required to review a medical screening questionnaire as well as reading and signing to comply with the site's GMP and personal hygiene rules prior to entering production areas. Contractors involved in maintenance are supervised by maintenance whilst on site.

Records were requested and reviewed for Pace Chemicals observed during the audit.

Movement of personnel, raw materials, packaging, rework, and waste do not compromise the safety of products. Process flow and procedures implemented do not compromise food safety.

Sufficient working space and storage capacity are provided for all operations.

N/A -4.3.5. There are no high-risk operations on site.
NA - 4.3.6. There are no high care operations on site.
NA - 4.3.7. There are no ambient high-care operations on site.
N/A - 4.3.9. There were no temporary structures on site

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

The site, building and facilities are suitable for the intended purpose.

Walls are constructed of concrete blocks and re-cast tilt up and were in a satisfactory condition.
South Wall of of Cooler 7 and North wall of Cooler 8 has some damage at the bottom and had a holes at 3 different locations.
Floors are constructed of concrete and were noted to be in good repair and facilitate cleaning.

Suitable drainage was noted in all factory areas and no evidence was seen of water pooling.

Drains flow from the highest risk towards lower risk areas and are trapped.

The plant drainage is on a separate system that drainage from common areas.

There was pooling water observed in dump wash area and in cooler 8.

Ceilings are constructed from steel and are appropriately maintained. All ceilings were seen to be clean.

All doors seen during the visit were found to be in a good condition and were easy to clean.

External doors and dock levelers are suitably proofed to prevent pest ingress, door discipline was observed to be satisfactory during the assessment.

Lighting provides suitable and sufficient lighting levels. Light intensity is monitored monthly areas identified for evaluation.

Bulbs, ELTs and strip lights are suitably protected.

During the site inspection it was noted that the factory storage and process areas were satisfactorily ventilated and there were no signs of condensation or excessive dust.

N/C-4.4.1. Damage (Hole) to South wall of cooler 7 and North wall of Cooler 8 near junction of floor and wall. Looks like damage from forklift.

N/A-4.4.3. Pooling water observed by bin wash area on the floor where stage the product bins before dumped

on the line. Also a pooling water observed in cooler 8 below the refrigeration units.

N/A - 4.4.4. There are no high-care or high-risk areas in the facility.
N/A - 4.4.6. There are no suspended ceilings or roof voids.
N/A - 4.4.7. There are no windows in production and storage areas.
N/A - 4.4.8. There are no windows in production and storage areas.
N/A - 4.4.13. There are no high risk areas in the facility.

4.5 Utilities – water, ice, air and other gases

All utilities to and within the production and storage areas are designed, constructed, maintained and monitored to control the risk of contamination.

Water used within the operation is potable and drawn from approved well source.
Water source is City of Yakima.
Water is used for sanitation and for employee use.

The water testing program and schedule was developed based on risk. Water is sampled from 3 sites and is tested for microbial and chemical parameters. Records reviewed from Mar 21, and Aug 29, 2017 indicated that the applicable regulatory guidelines were met.

An up-to-date diagram dated April 28, 2016 is available of the water distribution system on site, including holding tanks, water treatment and back-flow prevention valves in every line to main processing areas.

N/A – 4.5.3. Water used within the operation is potable and non-potable water is not required.
N/A - 4.5.4 There is no air, gases or steam in direct contact with product.

4.6 Equipment

Equipment is suitably designed for the intended purpose and is utilized to minimize the risk of product contamination.

Equipment observed was constructed of stainless steel and food grade materials that can be effectively cleaned.

Equipment in production areas is located to allow suitable access for cleaning and maintenance. Some equipment requires that safety guarding and panels have to be removed for effective cleaning. This takes place after production has finished.

Replacement parts, such as conveyor belts, are certified as being approved for food contact. The equipment direct contact with food is manufactured from stainless steel or food grade plastic and meets legal requirements.

4.7 Maintenance

An effective maintenance program is in operation for plant and equipment. The maintenance program addresses preventive, corrective, requested, and emergency repair tasks.

Planned maintenance is documented in Equipment Maintenance Purchasing& Locating QP-4.6.1.CA dated Aug 31, 2015. Planned maintenance through the manual system is scheduled and tracked to ensure timely completion. Planned maintenance is based on equipment manufacturer's recommendations and in the light of experience and planned corrective actions.

Pre-plant operation inspections are carried out to prevent any risk of product contamination from equipment damage. Results are recorded.

