INVERTEC NATURAL JUICE S.A.

Audit Report

1.Audit Summary			
Company name	INVERTEC NATURAL JUICE S.A.	Site Code	3612552
Site name	INVERTEC NATURAL JUICE S.A.		
Scope of audit	Pasteurisation of concentrated juice and puree from: Apples, pears, plums, prunes, kiwi, berries, grapes, asparagus, beets, bell peppers, cherries, peaches, celery, petivert, mushroom, onion, kale, spinach, chard, cabbage, colchina, pumpkin, tomato and carrots. Packaged in plastic bags inside drums, tote bins, flexi tanks or plastic pails		
Exclusions from scope	None		
Justification for exclusion	N/A		
Audit Start Date	2020-11-30	Audit Finish Date	2020-12-02
Re-audit due date	2021-11-30	Head Office	No

Additional modules included			
Modules	Result	Scope	Exclusions from Scope
FSMA Preventative Controls and FSVP Preparedness	Passed	Pasteurisation of concentrated juice and puree from: Apples, pears, plums, prunes, kiwi, berries, grapes, asparagus, beets, bell peppers, cherries, peaches, celery, petivert, mushroom, onion, kale, spinach, chard, cabbage, colchina, pumpkin, tomato and carrots. Packaged in plastic bags inside drums, tote bins, flexi tanks or plastic pails.	
Choose a module	Choose an item		

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	AA	Previous audit date	2019-05-30		
Certificate issue date	2021-02-12	Certificate expiry date	2022-01-11		

2. Audit Results

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

3.Company Details

Address	Avenida Carlos Condell N° 1899, Rengo, Región del Libertador Bernardo O'Higgins, Chile.		
Country	Chile	Site Telephone Number	+56 72 2741000
Commercial representative Name	Paulo Aceituno	Email	paceituno@invertc.cl
Technical representative Name	Manuel Tobar	Email	mtobar@invertec.cl

4.Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	51-500	No. of HACCP plans	1-3
Shift Pattern	3 productive shifts. 24 hours per day. 6 days per week. Sunday with no production shift.				
Subcontracted processes	No				
Other certificates held	Kosher and Organic				
Regions exported to	Asia North America South America Choose a region Choose a region Choose a region				

4.Company Profile

Company registration number	19556254152
Major changes since last BRCGS audit	No Major changes since last BRCGS audit

The company has its origins in the development of Montanari Companies, who started its activities in 1937 in Chile, building and managing important Industrial Plants, such as; Cimet Sindelen, Hunter Douglas, IPAC, Alumco and Veneval among others.

In the Agro-industry area, Invertec participates since 1988 through its parent company for this area INVERTEC FOODS, in 1997 INVERTEC NATURAL JUICE and in 2004 INVERTEC FROZEN FOODS. INVERTEC it´s an Agro-industrial conglomerate, strategically located in the Central Valley of Chile, its productions is focused in dehydrated fruit and vegetables and also their concentrated juice.

INVERTEC FOODS patrimony, NATURAL JUICE and FROZEN FOODS is composed of both INVERTEC capitals, with 82, 83% of shares and capital investment funds from Inversiones “Llaima” with 17,97%. INVERTEC majority market are ASIA and USA.

Production volume is 13120 tons of juice of vegetables and fruits.
FDA Registration number: 19556254152.
Chilean food processing authorization: Number 3754 from 2010, September, 21.

Reset audit date.

5.Product Characteristics

Product categories	07 - Dairy, liquid egg 12 - Beverages Category Category
Finished product safety rationale	Fruit juices with pH 3.1 - 4 and >60 ° Brix and vegetable juices with pH 4 - 6 and >34 ° Brix. All the products are filtered (1 mm) and pass through concentration at least 75°C, including fruits and vegetables puree.

High care	No	High risk	No	Ambient high care	No

Justification for area	The product corresponds to frozen vegetables and fruits, without history of pathogen growth and no cooking process.

5.Product Characteristics	
Allergens handled on site	Celery 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 certification granted by ECOCERT.
Product recalls in last 12 Months	No
Products in production at the time of the audit	Colchina Juice

6.Audit Duration Details			
On-site duration	20 man hours	Duration of production facility inspection	10 man hours
Reasons for deviation from typical or expected audit duration	+ 4h FSMA		
Next audit type selected	Announced		

Audit Duration per day			
Audit Day	Date	Start Time	Finish time
1 (start date)	2020-11-30	09:00	19:00
2	2020-12-01	08:00	19:00
3 (Finish date)	2020-12-02	08:00	13:00

	Auditor number	Name	Role
Auditor Number	176823	Marco Moreno	Lead Auditor
Second Auditor Number	N/A		Please select

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 1.1.11)				
Name/Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Manuel Tobar / Head of Control and Quality Management	X	X	X	X
Mauricio Moya / Plant Chief	X	X	X	X
Paulo Aceituno / Factory Manager	X	X	X	X
Pablo Meza / Head of Quality Assurance	X	X	X	X
Gustavo Urzua / Production Manager		X	X	
Elizabeth Jorquera / Head of Laboratory		X	X	
Rodrigo Salas / Sub manager of logistics and acquisitions		X	X	
Tomas Burgos / Sub Manager of Human Resources		X	X	
Ignacio Caro / Warehouse responsible		X	X	
Jorge Maldonado / Maintenance		X	X	

GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced
30 November 2020	BRCGS Food 8	Announced

Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No	Clause	Detail	Critical or Major	Ant. re-audit date

Critical			
No.	Clause	Detail	Ant. Re-audit date

Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	2.6.1	For Prune's juice product, although not an acrylamide hazard identification was required, although there are finished product controls.	To close the nonconformity meets haccp equipment, it is decided to add acrylamide in the hazard analysis.	HACCP team will meet every 4 months to assess unidentified hazards in the analysis.	The cause of the problem was because the hazard analysis of prune juice was widespread, not all associated hazards offining acrylamide were specified	2020-12-20	MMU

Minor							
					with remote probability according to the history of analysis performed on finished product.		
2	3.4.2	Risk assessment for the definition of audit frequency 2020 does not consider the risks of the organization's activities and processes	Quality assistant manager meets with head of quality assurance to consider the risks associated with the organization's activities and processes for defining the frequency of upcoming auditors.	Any activity will be analyzed by HACCP team to determine the level of risk that allows to set the frequency of the audit	Other aspects were considered for the assessment that did not include the risks associated with the activities.	2020-12-20	MMU
3	3.9.3	For the traceability exercise performed during the audit, the mass balance was not completed.	Quality Assistant Manager meets with head of planning to review nonconformance, analyze root cause and improvements to be developed.	In future traceability, the Head of Planning will verify that the mass balance is done in full.	The root cause of the problem was because the balance was massed only with the information	2020-12-20	MMU

Minor							
					associated with the chosenbatch, SAP system makes it difficult to perform the mass balance.		
4	4.2.1	While water wells were identified as sensitive areas in the vulnerability analysis, no action has been taken to protect the plant's water supply wells.	Non-conformity is reported to the plant manager and maintenance assistant manager to install protection on the perimeter of the well.	GMP during plant perimeter review will verify well perimeter protection.	Company is in the stage of expansion and modification, the protection to the well was removed for work in the sector.	2020-12-20	MMU
5	4.11.7.4	The definition of the frequency of the IPC 2020 monitoring programme was not based on a risk assessment.	Quality Assistant Manager coordinates meeting with plant manager, maintenance assistant manager, laboratory head and quality assurance manager to define the frequency of the CIP system based on risk assessment.	Updated instructions for operation of the CIP system, verification that the cleaning cycle is effectively fulfilled, control that good results are obtained.	The definition of the frequency of the IPC was determined by microbiological results.	2020-12-20	MMU
6	5.6.2.3	For the analysis of patulin carried out in the laboratory of the plant, although it is	Quality assistant manager with Head of Laboratory review the principles of	Head of laboratory will periodically verify that the patulin analysis is	The patulin analysis		

Minor							
		aligned with an international AOAC standard for the analysis of this compound; alignment with the principles of ISO/IEC 17025 was not demonstrated.	ISO/IEC 17025 to align the analysis of patulin that is carried out in the plant laboratory.	aligned with the principles of ISO/IEC 17025	aligned with AOAC's international standards had not been considered ISO/IEC 17025 on the understanding it was covered.		
7	6.4.1	There is no evidence of calibration of the conductivity meters used for the control of the CIP processes of lors concentrators 3 and 4.	Maintenance assistant manager coordinates the calibration of the conductivity meters.	A cadaster of all measuring equipment requiring calibration is performed to prevent uncalibrated devices from remaining.	The traffic meters had not been calibrated as newly installed equipment.	2020-12-20	MMU

Comments on non-conformities

Comments

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No	Clause	Detail	Re-audit due date

Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	13.1.13	Verification of PCC monitoring was delegated to the head of laboratory who did not have PCQI, i.e. has not met the requirement to participate and approve the cursor FSCPCA.	Verification will be performed by personnel who are PCQI.	Anyone who verifies CCP's rules will previously have a course approved to be PCQI, Quality Assistant Manager will review that training has been carried out by validated entity.	Requirement 6.4.1 was misinterpreted, the person performing verification received training from an individual who passed FSCPCA course, the verifier was not PCQI.	2020-12-20	MMU

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

Invertec Natural Juice S.A. management team, is committed to meeting global food safety standard, such as maintenance and improvement of their performance, were reviewed:

- Quality policy code I-GEN-001, revision 03 of 06-03-2019, signed by plant manager, Mr. Paulo Aceituno, communicated in staff induction and reinforced by publications in different places of the company (wall newspapers, casino , and sanitary filters).

- Work plan of the management team of January 2019, which is led by Mr. Paulo Aceituno (General Manager), which includes:
    - Ensure compliance with quality standards during
        - 2019: Fulfilled 100%
        - Natural KPI: 0.98
    - Ensure Food safety of products during the year 2019
        - 100% fulfilled
        - There was no customer recall, no safety claims or returns received.
    - Ensure compliance with the legal aspects of the destination markets of the production corresponding to the year 2019.
        - 100% fulfilled
        - He had no fines, incidents associated with deviations from legal aspects.
    - Ensure compliance with the implementation of corrective actions corresponding to third party audits.
        - 100% fulfilled
        - All non-conformities are closed

The objectives are reviewed with monthly frequency.

Managerial review of 2020 of 03-04-2020, that included reviewed of:

- Review of management system policy (No changes).
- Management system Objectives 2019 (Compliance with all the defined objectives is evidenced).
- Status of corrective and preventive actions.
- Result of audits carried out during the year 2018 (internal, external and customer).
- Feedback from the client, interested parties (complaints and claims). Claims management.
- Customer feedback, stakeholder opinion questionnaire.
- HACCP/BRC plan.
- Capacitation program.
- Identification of resource availability.
- Management review agreements.
- Review by the address is done with the established frequency.
- Meetings program made with monthly frequencies, from:
    - 15-01-2020.

- 19-02-2020.
- 12-03-2020.
- 08-04-2020.
- 11-05-2020.
- 17-06-2020.
- 08-07-2020.
- 05-08-2020.
- 09-09-2020.
- 03-10-2020.

