Audit Report

Global Standard for Food Safety Issue 7: July 2018

1.Audit Summary			
Company name	Congdon Packing LLC	BRC Site Code	1926166
Site name	Congdon Packing LLC		
Scope of audit	Washing and grading of apples and pears; packed into poly bags, clam shells and cardboard cartons.		
Exclusions from scope	None		
Justification for exclusion	NA		
Audit Finish Date	2018-08-22		
Re-audit due date	2019-09-24		

Voluntary modules included		
Modules	Result	Details
FSMA Preventative Controls and FSVP Preparedness	Passed	Washing and grading of apples and pears; packed into poly bags, clam shells and cardboard cartons.
Choose a module	Choose an item	
Choose a module	Choose an item	

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	A	Previous audit date	2017-09-19		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0

	Minor	6

3.Company Details

Address	1117 South 64th 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 Choose a region Choose a region Choose a region Choose a region
Company registration number	18097829518
Major changes since last BRC audit	None

4.Company Profile

Company Description

Congdon Packing LLC facility is located in city of Yakima, Washington established in 2003. Congdon Packing LLC is a wholly owned subsidiary of Congdon Orchards. Apples and Pears for domestic and export sales are packed in the facility. The packing plant is located at 1117 64 th Ave in Yakima WA currently employees 100 employees, and runs a single production shift followed by a full sanitation shift, five days a week. The facility packs about 25 million lbs of fruit every season. Packaged product is stored in another Congdon facility before shipped to customers.

5.Product Characteristics

Product categories	05 - Fruits, vegetables and nuts VM - FSMA Preventative Controls and FSVP Preparedness Category Category Category Category
Finished product safety rationale	Chilled < 39 F, Peracetic acid & Chlorine Dioxide wash.

High care	No	High risk	No	Ambient high care	No

Justification for area	BRC Decision tree is utilized.
Allergens handled on site	None Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	Organic
Product recalls in last 12 Months	No
Products in production at the time of the audit	Organic Bartlett Pears No. 70`s, 80`s.

6. Audit Duration Details

On-site duration	22 man hours	Duration of production facility inspection	9 man hours
Reasons for deviation from typical or expected audit duration	FSMA module was part of the audit, spent total 22 hours at the facility (18 hours for BRC, 4 hours for FSMA). Facility has only one packaging line.		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1	2018-08-20	10:00	17:00
2	2018-08-21	08:00	17:00
3	2018-08-22	07:00	15:00

	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
Scott Rosencranc/ Operations Manager	x			x
Edgar Pacheco /Assistant Technical Manager	x	x	x	x
Gene Woodin/Physical Plant Manager	x			

Non-Conformity Summary Sheet

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

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

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

Minor							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1	3.5.3.2	Formal agreement or contract with waste removal company Waste Management of Yakima was not available.	1. The waste management company was contacted and service agreement was received on 9/04/18.	1. Formal contact with waste management company was not available at time of the audit 2. The waste company does not have anything in writing that describes the services provided	A copy of the email from company services detailing services. ;A copy of the revised internal audit to reflect the revision made. ;The letter	2018-09-10	CELLERBECK

				3. The service is on a monthly to month basis pricking up the receptacle on a weekly basis until the services are ceased 4. Not requiring that the company will have a written agreement of the services provided. 1. A copy of the detailed services will be kept on file as the agreement of services. 2. The internal audit was revised on 9/04/18 to reflect that contractors shall be reviewed annually.	provided from waste service company.		
2	3.6.4	Specifications for Organic Bartlett Pears were not reviewed within 3 years; last revision on file was dated Oct 07, 2013. Conventional Pears specifications were reviewed on July 04, 2017.	1. The specification of the Organic Bartlett's were revised on 8/21/18.	1. The product specifications were not revised within the 3 years. 2. Due to no changes in the specifications of the product the revision was missed and not updated 3. Lack of training to the Food Safety Assistant to ensure that all of the product specifications are revised at least within every 3 years.	Revised spec for Org. Bartlett.;Refresher training given to the Food Safety Assistant on 8/23/18.	2018-09-04	CELLERBECK

				1. Refresher training was given to the FS assistant on 8/23/18 to review the procedures when reviewing customer specifications to be reviewed and updated every 3 years.			
3	4.6	Excessive grease was observed on bearing by pre-sorting station and there was no catch pan underneath. Open ended grey pipes were observed by sorting area.	1. The excess of the grease was removed 2. A catch pam was installed under the pre-sort bearings 3. The open ended pipes observed on the sorting area were closed.	1. Excess grease observed on the bearing by the pre-sort area and open ended pipes observed in the sorting area. 2. The catch pan had not been installed under the bearings and the open ended pipes had not been inspected 3. Lack on monitoring and inspecting the excess of grease 4. Lack of inspecting catch pans under motors. 5. Lack of maintenance personnel training 1. Refresher training given to the maintenance personnel to ensure that they understand the procedures to follow at all times. 2.	Copy of training attendance refresher. ;Copy of the inspection of interior and exterior. (pg. 3) ;Pictures of catch pans, closed pipes and excess grease removed.	2018-09-06	CELLERBECK