The maintenance procedure includes processes to minimize the risk of compromising product safety and legality during maintenance and cleaning. Following maintenance work a sign off acceptance procedure is in place to ensure that all foreign bodies and other contamination have been removed and the plant has been cleaned satisfactorily.

Lubricants and other engineering materials used on site are food grade and of know allergen status, with specifications being held with proof of suitability for use in food production.

The maintenance workshop and storage areas are tidy and well maintained.

The maintenance workshop is remote from production areas.

A suitable swarf mat is present at the exit from the maintenance workshop into production areas.

N/A-4.7.3. Temporary repairs are not permitted
N/A – 4.7.5. There are no high-risk or high-care areas on site.

4.8 Staff facilities

Staff facilities are suitably designed and operated to ensure the minimum of risk of product contamination. Male and female facilities include lockers, toilets and hand washing facilities.

Changing facilities are provided for staff and visitors. The changing facilities allow direct access to the production areas.

Storage areas were of a suitable size to accommodate all personal items.

There was no crossover of outdoor clothing and factory work wear noted during the visit. Each employee has a suitable locker.

There are hand-washing facilities at the entrance of all production areas and as required within production areas. Appropriate “wash hands” signs were available in appropriate locations. Hand washing facilities are hands free and supplied with warm water, foam soap, and disposable towels.

Adequate toilets are provided that do not open directly into production, packing or storage areas and at provided with hand wash facilities supplied with hot water, liquid soap and disposable towels. Appropriate “Wash hands” signs were present within the restroom areas.

Smoking is allowed in designated smoking area.

A working fridge available for staff to store their own food was inspected during the site tour and was found to be in a satisfactory condition. Eating and drinking are restricted to the break-room or designated offices and meeting rooms.

N/A - 4.8.4. There is no high-risk product produced.
N/A - 4.8.5. There is no high care product produced.
N/A - 4.8.10. Catering facilities are not provided.

4.9 Chemical and physical product contamination conRaw material handling, preparation, processing, packing and storage areas

Procedures are in place to cover the potential risk of chemical or physical contamination identified in HACCP plans.

4.9.1 Chemical control

An approved list of chemicals for purchase, product specifications, and SDS safety data sheets were available and verified for P-68 Primar and Peracetic Acid.

Specifications confirmed the chemicals were suitable for use in food production premises.

Cleaning chemicals were stored in bulk containers and dosed into appropriate clean containers at the time of use by trained staff.

All containers were suitably labeled.

Chemicals were segregated and securely stored with restricted access to trained personnel.
No strongly scented or taint-forming materials were observed during the on site audit.

4.9.2 Metal control

There is a documented knife policy QP-4.9.2.1CA dated July 31, 2015, which is controlled by a documented register and records of inspection.

Ingredients and packaging that use staples are avoided. Staples and paperclip are not permitted within the production areas and none were observed during the site inspection.

4.9.3 Glass, brittle plastic, ceramics and similar materials

No risk of product contamination from glass or brittle materials was identified

Documented procedure for handling glass and brittle materials Foreign Matter, Glass & Hard Plastic QP-4.9.3.1CA dated July 17, 2015 includes the list of all glass, brittle and similar materials detailing location, number and type and cleaning and replacing methods. Checks of glass, brittle, and similar materials are conducted on a weekly frequency base on risk of product contamination to review handling procedures in place. Records of the last glass and hard plastic audit dated Sept 01, 2017 & Sept 05, 2017 were reviewed during the assessment.

There is a documented and detailed glass breakage procedure on site Foreign Matter, Glass & Hard Plastic QP-4.9.3.1CA dated July 31, 2015, which requires that production stops, product and area is isolated, cleaned and inspected. Authorization is required before production can recommence, work wear is changed, footwear inspected, and records completed.

4.9.4 Products packed into glass or other brittle containers

N/A - Glass or brittle containers are not stored in the facility.

4.9.5 Wood

Wood pallets used in process are continuously monitored and discarded when damaged or splinters are observed, which could contaminate products.

4.10.1 Foreign body detection and removal equipment

The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.

N/A- 4.10.1.1- The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.
N/A- 4.10.1.2- The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.
N/A- 4.10.1.3- The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.

N/A- 4.10.1.4- The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.

4.10.2 Filters and sieves

N/A - Filters or sieves are not appropriate for the production process.

4.10.3 Metal detectors and X-ray equipment

N/A- 4.10.3.1.The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.

4.10.4 Magnets

N/A - 4.10.4.1. Magnets are not suitable to remove magnetic material from food product.

