



# 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, waxing and packaging apples in plastic clam shells, polybags, mesh bags and in cardboard cartons, and sorting and repackaging of pears into cartons.		
Exclusions from scope	None		
Justification for exclusion	N/A		
Audit Finish Date	2016-09-08		
Re-audit due date	2017-09-15		

Voluntary modules included		
Modules	Result	Details

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	C	Previous audit date	2015-01-29		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	7

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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)	>25k sq.m s	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	117347732354				
Major changes since last BRC audit	None				
<p>Company Description</p> <p>Congdon Packing and Storage LLC. 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, having 1 packaging line 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 58 million lbs apples in a season and ships products to both domestic and international markets.</p>					

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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		Based on BRC decision tree facility is low risk			
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		Gala Apples			



6. Audit Duration Details			
On-site duration	16 man hours	Duration of production facility inspection	8 man hours
Reasons for deviation from typical or expected audit duration	N/A		
Next audit type selected	Announced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1	2016-09-07	08:00	17:00
2	2016-09-08	6:30	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
Mark Blore/General Manager	x			x
Roberto Sanchez/Production Manager	x			x
Edgar Pacheco /Assistant Technical Manager	x	x	x	x

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# 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

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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	3.2.1	Facility had list of approved documents along with revision date, a document "Proc Bin Weight" used by receiver to record bin weight was not controlled document date or version number was not present on the document..	1. On 9/09/16 the form Processor Bin Weight, F-3.5.2.1M was created by the Food Safety department officially. 2. A refresher training was given to the Receiving personnel to detail the record control procedure	1. An uncontrolled form was being used by the receiving personnel that was not controlled by the Food Safety Department 2. The form was started being used internally by Congdon Packing as it only tracked the processor weights which was later turned into Famous and to the Grower Accountant 3. Unaware that this form was being used as it had not been brought up by the personnel	A copy of the refresher training with a copy of the completed new revised form.;A copy of the revised internal audit to reflect a statement of document control.	2016-09-23	CELLERBECK

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				<p>conducting this form 4. Lack of training to report any forms that were being used internally and not controlled by the Food Safety department</p> <p>1. Monitor during the internal audits to ensure that all of the forms controlled by Food Safety department are being used with latest revisions are being used.</p>			
2	3.4.4	Facility had program in place for monthly inspections for environment and processing equipment, follow up on the deviations was not completed on inspections performed in April and February.	<p>1. A refresher training was given to the employees responsible to assist in the facility inspections to ensure that any process deviations are notified, corrected and completion date is logged 2. A copy of the monthly facility inspection conducted for the month of September 2016 3. A copy of the CAR log in which each of the non-conformances were logged with solutions, completion and verification date.</p>	<p>1. Congdon Packing Co., LLC had a program in place for monthly inspection but these were not completed 2. The inspections were done by Cory Hixon the Assistant Technical Manager and was not following the procedure 3. Lack of training but with Cory no longer employed by the company we are in the transition of ensuring that all of these inspections are</p>	Training Refresher for employee.;A copy of the CAR Log updated to reflect the non-conformances from inspection;A copy of the monthly facility inspection for September 2016;A copy of the refresher training that was given to	2016-09-23	CELLERBECK

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				<p>conducted and completed</p> <p>1. The Assistant Technical Manager will verify and sign each of the monthly inspections after being completed to ensure that all of the corrective actions are in place. This will be logged in the CAR log.</p>	<p>employees after inspection</p>		
3	4.4.1	Room #4 had a damage on the south wall, one panel completely damaged	1. The wall inside of cold room #4 was replaced.	<p>1. The wall inside of cold room #4 was observed to be damaged 2. Refrigeration personnel had been replacing some of the damaged sections of wall but this wall was in really bad shape and was not replaced 3. Not enough time to work on all of the walls prior to startup of season 4. Due to the nature of the business, during the summer all of the employees are at the ConAg Packing</p> <p>1. The External/Internal Monitoring Log, F-</p>	<p>A copy of the pictures of the replacement of the wall inside of room #4.;A copy of the refresher training given to maintenance and refrigeration;A copy of the PM inspection refer to pg. 3</p>	2016-09-24	CELLERBECK