				Included in the monthly inspection, Exterior/Interior Monitoring log the inspection of the catch pans and the open ended pipes to ensure that any other are addressed properly			
4	4.7.2	Facility is required to perform maintenance pre-plant operation checks and record on the Pre-op Checks. Daily Pre-op Checks records were not completed by maintenance for Week of Aug 20, 2018.	1. The daily pre-operation checklist was completed for the week of Aug. 20th and the week of Aug. 27th on a daily basis as stated on the procedure 2. Refresher training given to the maintenance personnel on the procedures to follow daily pre-operational checklists on a daily basis	1. The maintenance personnel had not completed the daily pre-operational checklist as stated on procedure 2. The employee had completed the inspection first thing in the morning but had failed to document the inspection properly 3. Lack of knowledge of the procedure to document any inspection 4. Lack of employee training on the procedures to follow 1. Maintenance Pre-Op inspection F-4.6.1Y was revised on 9/06/18 to include the verification from Line Supervisor on a daily basis. 2. Training	Pre-Op checklist Aug. 27-31;Refresher training given to the maintenance personnel by the Ops Mgr.;Pre-Op checklist Sep. 4-5;Revision 10 of Pre-Op checklist completed Sept. 6-8;Pre-Op checklist Aug. 20-24;Training given to the Line Supervisor on verification of pre-op checklists	2018-09-10	CELLERBECK

				record given to the Line supervisor to verify that records are maintained legitimate and completed accordingly.			
5	4.11.1	In cooler #5, there were cob webs along the door edge and also the floor was wet and filthy by the door.	1. Cold room #5 floor along the edges was cleaned and the water was removed from this area.	1. Inside of cold room #5 along the edged it was observed dirty and wet from under the cooling unit no product was stored in this area of the cold room 2. Employees failed to address the cleanliness of this area due to fail of inspection 3. Lack of monitoring of this area in the monthly inspection log 4. Lack of employee training on the refrigeration personnel to understand that these areas shall be addressed 1. The interior/exterior inspection monitoring log was revised to include inspection of the cold room integrity and cleanliness. 2. Refresher training to the refrigeration personnel to	Refresher training given to the refrigeration staff. ;Inspection of cold rooms. (pg. 4);The quote to be completed on 12/14/18 Per General Manager, Mark Blore. ;Pictures of the cold room floor free of standing water and dirt.	2018-09-11	CELLERBECK

				understand the procedures. 3. Quote to insulate the piping inside of this cold room to prevent any future dripping. Expected completion date 12/14/18 per Mark Blore, General Manager.			
6	4.11.6	An air hose tip was sitting on the floor by the strapper machine in production area.	1. The hose was picked off the floor and tied to the area where it shall be stored after being used.	1. The hose was observed on the floor next to the strapper machine 2. This was used to blow off the excess of the strapper area 3. The equipment was used and not picked up after used. 4. Lack of training on f the employees to pick up after themselves. 1. Refresher training was given to the sanitation team to ensure that they understand to pick up all tools off the floor at all times.	Copy of the training attendance record.;Picture of the hose off the floor.	2018-09-05	CELLERBECK

Comments on non-conformities
NA

Voluntary Modules Non-Conformity Summary Sheet

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

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

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

FSMA Module Non-Conformity Summary Sheet

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

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

Minor							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1	15.3.10	Food Defence Plan was not signed by General manager.	On 9/13/18 the General Manager signed the Food Defense/Site Security Assessment of products.	1. The Food Defense Plan was not signed by the General Manager, 2. The company had developed the Food defense plan but it was never signed by the GM, 3. It had not been a requirement for the document to be signed in the past. 1. The company BRC/FSMA Assessment tool was revised to include the statement that the company GM will be the ultimate person to review, sign, and date the the site security/food defense assessment plan on a yearly basis.	Documents	2018-09-21	F. Escobar

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 Aug 10, 2018. 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. Less than 20% of Trouble Reports per 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 10, 2018 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 10, 2018.

Food safety, legality, and quality issues are discussed during weekly, meetings. Minutes of the management review meetings dated July 24, 2018 and Aug 14, 2018 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 USDA from the last on-site visit on Jan 11, 2018 was reviewed. Regulatory non-compliance was not observed.

A genuine hard copy and electronic 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 24, 2018 and was conducted on Aug 20, 2018.

The most senior production 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 Sept 09, 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 Position Emergency Backups QP-1.2.1Y Rev 8 dated July 31, 2016. Documentation indicated that the Assistant Technical Manager was deputized to replace the Technical Manager during an absence. Job descriptions for Operations Manager and Packing Line Supervisor were reviewed.

Employees (QC, Maintenance, shipper and operators) interviewed during the plant walkthrough 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

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 Training Institute on Mar 31, 2016. The other members of the team completed HACCP training on Aug 10, 2018.

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 Pears and Apples, 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
Known 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 alimentarius, FDA, USDA, BRC, WSU 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 21 HACCP team members); the most recent being Aug 10, 2018. 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 Jul 18, 2018 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 Pest Control Program and Preventive Maintenance Program included Annual Pest Control evaluation by PCO, EMP Program, revised SSOP's, Completed Maintenance Records and verified by Operations manager tasks are done and records are included and pre-operation inspections.

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

CCP 1: Product Washing Hydrocooler.

The corresponding critical limits were for CCP 1: Peracetic acid between 40 – 80 ppm Target is 75 ppm & pH 4 - 7. PAA is sprayed on pears and air dry.

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) 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.

Monitoring and Corrective Actions:
Online 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. 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 Food Safety Assistant. Records included date, time, and result of measurement. Records reviewed dated, e.g. Peracetic Acid 15.0 Chemical Log dated Aug 20, 2018 were reviewed.