4.10.5 Optical sorting equipment

N/A - 4.10.5. Optical sorting equipment is not used in the facility.

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

N/A -4.10.6. There is no packaging with rigid containers on site.

4.11 Housekeeping and hygiene

Housekeeping and cleaning systems are in place, which ensure appropriate standards of hygiene are maintained at all times and that risk of contamination is minimized. The site operates a 'clean as you go' policy during production hours with a full clean at the end of production.

Satisfactory standards of hygiene were seen on premises and equipment throughout the site inspection.

Documented cleaning procedures are available for building, plant, and equipment and they have been implemented.

The cleaning methods for processing equipment, food contact surface and environmental cleaning include
responsibility,
areas to be cleaned,
cleaning frequency,
cleaning methods,
cleaning chemicals,
chemical concentration
temperature
materials to be used,
records and verification system.

Records of cleaning performance dated Aug 28, 2017 and Sept 01, 2017 were on file.

For processing equipment, food contact surface and environmental cleaning in high care/high risk areas, limits of acceptable and unacceptable cleaning performance are defined by:

• visual appearance,
• ATP bioluminescence techniques,
• microbiological testing
• chemical testing as appropriate.

The cleaning and disinfection procedures and frequency to control listeria and E coli are validated by means of and records dated June 15, 2017 maintained.

Cleaning is appropriately scheduled and planned for non-production period. All cleaning personnel have received suitable training in the use of chemicals as well as the site's cleaning procedures and examples of

sanitation training records seen June 09, 2017.

The effectiveness of cleaning is assessed visually during the pre production start up checks. Production supervisors and QC inspectors conduct visual checks on the effectiveness of cleaning. Records were reviewed during the pre-operational inspection of Aug 28, 2017- Sept 03, 2017 and were found to be satisfactory.

Areas requiring corrective action are re-cleaned.

Verification of cleaning effectiveness is by ATP swabbing and environmental plate counts.

Environmental Listeria swab testing is conducted on a programmed random basis.

ATP results reviewed during the visit from Aug 23- Aug 30, 2017 were found to be satisfactory.

Cleaning equipment is fit and suitable identified for the intended use (flours, allergens, and glass), cleaned and stored in a hygienic manner to prevent contamination.

Equipment used for cleaning in dedicated for use in that area and identified by color.

All containers were suitably labeled.

4.11.7 Cleaning in place (CIP)

N/A - 4.11.7. There are no CIP operations on site.

4.12 Waste/waste disposal

Waste disposal is managed to prevent accumulation, risk of contamination and the attraction of pests.

Waste Management of Yakima waste company removes waste from site.

Waste areas seen during the visit were in a suitable condition with external waste collectors suitably covered.
Containers for cardboard, paper, were properly closed.
They are designed for ease of use and effective cleaning and they were maintained clean.
Waste containers are removed on a twice weekly basis.

Procedures are in place for the handling of unsafe product or substandard trademarked materials to prevent them finding their way on to the market.

4.13 Management of Surplus Food and Products for Animal Feed

There are effective process in place to ensure safety and legality of by-products. Apples does not meet the specifications are sent out for juice and are stored in lined containers.
N/A - 4.13.1. There are no surplus customer branded products in the facility.
N/A - 4.13.2. There are no nonconforming branded products sold to staff or passed on to charities.
N/A-4.13.3. There is no product designated for animal feed.

4.14 Pest control

The site has minimized the risk of pest infestation by contracting a competent pest control organization, who is servicing the site every day to rapidly respond to any issue.
Measures have been taken to control any pest activity identified through regular inspections to prevent it present a risk to products, raw materials or packaging.
The site has a pest control contract with Sprague pest control company (PCO).
The contractor makes monthly routine inspections.
A service contract is held at the front of the pest control manual detailing the frequency of visits, call outs and other details of the pest control program.
The contract includes rodents, flying insects, crawling vermin, and birds, and both internal and external traps and pesticide applications. The contract includes insect light traps (ILT) units, mechanical traps, bait stations.