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				4.7.1M completed by the Refrigeration personnel to inspect walls, floors and ceilings was reflected to ensure that an assessment is carried in each of the walls to ensure that these walls are in a set schedule and replaced.			
4	4.11.1	Housekeeping systems have failed to identify and clean the accumulation webs on ceiling above fan before dryer and a open ended metal pipe used to hold fans for drying has dust accumulated inside.	1. The cobwebs in the ceiling and around the motor areas were cleaned and the metal cover piece was mounted into the pipe.	1. Cobwebs observed on the ceiling, fans on dryer area, the motor guard and the pipe that is missing the cover 2. Facility was not kept up cleaned and periodically monitor to observed for any built up of cobwebs 3. It was not part of a routinely schedule to ensure that these areas are monitored  1. Refresher training given to the employees responsible to inspect the facility on a monthly basis. 2. The monthly Preventative Maintenance Exterior/Interior Checklist, F-4.7.1M	A document to reflect the pictures of the areas that were cleaned.;A copy of the PM checklist refer to pg. 2.;A copy of the refresher training to ensure that areas are inspected.	2016-09-24	CELLERBECK

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				was revised on 9/19/16 to ensure that a visual inspection for cobwebs is being monitored on a weekly basis			
5	4.14.8	Interior Rodent Trap #2a was not accessible to the pest control operator and was not inspected since Jan 2016. No action was taken by facility or PCO to correct the issue.	1. The trap was serviced on Sep. 13, 2016 by the Service Tech from Sprague	1. Trap #2A was no accessible for inspections since Jan. 2015 2. The trap was inaccessible due to being inside one of the rooms inside of dry storage room 3. The room was locked and service tech didn't have a key to access the room 4. The Service Tech didn't look for the Production Manager or notified anyone in the Food Safety Department that this trap was inaccessible 5. Lack of training to ask for the key when new Service Tech took over his new role last year.  1. Refresher training was given to the Sprague Service Technician. 2. A copy of key for the room was made and put in the	A copy of the refresher training given to Sprague Tech and Maintenance Team; A copy of the service report from Sprague Pest Control done on 9/13/16.	2016-09-24	CELLERBECK

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				Sprague manual for the service tech to use to ensure that this device is inspected. 3. After each of the service report the Assistant Technical Mgr. will verify that all traps are being inspected.			
6	7.2.1	Facility has no jewelry policy with exception of plain wedding band, shipping supervisor observed wearing necklace in the shipping area.	1. During the audit, the employee was asked to remove the necklace. 2. The policy was revised on 9/23/16 to reflect that no jewelry will be allowed in the processing areas.. 3. On 9/23/16 the shipping department was inspected to address that no jewelry was worn inside any of the processing and storage areas.	1. Employee was wearing a necklace when inside of the shipping dock and not allowed according to policy 2. Company policy states that no jewelry is to be worn in processing, storage and shipping areas. 3. The employee work the necklace and forgot to take it off. 4. Lack of employee training to ensure that no jewelry is to be worn.  1. Refresher training was given to the employee in the shipping department to ensure that he understands the procedure of no jewelry. 2. During the	A copy of the revised internal audit to reflect inspection for jewelry.;A copy of the refresher training given to employee about jewelry.;A copy of the company's policy on jewelry. ;A copy of the monthly inspection report conducted on 9/23/16.	2016-09-26	CELLERBECK

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				monthly inspection and during the internal audit ensure that no one is wearing any type of jewelry.			
7	7.4.6	Facility use blue disposable gloves to handle product, a box of gloves in processing area had used mesh packaging material in the box along with gloves.	1. On the day of the audit, the Assistant Technical Mgr. dispose of the box of gloves and the mesh bags 2. A refresher training was given to the QC personnel and backups to ensure that the gloves are kept intact and there is no cross-contamination. 3. A designated and labeled container was purchased for all of this cull product and handle the product appropriately	1. The mesh bags used to carry the out of spec product and show to the line supervisor was not stored properly 2. It was stored inside of the box of gloves to prevent from being thrown out 3. There was not a designated box to handle the out of spec product 4. Lack of training to ensure that gloves are kept intact at all times and not to pose a threat to contaminate.  1. A designated box was bought to carry the out of spec product and show the line supervisors 2. During the annual internal audit, the Assistant Technical Mgr. will observe to ensure that glove boxes are kept	A copy of the refresher training given to the QC employee.;The picture of the containers that were purchased for the cull product. ;A copy of the internal audit to ensure that gloves are inspected.	2016-09-23	CELLERBECK

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				intact and no risk of possible contamination			
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Comments on non-conformities
N/A

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## Voluntary Modules Non-Conformity Summary Sheet

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# 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 July 25, 2016. The policy is communicated to all staff by being displayed in common areas such as employee notice board and in 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 BRC audit score A
- 2 Employee safety 50% reduction from previous year
3. Customer Complaints 20% reduction than previous year.
4. Non conforming product target is zero.