Corrective actions are defined for each CCP in HACCP Plan. 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 10, 2018 are maintained.

Review of CCP and CP records for production dated Aug 09, 2018 to Aug 20, 2018 was conducted and they were sufficient. For example, Peracetic Acid 15.0 Chemical Log, dated Aug 09, 2018.

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.

These were documented on the HACCP Validation Process Flow QP-2.6.1Y Rev 5 7.1.5M Rev 1, dated July 13, 2015.

Example: Annual HACCP review was done on Aug 10, 2018

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 Quality Management, dated Aug 01, 2018 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, dated May 18, 2018 which is available as a 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-3.2.1Y 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-3.2.1Y 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 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 throughout the year. The scope and frequency of the audits documented in Internal Audits QP-3.4.1Y dated July 31, 2017 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: Principles of Internal Auditing dated July 31, 2018.

There were Internal audits throughout the year. The internal audit report for Training, completed on Mar 08, 2018 and Housekeeping & Hygiene completed on Sept 21, 2018 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. Completion of corrective actions was last verified on Aug 14, 2018.

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 Congdon Packing Monthly Inspections dated June 08, 2018 were reviewed. Inspections are conducted by Rach Food Safety Assistant, Food Safety Assistant and Assistant Technical Manager Aug 08, 2018 and Mar 23, 2017.

3.5 Supplier and raw material approval and performance monitoring

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 Pears, Apples and packaging material were identified as low-risk. There is no high 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 01, 2018. The hazard analysis, the risk of substitution or 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 Y Rev 8 dated July 31, 2017 is on site.

All suppliers are required to provide a GFSI recognized certificate or third party food safety certificate is acceptable as all ingredients and packaging material are considered low risk as per risk assessment and are operating effective traceability process.

GFSI recognized certificate for Pears from supplier performed traceability is Global Gap certified dated Nov 17, 2017, was reviewed and FSSC 22000 certificate was reviewed for Packaging material Poly bag valid till Sep 07, 2019 and they were found satisfactory.

The approved supplier list was updated on June 11, 2018. 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.

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 3.5.2.1. Y Rev 4 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
• certificates of conformance

The parameters for acceptance and frequency of testing are defined on Receiving QP 3.5.2.1. Y Rev 4 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 Firm Tech Inspection Form and Receiving Fruit Log dated Aug 20, 2018 & Aug 08, 2018.

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.Y, dated Aug 30, 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 most 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
NC-3.5.3.2. Formal agreement or contract with waste removal company Waste Management of Yakima was not available.

3.5.4 Management of outsourced processing and packing

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 was for pears dated July 31, 2018.

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 Organic Bartlett, dated Mar 2017 was reviewed and successfully compared with process specifications and customer requirements.
Finished product specification reviewed and approved by customer was Organic Bosc Pears Aug 03, 2018.

NC – 3.6.4. Specifications for Organic Bartlett Pears were not reviewed within 3 years; last revision on file was dated Oct 07, 2013. Conventional Pears specifications were reviewed on July 04, 2017.

3.7 Corrective and preventive actions

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. Y Rev 7, dated July 31, 2017.
Identified non-conformities that place the safety, legality, or quality of product at risk could arise from customer complaints, process analysis, internal and external audits, senior manager revisions, organizational issues, process measurements, auto-assessment, CCP failures, out of specification product, unsatisfactory pre-operational inspections, unsatisfactory environmental test results, and 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.

Corrective action procedure was followed when PCO identified weeds and shrubs on one side of the facility, facility had generated Corrective Action Request Form and implemented corrective action dated Aug 14, 2018.

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

3.8.1.Y., dated July 31, 2017. 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. Records of non-conforming product management will be maintained on Non Conforming Product Log. There was no product held or destroyed this year.

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 Bartlet Pears Lot #G109 manufactured on Aug 09, 2018, batch code 18G109221, and 314 cases manufactured. Dispatch details of the product manufactured were that 40 cases were shipped on Aug 13, 2017 to Vancouver BC shipment number 140699-8, cases were shipped on Aug 10, 2017 to Vancouver BC shipment number 1406899-8, 12 cases were shipped on Aug 16, 2018 to Chesterfield OR shipment number 141713-8, 12 cases were shipped on Aug 13, 2018 to Hammonton, NJ on shipment number 140866 and 205 cases are still sitting in the inventory. Traceability involved raw materials and packaging materials usage. The exercise performed on 1 hour and 59 minutes, achieved 100% forward traceability and a satisfactory mass balance check, where yield was 99%, 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 Grower Block ID.

Traceability of raw materials and packaging used is achieved using physical labeling of materials/products, by recording and systems identifying the allocation of materials to production 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 test undertaken by the site for raw material to finished products was conducted on Aug 15, 2018, using raw material Gold Russet Bosc Pears-, lot G118, processed on Sept 13, 2017. Full traceability was achieved on 1 hour 20 minutes, including a satisfactory mass balance check.

Traceability test undertaken by the site for finished product back to raw materials was conducted on Sept 13, 2017 using finished product Gold Russet Bosc Pears (60 ct, 70 ct, 80 ct and 100 ct) lot number G118, manufactured on Sept 13, 2017. Full traceability was achieved on 1 hour 20 minutes, including a satisfactory mass balance check.

All raw materials have been accessed for traceability.