A trap map dated Jan 18, 2017 was verified during the plant walkthrough and exterior inspection.
Bait stations and monitoring devices are identified by labels on each unit and on the wall above the location.
Procedures identify responsibilities and details pest control products used and methods of use.
SDS sheets are available for all materials used on site. The ones examined were for Contrac All Weather
Records of monitoring activities and pest control applications dated Aug 14, 2017 and May 16, 2017 respectively were on file.
All external bait stations were robust and found to be of a tamper resistant construction and were suitably secured. No spill baits were used. Toxic rodent baits were not used within production areas or storage areas where open product is present except when treating an active infestation.
None of the ILT and pheromone traps were noted in areas where they could potentially cause contamination.
The pest control contractor is contracted to conduct follow up visits in the event of an infestation until the problem is eradicated.
Potentially affected product is identified, evaluated and released or destroyed by the management.
The site and the pest control contractor have addressed all documented recommendations. Records of pest control inspections and action taken to address PCO recommendations dated Aug 14, 2017 were reviewed.
In-depth, documented pest control survey is undertaken annually by a pest control expert to review the pest control measures in place. A risk assessment justifying frequency has been completed.
The survey provided an in-depth inspection of the facility for pest activity, review the existing pest control measures in place, and make recommendations to improve the program.
The timing of the survey allows access to equipment for inspection where a risk of stored product insect infestation exists.
Records from inspections are assessed for trends on a regular basis. Fly catch trend analysis and rodent activity are conducted on a monthly basis.
Pest activity is reported to the QA as reviewed in records dated May 16, 2017.
N/A - 4.13.3. Preventative pest control on site is managed by a contracted third party.

4.15 Storage facilities

Storage areas on site for the storage of ingredients, in-process product, and finished products were noted to be suitable and in a satisfactory condition.

A documented procedure Harmonization Policy- Storage QP7.2.1M, dated July 22, 2016 is in place to maintain product safety and quality during storage. The procedure details, as appropriate:

• managing chilled and frozen product transfer between temperature controlled areas
• segregation of products where necessary to avoid cross-contamination (physical, microbiological or allergens) or taint uptake
• storing materials off the floor and away from walls
• specific handling or stacking requirements to prevent product damage.
Packaging materials are stored away from finished product and raw materials.

Returned packaging materials are rewrapped or covered when replaced in the storage area and clearly identified to maintain traceability.
Storage areas are maintained at 33 ºF within specification range of 29 ºF – 32 ºF.

Conditions are verified by temperature recording equipment with suitable temperature alarms or recorded manual temperature checks. Records of temperature monitoring are on file, e.g. records dated Aug 28, 2017 and Sept 01, 2017 were reviewed and found to be satisfactory

Stock rotation is managed by a FIFO system. Incoming materials are labeled with site codes, which provide the basis for tracing materials through the system.

N/A- 4.15.4. No products require controlled atmosphere storage.
N/A - 4.15.5 No materials, packaging or process equipment are stored outside.

4.16 Dispatch and transport

Management of dispatch and of the vehicles and containers used for transporting products from the site do not present a risk to the safety or quality of the products.

Procedures Transport & Delivery dated July 21, 2016 are in place to maintain product safety and quality during loading and transportation.

Vehicles are loaded and unloaded in covered loading bays

Loads on pallets are secured to prevent movement during distribution.

Loads are inspected before dispatch.
Loading was observed during the facility inspection and procedures were observed as being followed.

All vehicle or containers are inspected for cleanliness and suitability, to ensure they are free from strong odors, and equipped to maintain any temperature requirement. Records of inspections dated Aug Sept 12, 2017 were reviewed.

A shipping employee was interviewed regarding carrier inspection and answered per the documented procedure.

Procedures and devices are in place to ensure temperature requirements are met, which includes using data logging devices. Records of transportation of Gala Apples dated Sept 12 and Aug 29, 2017 were reviewed.

Procedures are in place and records of vehicle and equipment hygiene and maintenance measures were verified during the plant walk through and the traceability exercise.

Procedures are in place that includes any restriction on the use of mixed loads, security of products during transit, and notifying the company of any issues including equipment breakdown, accidents, or failure of refrigeration systems. Records of vehicle and equipment incidents are documented.

N/A - 4.16.6. Customer specifies and manages its own transport.

Details of non-applicable clauses with justification

Clause reference	Justification
4.2.3	N/A-4.2.3. Facility does not have storage tanks, silos or intake pipes with external opening.
4.3.5	N/A -4.3.5. There are no high-risk operations on site.
4.3.6	NA - 4.3.6. There are no high care operations on site.
4.3.7	NA - 4.3.7. There are no ambient high-care operations on site.
4.3.9	N/A - 4.3.9. There were no temporary structures on site
4.4.4	N/A - 4.4.4. There are no high-care or high-risk areas in the facility.
4.4.6	N/A - 4.4.6. There are no suspended ceilings or roof voids.
4.4.13	N/A - 4.4.13. There are no high risk areas in the facility.
4.5.3	N/A – 4.5.3. Water used within the operation is potable and non-potable water is not required.
4.5.4	N/A - 4.5.4 There is no air, gases or steam in direct contact with product.
4.7.3	Temporary repairs are not permitted
4.7.5	N/A – 4.7.5. There are no high-risk or high-care areas on site.