Targets of 2015 were achieved.

Senior manager chaired the annually 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.

Additionally Management meeting occurs on weekly basis which also included Ranch representative of Congdon facility.

Records of the meeting dated Aug 19, 2016 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 Meeting Minutes Records dated Aug 25, 2016, 2016.

Food safety, legality, and quality issues are discussed during monthly meetings. Minutes of the management review meetings dated April 21, 2016, Aug 11, 2016 and Feb 25, 2016 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 North West Horticulture and Horticulture convention
- 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), WSDA, Washington State L & I

Reviewed facility audit report by USDA dated Dec 15, 2015, no issues noticed.

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

The audit due date was Sept 30, 2016 and was conducted on Sept 07, 2016.

The most senior 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 July 06, 2016 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

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Position Emergency Backups QP-1.2.1M Rev 9 dated July 06, 2016. Documentation indicated that the Assistant Technical Manager was deputized to replace the Technical Manager during an absence. Documentation indicated that the position was responsible to Job descriptions for General Manager and Packing Line Supervisor were reviewed. Employees (QC, Maintenance, shipper and operators) interviewed during the plant walk through were aware of their responsibilities. Work instructions were located on the line and in office and were accessible to relevant staff through their supervisor. Those reviewed include Customer Specification Manual is present on the line for QC.

**Details of non-applicable clauses with justification**

Clause reference	Justification
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2 The Food Safety Plan – HACCP	
<b>HACCP Team:</b>	There is a multidisciplinary HACCP team led by the Technical Manager that completed HACCP training provided by Washington State University on April 19-21, 2010 and Assistant Technical Manager Feb 14-15, 2012. The other members of the team completed HACCP training on Aug 16, 2016.
<b>Product Description:</b>	A full description for product includes: origin of ingredients, physical properties and chemical properties, treatment and processing, 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
	No allergens present
<b>Process Flow Steps:</b>	Process flow diagrams were comprehensive and available for HACCP plan reviewed. Flow diagrams are verified minimum annually by site inspection (challenge by 8 HACCP team members); the most recent being Aug 16, 2016. Flow diagrams for the HACCP Plan, processes were verified during the site inspection and included all required elements.
<b>Hazards:</b>	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 16, 2016 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 program included environmental swabs, ATP swabs. Knife Policy and Training program, etc.
<b>CCPs and Critical Limits:</b>	Based on the hazard analysis, 1 CCP were defined for the HACCP plan: Concentration of Peracetic Acid (PAA) . The corresponding critical limits were for CCP 1: <40 to >80PPM
<b>Validation Method of CCPs:</b>	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 – document WSDA research document.
<b>Monitoring and Corrective Actions:</b>	Offline measurement monitoring systems are able to detect loss of control of CCP in time for corrective action to be taken.

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CCP Operators for CCP 1 were interviewed. The Operator were aware of the critical limits and monitored the CCP per written plan. They were 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 Assistant Technical Manager. Records included date, time, and result of measurement. Records reviewed dated, e.g. Peracetic Acid (PAA) 12.0 Chemical Log, Aug 12, 2016 were reviewed. Corrective actions are defined for each CCP in Peracetic Acid (PAA) 12.0 Chemical Log. Actions and responsibilities are defined with regards to any product manufactured when process was out of control.

**Details of non-applicable clauses with justification**

Clause reference	Justification
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**3 Food safety and quality management system**

**3.1 Food safety and quality manual**

The Food safety & Quality management dated June 20, 2016 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 & Quality Management System, Product Control and Process Control Manual which is available in the plant 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. 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`s and Assistant Technical Manager`s computer to ensure only the correct versions of documents are available. The company has a document control procedure Document and Data Control QP-3.2.1 M, July 25, 2016, 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 to create or modify documents. The Technical Manager and Assistant Technical Manager are the person responsible for document approval and release. The Food Safety Department is responsible for replacement of obsolete documents held in hard copy. Minor: 3.2.1 - Facility had list of approved documents along with revision date, a document "Proc Bin Weight" used by receiver to record bin weight was not controlled document date or version number was not present on the document..

