Audit Report

Global Standard for Food Safety Issue 8: August 2018

1.Audit Summary			
Company name	INVERTEC FOODS S. A	Site Code	1491837
Site name	INVERTEC FOODS S. A		
Scope of audit	Dehydration of fruits and vegetables of the species: apple, tomato, kale, celery, bell pepper and jalapeno pepper, packaged in plastic bags inside carboard boxes. Frozen IQF fruits and vegetables species: apple, cultivated blackberry, blueberry, raspberry, strawberry, cherries, kale, celery, spinach, bell pepper, tomato and jalapeno peppers, packed in plastic bags inside cartons and tote bins.		
Exclusions from scope	None		
Justification for exclusion	N/A		
Audit Finish Date	2020-10-21	Re-audit due date	2021-10-19
Head Office	No		

Additional modules included			
Modules	Result	Scope	Exclusions from scope
Choose a module	Choose an item		
Choose a module	Choose an item		

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit type	Announced
Previous audit grade	A	Previous audit date	2019-04-22		
Certificate issue date	2020-12-09	Certificate expiry date	2021-11-30		
Number of non-conformities		Fundamental	0		
		Critical	0		

Major	0
Minor	5

Company Details

Address	Av. Carlos Condell N° 1751, Rengo, Región del Libertador Bernardo O´higgins		
Country	Chile	Site Telephone Number	+56 72 2741000
Commercial representative Name	Paulo Aceituno	Email	paceituno@invertec.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 Rotating shifts 08:00 to 16:0016:00 to 00:0000:00 to 08:00.
Subcontracted processes	No
Other certificates held	Kosher certificate valid until August 2021.Certificate of organic operation, certificate NOP: 96338-Z-173041-2020, valid until February 2021.
Regions exported to	Oceania North America South America Europe Asia Choose a region
Company registration number	170208042009
Major changes since last BRCGS audit	No Mayor Changes.

Company Description

The Company has its origin on the Montanari enterprises, that began their activities in Chile in 1937 building and operating important industrial plants such as Cimet, Sindelen, Hunter Douglas IPAC, Alumco and Veneval, among others.
Invertec participates in the agribusiness sector through the holding that is constituted by: Invertec Foods, Invertec Frozen Foods, Invertec Natural Juice, Invertec Agrofoods and Invertec Agrícola Rengo. The Agribusiness holding is located strategically at Chile's central valley and its production operation centre is located in the city of Rengo, thus focussing on the fresh fruit production, export and commercial, activities, and on the frozen dehydrated processes for fruits and vegetables, and concentrated juices, as well.
Both factories have total employee of 400 workers (150 frozen and 250 dehydration).
Constructed area 9433 m2.
The factories are in operation since 1988, with a production of 200-240 tons per day.
3 productive shifts. 24 hours per day. 6 days per week. Sunday with cleaning shift from 08:00 to 18:00.
Productive shifts:
00:00-08:00
08:00-16:00
16:00-00:00.
Health Ministry food processing licence No. 1702 dated 08/04/2009.
FDA registration number 17444062090 dated 28-12-2018, valid until 31-12-2020.

The organization carried out the certificate extension in April 2020, and they will continue with the new cycle of audits, next audit October 2021.

5.Product Characteristics

Product categories	06 - Prepared fruit, vegetables and nuts 15 - Dried food and ingredients Category Category
Finished product safety rationale	Products frozen at -18C°, pH between 3 to 4.5 for fruits and blanching for vegetables. Dehydrated products, Aw: of 0.20 to 0.33 for low humidity products and from 0.62 to 0.70 for high humidity products, pH 4.5 for fruits and 6 to 7 for vegetables.

High care	No	High risk	No	Ambient high care	No

Justification for area	The product corresponds to frozen and dehydrated vegetables and fruits, without history of pathogen growth in raw materials and finished products.

Allergens handled on site	Celery Sulphur dioxide and Sulphites Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	Organic.
Product recalls in last 12 Months	No
Products in production at the time of the audit	Celery Granule No So2, Code D50100030, Lot FPT1002296.