4.8.4	N/A - 4.8.4. There is no high-risk product produced.
4.8.5	N/A - 4.8.5. There is no high care product produced.
4.8.10	N/A - 4.8.10. Catering facilities are not provided.
4.9.4.1	N/A - 4.9.4.1. Glass or brittle containers are not stored in the facility.
4.9.4.2	N/A - 4.9.4.2. Product is not packed into glass or other brittle containers.
4.9.4.3	N/A - 4.9.4.3. Product is not packed into glass or other brittle containers.
4.10.1.1	N/A- 4.10.1.1- The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.
4.10.1.2	N/A- 4.10.1.2- The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.
4.10.1.3	N/A- 4.10.1.3- The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.
4.10.1.4	N/A- 4.10.1.4- The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.
4.10.2.1	N/A - 4.10.2.1. Filters or sieves are not appropriate for the production process.
4.10.2.2	N/A - 4.10.2.2. Filters or sieves are not appropriate for the production process.
4.10.3.1	N/A- 4.10.3.1.The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.
4.10.3.2	N/A- 4.10.3.2.The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.
4.10.3.3	N/A- 4.10.3.3.The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.
4.10.3.4	N/A- 4.10.3.3.The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.
4.10.3.5	N/A- 4.10.3.4.The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.
4.10.4.1	N/A - 4.10.4.1. Magnets are not suitable to remove magnetic material from food product.
4.10.5.1	N/A - 4.10.5.1. Optical sorting equipment is not used in the facility.
4.10.6.1	N/A -4.10.6.1. There is no packaging with rigid containers on site.
4.10.6.2	N/A - 4.10.6.2. There is no packaging with rigid containers on site.
4.11.7.1	N/A - 4.11.7.1. There are no CIP operations on site.
4.11.7.2	N/A - 4.11.7.2. There are no CIP operations on site.
4.11.7.3	N/A - 4.11.7.3. There are no CIP operations on site.
4.13.1	N/A - 4.13.1. There are no surplus customer branded products in the facility.
4.13.2	N/A - 4.13.2. There are no nonconforming branded products sold to staff or passed on to charities.
4.13.3	N/A-4.13.3. There is no product designated for animal feed.
4.14.3	N/A - 4.13.3. Preventative pest control on site is managed by a contracted third party.
4.15.4	N/A- 4.15.4. No products require controlled atmosphere storage.
4.15.5	N/A - 4.15.5 No materials, packaging or process equipment are stored outside.
4.16.6	N/A - 4.16.6. Customer specifies and manages its own transport.

5 Product control

5.1 Product design/development

Product design and development are not performed in this facility.

5.2 Product Labelling

Product labeling seems to comply with regulations and contain information to enable the safe handling, display, storage, and preparation of products.
The procedure Labeling of Product QP-5.2.1M dated Aug 07, 2017, is in place to verify the technical contents of labels comply with specifications and legal requirements for the designated country of use; include information to enable the safe handling, display, storage, and preparation of products; and include a process to verify that ingredient and allergen labeling is correct. Label of Organic Gala and Granny Smith #90 was reviewed and it seemed to comply with requirements.
All labeling changes are managed by third party marketing company (First Fruit Marketing) and they send the final label to the facility for approval. The procedure also describe the process undertaken whenever changes occur to supplier of raw materials, the country of origin of raw materials, and legislation.
Organic claim is sustained by a completing annual organic audit that demonstrate that the claim is consistently met.
Procedure is in place to transfer initial information to the nominated third party (First Fruit Marketing Co) to ensure initial information and any change is communicated in a timely manner to design / modify product label.

5.3 Management of allergens

There are no allergens handled on this site.

5.4 Product Authenticity, claims and chain of custody

System are in place to assess the supply chain for vulnerability to food fraud, to control fraudulent or adulterated raw materials, to substantiate claims and chain of custody.

The process to access information on new or existing threats to the supply chain on adulteration or substitution of raw materials is in place. It is supported with information provided by trade association, government source (FDA Food Fraud Database), or private resource center. Apples and Pears are not listed on food fraud database for high risk.

The documented vulnerability assessment on Apples dated July 31, 2017 identified all raw materials are identified as low risk. The assessment was complete, accurate and contained sufficient detail. And covers all possible hazards.