**3.3 Record completion and maintenance**

Records, which demonstrate the effective control of product safety, legality and quality, are maintained. Documentation procedure Document and Data Control QP-3.2.1 M, July 25, 2016 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 upto 9 Months under CA storage from receiving until shipping, 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 once a 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. 2 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 conducted by NCS International dated Mar 18-19, 2014. There were Internal audits done once a year. The internal audit report for HACCP, Sanitation, Foreign Material, Pest Control was completed on Aug 12, 2016 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. Minor: Facility had program in place for monthly inspections for environment and processing equipment, follow up on the deviations was not completed on inspections performed in April and February.

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### 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 apples were identified as low risk.

Risk assessments of raw materials, packaging materials, and other products to identify potential risk to product safety, authenticity, legality, and quality were reviewed on April 10, 2016. 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 and Management QP-3.5.1M, dated Aug 04, 2015 is on site.

Suppliers are required a third party food safety certificate to ensure suppliers effectively manage safety and quality risks of raw materials, and are operating effective traceability process. Reviewed growers were Global GAP, SQF and WSDA certified.

The approved supplier list was updated on July 15, 2016. 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.

According to the supplier approval procedures exceptions are subject to same criteria as the regular suppliers.

### 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 QP-3.5.2.1M Rev 3 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
- certificates of conformance

The parameters for acceptance and frequency of testing are defined on Receiving 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 HR Spinner Co, dated Sept 12, 2016.

### 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 Contractor Approval QP 3.5.3.1M Rev 3 dated July 27, 2016 was reviewed and has been applied to

- pest control
- laundry services
- laboratory testing
- waste management.

Calibration services

Supervision of maintenance contractors is completed by maintenance supervisor.

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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 were Pest Control and Cintas.

### 3.5.4 Management of outsourced processing

N/A – 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, microbiological, or physical standards). Example of a raw material randomly selected for review: Clamshells, 6/14CT boxes.

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 Gala 49118 dated Feb 04, 2015 was reviewed and successfully compared with process specifications and customer requirements. Finished product specification reviewed and approved by customer was Granny Smith Apples, dated Oct 2014.

Specifications are reviewed whenever products change (e.g. ingredients, processing method) or at least every three years. Rainier Cherries, Red Sweet Cherry April 2014, and Dark Cherries Mar 15, 2015 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 and Preventive Action QP-3.7.1M dated July 15, 2015.

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.

No product was held because of quality or food safety issue.

### 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 QP-3.8.1M Rev 5, dated July 15, 2016. The procedure includes the requirement to staff to identify and report potentially nonconforming product; direct labeling 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. Reviewed records of non-conforming product management.

### 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 Avalon SB Galas, manufactured on Aug 12, 2016 batch code 16G47SB105, and 3769 cases manufactured. Dispatch details of the product manufactured were that 2880 cases were shipped on Aug 18, 2016 to Travellers Fruit Co, Katzman Produce and Rainier Fruit Wholesale, Boucherville Canada. Exercise performed in 19 minutes, achieved a number 100 % forward traceability and a satisfactory mass balance check.

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 manufacturer lot code.

Traceability of raw materials and packaging used is achieved using physical labeling of materials to production.

Finished goods are stored on pallets identified by pallet tag number 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 pallet tag.

Traceability is supported with "Famous" inventory management system.

Traceability undertaken by the site for finished product back to raw materials was conducted on date using finished product Wapato #7 Galas, 1670#7105, manufactured on Aug 12, 2016. Full traceability was achieved on 18 minutes, including a satisfactory mass balance check.

All the suppliers had third party certificates

Traceability is maintained for rework.

### 3.10 Complaint handling

A procedure Trouble Report 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 are received by third party marketing company via telephone, e-mail.

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 of complaint that demonstrated adequate investigation, resolution and corrective action: Fruit looked very tired, scald and sunburn present dated April 05, 2016

Complaint data and trends are reviewed at the quarterly management meetings. Complaint trend of 2015 was reviewed. Records of complaints 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 Incident Management QP-3.11.1M, dated July 27, 2016 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 named "Incident Traceability For Recall QP-3.11.1M" dated July 27, 2016. 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 annually and the most recent test was carried out on Aug 18, 2016. 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 / daily pack out schedule procedures / raw material specifications / 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 – Raw material is not purchased from an agent or broker.
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.