-
- Company has a telephone number that allows staff to communicate problems related to the safety, integrity, quality and legality of the product in a confidential manner, the number is published in a mural diary. There is no evidence of complaints from the implementation to date.
- In order to ensure the availability of resources, an Investment Plan for 2020 was evidenced, that includebeteen others:
  - Improve concentrator 1 and 2 trough union of 2 equipments and improve equipment performance.
  - Improve condition of feeding lines of raw material
  - Others
- Identification of scientific developments, participation in seminars and information provided by clients and suppliers are evident. There is evidence of new developments in team meetings with monthly frequency. The company is affiliated to Chilealimentos is the Association of Food Companies of Chile, a private entity of trade union nature, which gathers and represents companies of processed foods.
- Annual subscription is evidenced, in PARTICIPATE - BRC, of user: Manuel Tobar.
- The participation of Mr. Julio Necochea; Mauricio Moya (Plant Manager) is evident, present in start-up and closure meetings.
- Corrective actions implemented from previous visit are evidenced (Refer to non-conformities to clauses detected in 2019 BRCGS version 8.0).
- Organization does not use the certification mark, however it is evident that the following documents are kept under control:
- SGS Chile limitada - Code of Practice.
- Regulations governing the use of certification marks of SGS management systems.
- BRC Global Standards Directory Logo Guidelines.
- Presentation of SGS - Use of SGS certification marks

1.2 Organisational structure, responsibilities and management authority

Organization has defined and maintained an organizational structure for compliance and management requirements BRC version 8, were reviewed:

- Organizational chart of the organization which reflects the hierarchical level of the organization, communicated during inductions.
- Responsibilities regarding quality, legality and innocuity are defined in charge descriptors by those responsible. The descriptors contemplate the subrogance of charges.

The descriptors are known by the employees, which are communicated in inductions and in copies delivered for each position.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification

2 The Food Safety Plan – HACCP

Food Safety plans are based on the principles of Codex Alimentarius, scientific evidence, legal requirements, and customer requirements:

- HACCP team competences are reviewed, for the members:
  - Manuel Tobar G. (Quality management Manager);
    - ✓ Engineer in Administration.
    - ✓ Training in BRC 8 of 8 hours, from 09-05-2019.
    - ✓ Continuous Thermal process Trainee August 31 to September 1, 2020.
    - ✓ FSPCA training course (July 2016)
    - ✓ 18 years worked in the industry.
  - Elizabeth Jorquera (Head of laboratory).
  - Julio Necochea (Plant Manager)
  - Miguel Moya P. (Chief of Electrical Maintenance).
  - Gustavo Urzúa (Production Manager).
  - Pablo Meza P. (Head of Quality Assurance) (PCQI).
    - FSPCA training course certificate # 3fd35072 (July 2016) .
  - Carolina Valdés (Head of Microbiology).
  - Paula Gandarillas Corral (Customer Service Supervisor).
- Scope of the HACCP plans: The scope of HACCP Plans considers the processes of Reception, Selection, Packing, Cooling, Storage, and Delivery to Port of the products: Concentrated juice of fruit and vegetables, of the species: Apples, pears, plums , prunes, kiwis, berries, grapes, asparagus, beets, bell peppers, cherries, peaches, celery, PetiVert, Kale, spinach and carrots.

- Hazard analysis have been considered the control measures implemented to ensure a hygienic production environment, were reviewed:

  - Manual GMP code I-MM-GEN-002,
  - Hygiene and disinfection procedure - General method of cleaning and disinfection (MGL + D), code I-IT-L & S-001,
  - Hygiene and disinfection procedure - Unscheduled cleaning and disinfection order code I-IT-L & S-003,
  - Manual of pest control code I-MAN-PLG-001,
  - Instructive pest control code I-IT-PLG-001,
  - Instructive insect traps lamps (TUV), code I-IT-PLG-002,
  - Instructive control of catches of birds code I-IT-PLG-003,
  - Nest control instructions code I-IT-PLG-004,
  - Instructive mechanical control of weeds code I-IT-PLG-005,
  - Instructive control of rodents in trapping stations code I-IT-PLG-006,
  - Instructive control of rodents in baiting stations code I-IT-PLG-007,
  - Building maintenance instructions code I-IT-MAN-032,
  - Manual predictive maintenance code I-MN-MAN-001,
  - Instructive hygiene and personal presentation code I-IT-ACL-007
  - Personnel training procedure code I-PR-GEN-005,

- Instructive induction to personnel code I-IT-RRHH-002,
- Procedure for procurement operations area code I-PR-ADQ-001,
- Instructive risk of contamination by glass and hard plastic code I-IT-ACL-011,
- Instructive risk of contamination by glass code I-IT-MAN-008,
- Allergen control procedure code I-PR-GEN-004.

Information used to carry out hazards identifies scientific literature, hazard probability trends, origin markets legislation and customer requirements. A digital folder of scientific evidence is reviewed

Each product a specification has been established, were reviewed:

- Product description:
  - Processed products in Natural Juice Plant:
    - Apple clear Wa <0.70, pH <3.2 - 3.4, Brix 68 - 71.
    - Beets clear Wa <0.70, pH <4.5 - 5.5, Brix 64 - 68.
    - Raspberry clear Wa <0.82, pH <2.8 - 3.6, Brix 67 - 69.
    - Strawberry clear Wa <0.82, pH <3.1 - 3.6, Brix 64 - 68.
    - Blackberry clear Wa <0.82, pH <2.5 - 4.5, Brix 64 - 68.
    - Plums clear Wa <0.75, pH <2.7 - 3.7, Brix 64 - 68.
    - Blueberry clear Wa <0.82, pH <3.0 - 3.8, Brix 64 - 68.
    - Asparagus cloudy Wa <0.95, pH <4.0 - 6.0, Brix 39 - 41.
    - Petitvert cloudy Aw <0.95, pH <5.5 - 7.5, Brix 36 - 40.
    - Bell peppers Wa <0.95, pH <4.0 - 5.5, Brix 36 - 40.
    - Celery cloudy Wa <0.65, pH <4.5 - 6.5, Brix 29 - 30.
  - Primary packaging: Product packed in polyethylene bags or aseptic bag.
  - Secondary packaging: metallic drums from 55 to 60 gallons.
  - Useful life: 24 months in storage conditions, indicated.
  - Storage conditions: It must be stored under temperature conditions between 0 to 7ºC or -18ºC depending on the product.
- Expected use:
  - Vulnerable group: People allergic to celery (the plant does not export to Europe, there is only one customer for celery that is in the US, where celery is not an allergen).
  - Intended use is industrial consumption of natural juice with the addition of water.

Flow diagrams, which have been verified by the HACCP team:

- Processed products in Natural Plant verified between January to June 2020:
  - Apple juice clear (26 phases),
  - Raspberry juice clear (22 phases),
  - Strawberry juice Clear (23 phases),
  - Blackberry juice clear (22 phases),
  - Blueberry juice clear (22 phases),
  - Cherry juice clear (22 phases),
  - Plums juice clear (22 phases),
  - Peach juice (22 phases),
  - Grape juice clear (20 phases),
  - Kiwi juice clear (22 phases),
  - Beets juice clear (23 phases),
  - Carrot juice cloudy (23 phases),
  - Bell peppers cloudy juice (22 phases),
  - Asparagus juice cloudy (20 phases),
  - Petit vert juice cloudy (20 phases),
  - Celery juice cloudy (21 phases),
  - Apple juice cloudy (20 phases),

- Plums juice cloudy (22 phases),
- Pears juice clear (25 phases)
- Cabbage juice (20 fase),
- Colchina juice (20 fase),
- Pumpkin juice (20 fase),
- Chard juice (21 phases),
- Tomato juice (21 phases),
- Spinach juice (21 phases),

- Pure kiwi, raspberry, apple, strawberry, blueberry, cherry, prune, blackberry, verified on between January to June 2020.

Hazard Analysis and determination of CCP:

- Following Hazards have been identified:
  - Physical: Metal particilas and remains of containers.
  - Chemicals: Patulin, Pesticides and Heavy metals.
  - Biological: E. Coli and Salmonella.

Criteria applied to determine hazard effects:

- Risk analysis performed in line with NCh 2861, considering the following information:
  - Criteria applied for determining hazard effect, i.e. severity/likelihood.
    - Severe: permanent disability, death or loss of body parts.
    - Significant: injury or illness with no disabilities involved.
    - Moderate: mild injury or illness.
    - Minor: no injury or illness.
  - Criteria for determining likelihood of hazard.
    - Certain: more than twice a year.
    - Likely: once or twice every 2 or 3 years.
    - Possible: Once or twice every 5 years.
    - Unlikely: it might occur sometime.
  - Criteria for determining significant hazards (severity x likelihood):
    - Significant:
      - Severe x possible, likely, possible, and unlikely.
      - Significant x possible and unlikely.
      - Moderate x certain.
    - Non-significant:
      - Severe x moderate and minor.
      - Moderate x likely, possible, and unlikely.
      - Minor x certain, likely, possible, and unlikely.

Organization used Codex Alimentarius decision tree found on the to determine CCP.

CCP determination, analysis is performed using CODEX decision tree raised, hazard analysis identified:

- Methodology applied by the organization has identified the following critical control points:
  - CCP 1: Patulin chemical hazard, in the selection table phase.
    - Critical limit: <5% of fruit admitted to rotten production. Patulin <50 ppb of patulin and <10 ppb of patulin in baby foods.
    - Monitoring: Measurement of fruit rot percentage after the selection line, every 4 hours and at the end of each process.

- Corrective measures: Inform the supervisor of the grinding area, stop the passage of the product and remove the rotting fruit with the selection belt stopped, segregate the processed product from the last correct measurement and identify as product under observation, Re-establish the process and verify normal conditions of operation.
- Records: Selection control

- CCP 2: Biological biological hazard E. coli 0157: H7, in concentrated phase.
  - Critical limit: Minimum 75 ° C (operating limit of 80 ° C x maximum flow of 85%.
  - Monitoring: Concentration and temperature flow every 2 hours.
  - Corrective Measures: Inform the supervisor of the concentrate area, stop the product passing through, segregate the processed product from the last correct measurement and identify it as a product under observation, adjust the concentrator's operating parameters to meet the critical operating limits, once the process is re-established verify the normal operating conditions of the equipment.
  - Records: Evaporation record

- CCP 3: Physical hazard foreign objects above 7 mm and 2 mm for baby food, everything is filtered with filters of 1 mm, in filtered phase.
  - Critical limit: Integrity of the filter.
  - Monitoring: Preliminary and subsequent inspection of the filter for each packaged batch.
  - Corrective measures: Inform the supervisor of the packaging area, segregate the packaged product for reprocessing, replace the defective filter.
  - Records: Filter control record.

- CCP 4: Biological hazard E. Coli 0157: H7, in the pasteurization phase of puree.
  - Critical limit:Temperature and flow control according to the lethality table by product.
  - Monitoring: Flow and temperature every 2 hours.
  - Corrective Measures: Inform the supervisor of the concentrate area, stop the product passing through, segregate the processed product from the last correct measurement and identify it as a product under observation, adjust the concentrator's operating parameters to meet the critical operating limits, once the process is re-established verify the normal operating conditions of the equipment.
  - Records: Tasteurizator record.
- CCP 5: Danger of adulteration of the finished product, in the phase of product dispatch.
  - Critical limit: 100% Integrity of product stamps.
  - Monitoring: Visual inspection of filter integrity for all containers.
  - Corrective Measures: Inform the finished product warehouse supervisor, stop the dispatch and segregate the compromised product, release or cancel the product as appropriate,
  - Record: Dipatched Control Record
- Monitoring records are verified, verified by means of signatures which it considers, the control over the realization of the monitoring, the taking of corrections in the cases of deviations and the generation of non-conforming products, monitoring of CCP monitoring.