Claims of organic ingredient is assured by maintaining purchasing records, traceability of raw material usage, and final product packing records. The last documented mass balance tests reviewed was on Organic Opal Apples G30 on Dec 23, 2016.

The status of Organic is supported by the Organic certificate issued by Washington State Department of Agriculture issued on May 23, 2017.

N/A- 5.4.3.There is no raw material used in the facility is considered at the risk of adulteration or fraud.
N/A - 5.4.6. There are no identity preserved claims made.

5.5 Product Packaging

Finished products are packed in bags and clam shells.

Certificates of conformity available for all packaging materials in direct contact with food confirm they conform

to FDA legislation or there is chemical migration testing completed with accompanying letter of guarantee. The packaging is suitable for the intended use. Certificate of conformity dated date for clam shells issued by Peninsula Packaging Company on Jan 17, 2017 was reviewed.

Printed product bags are used and appeared suitable for use.

5.6.1 Product inspection and testing

Inspection and analysis to confirm product safety, legality and quality are undertaken.

There is a scheduled program of testing covering products and the processing environment, which include microbiological, chemical, physical, and sensory testing according to risk. Test methods, frequencies, and specified limits are defined in Product Inspection and Testing QP-5.6.1M, dated Aug 07, 2017.

Risk assessment has determined that environmental monitoring is tested every monthly.

Tests are carried out for raw materials, work in progress, and finished product for sensory attributes, according to product specification.

The processing environment is tested for Listeria and E coli according to risk, in conformance with criteria set in Environmental Monitoring Procedure QP4.11M dated Aug 07, 2017.

Testing and inspection records are reviewed by Food Safety Assistant and production management and appropriate actions are implemented promptly to address any unsatisfactory results or trends, as reviewed in In Line QC Form dated Sept 05, 2017 and Aug 28, 2017.

Third party marketing company perform shelf life validation.

5.6.2 Laboratory testing

The external laboratory contracted for pathogen testing is Cascade Analytical.

The laboratory has gained recognized laboratory accreditation in accordance with the requirements and principles of ISO 17025 by: Perry Johnson Laboratory Accreditation Inc. for the schedule of Listeria and E coli tests required by the company. accreditation no: 74266 valid starting May 14, 2013 was reviewed.

N/A – 5.6.2.2. There is no laboratory on site.
N/A – 5.6.2.4. An accredited laboratory is used and there is no laboratory on site.

5.7 Product release

Product release procedures are in place

N/A – 5.7.1. Positive release is not required.

Details of non-applicable clauses with justification

Clause reference	Justification
5.1	Product design and development are not performed in this facility.
5.1.1	N/A - 5.1.1. Product design and development are not performed in this facility.
5.1.2	N/A-5.1.2. Product design and development are not performed in this facility.
5.1.3	N/A-5.1.3. Product design and development are not performed in this facility.
5.1.4	N/A - 5.1.4. Shelf life trials are not performed in this facility.

5.3	N/A – 5.3 There are no allergens handled on this site.
5.3.1	N/A – 5.3.1. There are no allergens handled on this site.
5.3.2	N/A – 5.3.2. No allergens have been identified.
5.3.3	N/A – 5.3.3. There are no allergens handled on this site.
5.3.4	N/A – 5.3.4. There are no allergens handled on this site.
5.3.5	N/A – 5.3.5.There is no rework containing allergens used on this site.
5.3.6	N/A – 5.3.6. There are no allergens handled on this site.
5.3.7	N/A - 5.3.7. There are no free from allergen claims made by the site.
5.3.8	N/A - 5.3.8. There are no allergens handled on this site.
5.4.3	N/A- 5.4.3.There is no raw material used in the facility is considered at the risk of adulteration or fraud.
5.4.6	N/A - 5.4.6. There are no identity preserved claims made.
5.6.2.2	N/A – 5.6.2.2. There is no laboratory on site.
5.6.2.4	N/A – 5.6.2.4. An accredited laboratory is used and there is no laboratory on site.
5.7.1	N/A – 5.7.1. Positive release is not required.

6 Process control

6.1 Controls of operations

Production specifications are available for all products, which include any equipment settings. The company has procedures that verify that the processes and equipment are capable of producing consistently safe and legal products with the desired quality characteristics.

Documented process specifications and work instructions for:
• equipment process settings
• cooling times and temperatures
• labeling instructions
• coding and shelf life marking
• any additional critical control points identified in the HACCP plan are incorporated into the daily production control records.