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#### 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. Planted areas are kept to a minimum and are well maintained. 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 to protect products from theft or malicious product contamination while on site.

A security program is documented in Food Defense and Security Policy QP-4.2.1M Rev 9 dated July 28, 2016. 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.
- Vehicle trailers are locked and sealed before leaving the site

The site is a registered food business. Ref 117347732354.

##### 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 July 28, 2016 showing the processing and handling areas depicts closed area, low risk areas, and non-product areas, was verified on site.

The site map dated Aug 29, 2016 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 chemical supplier, pest control contractor during the audit.

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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.

**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 block and pre-cast tilt up and were in a satisfactory condition.  
 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.  
 All machinery was positively ducted to the drain.  
 When this was not possible, floors were able to cope with the flow of water to the drains and dedicated sanitation staff is in charge of squeegeeing remaining water.  
 The plant drainage is on a separate system that drainage from common areas.  
 Ceilings are constructed from structural steel sandwich panels with wood frame and are appropriately maintained. All ceilings were seen to be clean.  
 Glass windows were protected against breakage.  
 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 annually at production 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.  
 Minor: Room #4 had a damage on the south wall, one panel completely damaged.

**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 municipal water City of Yakima.  
 Water is used for washing apples, for sanitation, and for employee use.  
 Annual certificates from the water supplier are held on file confirming potability.  
 Certificates of analysis from process water sampled at closest place to use in contact with food dated Aug 17, 2016 are held on file confirming potability.  
 An up-to-date diagram dated Dec 28, 2012 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.

**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 Maintenance Schedule daily, weekly, monthly and annually. Planned maintenance through the manual system is scheduled and followed to ensure timely completion. Planned maintenance is based on equipment manufacturer's recommendations and in the light of experience and planned corrective actions.

Daily and weekly start-up checks are carried out to prevent any risk of product contamination from equipment damage. Results are recorded reviewed records for Aug 15, 2016 and Aug 23, 2016.

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.

#### 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.

Lockers 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, liquid 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 / adequate air dryers. Appropriate "Wash hands" signs were present within the restroom areas.

Smoking is only permitted in the designated area outside the factory building. Containers for smokers waste are provided. Signs are present to remind smokers to wash their hands prior to re-entering the production facility.

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.

#### 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 chemicals Shield Bright PAA-5.0, Chlor Clean CH2O and Lubemaster Pureplex grease. 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.M Rev 4 dated Aug 31, 2015, which is controlled by a documented register and records of inspection reviewed for Aug 12, 2016 and Aug 26, 2016.

Ingredients and packaging that use staples are avoided exception being staples used on bin tags. Facility had done risk assessment and monitoring program in place to prevent foreign material contamination.

#### 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 and Hard Plastic dated QP-4.9.3 M Rev 7 dated Aug 31, 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 based on risk of product contamination. Records of the last glass and hard plastic audit dated Aug 12, 2016 and Aug 26, 2016 were reviewed during the assessment.

There is a documented and detailed glass breakage procedure on site Foreign Matter, Glass and Hard Plastic dated QP-4.9.3 M Rev 7 dated Aug 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. Apples are received in wooden bins and facility had program in place to monitor the wooden bins.

#### 4.10.1 Foreign body detection and removal equipment

Risk analysis on Metal determined that metal detection equipment not required for this process, very low risk product.

The Hazard Analysis Worksheet Metals in Packing Process dated May 12, 2016 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

The HACCP hazard analysis has justified the absence of metal detection systems.