- Critical control point monitoring is reviewed, to:
  - CCP 1: Selection control record N-RG-HACCP-010 for lines 4, 5 and 6 were evidenced :
    - From February to October of 2020, no issues were detected.
  - CCP 2: Concentrator temperature and flow control record N-RG-HACCP-014 (evaporator 4); N-RG-HACCP-001 (evaporator 1,2 and 3) of:

- From February to October of 2020, no issues were detected.
- CCP 3: Filter integrity control record N-RG-HACCP-003 were evidenced:
  - February to September 2020 no issues were detected
- CCP 4: Pasteurization record of:
  - From February to October of 2020, no issues were detected.
- CCP 5: Record control dispatch Bedrum and tote bins of:
  - From February to October of 2020, no issues were detected.

Corrective actions are defined in the HACCP plans.

Validations performed by the HACCP team are evident:

- Validation of control points:
  - CP 1, Presence of pesticides in reception phase of 24-05-2019, carried out through pesticide analysis review of 2017-2020 (28 analyzes of raw materials and 32 analyzes of finished products).
  - CP 2, Reduction of E. Coli in chlorination phase washing tubs March 2013.
- Validation of critical control points:
  - CCP 1 of 24-05-2019, through analysis 2017-2020 indicates that the finished products are under 20 ppb of patulin.
  - CCP 2 and 4 of March 2008, carried out through thermal process validation.
  - CCP 3 of 18-05-2012 an evaluation of filter brakeage detection effectiveness was doing, that was effective. Additionally, from 2012 filters were maintained without breakages.
  - CCP 4 of 03-03-2014, made by validation of thermal process.
  - CCP 5 of 03-01-2019, made by exercising in the field.

Verification system activities are contemplated when:

- Verification activities of the system include: Checks of CCP monitoring, with daily frequency, checks of monitoring of BPM, finished products analysis results, carried out by Head of Quality Assurance and Internal Audit.
- Update of HACCP plans, is carried out by the team last revision of 13-06-2020.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

3. Food safety and quality management system

3.1 Food safety and quality manual

Quality manual, meets its intended purpose, evidenced in document reviewed and during audit, were reviewed:

- Quality manual, code I-MN-GEN-001, revision 07 of 09-06-2020.
- All documents are digital and paper ready for consultation by key personnel.
- Clauses mentioned in the quality manual were aligned with BRC 8.0 standard, with aim of ensuring communication of system implementation.
- P|rocedures are available on a web platform and printed for staff consultation.

People who do not have email and / or do not have access to the Web Platform, have access to hard copies of documents. During the visits to the facilities it is evident that the documents are available for consultation.

3.2 Document Control

A effective document control system is evidenced, observed during the process and documents consulted during the development of this audit, is reviewed evident:

- Document control procedure code I-PR-GDT-001, revision 05 of 27-01-2020, is revised:
  - Master list of documents and records Code I-RG-GDT-001.
  - Method of identification and authorization of controlled documents.
  - Records of the reasons for any change or modification of documents (Clause 6).
  - External documents control.

3.3 Record completion and maintenance

Recordkeeping procedure was observed during process and records reviewed, were evidenced:

- Control of records procedure code I-PR-GDT-002, revision 04 of 27-10-2020, that includes:
  - Records handling was mentioned in each system document and records control by areas. Authorization of records is carried out by the records verifiers for each department of the company.
  - Amendments records control was mentioned in clause 4.4.3 of procedure I-PR-GDT-002 (Amendments were not evidenced in a way other than that mentioned).
  - Electronic formats are maintained in safe conditions, restricted access and change control
  - Backup copies are made to avoid loss.
  - Records are saved considering the product shelf life, plus twelve months

3.4 Internal audits

Effective verification of processes required by the BRCGS version 08 is evidenced, was reviewed:

- Procedure internal audits of management system code I-PR-GEN-002, revision 03 of 17-06-2020, which includes: Audit program for the year 2020-2021, which includes programming of 4 audits throughout the season products included in the scope (Development of its activities). Risk analysis for frequency determination audits code I-DC-GEN-015, revision 004 of 08-06-2020
- Internal Audit program was established with 1 audit per Chapter for 2020-2021 season I-DC-GEN-001 version 5.
- List of internal auditor's code I-DC-GEN-002, revision 005, date 05-04-2019 the powers of:
  - Maria Carolina Valdes Baros
  - Milena Soto Fuentes
  - Pablo Meza

- Ornella Carrasco Olivares
- Angelo Gangas

Training in BRCGS issue 8 and internal auditor records were evidenced, about Internal Audit record training at 2015 and update in BRCGS version 8 on April 11 and May 10, 2019

- Internal audit reports of:
  - April from 03 to 20, 2020 for clauses 01 of the BRC standard (0 non-conformity).
  - April from 03 to 20, 2020 for clauses 02 of the BRC standard (0 non-conformity).
  - April from 07 to 23, 2020for clause 03 of the BRC standard (0 non-conformity).
  - May from 14 to 29, 2020 for clauses 04 of the BRC standard (02 non-conformities).
  - June from 03 to 15, 2020 clause 05 (1 non-conformity)
  - June from 13 to 15, 2020 clause 06 (1 non-conformity)
  - August from 4 to 15, 2020 clause 07 (0 non-conformity)
  - June from 13 to 25, 2020 clause 13 (0 non-conformity)

- All non-conformities have been addressed by process owners and manged according to corrective actions procedure.

- In addition to Audit program, inspection Program was defined, that include a monthly frequency of inspections of processes and facilities records of august to November 2020 were reviewed.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

An approval, raw materials suppliers monitoring and packaging material effective system is evidence according to Suppliers Evaluation and approval procedure I - PR- ADQ- 002 revision 7 21-03-2019, it is reviewed:

- Evaluation of risks of raw materials, supplies and packaging material in contact and non-contact, is reviewed:
  - Analysis of raw materials, for fruits coming from fields, supplies and materials in contact, is carried out in Hazard Analysis by process stages in HACCP plans.
  - Raw materials Risk Evaluation of 18-03-2020.
  - All fruit raw material suppliers have been considered as high risks, and materials in contact and inputs as low risk.
- Implementation of the evaluation criteria defined in Procedure Approval and Evaluation of suppliers code I-PR-ADQ-002, revision 007 of 21-03-2019, were evidenced:
  - Control of raw materials, carried out by the Agricultural Department, controls are reviewed:
    - List of suppliers of raw materials 2020, with a total of 39 suppliers, the compliance of approval process of following suppliers Audit reports 2020 were verified:
      - Audit report Jorge Ahumada Valderrama
      - Soc. Agricola Palma
      - Sociedad Agricola Valcam
      - Soc.Agricola Palma Ltda.
      - Invertec Agrofood S.A., GlobalGap Certificate GGN 4049928401557, Valid Until March 21,2021.
    - supplier auditing program of:
      - 13-02-2020 to Supplier Cartocor supplier of cases.
      - 15-01-2020 to Supplier Plásticos Bio-Bio supplier of bags.
      - 24-02-2020 to Supplier Corplastic supplier of bags.
      - 24-02-2020 to Supplier Corplastic supplier of bags
      - 24-02-2020 to Supplier Rheem supplier of drums.
- No purchase of raw materials is made to agents or brokers. Direct purchases are made to producers.
- Traceability for raw materials fruit and vegetables is guaranteed by the Agricola department of Invertec and for materials in contact, traceability exercises considered in surveys are carried out.
- Exceptions are defined Suppliers Evaluation and approval procedure I - PR- ADQ- 002 revision 7 21-03-2019. It is contemplated for purchases in case of lack of fruit for the fulfillment of programs committed to customers or sales offered directly by suppliers not considered in the list

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Controls to prevent the entry of raw materials and packaging material that does not meet the specifications defined by Invertec Natural Juice S.A. are evidenced, is reviewed:

- Manual for management of suppliers and raw materials code I-MN-MPR-002, revision 05 of 18-11-2020. It is evident that the organization has an agricultural department for the control of producers of raw materials and Sub-Management of Logistics and acquisitions for the control of materials in contact, with evaluations based on the risk with compliance with the requirements of clause 3.5.1.2. of the BRC.
- Controls for raw materials, materials in contact and supplies are defined in HACCP plans and for other requirements, are described in the rules by species, are reviewed:
- Procedure for receipt of supplies code I-IT-BOD-001 revision 03 of 25-04-2019.
- Reception procedure and weighing of raw material code I-IT-BYC-001, revision 03 of 24-04-2019.
- Manual of raw materials I-MN-MPR-002 Manual of raw materials, revision 004 of 07-04-2019.
- Registration of receipt of raw materials with inspections of samples, from:
    - Reception records June to November 2020 of granny apples, tomato, Colchina, red pepper were evidenced.
    - Reception records June to November 2020 of Drums and bags were evidenced.

- Organization has established that any change in raw materials is timely communicated to the raw materials supervisor so that only the correct version is accepted at the reception, once approved it is released for use, acoording to procedure I-PR-ADQ-002.
- No receptions of live animals are made.

3.5.3 Management of suppliers of services

It shows that there are formal agreements with service providers, in which control measures are defined by risk analysis, is reviewed:

- The approval and evaluation of service providers is carried out through the procedure I-PR-ADQ-002, Revision 007 of 21-03-2019 which contemplates the control of the services of:
    - Pest control.
    - Food.
    - Transports of finished products.
    - Security.
    - Waste transport.
    - Analysis laboratories.
- Agreements with sub-contracted companies are reviewed:
    - Contract with company Plagisur of 02-01-2013 (Pest control).
    - Contract with company transport of 06-01-2020.
    - Contract with company Apunto of 07-03-2018 (Food services).
    - Contract with company GZ Seguridad S.A., dated on 10-11-2014 (Security).
    - Contract with company Rio Negro of 09-01-2015

3.5.4 Management of Out sourced processing

No outsourced processes.

3.6 Specifications

The specifications have been defined in procedure, according to customer requirements. Acceptance specifications and modifications are agreed with customers, we review:

- The specifications of raw materials, and finished products, are defined by the Agricultural, Production, Quality and Commercial Areas, are reviewed:
    - Specifications of raw materials:
        - N-DC-MPR-001 Specification M.P Peti Vert Rev.4
        - N-DC-MPR-002 Specification M.P Celery Juice Rev.4
        - N-DC-MPR-002 MP Celery Specification Rev.2
        - N-DC-MPR-003 Specification MP Cranberry Rev.1
        - N-DC-MPR-004 MP Betarraga Rev.1 Specification
        - N-DC-MPR-005 Specification MP Cherry Rev.1
        - N-DC-MPR-006 MP Dried Plum Specification Rev.1
        - N-DC-MPR-007 Specification MP Durazno Rev.1
        - N-DC-MPR-008 Specification MP Stud Rev.1
        - N-DC-MPR-009 MP Raspberry Specification Rev.1
    - Finished product specifications (165 Specifications):
        - N-DC-PRD-001 Apple Juice Concentrate Clear Rev.2
        - N-DC-PRD-018 Raspberry Juice Concentrate Clear . Rev.2
        - N-DC-PRD-030 Blueberry Juice Concentrate Clear. Rev.2
        - N-DC-PRD-038 spinach Juice Concentrate Cloudy.Rev.3
        - N-DC-PRD-071 Swiss Chard Juice Concentrate Clear 65 BRIX. Rev.3
        - N-DC-PRD-082 Blueberry Puree Single Strength Aseptic. Rev.1
        - N-DC-PRD-083 Raspberry Puree Single Strength Aseptic. Rev.1
        - N-DC-PRD-091 Celery Juice Concentrate Cloudy. Rev.2 florida Food
        - N-DC-PRD-099 Apple Juice Concentrate Clear aseptic - Jumex. Rev.1
- Specifications are agreed with clients and communicated through a production program.
- Specifications are reviewed by the Commercial Management with clients before each season.
- Specifications are modified according to agreements with clients, with version control. Specification revision is evidenced before each season.