3.10 Complaint handling

A procedure Product /Customer Complaints QP3.10.1Y dated July 31, 2017 on site to handle Customer and consumer complaints effectively and information is used to reduce recurring complaints.

Complaints are addressed by Technical Manager mail, 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 in Org. Bosc

pears dated Nov 30 2016.

Complaint data and trends are reviewed at the monthly management meetings. Complaint trend of 2017-18 was reviewed. Records of complaints 2 related with quality defect (decaying) 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 QP 3.11.1Y, dated Aug 01, 2018 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 QP 3.11.1Y dated Aug 01, 2018. 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 annually and the most recent test was carried out on Aug 15, 2018. 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 Customer Specifications and Grade requirements for Pears Organic and Conventional.

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.
3.5.1.4	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. There 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.

Congdon Orchards are present on all four sides of the building.

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 protect products from theft or malicious product contamination while on site.

A security based on risk is documented in Food Defense and Security Policy QP-4.2.1.Y dated Aug 06, 2018. 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
• 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 XXXXXXXX9518.

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 Sept 07, 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 16, 2018 defines access points for personnel and raw material (including packaging), routes for personnel, raw materials, removal of waste, 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.

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.

Suspended ceiling is included in pest control program and area is inspected by PCO quarterly.
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.

Glass windows were protected against breakage.

Ceilings are constructed from structural steel sandwich panels with wood frame 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 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.

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 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 parameters monthly and annually a water sample is sent out for chemical testing. Records reviewed from Mar 28, 2018 and Aug 14, 2018 indicated that the applicable regulatory guidelines were met.

An up-to-date diagram dated Sept 07, 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.

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.

NC -4.6. Excessive grease was observed on bearing by pre-sorting station and there was no catch pan underneath. Open ended grey pipes were observed by sorting area.

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.Y 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.

Temporary repairs are not permitted

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.

NC-4.7.2 Facility is required to perform maintenance pre-plant operation checks and record on the Pre-op Checks. Daily Pre-op Checks records were not completed by maintenance for Week of Aug 20, 2018.

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, liquid / foam soap, and disposable towels / air dryers.

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 control

Raw 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 by DM-7 Lubricant Spray and Shield Brite PAA 15.0.

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-4.9.2.1Y Rev 4 dated Aug 31, 2015, which is controlled by a documented register and records of inspection dated Aug 20, and Aug 08, 2018.

Ingredients and packaging that use staples are avoided. Paperclip are not permitted within the production areas and none were observed during the site inspection. Staples are allowed for bin tags and facility had done a risk assessment and no issues observed.

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-4.9.3.1Y Rev 8 dated Aug 01, 2018 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 to review handling procedures in place. Records of the last glass and hard plastic audit dated Aug 10, 2018 & Aug 11, 2018 were reviewed during the assessment.

There is a documented and detailed glass breakage procedure on site Foreign Matter, Glass & Hard Plastic QP-4.9.3.1A dated Aug 01, 2018, 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

Glass or brittle containers are not stored in the facility.

4.9.5 Wood

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

4.10 Foreign-body detection and removal equipment

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.

4.10.2 Filters and sieves

Filters or sieves are not appropriate for the production process.

4.10.3 Metal detectors and X-ray equipment

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

Magnets are not suitable to remove magnetic material from food product.

4.10.5 Optical sorting equipment

Optical sorting equipment is not used in the facility.

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

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 09, 2018 Aug 13, 2018 were on file.

For processing equipment, food contact surface and environmental cleaning 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, Salmonella & E coli are validated and records dated Aug 14, 2018 and Mar 28, 2018 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 Aug 08, 2018.

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 June 05- June 17, 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 08, 2018 – Aug 20, 2018 were found to be satisfactory.

Cleaning equipment is fit and suitable identified for the intended use, cleaned and stored in a hygienic manner to prevent contamination except as indicated in the minor noon-conformity.

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

All containers were suitably labeled.

NC-4.11.1 In cooler #5, there were cob webs along the door edge and also the floor was wet and filthy by the door.
NC- 4.11.6 An air hose tip was sitting on the floor by the strapper machine in production area.

4.11.7 Cleaning in place (CIP)

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 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.

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 monthly 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 Sprauge 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 01, 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 Blox
Records of monitoring activities and pest control applications dated June 25, 2017 and July 02, 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 July 13, 2018 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 Aug 21, 2018 and July 13, 2018.

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 QP7.2.1Y, dated Aug 01, 2018 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 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 35 ºF within specification range of 30 ºF – 35 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 13, 2018 and Aug 11, 2018 were reviewed and found to be satisfactory
Storage areas are within specification range of 29 ºF – 38 ºF.

Conditions are verified by temperature recording equipment with suitable temperature alarms. Records of temperature monitoring are on file, e.g. records dated Aug 08, 2018 to Aug 13, 2018 were reviewed and found to be satisfactory

Cardboard cartons are stored outside observed covered with plastic liners and are inspected before brought into the facility reviewed records dated Aug 09, 2018 and Aug 14, 2018, found 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.

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 May 31, 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 moved into other Congdon facility in Yakima. All the products are shipped to another Congdon facility; there are no direct shipments to customers from this facility.

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 21, 2018 and Aug 10, 2018 were reviewed.
A shipping employee was interviewed regarding carrier inspection and answered per the documented procedure.

Procedures are in place to ensure temperature requirements are met, which includes system to verify and record the correct operation of refrigeration equipment. Records of transportation of Pears dated Aug 21, 2018 were reviewed. Products are not shipped directly to customer from this facility, products are transferred to other Congdon facility which is about 15 minutes away. Products are stored and shipped from other facility.