#### 4.10.4 Magnets



N/A - Magnets are not suitable to remove magnetic material from food product.
<b>4.10.5 Optical sorting equipment</b>
Manufacturer instructions are followed.
<b>4.10.6 Container cleanliness – glass jars, cans and other rigid containers</b>
N/A - There is no packaging with rigid containers on site.
<b>4.11 Housekeeping and hygiene</b>
<p>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.</p> <p>Documented cleaning procedures are available for building, plant, and equipment and they have been implemented.</p> <p>The cleaning methods for processing equipment, food contact surface and environmental cleaning in high care/high risk areas include</p> <ul style="list-style-type: none"> <li>responsibility,</li> <li>areas to be cleaned,</li> <li>cleaning frequency,</li> <li>cleaning methods,</li> <li>cleaning chemicals,</li> <li>chemical concentration</li> <li>temperature</li> <li>materials to be used,</li> <li>records and verification system.</li> </ul> <p>Records of cleaning performance dated June Aug 12, 2016 and Sept 08, 2016 were on file.</p> <p>For processing equipment, food contact surface and environmental cleaning, limits of acceptable and unacceptable cleaning performance are defined by:</p> <ul style="list-style-type: none"> <li>• visual appearance,</li> <li>• ATP bioluminescence techniques,</li> </ul> <p>Cleaning is appropriately scheduled and planned for nonproduction 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 Aug 11, 2016.</p> <p>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 preoperational inspection of Aug 22, 2016, Aug 26, 2016 and Aug 12, 2016 and were found to be satisfactory.</p> <p>Areas requiring corrective action are re-cleaned.</p> <p>Verification of cleaning effectiveness is by ATP swabbing.</p> <p>Environmental E.coli and Listeria swab testing is conducted on a quarterly basis. Reviewed results of third quarter dated Aug 26, 2016 were found to be satisfactory.</p> <p>Swabbing results reviewed during the visit from Aug 12, 2016 to Aug 26, 2016 were found to be satisfactory.</p> <p>Cleaning equipment is fit and suitable identified for the intended use (floors and glass), cleaned and stored in a hygienic manner to prevent contamination.</p> <p>All containers were suitably labeled.</p> <p>Minor: Housekeeping systems have failed to identify and clean the accumulation webs on ceiling above fan before dryer, a open ended metal pipe used to hold fans for drying has dust accumulated inside.</p>
<b>4.11.7 Cleaning in place (CIP)</b>
N/A - There are no CIP operations on site.
<b>4.12 Waste/waste disposal</b>
<p>Waste disposal is managed in to prevent accumulation, risk of contamination and the attraction of pests.</p> <p>Waste Management Systems of Yakima waste company removes waste from site.</p> <p>Waste areas seen during the visit were in a suitable condition with external waste collectors suitably covered.</p> <p>Containers for regular garbage bins, cardboard, paper, and metal waste were properly closed.</p>

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They are designed for ease of use and effective cleaning and they were maintained clean. Waste containers are removed on minimum weekly or more frequent based on demand. 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. Surplus or downgraded product will be removed from the customer packaging into wooden bins and before it leaves the facility.

**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 interior exterior 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 and both internal and external traps and pesticide applications. The contract includes insect light traps (ILT) units, mechanical traps / glue boards and bait stations.

Facility does interior inspection of rodent traps weekly by trained maintenance personnel.

A trap map dated April 11, 2016 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 Talstar P Professional Insecticide.

Records of monitoring activities and pest control applications dated June 12, 2016 and May 25, 2016 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 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 June 14, 2016 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.

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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 Food Safety Personnel or designate as reviewed in records dated Aug 16, 2016 and Sept 07, 2016.

Minor: Interior Rodent Trap #2a was not accessible to the pest control operator and was not inspected since Jan 2016. No action was taken by facility or PCO to correct the issue.

#### 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 Storage Assessment QP-4.15.1M, dated July 21, 2016 is in place to maintain product safety and quality during storage. The procedure details, as appropriate:

- managing chilled product transfer between temperature controlled areas
- segregation of products where necessary to avoid cross-contamination (physical, microbiological) 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 within specification range of 32 °F – 36 °F.

Conditions are verified by temperature recording equipment with suitable temperature alarms and daily recorded manual temperature checks. Records of temperature monitoring are on file, e.g. records dated Aug 20, 2016 were reviewed and found to be satisfactory

Controlled atmosphere storage areas are effectively controlled; records dated Aug 19, 2016 and Aug 21, 2016 were reviewed and found to be satisfactory under required conditions.

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.

#### 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 And Delivery QP-4.16.1M dated July 27, 2016 are in place to maintain product safety and quality during loading and transportation.

Loading dock areas are temperature controlled.

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 truck inspections dated Sept 07, 2016 and Aug 12, 2016 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 or system to verify and record the correct operation of refrigeration equipment. Records of transportation of Gala Apples dated Sept 07, 2016 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.