3.7 Corrective and preventive actions

Correction and corrective actions used as a tool to solved system deviations and effectiveness analysis with objective to avoid their recurrence were evidenced:

- Procedure corrective and preventive actions code I-PR-GEN-006, revision 05 of 08-06-2020.
- Preventive and Corrective actions process was reviewed:
    - Closure of non-conformities of internal audits.
    - Corrective actions implemented for audit deviations 2020 records were evidenced.
    - Records of detections of non-conformities and corrective actions of period.

Procedure corrective and preventive actions code I-PR-GEN-006, considers trends analysis and actions led by Quality Assurance Manager.

3.8 Control of non-conforming product

Identification of potentially unsafe products and non-conforming products, which are identified and segregated to prevent their accidental release, analysis of trends for taking corrective actions.

- Non-compliant product procedure code I-IT-LAB-008, revision 04 of 14-07-2020, which includes:
  - Analysis of non-conforming product trends for the 2018-2019 season.
  - Those responsible for the treatment of non-conforming products identified in the plant are: Head of Control and Quality Management.
  - Records of Non-conforming products 2020 were evidenced.

3.9 Traceability

Effective process observed during the review process and exercises performed in situ evidence is reviewed:

- Procedure of market recall and product traceability code I-PR-PLA-001 revision 11 of 15-06-2020, which includes the operations controls for the operation and improvements in the performance of the traceability process.
- Compliance is evidenced in the identification of raw materials and intermediate products.

- Audit traceability Exercise: Beet cloudy juice, 60º brix in drums 280 kg, manufacturing date 09-03-2020, Lot NPT 1001537, corresponding to 1160 kilos, with start time: 09:00; term: 12:50 pm.

- Traceability exercises carried out by the organization are reviewed:
  - Mock executed at 19-11-2020; Reception date 31-07-2019 recepction record 040311 for raw material celery, 442 bins, to final product lot: 19036 - 9526, code PTJ 63100064 with duration of 2:05 hours (Exercise from raw material to finsih product).
  - Reception date 28-02-2020, final product Jugo Apio Cloudy; 55 gal; 45º Bx; 250 kg code: PTJ63100064 lot: 19036-9476 to Reception date 16-04-2019 recepction record 031286 for raw material celery, 587 bins, lasting 2 hours (Exercise from finished product to raw material).

Traceability is maintained for the reprocessed products identified in the flowchart, to be considered in the traceability procedure.

3.10 Complaint-handling

Effective process, evidenced in claims treatment and trend analysis is reviewed:

- Procedure for managing customer complaints, code I-PR-ATC-001, revision 03 of 04-17-2019. person in charge of the treatment of the claims is the person in charge of the clients' request, who has training in the process.
- 2019-2020; 03 were receipt complaints received to date (All for quality), all accepted and managed
- Trend analysis in Excel spreadsheet is evidenced, for the 2018-2019-202 season. For the current season of apples there are no claims to date.
- All accepted claims are treated, through corrective actions, by committee of all the plants in conjunction with the Plant Management.

3.11 Management of incidents, product withdrawal and product recall

Organization has implemented procedures to treat incidents, withdrawals and product recalls, which has been verified through exercises. Incidents were not evidenced in period 2020, were reviewed:

- Crisis management procedure code I-PR-GEN-007, revision 03 of 11-06-2020, which includes the identification of the following incidents:
  - Electric shut down.
  - Drinking water cuts.
  - Accidents of finished product in transit.
  - Flood.
  - Fire.
  - Natural disasters.
  - Problems of staff availability.
  - Intentional contami nation or sabotage.
- Procedure of market recall and product traceability code I-PR-PLA-001 revision 11 of 15-06-2020, which includes:
  - Responsibilities.
  - Classification of withdrawals: Class I, Class II and Class III.
  - Flow of the process of product recovery and product recall.
- Fictitious exercise is reviewed by the organization of 10-01-2020 to product CeleryCloudy, 55 gal; 45° BRIX Juice fo foreing bodies detection in product, the exercise lasted 2 hours quantity of product 19.000 kilos committed, customer Florida Products, PTJ 19036-9472. It was concluded that the product is under compliance based on evidence of control measures.

Considered in the procedure to inform the certifying body in case of withdrawals Ms. Verónica Muñoz, phone +56 2 28989635, within 72 hours there have been no situations that merit the recovery of products.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

4. Site standards

4.1 External standards

Hazards controlled by organization, from outside of the facility and its surroundings, were reviewed:

- Design of the facilities allow sufficient hermeticity of potential contamination of the environment and surrounding land, there is a permanent control of the periphery by GMP monitor, register I-RG-GMP-002 perimeter inspection plant is used.
- Facilities has a total area of 6000 square meters and 3,000 square meters built.
- Gardens are well maintained, not representing a pest attraction. External circulation roads are paved and in good condition.
- Buildings are of solid construction and thermopanel.

4.2 Site security and food defence

Identification and action plans for potential safety hazards are evidenced, in compliance with the request of clause 3.11.1. No incidents to date shown, we review:

- Bioterrorism control procedure code I-PR-GEN-003, revision 05 of 16-04-2019, that include:
    - Vulnerability matrix access control and product of 01-06-2020. Which includes analysis by areas and control measures.
    - A plan of the facilities is shown, indicating the sectors where the fruit is packed (finished product).
- Following control measures were implemented:
    - Induction to the staff before each season on the requirements for entry plant and travel for contracted personnel, such as people working on behalf of the organization.
    - Guards company with 24-hour control (Emprea GZ Seguridad).
    - For personnel hiring by verification of the address Issued by Carabineros de Chile.
    - Inside the facilities there are security cameras monitored by the plant manager and security personnel.
- Bioterrorism procedure, code I-PR-GEN-003, revision 05 of 16-04-2019, considers the following control measures:
    - Security Policy code I-DC-GEN-01, revision 01 of 05-01-2018.
    - Access control procedure for the plant I-IT-RRHH-001, Revision 003 of 15-03-2019.
    - Permanence of personnel in the plant I-IT-RRHH-003, Revision 003 of 22-02-2019.
    - Surveillance I-IT-RRHH-004, Revision 003 of 02-25-2019.
    - Surveillance control cameras I-IT-RRHH-005 Revision 003 of 03-05-2019.
- Registration records:
    - Health Resolution No. 3754 of 21-09-2010.

FDA Registration number: 19556254152 of 12/31/2019 (Valid for 12 months), managed through U.S Agent for FDA: Registrar Corp.

4.3 Layout, product flow and segregation

Design to develop of operations, consider elements to prevent cross-contamination, which complies with applicable law, were reviewed:

- Plans of facilities reviewed on 22-05-2019, which contemplate:
    - Staff access and displacement plan.
    - Access and displacement plan for raw materials and packaging materials.
    - Map with routes for the elimination of waste.
    - Plane for reprocessing.

- Plane with production flow.
- Location map of the facilities.

- Informartion is delivery is made to all personnel entering the plant with instructions on procedures to access the facilities and the requirements of the areas they visit, emphasizing the risks and possible contamination of the products.
- Designated person to supervision of contractors are in charge of each process area, where the services are provided, with verifications made by the Risk Prevention Officer.
- Contractor control and visits is carried out. Business cards are delivered and health questionnaires are applied, before entering the plant.
- Sufficient spaces are evident for the development of operations, as observed during the visit to facilities.
- Provisional structures was not evidenced during facilities visits and as declared by organization members.

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

Infrastructure development of operations comply with private standards of hygienic engineering, this is reviewed:

- Solid and easily washable construction walls are shown, smooth without roughness.
- Refined and concrete floors, resistant to cleaning procedures.
- No drainage design and maintenance problems are observed.
- Ceilings are adequate and maintained by the maintenance department of the Retiro plant.
- There are no false ceilings and no hollow spaces
- Walkways are adequate to avoid contamination of the products, with restricted traffic.
- No glass windows are produced in the production sector, with risk for the products.
- Doors are in good condition, with slats to prevent the entry of pests, process rooms and cameras.
- The lighting is controlled by measurements made by mutuality, it is evidenced compliance with DS 977 and DS 594, according to report No. 01/2018 of 14-08-2018.
- No evidence of condensation in processing rooms or in beds for the protection of raw materials or finished products.

4.5 Utilities – water, ice, air and other gases

Production and storage areas services, have hazard identification and determination of controls this is reviewed:

- Water control manual I-MN-AGU-001, revision 003 of 07-03-2019, is revised:
  - Well with a depth of 38 meters, which has a non-return valve.
  - Physical Chemistry Analysis No. QL 145061 of 20-02-2020 conducted by the Quality Lab (carried out annually).
  - Microbiological analysis performed by Quality Lab (carried out monthly):
    - No. QL 153852 of 14-05-2020.
    - No. QL 151925 of 30-04-2020.
    - No. QL 164194 of 22-10-2020.
  - Daily Control chlorine water network of June and July (Carried out twice for each shift). Control of chlorine water network (0.2 to 2 ppm)
- Water map distribution system of the points of use of treatments and elimination. Descents of water that allow the taking of samples were identified.
- Used of direct steam in the process of scalding and aseptic packaging, for which use of culinary filter PALL (Food and Beverage) is contemplated. 2020 Maintenance was reviewed.
- No air or other gases are used as ingredients in direct contact.

4.6 Equipment

Equipment used in operations are materials that minimize the risk of contamination to the product, was reviewed:

- Equipment used for operations was made of materials that minimize the risk of contamination.
    - Equipment design guarantees that it can be cleaned and maintained effectively.
    - Technical specifications and the suitability certificates in contact with food were verified.
    - Technical sheets and certificates of aptitude for direct contact with food were reviewed.