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.

Details of non-applicable clauses with justification

Clause reference	Justification
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.
4.4.7	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
4.7.5	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	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- 4.10.1.1- The HACCP hazard analysis has not identified any potential foreign body risks that require the need for foreign body detection or removal systems.
4.10.1.4	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.
4.10.2.1	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	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	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	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	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	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	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	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	There are no CIP operations on site.
4.11.7.2	There are no CIP operations on site.
4.11.7.3	There are no CIP operations on site.
4.13	There is no by product of primary activity.
4.13.1	There are no surplus customer branded products in the facility.
4.13.2	There are no nonconforming branded products sold to staff or passed on to charities.
4.13.3	There is no product designated for animal feed.
4.14.3	Preventative pest control on site is managed by a contracted third party.
4.16.6	N/A - 4.16.6 Facility owned truck are used to transfer product to other Congdon facility.

5. Product control

5.1 Product design/development

Product development is 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-5.2.1Y dated May 08, 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 Org Bartlett 70 US#1 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.

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

The company has reviewed all its raw materials, intermediate, finished products, and there is no allergen identified in the facility. These are detailed in Allergen Control & Risk Analysis dated Aug 31, 2016. Allergen Awareness training is provided to all the employees and employees are required to wash hands before entering the facility.

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, FDA Fraud and Substitution database and WSDA.

The documented vulnerability assessment on Apples and Pears, dated Aug 01, 2018 no raw material or packaging material is identified as high risk. The assessment was complete, accurate and contained sufficient detail. And covers all possible hazards.

Assurance controls implemented for Apples and pears included
included:
- Letter of guarantee
- supply chain audits
- enhanced supplier approval checks
- change to the supply chain
- Product verification program

Records of assurance controls was reviewed, e.g Record SQF and Global GAP from suppliers valid till Oct 18, 2018 and Jan 05, 2019.

Claims of organic 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 Bartlett Pears on Aug 06, 2018.

The status of Organic is supported by the corresponding certificate issued by WSDA issued on June 23, 2017.

Process flow and potential areas for contamination or loss of identify are identified in Process Flow Chart Organic Pears/Apples dated Aug 10, 2018.

Organic materials are clearly identified in segregated storage areas.

Production is scheduled to be first on line and uses dedicated equipment and utensils.
On site inspection of these lines reflected good controls.

5.5 Product packaging

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 for clamshells and bags issued by Peninsula Packaging Company and Fruit Packers Supply Inc. issue on Jan 08, 2018 and Jan 01, 2018 was reviewed.

Product contact liners appeared suitable for use.

5.6 Product inspection and laboratory testing

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 Inspection and Testing QP-5.6.1Y, dated Aug 31, 2016.

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

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 Environmental Monitoring Plan QP-4.11.3Y Rev 4 dated May 09, 2018.

Testing and inspection records are reviewed by quality and production management and appropriate actions are implemented. Reviewed MRL results for Pears dated Mar 09, 2018 and found to be satisfactory

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: L17-273 valid starting May 14, 2013 and valid until July 31, 2019 was reviewed.

5.7 Product release

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	Product development is not performed in this facility.
5.1.2	Product development is not performed in this facility.
5.1.3	Product development is not performed in this facility.
5.1.4	Shelf life trials are not performed in this facility.
5.2.3	There are no product claims made.
5.3.2	There is no allergen handled at the facility.
5.3.4	There are no allergens handled on this site.
5.3.5	There is no rework containing allergens used on this site.
5.3.6	There is no rework containing allergens used on this site.
5.3.7	There is no rework containing allergens used on this site.
5.3.8	There is no rework containing allergens used on this site.
5.6.2.2	There is no laboratory on site.

5.6.2.4	An accredited laboratory is used and there is no laboratory on site.
5.7.1	Positive release is not required.

6. Process control

6.1 Control 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 Packing Instructions
• 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 weight checks, label checks, plu verification and date code checks.
Reviewed Tub PLU Verification and In Line QC Form for Aug 09, 2018.
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 08, 2016 and Sept 20, 2016 were reviewed. Examples of documented controls seen on site and by record: PAA 15.0 Chemical Log
Interview of Operators confirmed understanding of process controls and critical limits in the process, reviewed records for Aug 09, 2018 and Aug 20, 2018

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.

This was reviewed during the site walk through/ or change over.
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 labelled.

Checks include
• date coding

• quantity indication
• bar coding
• country of origin.

Records, e.g. Net Weight Check and QC Final Packaging dated Aug 09, 2018 are maintained.

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 Organic Bartlett pears every batch. Results are recorded and verified by QC.

Weight control reviewed during the site inspection and the traceability study were found to be satisfactory. Reviewed records for Net Weight Check For Packed Fruit dated Aug 09, 2018.

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: bench top scales is calibrated by Western Scale chemicals reviewed documents for Aug 10, 2018. pH Meter calibration dated Aug 13, 2018.
Calibration is performed by the 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	The processing conditions do not require regular validation.
6.2.4	There is no vision equipment to check product label and printing.
6.3.2	Bulk product is not handled in the facility.