Third party marketing company arrange transportation is GFSI certified.

**Details of non-applicable clauses with justification**

Clause reference	Justification
4.2.3	4.2.3 N/A - External silos or tanks are not present.
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.
4.4.7	N/A - 4.4.7. There are no windows in production and storage areas.
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	4.7.3 N/A Temporary repair is not allowed in the facility.
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.
4.10.1.2	4.10.1.2- N/A - based on risk assessment and nature of product foreign body detection is not used.

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4.10.1.3	4.10.1.3- N/A - based on risk assessment and nature of product foreign body detection is not used.
4.10.1.4	4.10.1.4- N/A - based on risk assessment and nature of product foreign body detection is not used.
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	4.10.3.1 N/A- The HACCP hazard analysis has justified the absence of metal detection systems
4.10.3.2	4.10.3.2. N/A- The HACCP hazard analysis has justified the absence of metal detection systems
4.10.3.3	4.10.3.3. N/A- The HACCP hazard analysis has justified the absence of metal detection systems.
4.10.3.4	4.10.3.4. N/A- The HACCP hazard analysis has justified the absence of metal detection systems
4.10.3.5	4.10.3.5. N/A- The HACCP hazard analysis has justified the absence of metal detection systems
4.10.4.1	N/A - 4.10.4.1. Magnets are not suitable to remove magnetic material from food product.
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.
4.13.2	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. No product was given out for animal feed.
4.15.5	N/A - 4.15.5 No materials, packaging or process equipment are stored outside.

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<b>5 Product control</b>
<b>5.1 Product design/development</b>
Product development is not performed in this facility.
<b>5.2 Product Labelling</b>
Product labeling seems to comply with regulations and contain information to enable the safe handling, display, storage, and preparation of products.  The procedure Labelling of Product QP-6.2.1M dated July 21, 2016, 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 Gala Apples was reviewed and it seemed to comply with requirements.  All labelling 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.  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.
<b>5.3 Management of allergens</b>
N/A – There are no allergens handled on this site
<b>5.4 Product Authenticity, claims and chain of custody</b>
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, FDA Fraud and Substitution database and WSDA. The documented vulnerability assessment on Apples, dated July 21, 2016 and Aug 16, 2016. No ingredient is identified as high risk. The assessment was complete, accurate and contained sufficient detail. And covers all possible hazards. Assurance controls implemented for Apples included: <ul style="list-style-type: none"> <li>• Letter of guarantee</li> <li>• supply chain audits</li> <li>• enhanced supplier approval checks</li> <li>• change to the supply chain (e.g. a change of supplier or a move to a shorter supply chain).</li> </ul> Records of assurance controls was reviewed, e.g Record Global GAP from supplier dated Dec 04, 2016. Records of receiving and production are kept for Pink lady variety of apples, to verify identity. The status of Organic is supported by the corresponding certificate issued by WSDA issued on Sept 14, 2015.
<b>5.5 Product Packaging</b>
Finished products are packed in Clam shells, poly bags, trays, mesh bags and poly bags.  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 Jan 07, 2008 for clam shells and trays issued by H.R. Spinner on Jan 05, 2009 and Jan 08, 2012 was reviewed.

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Product contact liners appeared suitable for use.

**5.6.1 Product inspection and testing**

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 July 21, 2016.

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

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

The processing environment is tested for microbial indicators according to risk, in conformance with criteria set in Congdon Packing and Storage MRVP Program dated Aug 02, 2010.

Testing and inspection records are reviewed by quality and production management and appropriate actions are implemented.

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: ilac-MRA for the schedule of E coli, Listeria and other microbes, environmental and chemicals tests required by the company. accreditation no: L15-275 valid starting May 14, 2013 and valid until Aug 12, 2017 was reviewed.

**5.7 Product release**

Positive Release is not required

**Details of non-applicable clauses with justification**

Clause reference	Justification
5.1	N/A-5.1: Shelf life trials are not performed in this facility.
5.1.1	N/A-5.1.1: Product development is not performed in this facility.
5.1.2	N/A-5.1.2: Product development is not performed in this facility.
5.1.3	N/A-5.1.3: Product development is not performed in this facility.
5.1.4	N/A-5.1.4: Shelf life trials are not performed in this facility.
5.2.3	N/A - 5.2.3. There are no product claims made.
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.