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	According to the PWS.		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2020-10-19	11:00	18:00
2	2020-10-20	09:00	18:00
3 (end date)	2020-10-21	09:00	14:00

	Auditor (s) number	Name	Role

Auditor Number	176752	Natalia Garrido	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 Quality management and Assurance	X	X	X	X
Pablo Mesa P. - Quality Assurance Chief	X	X	X	X
Paulo Aceituno - Plant Manager	X	X	X	X

GFSI Audit History

Date	Scheme/Standard	Announced/Unannounced
21 April 2020	Covid Extension	Announced

Non-Conformity Summary Sheet

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

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

Major							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	1.1.2	Although the site has an implemented safety culture plan, the effectiveness of some of the activities implemented has not been evaluated: ✓ Promote Healthy and Hygienic Practices. ✓ Timely inform all workers about the different	Quality Deputy Manager, meeting schedule to implement the evaluation methodology of the activities implemented in the safety culture plan.	The effectiveness of the actions implemented in the safety culture plan will be reviewed quarterly.	The management team of the establishment has defined and maintains a clear plan to promote the development and continuous improvement of a culture of quality and food safety, but the frequency of evaluation of the activities was not established.	2020-11-16	Natalia Garrido

		standards established in the company to ensure food safety.					
3	4.4.2	During the visit to the facilities, it was observed that the floor coming out of the quality laboratory was in poor condition, which allows water stagnation.	Deputy maintenance manager, coordinates with the contractor company, the repair of the floor located in the laboratory exit.	Maintenance area will be scheduled to carry out a partial revision and repair of the floors to prevent further deterioration.	The poor condition of the floor is due to displacement of machines that were fixed, when removing the equipment, part of the floor deteriorated.	2020-11-16	Natalia Garrido
2	4.4.8	During the visit to the facilities, it is observed that the entrance gate to the production area was not fixed.	Maintenance Deputy Manager meets with the Plant Manager to fix the entrance gate to the dehydrated plant preparation room.	Weekly GMP monitor will check facilities and tightness, the status of the gates will also be considered.	Gate received a knock, moving from his position, this was not fixed which allowed the displacement.	2020-11-16	Natalia Garrido
4	4.6.1	During the visit to the facilities, it was observed that the base of the X-ray vibrator showed rust in some places.	Maintenance Deputy Manager and Plant Manager meet to remove the vibrator that has rust from the base room and repair it.	Structures with rust will be removed from the rooms, when they show the presence of corrosion they will be painted immediately or changed.	Not enough varnish and coating was added to the vibrator frame to prevent oxidation.	2020-11-16	Natalia Garrido
5	4.14.5	During the tour of the	Chief of plant issues a work order to place	Pest control company on their weekly visits	Production staff disconnect TUV	2020-11-16	Natalia Garrido

		facilities, it is evident that stations identified as 13 M and 13 N were out of place in the entrance area to the production area; TUV equipment No. 18 was de-energized.	another plug so that TUV equipment will not be disconnected, when production uses the sealer. Personnel training is carried out, remembering that after cleaning they leave the traps in the area that corresponds to them.	will immediately report non-compliance related to disconnected TUV equipment or traps out of position.	equipment to use sealer, another plug was missing. Hygiene workers when cleaning the corridor, move the traps, leaving them out of position.		

Comments on non-conformities

1. Senior management commitment

1.1 Senior management commitment and continual improvement

The Invertec Foods S.A. Management team is committed to complying with the food safety global regulation, as well as maintaining and improving performance. Items were checked as detailed below:

- The Quality policy dated 06.03.2019, was signed by the plant manager Paulo Aceituno and communicated through induction training.
- The safety culture plan is reviewed:
  - ✓ Where the following strategic objectives are defined:
    - Promptly inform all workers about the different standards established in the company to ensure food safety.
    - Make daily records on compliance with the standards and requirements of the company that influence the safety of the product.
    - Promote Healthy and Hygienic Practices.
    - Establish cleaning intervals for production areas and equipment.
    - Analyze the raw material to validate that it meets the characteristics or conditions required to produce a safe product suitable for human consumption.
    - Control and certify the quality and safety of the product in process and finished.
    - Validate the Quality of Water for food production.
    - Guarantee optimal conditions for food storage.
    - Verify adequate lighting conditions for the Production and Inspection areas.
  - ✓ The monitoring frequency for each of these objectives is defined.
  - ✓ The effectiveness measurement for the year has not been carried out.