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, Line Operator, Shipper, Maintenance, 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 Aug 21, 2018

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 09, 2018.
The training program Training Needs QP-7.1.1Y Rev 5, 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 2018 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 06, 2016 an8 refresh training on the site's allergen handling procedures used by the company as observed in training records dated Aug 09, 2018.
Training courses reviewed were:
HACCP Training, GMP Training, Food Defense, sanitation training, GMP`s & allergen 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. No evidence of non compliance observed during the factory inspection.

Requirements for personnel hygiene are documented in Personal Hygiene Requirements QP-7.2.1Y, dated Aug 01, 2018. 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 09, 2018 and Aug 20, 2018 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 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-7.2.1Y Rev 10, dated Aug 01, 2018. Personal medicines are not permitted in production areas and are stored in personal lockers. No evidence of non-compliance observed during the factory inspection.

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-7.2.1Y Rev 10, dated Aug 01, 2018 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 Requirements QP-7.2.1Y Rev 10, dated Aug 01, 2018, 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, beard net, apron, gloves, as appropriate.
Visitors / contractors are provided with a hairnet, 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 (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.
Protective clothing is laundered by Cintas. Cleaned laundry is inspected and, if unsatisfactory, is returned to the laundry company or in-house laundry.
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	Colored plaster that contains a metal detectable strip is not used in the facility
7.4.4	This is not a high risk or a high care areas.

Module 8 - Traded Goods

Scope	NA

8.1 Approval and performance monitoring of manufacturers/packers of traded food products

8.2 Specifications

8.3 Product inspection and laboratory testing

8.4 Product legality

8.5 Traceability

Module 9: Management of Food Materials for Animal Feed

Scope	NA

9.1 Management Commitment

9.2 HACCP

9.3 Outsourced Production

9.4 Specifications

9.5 Traceability

9.6 Chemical and Physical Product Contamination Control

9.7 Labelling
9.8 Training

Module 11: Meat supply chain assurance

Scope	**NA**
11.1 Traceability	
11.2 Approval of meat supply chain	
11.3 Raw material receipt and inspection	

11.4 Management of cross-contamination between species
11.5 Product testing
11.6 Training

Module 12: AOECS Gluten-free Foods

Scope	**NA**
12.1 Senior management	
12.2 Management of suppliers of raw materials and packaging	

12.3 Outsourced production

12.4 Specifications

12.5 Management of gluten cross-contamination

12.6 Management of incidents, product withdrawal and product recall

12.7 Labelling

12.8 Product inspection and laboratory testing

Module 15 FSMA Preventive Controls Preparedness Module

Version 2 July 2018

Item no.	Clause	Module item	Conforms (Y/N) or Not	Comments

			Applicable (NA)	
1	15.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.	Y	There was enough lighting in the facility including bathrooms, sinks and lockers. Facility performs monthly light intensity inspections and found satisfactory.
2	15.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.	Y	Facility had 2 back flow preventers at the main line and are inspected annually by third party.
3	15.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.	Y	Equipment observed was constructed of stainless steel and food grade materials that can be effectively cleaned. Seams on food contact surfaces observed to be smooth.
4	15.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.	N/A	Ice is not used in the facility.
5	15.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.	Y	Facility had policy in place not to mix or reduce any product that is exceeding the minimum tolerance levels. It is described on Self-Assessment dated Aug 06, 2018
6	15.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably	Y	Facility had policy in place not to mix or reduce any product that is exceeding the minimum tolerance levels. It is described

		foreseeable hazards, which are associated with the food or facility: • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety		on Self-Assessment dated Aug 06, 2018
7	15.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine “hazards requiring a preventive control” (i.e., significant hazards).	Y	Hazard analysis is completed at the each process step, Biological, Physical, Chemical, radiological and economic adulterants were considered during hazard analysis.
8	15.1.8	Establish one or more preventive control(s) for each identified “hazard requiring a preventive control” (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.	Y	All identified hazards are evaluated on Hazard Analysis worksheet & Preventive Control Process Steps dated July 18, 2018.
9	15.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: • Notifying consignees of how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out	Y	The company has developed a product withdrawal and recall procedure Incident Traceability for Recall QP 3.11.1Y dated Aug 01, 2018. The procedure includes identification of the recall management team and written guidance provided to key staff. First fruit marketing company ships all the product they will send notification to the customers and describes what to do with the product and

		• Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product		customer is to complete Recall Response Form with all the required information. Effectiveness of the recall is verified by reviewing Recall Response Form & Disposition plans.
10	15.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.	Y	Written monitoring procedure for Preventive controls is part of the food safety plan, Doc F-2.1.1Y Rev 8 describes Preventive control monitoring procedure.
11	15.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRC sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).	Y	Written procedure for Preventive controls is part of the food safety plan, DocF-2.1.1Y Rev 8 describes Preventive control Corrective Preventive action procedure.
12	15.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.	Y	Preventive Control Verification Validation Log QP-2.2.1M dated Aug 08, 2018 describes requirement of validation of preventive control before implementation and within 90 days if any alteration or change to preventive controls
13	15.1.13	The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a	Y	Records are reviewed on next working day as per company policy, and reviewed PC records dated Aug 09, Aug10 and Aug 14 and found satisfactory.