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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.
5.4.6	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	N/A – 5.7. Positive release is not required.
5.7.1	N/A – 5.7.1. Positive release is not required.

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## 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:

- Production Pre-operational Checklist
- Daily Packout schedule.
- equipment settings
- labeling instructions
- Plu verification
- coding
- any additional critical control points identified in the HACCP plan are incorporated into the daily production control records.

Process monitoring includes, visual checks, pressure, storage and process temperatures, weight checks, label checks, plu verification 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 Aug 12, 2016 were reviewed. Examples of documented controls seen on site and by record: PAA 12.0 Chemical Log.

Interview of Operators confirmed understanding of process controls and critical limits in the process, reviewed records for Aug 12, 2016 and Sept 07, 2016

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

### 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. Methods and responsibilities were observed during the plant inspection at packaging line.

Checks to ensure that only the correctly printed materials are available in packaging lines are documented in QC Final Packaging Inspection and observed implemented at packaging line.

Documented checks at line start-up, following product changeover, and changes in batches or packaging are performed, as observed during 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
- quantity indication
- bar coding
- country of origin.

Records, e.g. Net Weight Check and QC Final Packaging dated June 08, 2016 are maintained.

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### 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 to minimum weight.

Checks are made on Gala Apples every batch. Results are recorded and verified by production supervisor.

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 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: Packaging Bagger Scale, bench scales are calibrated by Western Scale chemicals reviewed documents for July 27, 2016. pH Meter calibration dated Sept 06, 2016.

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. There is no vision equipment to check product label and printing.

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## 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 walk through (Receiver, Line Operator, Shipper, QC 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.

Contractors have receive the same orientation training as permanent staff. Orientation training records were reviewed during the visit for Pest Control dated June 14, 2016

Temporary workers are not used. 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 QC dated Aug 03, 2016

The training program Training Needs QP-7.1.1M Rev 4, updated on Sept 01, 2015 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 2016 were:

- Good Manufacturing Practices.
- HACCP
- CCP;
- Tasks identified as critical to meeting the effective implementation and maintenance of the BRC System.
- Food defense,
- Allergens,
- Quality,
- Sanitation

Review of effectiveness of training is implemented by testing the knowledge after training or on-the-job assessment.

All training is delivered in English & Spanish and understood by trainees.

All relevant personnel have received allergen awareness training during orientation as observed in training records dated Aug 30, 2016 and refresh training on the site's allergen handling procedures used by the company as observed in training records dated Aug 11, 2016.

Training courses reviewed were:

HACCP Training, GMP Training, Food Defense and sanitation training

The effectiveness of the training is monitored by one-to-one appraisals, team performance monitoring by line managers, 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.

Requirements for personnel hygiene are documented in Personal Hygiene Requirements QP-7.2.1M, dated July 27, 2016. 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 Personnel Hygiene Monitoring Log dated Aug 11, 2016 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.

Hands are cleaned at an appropriate frequency in production areas where there are additional hand washing facilities.

Cuts and grazes on exposed skin are covered by blue 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 Requirement QP-7.2.1M rules, dated July 28, 2016. Personal medicines are not permitted in production areas and are stored in



personal lockers. No evidence of non-compliance observed during the factory inspection.  
 Minor: Facility has no jewelry policy with exception of plain wedding band, shipping supervisor observed wearing necklace in the shipping area.

### 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 Requirement QP-7.2.1M rules, dated July 28, 2016 to 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 Visitor Sign In, 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 Requirement QP-7.2.1M rules, dated July 28, 2016, 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, apron, gloves, as appropriate. Visitors / contractors are provided with a hairnet, beard.

The company has documented and communicated to all employees, contractors and visitors the rules regarding the wearing of protective clothing in specified work areas (closed product, low risk). 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 sleeve, apron and gloves. 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 moustaches.

No evidence of noncompliance observed during the plant inspection.

Home laundering is performed for protective clothing worn in enclosed product and low-risk areas.

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

Colored disposable gloves, suitable for food use, are available. These are worn for a maximum of 2 hours or every time they get contaminated i.e. staff touch their noses, cough, pick up waste, at every break or when visiting the toilets.

Aprons, and sleeves are replaced as needed and new one given every morning.

#### Details of non-applicable clauses with justification

Clause reference	Justification
7.2.4	N/A – 7.2.4 Colored plaster that contains a metal detectable strip 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.

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