4.7 Maintenance

Maintenance process is in place and consider hazards control from equipment, were reviewed:

- Manual of preventive maintenance code I-MN-MAN-001, revision 05 of 15-05-2020, which includes:
    - Verification master predictive maintenance of 2020, which includes weekly verifications with last verification on March 2020.
    - Preventive maintenance master program: Grinding lines of Apple No. 1, Apple No. 2, Vegetables No. 1 , Vegetables No. 2, Stone fruit, Berries, Grape.Auxiliar (Strawberry).
    - Pressed Lines: Fabric press: Press with decanter (2 teams), Press with decanter (2 teams).
    - Filtering lines: 8 ponds, Tangential filter., Pressure filter, Vacuum filter, Centrifuge.
    - Certificate of magnetic measurements No. 3573 of 11-11-2016, made by POLIMIN LTDA., For magnetic trap of 5 tubes of 1 inch in diameter and 90 mm in length (It is done frequently every three years).
- Preventive maintenance is evident during the year 2020.
- Daily and weekly inspections according to risk.
- Provisional maintenance is closed within the shift (they include criteria for momentary repairs), which are defined in the maintenance log, often in turn.
- Execution of cleaning after a maintenance intervention is the responsibility of the plant cleaning staff, with verification by toilet monitors, defined in the Manual of preventive maintenance code I-MN-MAN-001, revision 04 of 17-03-2019 (Registered in Work Orders).
- Use of food grade lubricants and oils, is reviewed:
    - Bel Ray No Tox lubricant, declaration of non-use of allergenic components.
    - Allergen statement on Bel-Ray No-Tox® Food Grade lubricants, from March 13th, 2015
    - General service workshops and another located in Presizer, is separated from the production facilities.

4.8 Staff facilities

Adequate facilities number of employees, with engineering controls and standards to avoid potential cross contamination are evident this is reviewed:

- Personnel Facilities, women and men are shown, separated from process lines; enough quantity to number of workers, according to DS No. 594.
- Entry of process areas only entry of personnel with uniform, without personal effects is allowed.
- People have lockers for shelter of street clothes, for which work clothes are delivered before entering the plant. During visit were evidence use of Cloth bag with separation of work clothes with street clothes.
- Sanitary filter sinks, prior to entering production sector, indicative signs of the procedure are observed.
- Faucets are automatic (knee), it has Sanitizing soap and disposable paper for drying. Warm and cold water

- Bathrooms separated from production sectors; in them there are also sinks with cold and warm water; Sanitizing soap and paper for drying hands.
- According to national legislation, smoking is not allowed in facilities of food companies.
- Only place allowed for food intake is plant catering (food is not allowed into the plant).
- Catering is separated from the areas of work managed by Casinos APUNTO company, there is evidence of controls in GMP inspections.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

Chemical control:

- Warehouses of supplies operation proceduires code I-PR-BOD-001, revision 02 of 21-03-2018, is revised:
  - Approved list of chemical products 2020 (Includes 10 products).
  - Technical specification with confirmation of suitability for use in a food processing environment.
  - Identification of containers of chemical products - Chemical store is blocked with restricted access.
  - Training of personnel in the use of the chemical products used.
- In the field visit, separate wineries are shown, and with access control (locked), the technical and HDS data sheets are evident. It is evidenced in the winery of chemical products that are properly labeled, segregated.
- Products used do not have odours, which is considered in control of purchase of products, uses of products.

4.9.2 Metal control

Control of metals:

- Organization has a policy I-DC-GEN-001, Rev.1, 05-01-2018 on metal control and sharp instruments of 05-01-2018, controls are carried out to prevent cross contamination.
- Ingredients used and packaging with staples or other foreign body hazards is not allowed (No ingredients and containers with staples or dangerous bodies are visible on site visits).

4.9.3 Glass, brittle plastic, ceramics and similar materials

Glass materials control, brittle plastics, ceramics and other similar materials:

- Policy of use and handling of glass and hard plastic policy I-DC-GEN-001, Rev.1, 05-01-2018, is revised:
  - Identification of quantity and state of fragile elements (Contemplate 5 areas).
  - Inspections are carried out once a week. Revised records for the following dates: March, June to August 2020, made by maintenance personnel: Door inspection, lighting, lubrication tools, mirrors.
  - Control of lenses made by quality assurance (weekly).
- Instructive of risk of contamination by glass and hard plastic code I-IT-ACL-011, revision 02 of 04-09-2018, which considers identification and control of sources of hazards. No incidents to date.
- In case of detection of an event with a potentially compromised product, product is retained and treated using the non-compliant product procedure.
- Windows with potential of comtamination are all protected.
- All luminaires are protected with breakages of these

4.9.4 Products packed into glass or other brittle containers
No containers of glass or other brittle materials are used
4.9.5 Wood
. Wood control: • The organization has a Policy I-DC-GEN-001, Rev.1, 05-01-2018 on the use of wood. • Wooden pallets used in process are certified according to NIMF 15. • Daily control of integrity of the wooden pallet code I-RG-GMP-008, records of period were reviewed.
4.9.6 Other physical contaminants
Other physical contaminants control: • Container control measures are evidenced during the process of receipt of raw materials. • Organization implemented pencil control areas of open products of a single body with no moving parts. Compliance is evidenced during the visit to the facilities
4.10 Foreign-body detection and removal equipment
4.10.1 Selection and operation of foreign-body detection and removal equipment

Effective measures control to reduce dangers from foreign bodies were evidenced:
• A risk assessment documented in the HACCP plan is reviewed, and a decision tree recommended in the BRC 8 implementation guide.
• Fireugn bodies implementation detection equipment has not been required, with implemented controls, refer to:
  • Filters.
  • Magnetic traps.
• Control measures are specified with emphasis on: Type, location and sensitivity of the detection equipment.
• Frequency with which the detection and / or removal of foreign bodies are performed was based on risk.
• Investigation ofr foreign Bodies is carried out by maintenance department, laboratory, quality assurance (No incidents are evidenced during the period)

4.10.2 Filters and sieves
• CCP 3: Physical hazard, filter-controlled, for extraneous particles above 7 mm and 2 mm for baby food, 0.5 and 1 mm filters are used. • The filters are inspected for each batch of packaging registration N-RG-HACCP-003 Filtering Control. CCP 3: Filter control register of From February to October of 2020, no issues were detected.
4.10.3 Metal detectors and X-ray equipment
• Decision tree regarding the determination of the use of a metal detector and, on the one hand, it is not a requirement of the client and, on the other hand, all other questions are met with the answer that is no.
4.10.4 Magnets
• Certificate of magnetic measurements No. 3573 of 11-11-2016, made by POLIMIN LTDA., For magnetic trap of 5 tubes of 1 inch in diameter and 90 mm in length. Performed frequently every three years

4.10.5 Optical sorting equipment

There is no identified need to use optical sorting device as detection methodology according to risk analysis (Requirement 4.10.5).

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

Rigid containers that require cleaning are not used (Requirement 4.10.6).

4.11 Housekeeping and hygiene

Cleaning and sanitation program was evidenced by areas, effective results observed in microbiological analysis and validation by organization, were reviewed:

- It is observed during the visit to the facilities that the equipment is in good conditions of cleanliness and hygiene.
- GMP Manual code I-MM-GEN-002, revision 04 of 23-02-2017, which includes:
    - 63 work instructions specifically for each team, such as:
        - Instructions for cleaning the press.
        - Instructions for cleaning concentrators.
        - Master plan for hygiene and sanitation of natural juice plant, weekly record of execution of the program of activities of deep cleaning.
        - The technical sheets and safety sheets of the chemical products are maintained.
    - Controls and performance measurements are reviewed:
        - Check list reception toilets for June to august 2020.
        - Cleaning control by Bioluminescence of june 2020.
        - Control sheet for internal microbiological analysis of surfaces external microbiological analysis performed by QualityLab laboratory:
            - No. QL 153850 of 25-05-2020.
            - No. QL 151918 of 30-04-2020.
            - No. QL 151917 of 30-04-2020.
- Daily and deep cleaning procedures are evidenced (Once a week), with training of personnel in cleaning and sanitization methods, and waste disposal. Work that is done at the terms of the processes.
- Resources are available to carry out clearing and cleaning tasks.
- Hygiene personnel were trained and is competent to perform their tasks.
- Personnel training in sanitation was reviewed, regarding the handling of chemicals, caustic soda, peroxide, nitric acid.
- Rest of training depends on area in which they will work and the explanation through work instructions. Organization has a reagent kit to measure concentration
- Cleaning equipment is suitable, specific for the cleaning identified by color, with marked shelter sectors. Compliance is observed as observed during the visit to the facilities.

4.11.7 Cleaning in place (CIP)

CIP circuits. The organization works under a master hygiene and sanitation program, based on the annual production program. CIP is done once a week to the whole team, but on some devices 2 to 3 times per week.

- Performance of control measures is reviewed:
    - Microbiological analysis with biweekly frequency.
    - CIP cleaning records of June 2020,

- In the Instructional Circuit N-IT-H & S-002, the diagram of the CIP washing lines and the execution methodology are shown (no dead spots are evident). A drain pump is used to ensure that no cleaning liquids (CIP) accumulate in the tanks.
- Regarding the CIP cleaning procedure, were reviewed:
  - Procedure: Rinse or drag with water, application of caustic soda, with circulation time between 15-30 minutes of neutralization of citric acid, rinsing, application of peracetic acid.
  - Circuits and the soda are neutralized with citric acid and tests with phenolphthalein to verify existence of traces of caustic soda.

4.11.8 Environmental monitoring

Environmental monitoring program of 01-01-2019 risk assessment based, which includes sampling protocol, sampling points by zones, indicator organisms, test methods and evaluation of results with monthly frequency.

- Limits of control are defined and monitored by means of microbiological analysis of surfaces, manipulators and environment were reviewed:
  - Reports of microbiological analysis of the environment carried out by the QualityLab laboratory:
    - No. QL 164192 of 22-10-2020
    - No. QL 153850 of 25-05-2020.
    - No. QL 164191 of 22-10-2020.
    - No. QL 153851 of 25-05-2020.

- Review program is scheduled on an annual basis, or when the results indicate its modification is not necessary.

4.12 Waste

Waste removal is evidenced pursuant to national legislation, such as internal procedures to minimize risks of contamination and proliferation of pests, this is reviewed:

- Instructive waste disposal code I-IT-GEN-005, revision 02 of 04-04-2018, which includes:
  - All waste is eliminated through authorized companies.
  - The disposal of liquid waste after primary treatment is directed to a surface water course (DS 90).
  - Removal of solid waste is removed by Transportes Rio Negro, records of June to August 2020 were reviewed.
- Garbage storage area is removed from the processing areas, is clean, closed and does not represent a risk of attracting pests.
- Waste collection containers are: Clearly identified, designed to facilitate its use and clean, maintain and clean effectively.
- Organization only works with specialized companies and with authorization for the elimination or destruction of certain materials.

4.13 Management of surplus food and products for animal feed

All surpluses of customers are eliminated as defined by requirement 4.12 or customer inquiries and are not considered supersedes for sale or for animal feed.

- It was defined that all the order indicated in the order will be sent to the customer, in case there is a production surplus, the packaging material is destroyed and the product can be reprocessed depending on the type of product in question.
- No product is intended for animal feed

4.14 Pest management

Preventive pest control program to reduce the risk of infestation observed in control measures such as sealing of the plant, waste withdrawals, cleaning and sanitation programs, and monitoring conducted in the period, this is revised:

- Manual of pest control code I-MAN-PLG-001, revision 02 of 04-04-2018, which includes:
  - Instructive pest control code I-IT-PLG-001, revision 02 of 04-04-2018.
  - Instructive Insect Trap Lamp (TUV), code I-IT-PLG-002, revision 02 of 09-04-2018.
  - Instructive control of catches of birds code I-IT-PLG-003, revision 02 of 09-04-2018.
  - Nest control instructions code I-IT-PLG-004, revision 02 of 09-04-2018.
  - Instructive mechanical control of weeds code I-IT-PLG-005, revision 02 of 09-04-2018.
  - Instructive control of rodents in trapping stations code I-IT-PLG-006, revision 02 of 09-04-2018.
  - Rodent control instruction in baiting stations code I-IT-PLG-007, revision 02 of 09-04-2018.
- Organization works with external company Plaguisur, it is revised:
  - Resolution No. 5072, 11-11-2010 and Resolution No. 694, 07-12-2016.
  - The frequency of inspections is determined based on the risk assessment.
  - Integrated pest management program from 16-04-2018.
- We work with an external pest company.
- Map of monitoring devices:
  - 136 devices in legano perimeter.
  - 98 devices in close perimeter.
  - 36 live capture traps (Interior of plant).
  - 8 TUV devices.
- Documentation and pest control records are well maintained.
- An updated plan of complete site that identified location of numbered pest control devices - identification of baits - responsibilities are clearly defined - there is a detail of the products used for pest control.