		reasonable timeframe after the record is created.		
14	15.1.14	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Sampling procedure to include method, quantity, frequency, and number of samples • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected	N/A	Product testing is not used as verification activity.
15	15.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected	Y	The processing environment is tested for microbial indicators according to risk, in conformance with criteria set in Environmental Monitoring PlanQP-4.11.3Y Rev 4 dated May 09, 2018. Sampling schedule, number of samples, and lab required are detailed in the procedure.
16	15.1.16	Devices used to verify preventive controls must be calibrated.	Y	All devices and equipment used to monitor preventive controls are calibrated on predetermined frequency. Thermometer are calibrated monthly, pH meter & scales are calibrated annually.
17	15.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food	Y	PCQI had completed FSPCA Preventive Controls for Human Food Training, and had 7 years

		safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		of experience working in food industry in quality and food safety department. Back up PCQI had more than 30 years of experience in food industry.
18	15.1.18	All records required by 21 CFR § 117 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable	Y	Date and time of activity is recorded on the form, followed by initials or signature of individual performing the task and verifier. Form is identified for each facility by form number and name.
19	15.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.	Y	General manager of the facility had signed the food safety plan dated Aug 10, 2018.
20	15.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.	Y	Facility had Document & Data Control QA-3.2.1Y dated July 31, 2017,which states records are kept at the facility for 2 years.
21	15.1.21	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the	Y	The supplier approval procedure Supplier Evaluation & Management QP-3.5.1 Y Rev 8 dated July 31, 2017 is on site. All suppliers are required to provide a GFSI recognized certificate or third party food safety certificate is acceptable as all ingredients and packaging material are considered low risk as per

		receiving facility is responsible for verifying implementation of the control.		risk assessment and are operating effective traceability process. All raw material is produced by approved suppliers.
22	15.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients. Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.	Y	Supplier Evaluation & Management QP-3.5.1 Y Rev 8 dated July 31, 2017 describes that material from be received from any unapproved supplier.
23	5.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter at an adequate frequency.	Y	Facility verifies that supplier had third party food safety certificate. MRL`s are tested for all suppliers annually including new supplier reviewed MRL`s for Gala lot 96A from Congdon Orchards dated Nov 2017.
24	15.2.1	Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: - During holding, human food by-products for use as animal food must be accurately identified. * Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed. * Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the	N/A	No by product is sent out for animal feed.

		human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		
25	15.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart. One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.	Y	PCQI developed the Food Defence Plan & Security Policy dated Aug 23, 2018, along with back up PCQI and management team. Technical Manager (PCQI) in conjunction with General Manager is responsible for food security.
26	15.3.2	The site shall have a written food defense plan, which includes the following: • A vulnerability assessment identifying significant vulnerabilities and actionable process steps • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification	Y	PCQI developed the Food Defence and Security Policy QP-4.2.1.Y dated Aug 06, 2018.
27	15.3.3	A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum): • Scale and severity of threat if a contaminant is added to product • Degree of physical access to the product	Y	Vulnerability assessment is completed on Aug 01, 2018 and documented in "Vulnerability Assessment QP-5.4.2. Rev 3 and covers all the requirements of standard, employees and various other factors are considered.

		• Ability of an attacker to successfully contaminate product—including consideration of an inside attacker A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.		
28	15.3.4	Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment. Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability.	Y	Vulnerability Assessment explained the mitigation strategies, i.e. controlled access to chemical, pre-screening of employees before, restricted access to the building.
29	15.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies. Procedures shall include recordkeeping requirements for all monitoring activities.	Y	Written monitoring instructions are present in Food Defence and Security Policy QA 4.2.1M Rev 11 dated Aug 06, 2018. Monitoring activities are recorded on Site Security Monitoring Log –Production.
30	15.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria: • Method for identifying and correcting a lack of implementation • Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective actions		Written corrective action instructions are present in Food Defence and Security Policy and on Monitoring Log QA 4.2.1Y Rev 11 dated Aug 06, 2018. Corrective actions will be recorded on Site Security Monitoring Log – Production.

31	15.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to verify implementation of mitigation strategies. Verification procedures shall include: • A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days) • Other verification activities as appropriate (e.g., internal audit) • Method for verifying that reanalysis of the food defense plan was conducted • Frequency for verification activities • Recordkeeping requirements of all verification activities	Y	There were written verification requirements for records and programs in document Food Safety Varication /Validation dated July 13, 2015 and FSMA Self-Assessment Tool dated Aug 06, 2018.
32	15.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever • A change in facility operations which creates a new significant vulnerability • Knowledge about a new threat applicable to the food or facility becomes known • Mitigation strategies are not implemented as intended • FDA requires reanalysis based on new threats or scientific evidence	Y	Facility review Food Defense Plan annually and whenever a new threat discovered, if mitigation strategies are not working etc as explained on the Food Defence and Food Security Policy QP 4.2.1Y dated Aug 06, 2018.

33	15.3.9	All records required by 21 CFR § 121 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable	Y	All records have date and time of activity, signature. Reviewed records Chemical Monitoring Log dated Aug 06, 2018 and Aug 14, 2018.
34	15.3.10	The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.	N	Food Defence Plan was not signed by General manager
35	15.3.11	All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.	Y	Facility had Document & Data Control QA-3.2.1Y dated July 31, 2017, states records are kept at the facility for 2 years
36	15.4.1	Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used. A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.	Y	Forklifts are used inside the facility are inspected on regular basis to ensure they meet cleanliness requirements. Trucks are arranged by Third party company and is inspected by facility before loading and recorded on Truck inspection log reviewed records dated Aug 20, 2018 and Aug 22, 2018.