- Regarding the objectives, the following are established:
  - ✓ Ensure compliance with quality standards during 2019: Fulfilled 100%
  - ✓ KPI Foods: 0.98, KPI Frozen: 0.99.

  - ✓ Ensure the 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

  - ✓ Ensure compliance with the implementation of corrective actions corresponding to third party audits.
  - ✓ 100% fulfilled
  - ✓ Objectives are checked monthly, evidence of meeting in minutes.

- Minutes of the manager review are reviewed, carried out annually, carried out on 03.04.2020.
  - ✓ The following topics were reviewed:
    - Policy.
    - Objectives of the integrated management system.
    - Corrective actions.

- Audit results.
- Feedback from customer, interested.
- Interested parties (complaints and claims).
- Claims management.
- Follow-up of previous review agreements.
- Haccp / BRCGS Plan.
- Training program and its evaluation of its effectiveness.
- Identification of availability of resources.
- Authenticity.
- Food defence.
- Estimated schedule of the next meeting.
- Review outputs by management.

✓ Ensure compliance with quality standards during 2019: Fulfilled 100%

- Minutes of meetings held monthly are reviewed:
  - ✓ 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.

- The site has a telephone number 72 2 741048, in which employees can make their complaints confidentially.
- The organization holds annual meetings where budgets are defined annually.
- The company has scientific development, sectoral information, participates in seminars and has information provided by clients and suppliers. The company reviews new development in monthly meetings. Evidence of “scientific folder”.
- Annual subscription to PARTICIPATE – BRC.
- The organization carried out the certificate extension in April 2020, and they will continue with the new cycle of audits, next audit October 2021.
- The Plant Manager took part in opening and closing meetings.
- Corrective actions for non-conformities of previous audit were implemented considering clause analysis.
- The organization does not use the logo of the standard.

1.2 Organisational structure, responsibilities and management authority

- Organisational chart showing hierarchy, communicated through induction training.
  - ✓ Organization chart updated on 10.10.2020 is reviewed.
- The organizational structure shows a Plant Manager, as the highest authority of the entire site. The heads of the different areas depend on this charge, production, maintenance, quality, others.
- Responsibilities pertaining to quality, legality and food safety are defined in job descriptions. The documents also include deputies.
- The personnel are aware of the Jobs descriptions, being communicated through induction training

and physical copies.
- Deputies are present en initial meeting

Details of non-applicable clauses with justification	
Clause/Section reference	**Justification**
1.1.13	The organization does not use the logo of the standard.

2 The Food Safety Plan – HACCP

The organisation has food-safety plans based on the Codex Alimentarius principles, scientific development, as well as legal and client requirements. Documents were checked as detailed below:

- HACCP team members, all with courses in HACCP and BRC 8:
  - ✓ Head of Quality Management and Assurance. Food safety Leader.
  - ✓ Head of maintenance
  - ✓ Head of plant
  - ✓ Head of electric maintenance
  - ✓ Head of Frozen laboratory
  - ✓ Head of Dehydrated laboratory
  - ✓ Microbiologist
  - ✓ Quality Assurance Chief.
  - ✓ Client support supervisor
  - ✓ Described in FO-MAN-HACCP-001.

- HACCP plan scope:
  - ✓ Dehydration of fruits and vegetables of the species: apple, tomato, kale, celery, bell pepper and jalapeno pepper, packaged in plastic bags inside carboard boxes. Frozen IQF fruits and vegetables species: apple, cultivated blackberry, blueberry, raspberry, strawberry, cherries, kale, celery, spinach, bell pepper, tomato and jalapeno peppers, packed in plastic bags inside cartons and tote bins.

- Regarding the pre-requisites, the following instructions and procedures are handled:
  - ✓ I-IT-ACL-007 Hygiene and personal presentation Rev.2.
  - ✓ I-IT-ACL-011 Risk of contamination by glass and hard plastic Rev.3.
  - ✓ I-IT-H & S-001 General Cleaning and Disinfection Method Rev.5.
  - ✓ I-IT-L & S-002 Periodic Cleaning Method Rev.3.
  - ✓ I-IT-L & S-003 Unscheduled cleaning and disinfection order Rev.4.
  - ✓ I-IT-MAN-008 Risk of glass contamination Rev.3.
  - ✓ I-IT-MAN-032 Maintenance of buildings Rev.4.
  - ✓ I-IT-PLG-001 Pest Control Rev.3.
  - ✓ I-IT-RRHH-002 Staff induction Rev.3.