Chemical baits are not used inside the facilities, only capture tarps are used.

- Insects and pheromone traps are located in such a way that they do not produce contamination of the product.
- Exceeding thresholds, which identify infestation states, for the period.
- Reports delivered by PLAGISUR, with biweekly frequency, visits records and monitoring work report of June to August 2020 were evidenced.
- Pest monitoring records include recommendations that are managed as observed during the review of controls during the period.
- In-depth study conducted on 11-08-2020 by the expert Mr. Luis Troncoso. (Head of technician Plaguisur), their competences are reviewed:
- Graphical evolution of pest activity in Retiro plant, from:
  - Analysis of the period from October to October 16, 2020.
  - It is assumed that all recommendations have been addressed.

Training is provided to plant personnel where the signs of pest activity are revealed and how problems can be helped, according to the registration of 06-09-2020 with a duration of 1 hours for 10 attendees.

4.15 Storage facilities

Facilities safeguarding raw material, packaging, products in process and finished suitable for the maintenance of products are evident, this is reviewed:

- Instructional storage of the finished product code I-IT-CAM-013 revision 02 of 04-11-2018, which includes:
  - Facilities with logical flow of operations.
  - Instructive transfer of raw material, code F-IT-PRD-023 revision 02 of 21-03-2018.
  - Instructive cleaning of the finished product warehouse I-IT-HYS-053 revision 02 of 21-03-2018.
- Frozen cameras are exclusive use for finished products and products to process, were reviewed:
  - 2 cameras of -18ºC, records of June and July were evidenced.
  - 2 cameras of 0ºC, records of June and July were evidenced.
- Monitoring records of the period code I-RG-ACL-041 are reviewed. Controlled values are within the -18 ° C limit. and 0 ° C.
- No products are stored in a controlled atmosphere.
- Do not carry out outdoor storage.
- Records are evidenced, which are used in evaluation of suppliers.
- Material warehouse works under the FIFO or FEFO system, as appropriate, controlled by the SAP system.

4.16 Dispatch and transport

Management procedures for shipments of finished products, ensuring the safety and quality of products are evident, we review:

- Dispatch is carried out in vehicles suitable for transporting frozen products and products at room temperature (legal requirements).
- Traceability is maintained during transport, through the route sheets and cargo details, as defined in Instruction for finished product code N-IT-CAM-013, revision 03 of 05-01-2019.
- No dispatched were perform during audit process days.
- Shipment is made by refrigeration personnel from a shipment order and in a specific area for loading of finished products, records of container dispatched was evidenced for:
  - 05-10-2020 of container MN13V35056-4.
  - 09-03-2020 GESU904531-4
- Product temperatures are verified before loading and use of temperature recorder, with photographic record, checked during traceability exercises and in charges during field visits.
- The maintenance and cleaning procedures of the vehicles are the responsibility of the transporters with inspection controls before each load, records are reviewed in the revised dispatches.
- Procedure considers restrictions for mixed loads of products defined in the scope.
- No full load is made (Products from other plants).
- Safety conditions, breakdowns and incidents are monitored by thermographers in loads of each truck with photographic records.
- Agreements between the company and transport companies, and insurance contracted by Invertec Natural Juice S.A.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification

5. Product control

5.1 Product design/development

Effective procedure is evident for the new designs treatment and its modifications, is reviewed:

- Development process is responsibility of Program Managers, who are responsible for issuing the rules by species. Quality assurance manager is responsible for updating HACCP plans and controls for customer compliance.
- No new developments in the period.
- New products are controlled through product descriptions, which are approved by the HACCP team, changes are analyzed by hazard analysis and changes in shelf life are reviewed.
- Life tests, by product, are reviewed:
  - Microbiological analyzes performed by LABSER laboratory, for the different products.
  - Sensory evaluation instructions, code FF03.2-IT-ES-01-00.
  - Product shelf life study of Asparagus concentrate juice with start date on 17-03-2015 to March 2018.
  - Product shelf life study Concentrated celery juice Cloudy with start date on 21-10-2016 in preparation.
- Labeling is done according to the target market and customer requirements

5.2 Product labelling

Procedures to ensure compliance with legal requirements and information to food chain through product labels, were reviewed:

- Instructive control of labeling code IT-GEN-003, revision 03 of 15-03-2019, which defines the operational criteria for:
  - Reception of labels provided by customers by COMEX and Business Unit Manager.
  - Review of legal requirements is carried out by Quality Assurance Supervisor, with approval of Technical Customer Service Manager.
  - Incorporation of labeling information in production order, with planning manager responsibility.
  - Labels review prior to production with responsibility of natural laboratories staff.
  - Labels approval through signatures with responsibility of laboratory personnel.
- All labels are reviewed and defined during the design and development process.
- No attribute declarations have been made to satisfy a specific group of consumers.
- Information contained in labels, which is provided by customers or by a third party is defined in specifications control such as language, address or other requirements necessary for marketing at final destination.
- Product does not consider instructions for cooking.

5.3 Management of allergens

Hazard analysis and control measures implemented to catering allergen management were evidenced. Not evidence of allergen in raw material and packaging material, were reviewed:

- Manual of allergen management code I-MN-ACL-001, edition 03 of 12-06-2020, that includes:
  - Allergen policy of 01-19-2016, signed by the Plant Manager.
  - Identification of allergens according to destination markets that are subject to labeling code I-MN-ALE-001, consider: Europe, Chile, USA, Japan, Australia, and Canada.
- According to the analysis carried out by the organization, celery and food served in the casino have been identified as the sole allergen.
- Risk assessment, by sector which considers probability based on the qualitative performance of control measures implemented. With main source the raw material Celery, and Casino only source of food consumption.
- No allergens have been identified in raw materials and contact materials.

Cleaning procedures are not required to ensure contamination by allergens, as evaluated by the organization

5.4 Product authenticity, claims and chain of custody

Risk analysis and controls determination to all product descriptions and claims are legal and appropriate, were reviewed:

- Instructive authenticity control code I-IT-GEN-002, revision 05 of 13-04-2020, which contemplates the methodology and sources of adulteration information, such as:
  - www.SAG.cl, RIAL Chile repor, Customers, www.minsal. Cl, www.foodfraud.org.
- Analysis of authenticity failure mode of 14-03-2020, which includes:
  - Raw Materials.
  - Materials in contact (According to the definition of the standard's raw material).
  - Authenticity evaluation criteria are considered:
    - Historical evidence of substitution or adulteration.
    - There is temporary proof of substitution or adulteration.
    - There are Economic Factors.
    - Ease of adulteration in the food chain.
    - Complexity to Perform Analysis.
    - Nature of the raw material.
  - The identification of potential frauds in multerisiduos analysis by producers is evident.
- In case of doubts of adulteration the organization contemplates the realization of the taking of samples for the accomplishment of analysis of multiresiduos (Main source of adulteration of information).
- Raw material status statements are not made on finished packaging labeling.
- Kosher Certification valid until August 2021, signed by Itzhack Shaked Rabbi of the Jewish Orthodox comunity Chile.
- Organic certification granted by ECOCERT, Valid Auntil February 2021.

5.5 Product packaging

Effective procedure for the product packaging is evidence, is reviewed:

- Packaging requirements were reviewed by design and development process and communicated to suppliers through purchase orders, certificates of conformity were evidenced reviewed.
- Storage of containers in the exclusive use of materials warehouse, through controlled deliveries and according to the container specification matrix, validated through the performance of tests.
- All the bags in contact with the product are transparent, aseptic and non-aseptic bags. Analysis report No. 1396 of migration dated 27-02-2014 is reviewed.

- All the bags in contact with the product are white or transparent.
- Obsolete packaging is returned to customers or sent for recycling with SOREPA company. No shipments during the period

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Inspections and analyses were evidence to confirm the safety, legality and quality of the product, review:

- Analysis program that includes internal and external analyzes, defined in instructions:
    - Microbiology finished products,
    - Determination of nitrates and nitrate of nitrogen,
    - pH control,
    - Determination of enzymatic activity,
    - Protein control,
    - Cleaning control by bioluminance,
    - Sample taking in process,
    - Use of condutivimetro,
    - Starch in fruit juices,
    - Determination of viscocity in paprika juices,
    - samples raw materials for pesticide analysis,
    - control of black spots in concentrated juice.

- Analysis and follow-up of compliance with the specifications are carried out by quality control department, through microbiological analyzes carried out by an internal laboratory and an external laboratory QualityLab accredited ISO/IEC 17025.
- Analysis of trends of pesticide results and microbiological analysis is reviewed. Analyzes conducted by the organization of June and july 2020 were reviewed.
- Controls are evidenced on the useful life of products, based on controls defined in requirement 5.1.4.

5.6.2 Laboratory testing

Were reviewed:

- Analyzes of patogens are carried out by Frozen Plant laboratory, and with verifications with QualityLab Laboratory.
- Laboratory of physical and chemical analysis is separated from the process rooms, with a design that allows assurance of analysis, protection of personnel and products.
- Laboratory is separated from the process rooms, with a design that allows the assurance of analyzes, protection of personnel and products.
- Performed in external laboratory accredited ISO/IEC 17025:
    - Laboratory accreditation QualityLab Limited effective until 31-01-2021, certified number 4861.01, 02 and 03.
    - Ceimic Chile accreditation valid until December 31, 2021, certified number 4669.01.
- The limits of analysis are defined in DS 977, ASOEX and requisiotos agreed with clients.

5.7 Product release

Effective product release procedures are evidenced, this is reviewed:

- Quality control is responsible for ensuring that all finished products that do not meet specifications are clearly identified.
- Quality control department carries out inspections according to the specifications according to the Manual of the species, which is applicable in compliance with the release.
- Release records were evidenced, certificate of analysis:
    - Product BLUEBERRY JUICE CONCENTRATE CLEAR 65°BX 300 KG 60 GAL
    - Customer SHANDONG CHIA MEEI FOOD INDL CORP
    - Lot Number NPT1001037 to NPT1001056
    - Production Date 30-01-2020
    - Container CXRU 103578-0
    - Shipment J-314000360
    - N°Drums 78

    - Product BLUEBERRY JUICE CONCENTRATE CLEAR 65°BX 300 KG 60 GAL
    - Customer GLOBAL NATURAL FOODS
    - Lot Number NPT1001649 to NPT1001667
    - Production Date 13-03-2020
    - Container MNBU 414950-5
    - Shipment J-314000511
    - N°Drums 75

5.8 Pet Food

The organization does not include pet food within the developed processes

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

6. Process control

6.1 Control of operations

Documented procedures which guarantee the operational process controls for compliance with specifications and legal and safe products are evident, we review:

- Product specifications are used for process control.
- During the visit to the facilities of following process was evidenced: Colchina specification.
- Control of product specifications was evidenced, carried out by laboratory personnel and line managers.
- Organization conducts online monitoring of temperatures.