37	5.4.2	The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary Transportation rule. Where the site acts as the shipper or receiver, it shall ensure compliance with the rule. Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.	N/A	Third party marketing company arrange the transportation. It is written in the procedure Transportation and Delivery QP 4.16.1. when truck is loaded First Fruit is responsible for the product
38	15.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier. Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.	N/A	Third party marketing company arrange the transportation. It is written in the procedure Transportation and Delivery QP 4.16.1. when truck is loaded First Fruit is responsible for the product
39	15.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.	N/A	Third party marketing company arrange the transportation. It is written in the procedure Transportation and Delivery QP 4.16.1. when truck is loaded First Fruit is responsible for the product.
40	15.4.5	Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether	N/A	Third party marketing company arrange and manage transportation.

		the food was subject to temperature abuse.		
41	15.4.6	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. • Sanitary condition of vehicles and transportation equipment • Following shipper's sanitary specifications (including pre-cooling requirements where applicable) • Recording compliance with operating temperature where critical to food safety • Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper	N/A	Third party marketing company arrange the transportation. It is written in the procedure Transportation and Delivery QP 4.16.1. when truck is loaded First Fruit is responsible for the product.
42	15.4.7	Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers • Awareness of potential food safety problems that may occur during food transportation • Basic sanitary transportation practices to address those potential problems • Responsibilities of the carrier	N/A	Third party marketing company arrange the transportation. It is written in the procedure Transportation and Delivery QP 4.16.1. when truck is loaded First Fruit is responsible for the product.
43	15.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.	Y	Facility keep records at the site for minimum 2 years. All the records are retrievable within 24 hours.

44	15.4.9	The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours.	Y	Facility had program in place to inspect the carriers and ensure they are clean and capable of transporting product within required parameters. Truck inspection Log is completed all the shipments reviewed records dated Mar 30 , 2018 and Sept 05, 2018. All records are kept at site for 2 years.
45	15.5.1	Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following: • Principles of food hygiene and food safety Produce safety standards applicable to an individual's job	Y	GMP Training is provided to all employees before handling the product.
46	15.5.2	Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following: • Recognizing produce contaminated with known or reasonably foreseeable hazards • Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment	Y	Job specific training is provided to employees before handling the product reviewed training records.
47	15.5.3	One or more supervisors or individuals responsible for the operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA.	Y	PCQI Training was completed by Technical Manager and Assistant Technical Manager.
48	15.5.4	A supervisor shall be identified with responsibility for the operation	Y	Technical Manager is responsible to ensure

		and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.		compliance with regulatory requirements, it is described on the job description of Technical manager and technical manager is identified on Organization chart.
49	15.5.5	Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.	Y	All employees are required to wash hands before entering processing floor, wear gloves when handle product.
50	15.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce. Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.	Y	City water is used for washing the fruits and water is tested monthly by the facility and annual test report from city was on file, last water test was done on Aug 16, 2018 and found satisfactory.
51	15.5.7	Agricultural water treatment must be delivered and monitored at a frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable generic Escherichia coli (E. coli) in 100mL.	N/A	Facility does not use any agricultural water.
52	15.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.	Y	Reviewed water test dated Aug16, 2018 and meets the regulatory requirements.

53	15.5.9	Where agricultural water does not meet microbial quality criteria or is determined to be unsafe and not of adequate sanitary quality, water use must be discontinued along with treatment or other correction that reestablishes sanitary quality and microbial criteria. Where water treatment is not performed, re-inspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or food contact surfaces, correction, and verification of correction to ensure water meets microbial quality criteria.	N/A	Facility does not use any agricultural water.
54	15.5.10	Agricultural water testing may be performed by the site (or site representative) or by a third party provided representative samples of the site's water source is secured. Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency (EPA), ‘‘Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA–821–R–09–007),’’ December, 2009 or equivalent method.	N/A	Facility does not use any agricultural water.
55	15.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris).	Y	Water used at the facility for washing is monitored continuously and replaced at regular intervals, peracetic acid levels are monitored in the water and water is tested monthly reviewed dated Aug 23, 2018

		Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce.		
56	15.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.	Y	Any fruit touches the ground is trashed as verified during facility tour.
57	15.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces.	Y	Sewage disposal is separate and no issues observed.
58	15.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.	Y	Facility had 2 back flow preventers which are tested annually last test was done on Aug 20, 2018.
59	15.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.	Y	All food safety records are reviewed within 24 hours as per policy.
60	15.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours. Records related to equipment or processes used by the site for analyses, sampling, or action plans—including the results of scientific studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued.	Y	Records are retained for 2 years in the facility and are accessible within 24 hours.
61	15.5.17	Specific additional requirements for the harvesting, packing, and holding of sprouts.	N/A	Facility does not do sprouts.

		Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes. The environmental monitoring plan shall include the following criteria: • Target test (i.e., Listeria spp. or L. mono) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are samples collected) • Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces) The plan shall describe aseptic methods for sample collection and testing according to FDA's ‘‘Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples,’’ Version 1, October 2015 (or equivalent).		
62	15.5.18	Specific additional requirements for the harvesting, packing, and holding of sprouts. The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono. If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process: • Resample positive surfaces and the surrounding area to determine the extent of contamination	N/A	Facility does not do sprouts.

		• Clean and sanitize the affected and surrounding areas • Resample and re-test to confirm the elimination of Listeria spp. or L. mono • Conduct finished product testing as appropriate • Take additional action to prevent recurrence and to prevent adulterated food from entering commerce		