Process monitoring includes, storage and process temperatures, weight checks, label checks and date code checks.
Critical physical and chemical controls are monitored and recorded though the process.

Manual documentation of all records is made continuously on a records of testing of June 20, 2017, were reviewed. Examples of documented controls seen on site and by record: PAA 12.0 Chemical Log and service report by third party to validate the settings.
Interview of Operators confirmed understanding of process controls and critical limits in the process, reviewed records for Sept 12, 2017 and Aug 28, 2017.

Corrective action and non-conforming product procedures are in place in the event of process failure.

N/A – 6.1.4. The processing conditions do not require regular validation.

6.2 Labelling and Pack Control

Controls are in place ensure products are correctly labeled and coded.
Only the packaging material for immediate use is available to the packaging machines. Its control is governed by procedure Labeling of Product QP-6.2.1.M Methods and responsibilities were observed during the plant inspection at production line.

Checks to ensure that only the correctly printed materials are available in packaging lines are documented in Main Sizer Trayline/Packaging/Label & PLU Verification and observed implemented at production line.
Documented checks at line start-up, following product changeover, and changes in batches or packaging are performed, as observed during site walk through and reviewed in Main Sizer Packaging/Label & PLU Verification dated Sept 12, 2017.

This was reviewed during the site walk through.
Documented checks of the packaging lines are carried out at the start of packaging, during the packaging run, when changing batches of packaging material, and at the end of each production run to ensure products are packed into correct packaging and correctly label

Checks include
• date coding
• batch coding
• quantity indication
• bar coding
• country of origin.

Records, e.g. QC Final Packaging Inspection and Net Weight Checks dated Sept 05, 2017 are maintained.

N/A -6.2.4. - Online vision equipment is not used.

6.3 Quantity-weight, volume and number control

The plant operates a quantity control system, which conforms to legal requirements in the country where the product is sold and customer requirements.
Products are packed according weight and count.

Checks are made on all finished products every 20 minutes. Results are recorded and verified daily by QC and record Net weight check reviewed dated Sept 05, 2017 and Sept 12, 2017..

Weight control reviewed during the site inspection and the traceability study were found to be satisfactory.

Suitable controls are in place for handling bulk quantity product.

6.4 Calibration and control of measuring and monitoring devices

The company has identified measuring equipment used to monitor critical control points, product safety and legality. The identified measuring equipment is calibrated to a recognized national standard.

A list of identified measuring equipment used to monitor CCPs, product safety and legality is in place.

Equipment is identified and marked with a reference number and calibration due dates.

Procedures and records to control only authorized staff adjust equipment.

Records of all calibration checks and associated actions are maintained. Examples of equipment calibrated reviewed at audit: scales, PAA pumps, pH probes and Thermometers.

Calibration is performed by the on-site Laboratory using weight traceable to National Standards. Records were reviewed.

The procedure to record actions taken when the prescribed measuring and monitoring devices are found not to be operating within specified limits is in place.

Details of non-applicable clauses with justification

Clause reference	Justification
6.1.4	N/A – 6.1.4. The processing conditions do not require regular validation.
6.2.4	N/A -6.2.4. - Online vision equipment is not used.

7 Personnel

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

Personnel interviewed during the plant walk through were able to demonstrate competency to conduct their activities. Training procedures are in place.
Personnel interviewed during the plant walkthrough (Receiver, Cherry Crushing, CCP Operators, Maintenance and Production Supervisor) were knowledgeable of their responsibility and properly supervised.
Staff have receive training on induction training, covering basic sickness reporting together with health and safety, personal hygiene rules, allergens, quality requirements, basic HACCP, cleaning, machine operation, quality inspections, and sampling, as appropriate.
Orientation training records were reviewed during the visit for:
Sorter dated Aug 18, 2017 and Packer dated Aug 21, 2017
The procedure for training and monitoring staff engaged in CCP activities is in place. Records for operators are maintained in files and are updated.
CCP training records were reviewed during the visit for:
CCP training Lab Tech dated Aug 17, 2017
CCP training Safety Assistant dated Dec 13, 2016
The training program Training Needs QP-7.1.1M, updated on Aug 09, 2017 includes provisions for identifying refresh training needs and implementation of training courses accordingly. A job training matrix is maintained detailing the site role, skill description, and work instructions required for each role. Training courses scheduled in the training program of 2017 were:
• Good Manufacturing Practices.
• Applying food regulatory requirements;
• HACCP
• CCP;
• Tasks identified as critical to meeting the effective implementation and maintenance of the BRC System.
• Food defense,
• Allergens,
• Quality,
Review of effectiveness of training is implemented by testing the knowledge after training or on-the-job assessment.
All training is delivered in English and Spanish and understood by trainees.
All relevant personnel have received allergen awareness training during orientation as observed in training records dated Aug 30, 2017 and refresh training on the site's allergen handling procedures used by the company as observed in training records dated Aug 22, 2017.
Training courses reviewed were: GMP`s, Food Defense, Calibration, CCP Monitoring and Sanitation.
The effectiveness of the training is monitored by one-to-one appraisals, team performance monitoring by line supervisors, review of the results of internal audits, or review of records.