- Organization does not have online monitoring measurements.
- In case of variations of the process equipment, setup equipment is programed by competent staff, validation is contemplated through the results of microbiological analysis and field tests, by lot of products per line.
- Failures in equipment, compromised products are controlled by maintenance procedure.
- Pontentialy affected products are treated as non-conforming products, as defined in: Procedure product not compliant code I-IT-LAB-008, revision 03 of 18-03-2019.

6.2 Labelling and pack control

Control procedures to ensure labelling and product packaging control are evident, were reviewed:

- Instructive control labeling code IT-GEN-004, revision 03 of 15-03-2019, which includes:
  - Definition of labels is done by product specification, with responsibility of the commercial team who verify the legal requirements of destination countries.
  - Unique coding per box.
  - Reviews of labels made by laboratory managers.
- Process start controls are performed by laboratory control personnel, refer to:
  - Labelling instruction defined in Production Order.
  - Labelling and packaging control, code I-RG-GEN-012.
- On site visits, compliance with requirements such as verifications of label impresion, programming of label printing and during production process was evidenced for (01-12-2020), reviewed of process line and finished products packaging.
- No online display equipment is used for label monitoring.

6.3 Quantity, weight, volume, and number control

Organization has defined effective amounts control, were reviewed:

- Quantity control is carried out by means of production report by producer, and by process.
- Organization has quality controls on lines, qeight of every unit is controlled.
- On site visits, compliance with requirements such as verification of label impressions, programming of label printing and during the production process, records of compliance of june 2020.
- Checks of weights online are not established

6.4 Calibration and control of measuring and monitoring devices

Implemented procedures ensure that monitoring and measurement equipment are calibrated or verified, were reviewed:

- Procedure calibration and verification code N-PR-MAN-001, version 03 of 04-05-2015, which includes:
  - Program of checks and calibrations of equipment code N-DC-MAN-001, which includes 35 teams.
  - Instructions for verification of temperature, pressure and measuring instruments equipment (Turbidimeter, Spectrophotometer, Centrifuge, Rota steam, Thermometers, Manometers, Flowmeters, Scales and masses).
- Verification:
  - Thermometers verification
  - Standard control 60º Brix of June 2020.
  - Acid pattern control of June 2020.
  - Verification refractometer of June 2020.
  - Spectrophotometer Verification U-1900.

- Calibrations standard instruments between others following records were evidenced:
  - Certificate or thermometers, mas pattern, flowmeters where evidenced for 2020
  - Calibration certificate of pattern mass of 150 kg of transit time No 34468 of 11-02-2020.
  - Calibration certificate of pattern mass of 1200 grs kg of transit time No 34468 of 11-02-2020.
  - Certificate of preventive maintenance and calibration of HPLC of 05-10-2020.

Instrument whose verification or calibration is above the permitted error is reported to the HACCP leader which defines the replacement of the equipment or its repair and taking of actions for potentially compromised products.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

7. Personnel

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

Managing staff skills process, implemented by organization is effective, noted in the review process and interviewing staff, were reviewed:

- Manual training, knowledge, competence code I-MN-PRP-003, revision 01 of 21-03-2011, which includes the training of all personnel and personnel working on behalf of the organization.
- The competences defined for each position can be found in the job descriptors, through which gaps are identified for the taking of actions, during the visit to the facilities, competent personnel is evidenced. Seasonal induction includes general training on allergens.
- Delivery of diptych to all contractor personnel is evident at the entrance of the plant, with an acceptance record (Compliance is evidenced when entering the plant). That includes forrmation records made in the period, with topics:
  - Critical Control point monitors of 25-10-2020.
  - New personal induction talk on 03-04-2020, 06-08-2020, 20-07-2020, 14-07-2020, 13-07-2020.
  - Labelling and packaging process 19-02-2020
  - Allergens 19-02-2020
- Measurement of the effectiveness of the training is evidenced by tests and measurements of compliance with objectives, such as for induction of the start of the season by means of good manufacturing practices (GMP) records.

Competences are revised in an indirect way, for the personnel of season the monitoring of hygiene of the personnel is done and control of microbiology of hands; For Headquarters, an annual performance evaluation is done for plant personnel

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

Identification of controls for personal hygiene is evidenced, effective review process and monitoring records observed, we review:

- Instructive hygiene and personal presentation code I-IT-ACL-007, version 02 of 04-09-2018, which includes:
    - Personnel hygiene control record for June and July 2020.
    - Report of manipulative microbiological results carried out by an internal laboratory in June and July of 2020, carried out by internal laboratory.
    - Rules and regulations are defined in internal regulations communicated in inductions.
- Sanitary filters (Soap, water, disposable towel and garbage cans) and proper use by operators are evidenced in the field visit.
- Plant has a polyclinic, resolution No. 2321 of 10-07-2009, with hours of service from 08:00 to 18:00 hours. In which there is a paramedic who makes the immediate attention and makes referrals to mutuality in the cases that are required. First Aid Clinics care certificates of 2019 are reviewed.
- Metal detection equipment is not used according to the risk analysis carried out by the organization.
- Handling medications procedure for communicated to staff through induction is evidenced. The plant has first aid salt administered by: Nursing technicians, in three shifts.

7.3 Medical screening

Effective controls to prevent sick people to be a source of contamination evidenced during site visit and reviewed process, were review:

- Instructive hygiene and personal presentation code I-IT-ACL-007, version 02 of 04-09-2018, which defines Health declarations of personnel made by a polyclinic professional.
- Upon admission to the facilities, there is evidence of disease consultation to the audit team on 30, 1 and 2-11-2020.

Employees who develop symptoms of diseases carry out direct communication with the aim of evaluating their status is sent to first aid room, to be referred to mutual safety or change of job.

The organization defined a contingency plan and a detail of measures described in I-IT-PRP-014 Occupational Risk Prevention Protocol to Avoid COVID -19 contagion. Rev.3 that describe all measures that organization defined for prevention of contagion. Other documents described specific measures: I-IT-PRP-015 Disinfection protocol for common areas to prevent COVID - 19 contagion. Rev 1; I-IT-PRP-017 COVID-19 Suspicious Case Management Instructions. Rev1; I-IT-PRP-018 Access Control for Trucks and suppliers COVID Infection prevent. Rev1 "

The main prevention measure to avoid contagion described in document I-IT-PRP-014 Occupational Risk Prevention Protocol to Avoid COVID -19 contagion. Rev.3 are following:
-100% of Staff, must be trained to develop awareness about COVID 19 contagion prevention and symptoms.
- Physical redistribution policy for work position and canteen facilities with a maximum of 2 people per table and increase the number of shifts to reduce number of people.
- Footbath Installation (quaternary ammonium) to sanitize the footwear of all people who enter the plant.
- Temperature control at entrance of the plant with an infrared thermometer, actions will be taken in case of people with more than 37.8 ° C of temperature.
-The alcohol gel application points of were increased in all high traffic (before using the tourniquet and after it, casino, bathrooms, workstations) and product handling zones.
-All meetings were reduced to strictly necessary, and a promotion of video calls or conferences was implemented.
-Visits are restricted, they can enter only with the authorization of plant Manager, and all must be comply with plant entry control that the same than plant staff and health declaration.
- Any worker with symptoms should inform their respective line manager and go to the polyclinic.
'- Work Shifts were modified to the 5x2 mode of 12 hours each, to decrease the flows and crowding of people.
- During quarantine and pandemic condition the hiring of new people is frozen.

- Once a week, sanitation is carried out on company yards and streets.
- Daily sanitation with quaternary ammonium of offices, doors, handrails, bathrooms, casino, porter, Roman.
- All people visits, and staff must be used mask in company facilities.
- A mask is delivered to all plant personnel; its use is mandatory in all the dependencies of the organization.
- The line manager must be reinforcing to teams hand washing and self-care.
- Access is not allowed for contractors without previous plan manager authorization. Suppliers must comply with all control entrance measures.
- There are raw material suppliers in different regions of Chile , that allow supply the plants without inconvenience. This strategy helps to not stop processes in case of any supplier is in quarantine. The organization also maintains a stock of materials in warehouse.
- A Alternate fruit and vegetable production program whose purpose is not to stop production, always to maintain availability of raw materials.
- All measures may have some modification and will be related to the contingency of the moment and the instructions issued by the Sanitary pertinent authorities.

Agreed Action point 1: .To manage potentially asymptomatic Staff people. The organization must carry out an evaluation of ways to obtain a declaration of symptoms that could be associated with COVID-19.

7.4 Protective clothing: employees or visitors to production areas

Effective procedures to ensure appropriate protective clothing to enter the production areas, observed during place visit and procedure review, were reviewed:

- Instructive hygiene and personal presentation code I-IT-ACL-007, version 02 of 09-04-2018, which considers:
  - Hygiene and personal presentation control.
  - The cleaning of the uniform is the responsibility of the operators, and they are monitored before the start of work.
  - During visits to facilities workers are shown with clean uniforms.
- Protective clothing, is provided by the organization refer to apron without pockets and without buttons, Use of hood and cap, and the use of masks is contemplated to personnel with beard or mustache.
- Cleaning of the uniform is carried out by the operators, as arranged by the organization. Verification is carried out during the control of aspects of the personnel.
- Organization determines the use of gloves, according to the operations carried out and with replacement whenever necessary.
- Organization does not have clothes that can not be washed, the coifs and masks are disposable.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

Template control	Food	Version	1.0

8. High-Risk, High-Care and Ambient High-Care Production Risk Zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
N/A.
8.2 Building fabric in high-risk and high-care zones
N/A.
8.3 Maintenance in high-risk and high-care zones
N/A.
8.4 Staff facilities for high-risk and high-care zones
N/A.
8.5 Housekeeping and hygiene in the high-risk high-care zones
N/A.
8.6 Waste/Waste disposal in high risk, high care zones
N/A.
8.7 Protective clothing in the high-risk high-care zones
N/A.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

9 - Traded Products

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

N/A.

9.2 Specifications

N/A.

9.3 Product inspection and laboratory testing

N/A.

9.4 Product legality

N/A.

9.5 Traceability

N/A.

Module 11: Meat supply chain assurance

Scope	**N/A.**

11.1 Traceability

N/A.

11.2 Approval of meat supply chain

N/A.

11.3 Raw material receipt and inspection

N/A.

11.4 Management of cross-contamination between species
N/A.
11.5 Product testing
N/A.
11.6 Training
N/A.

Module 12: AOECS Gluten-free Foods	
Scope	**N/A.**
12.1 Senior management	
N/A.	
12.2 Management of suppliers of raw materials and packaging	
N/A.	
12.3 Outsourced production	
N/A.	
12.4 Specifications	
N/A.	
12.5 Management of gluten cross-contamination	
N/A.	

12.6 Management of incidents, product withdrawal and product recall
N/A.
12.7 Labelling
N/A.
12.8 Product inspection and laboratory testing
N/A.

Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018			
Clause	Module item	Conforms Y/N	Comments
13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.	Y	Enough lightning. In compliance with Chilean regulation.
13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.	Y	Water distribution system has a check valve to avoid cross contamination between the piping systems that discharge wastewater.
13.1.3	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	Y	Equipment is made of stainless steel except for food grade plastic materials (ribbons). Hazards identification in HARPC plan is evidenced, controlled by the maintenance process.

	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.		
13.1.4	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 manufactured and used in processes.
13.1.5	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	Quality control department reviews all online process products, based on compliance with the specifications. Products that do not meet the requirements (Acceptable Hazard Limits) are treated as defined by the non-compliant product procedure.
13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to	Y	Hazard analysis carried out by the organization considers reasonably foreseeable hazards, considering the required criteria. They are not considered RTE foods.

	packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety		
13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine “hazards requiring a preventive control” (i.e., significant hazards).	Y	The risk analysis developed by the organization in the HARPC, has identified 2 preventive controls.
13.1.8	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	The defined preventive controls are: 1. Presence of pesticides in reception phase. 2. Reduction of E. Coli in chlorination phase washing tubs.
13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: • Notifying consignees of	Y	Compliance is evidenced according to the review of the Crisis management procedure code I-PR-GEN-007, revision 03 of 04-02-2019.

	how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out • Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product		
13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.	Y	Were reviewed: • Water control manual I-MN-AGU-001, revision 003 of 07-03-2019. • Procedure Approval and Evaluation of suppliers code I-PR-ADQ-002, revision 007 of 04-09-2018.
13.1.11	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	There is evidence of the implementation of: • Procedure corrective and preventive actions code I-PR-GEN-006, revision 04 of 15-04-2019. • Non-compliant product procedure code I-IT-LAB-008, revision 03 of 03-18-2019.
13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring	Y	The validations to preventive controls of the HARPC are evidenced, led by PCQI on: • Validation of control points: • CP 1, Presence of pesticides in reception phase of 24-05-2019,

	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.		carried out through pesticide analysis review of 2017-2020 (28 analyzes of raw materials and 32 analyzes of finished products). • CP 2, Reduction of E. Coli in chlorination phase washing tubs March 2013. •
13.1.13	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 reasonable timeframe after the record is created.	N	Verification of the monitoring of the CCPs was delegated to the head of the laboratory who is not a PCQI, that is, she has not fulfilled the requirement to participate and pass the FSCPCA course.
13.1.14	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	Y	Environmental monitoring program of 01-01-2019 risk assessment based, which includes sampling protocol, sampling points by zones, indicator organisms, test methods and evaluation of results with monthly frequency. • Limits of control are defined and monitored by means of microbiological analysis of surfaces, manipulators and environment were reviewed: • Reports of microbiological analysis of the environment carried out by the QualityLab laboratory: • No. QL 164192 of 22-10-2020 • No. QL 153850 of 25-05-2020. • No. QL 164191 of 22-10-2020. • No. QL 153851 of 25-05-2020.

	• Laboratory conducting analysis • Corrective action procedure where pathogen is detected		• Review program is scheduled on an annual basis, or when the results indicate its modification is not necessary.
13.1.15	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	Environmental monitoring program of 01-01-2019 risk assessment based, which includes sampling protocol, sampling points by zones, indicator organisms, test methods and evaluation of results with monthly frequency. • Limits of control are defined and monitored by means of microbiological analysis of surfaces, manipulators and environment were reviewed: • Reports of microbiological analysis of the environment carried out by the QualityLab laboratory: • No. QL 164192 of 22-10-2020 • No. QL 153850 of 25-05-2020. • No. QL 164191 of 22-10-2020. • No. QL 153851 of 25-05-2020. • Review program is scheduled on an annual basis, or when the results indicate its modification is not necessary.
13.1.16	Devices used to verify preventive controls must be calibrated.	Y	For the temperature controls, verifications with calibrated instruments are shown. For the analyzes, the realization with accredited laboratories ISO/IEC 17025 records was evidenced.
13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls,	Y	Manuel Tobar G. (Head of Quality Control and Management); • Administration Engineer. • Training in BRC 8 from 16 hours. • Training: Course FSPCA Preventive Controls for Human Food of 16 hours. • 17 years worked in the industry.

	review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		
13.1.18	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	Compliance is evidenced as observed during the review of records.
13.1.19	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	HACCP plans are signed by the General Manager and Head of FSMA Advisor.
13.1.20	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	Y	All required records are kept for 48 months. No off-site records are stored. Recordkeeping procedure was observed during process and records reviewed, were evidenced: • Control of records procedure code I-PR-GDT-002, revision 04 of 27-10-2020, that includes:

	within 24 hours with the exception of the food safety plan, which must remain onsite.		• Records handling was mentioned in each system document and records control by areas. Authorization of records is carried out by the records verifiers for each department of the company. • Amendments records control was mentioned in clause 4.4.3 of procedure I-PR-GDT-002 (Amendments were not evidenced in a way other than that mentioned). • Electronic formats are maintained in safe conditions, restricted access and change control • Backup copies are made to avoid loss. Records are saved considering the product shelf life, plus twelve months
13.1.21	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 receiving facility is responsible for verifying implementation of the control.	Y	Implementation of the approval Quality manual, code I-MN-GEN-001, revision 06 of 02-04-2019. An approval, raw materials suppliers monitoring and packaging material effective system is evidence according to Suppliers Evaluation and approval procedure I - PR- ADQ- 002 revision 7 21-03-2019, it is reviewed: • Evaluation of risks of raw materials, supplies and packaging material in contact and non-contact, is reviewed: • Analysis of raw materials, for fruits coming from fields, supplies and materials in contact, is carried out in Hazard Analysis by process stages in HACCP plans. • Raw materials Risk Evaluation of 18-03-2020.
13.1.22	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	Y	There is evidence of risk analysis for suppliers with defined control measures. An approval, raw materials suppliers monitoring and packaging material effective system is evidence according to Suppliers Evaluation and approval procedure I - PR- ADQ- 002 revision 7 21-03-2019, it is reviewed: • Evaluation of risks of raw materials, supplies and packaging material in contact and non-contact, is reviewed:

	temporary basis from unapproved suppliers.		• Analysis of raw materials, for fruits coming from fields, supplies and materials in contact, is carried out in Hazard Analysis by process stages in HACCP plans. • Raw materials Risk Evaluation of 18-03-2020. More details please see 3.5.1
13.1.23	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	All raw materials and packaging materials are analyzed in HARPC plans, by the design and development procedure before the definition of the product specification. More detail see 3.5.1
13.2.1	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-	N/A	No by products of human food are produced and distributed as animal feed.

	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 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.		

13.3.1	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	The food defense plan as the vulnerability analysis has been carried out by the PCQI of the plant.
			
			Identification and action plans for potential safety hazards are evidenced, in compliance with the request of clause 3.11.1. No incidents to date shown, we review:
			
			• Bioterrorism control procedure code I-PR-GEN-003, revision 05 of 16-04-2019, that include:
			
			  • Vulnerability matrix access control and product of 01-06-2020. Which includes analysis by areas and control measures.
			  • A plan of the facilities is shown, indicating the sectors where the fruit is packed (finished product).

13.3.2	The site shall have a written food defense plan, which includes the following: • A vulnerability assessment identifying significant vulnerabilities and actionable process steps	Y	The food defense plan as the vulnerability analysis has been carried out by the PCQI of the plant. Identification and action plans for potential safety hazards are evidenced, in compliance with the request of clause 3.11.1. No incidents to date shown, we review: • Bioterrorism control procedure code I-PR-GEN-003, revision 05 of 16-04-2019, that include:

	• Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		• Vulnerability matrix access control and product of 01-06-2020. Which includes analysis by areas and control measures. • A plan of the facilities is shown, indicating the sectors where the fruit is packed (finished product).
13.3.3	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 • 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	Y	Following control measures were implemented: • Bioterrorism procedure, code I-PR-GEN-003, revision 05 of 16-04-2019, considers the following control measures: • Security Policy code I-DC-GEN-01, revision 01 of 05-01-2018. • Access control procedure for the plant I-IT-RRHH-001, Revision 003 of 15-03-2019. • Permanence of personnel in the plant I-IT-RRHH-003, Revision 003 of 22-02-2019. • Surveillance I-IT-RRHH-004, Revision 003 of 02-25-2019. • Surveillance control cameras I-IT-RRHH-005 Revision 003 of 03-05-2019. Inside the facilities there are security cameras monitored by the plant manager and security personnel.

	operation was or was not identified as an actionable process step.		
13.3.4	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	Action plans implemented by thorganization have monthly follow-ups in order to evaluate their effectiveness.
13.3.5	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	Bioterrorism procedure, code I-PR-GEN-003, revision 05 of 16-04-2019, considers the following control measures: • Security Policy code I-DC-GEN-01, revision 01 of 05-01-2018. • Access control procedure for the plant I-IT-RRHH-001, Revision 003 of 15-03-2019. • Permanence of personnel in the plant I-IT-RRHH-003, Revision 003 of 22-02-2019. • Surveillance I-IT-RRHH-004, Revision 003 of 02-25-2019. • Surveillance control cameras I-IT-RRHH-005 Revision 003 of 03-05-2019. Surveillance control cameras I-IT-RRHH-005 Revision 003 of 03-05-2019.
13.3.6	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	Y	The implementation of: Procedure corrective and preventive actions code I-PR-GEN-006, revision 04 of 15-04-2019.

	correcting a lack of implementation • Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective actions		
13.3.7	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	Y	Food defense plan contemplates the verification of control measures by PCQI and through internal audit.

	• Frequency for verification activities • Recordkeeping requirements of all verification activities		
13.3.8	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	Food Safety Plan is reviewed on an annual basis or when changes occur.
13.3.9	All records required by 21 CFR § 121 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or	Y	Compliance was evidenced for the records reviewed during audit process.

	conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
13.3.10	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.	Y	Plan was signed by the Plant manager of company and PCQI.
13.3.11	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	Records are kept for 48 months.
13.4.1	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	N/A	The responsibilities of transportation in the US are of the importers.

	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.		
13.4.2	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	
13.4.3	Where the site arranges transportation, it shall document sanitary design requirements	N/A	

	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.		
13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.	N/A	
13.4.5	Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.	N/A	
13.4.6	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	N/A	

	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		
13.4.7	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	
13.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or	N/A	

	electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.		
13.4.9	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.	N/A	
13.5.1	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	N/A	It is evident that all personnel and subcontractors have training in Principles of hygiene and food safety, in inductions before entering work.
13.5.2	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	N/A	

	equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment		
13.5.3	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.	N/A	
13.5.4	A supervisor shall be identified with responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.	N/A	
13.5.5	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.	N/A	
13.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated	N/A	

	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.		
13.5.7	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	
13.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.	N/A	
13.5.9	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	N/A	

	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.		
13.5.10	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	
13.5.11	During harvest, packing and holding operations (e.g., hydrocooling,	N/A	

	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). 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.		
13.5.12	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.	N/A	
13.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces.	N/A	
13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.	N/A	

13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.	N/A	
13.5.16	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.	N/A	
13.5.17	Specific additional requirements for the harvesting, packing, and holding of 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)	N/A	

	• 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).		
13.5.18	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	N/A	

	shall occur as a part of the corrective action process: • Resample positive surfaces and the surrounding area to determine the extent of contamination • 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		