7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

There are documented standards for personal hygiene for employees, visitors and contractors. No evidence of non compliance observed during the factory inspection.

Requirements for personnel hygiene are documented in Personal Hygiene Requirements QP-7.2.1.M, dated Aug 09, 2017. The site personal hygiene rules are communicated to staff by means of orientation training, refresher training and bulletin boards posted in the main entrance.

Daily inspections are used to monitor compliance with requirements. Records Employee Hygiene Monitoring Log dated Aug 28, 2017, Sept 12, 2017 were reviewed.

Hand cleaning is documented within the hygiene policy. All personnel are required to wash their hands when entering the factory, after using the toilets, eating, smoking, blowing noses or sneezing or handling shoes. No evidence of non-compliance observed during the factory inspection.

Cuts and grazes on exposed skin are covered by detectable blue metal strip bandages that are issued and monitored. In addition to this protection, colored gloves are used in the food processing area.

The procedure for the control of personal medicines is included in the Personal Hygiene Requirements QP-7.2.1.M, dated Aug 28, 2017. Personal medicines are not permitted in production areas and are stored in the lunchroom. No evidence of non-compliance observed during the factory inspection.

N/C - An employee at production line observed drinking water from the water fountain without removing the gloves before drinking water neither did wash hands after, before return to work, contrary to company policy.

N/A – Metal Detector is not used in the facility

7.3 Medical screening

The plant's personal hygiene standards and medical screening procedures are documented, and adopted by all personnel, including contractors and visitors to the production facility.

The procedure Personal Hygiene Requirements QP-7.2.1.M, dated Aug 28, 2017 report infection, disease, or condition when returning to work or which they have in contact is on site. The site has made employees aware of the symptoms of infection, disease or condition, which would prevent them working with open food through the new employee training and refresh good hygiene practices course. Training material was reviewed.

Visitors and contractors review a health questionnaire, which is checked by an appropriate manager, or confirm that they are not suffering from any symptoms, which may put product safety at risk before entering the raw material preparation, processing, packing, and storage areas.

The procedure that document actions to be taken where employees, contractors, or visitors declare they are suffering from or have been in contact with an infectious disease is included in Personal Hygiene Requirements QP-7.2.1.M, dated Aug 28, 2017, which include relocation to a role where they are not in contact with open products or limited access to open product areas, among others.

7.4 Protective clothing: employees or visitors to production areas

Protective clothing provided for staff includes hairnet, bead net, gloves, apron, as appropriate.

Visitors / contractors are provided with a hairnet and beard net.
The company has documented and communicated to all employees, contractors and visitors the rules regarding the wearing of protective clothing in specified work areas. This includes policies relating to the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, lunchroom, and smoking area). The rules are included in orientation training and are posted in main personnel entrances. No evidence of noncompliance observed during the factory inspection.
All employees are issued with new disposable apron everyday. Work wear was seen to be of suitable design to prevent contamination of the product.

Plant personnel are required to wear disposable hairnet, which fully contains scalp hair.

Beard nets are provided as needed for beards and mustaches.

No evidence of noncompliance observed during the plant inspection.

Protective clothing are disposable and disposed off after each use.

Hairnets and beard nets are changed daily as needed, based on risk

Colored disposable gloves, suitable for food use, are available.

These are changed whenever staff touch their noses, cough, pick up waste, at every break or when visiting the toilets.

N/A - 7.4.4. This is not a high risk or a high care areas.
N/A - 7.4.7. All items are suitable for laundering.

Details of non-applicable clauses with justification

Clause reference	Justification
7.2.4	N/A – 7.2.4. Metal Detector is not used in the facility
7.4.4	N/A - 7.4.4. This is not a high risk or a high care areas.
7.4.7	N/A - 7.4.7. All items are suitable for laundering.