- ✓ I-MN-GEN-002 GMP Manual Rev.6.
- ✓ I-MN-MAN-001 Preventive Maintenance Manual Rev.4.
- ✓ I-MN-PLG-001 Pest Control Rev.3.
- ✓ I-PR-ADQ-001 Acquisitions area operation Rev.3.
- ✓ I-PR-GEN-004 Allergen Control Rev.4.
- ✓ I-PR-GEN-005 Staff training Rev.4.

SGS

HACCP food-safety plans:

- HACCP Foods manual, code FO-MAN-HACCP-001 rev05 dated 10.10.2020.
- HACCP Frozen manual, code F-MN-HACCP-001 rev06 dated 10.10.2020.

Product descriptions:

- Products processed at Foods plant:
  - ✓ Dehydrated apple:
    - High-moisture (15 to 25%) dehydrated apple: Aw < 0.75, pH < 4.0.
    - Low-moisture (5%) dehydrated apple: Aw < 0.40, pH < 4.0.
    - High-moisture (15 to 26%) dehydrated apple rings and dices: Aw < 0.75, pH < 4.5.
    - Stabilised (5%) dehydrated apple: Aw < 0.40, pH < 4.0.
    - Vacuum packed apple chips: Aw < 0.4, pH < 4.0. 15 a 26% moisture.
    - Washing with chlorinated water and addition of sodium metabisulfite.
  - ✓ Dehydrated bell pepper: Aw < 0.40, pH < 6.0. Maximum moisture is 6%. Washing with water and chlorine solution. Addition of citric acid, sodium bicarbonate and sodium carbonate.
  - ✓ Dehydrated tomato: Aw <0.40, pH <4.5. Maximum moisture is 6%. Washing with chlorinated solution and heat treatment.
  - ✓ Dehydrated celery. Aw <0.94 and pH <5.0. Washing with chlorinated solution.
  - ✓ Apple without sulphites: Eighteen and 12 months for stabilised apple and apple chips respectively.

    - Primary packaging: HDPE bags.
    - Secondary packaging: double-wall corrugated cartons.
    - Shelf life: 24 months in adequate storage conditions.
    - Storage conditions must be below 15°C.

- Frozen product plant:
  - ✓ Apples: Aw <0.8, pH <4.5, Brix 11-13. Addition of ascorbic and citric acid. Washing with chlorinated solution.
  - ✓ Tomatoes: Aw <0.8, pH <4.5, Brix 7-8.
  - ✓ Bell pepper: Aw <0.75, pH <6.0, Brix 4-5. Washing with chlorinated solution and scalding thermal treatment.
  - ✓ Raspberries: Aw 0.97, pH <3-4.5, Brix 9-12. Washing with chlorinated water.
  - ✓ Blueberries: Aw 0.98, pH < 3-4.5, Brix 9-12.
  - ✓ Strawberries: Aw 0.98, pH < 3-4.5, Brix > 8.
  - ✓ Blackberries: Aw 0.97, pH < 3-3.5, Brix 10-12.
  - ✓ Cranberries: Aw 0.98, pH 3-3.5, Brix 3-4.5.
  - ✓ Spinach: Aw 0,98, pH 5.5, Brix 4-9.
  - ✓ Celery: Aw 0,98, pH 5.5, Brix 4-9.
  - ✓ Kale: Aw < 0.7, pH 6-6.8, Brix 4-9.

    - Frozen apple can be added with ascorbic acid and citric acid according to client requirements.

- Primary packaging: 60 to 100 microns HDPE bags.
- Secondary packaging: double-wall corrugated cartons.
- Shelf life: 24 months stored at -18 ± 2º C.

Intended use:

- 99% of the production is for industrial use, secondary process at production plant 1% is direct retail.
  Dehydrated products:
  - ✓ Bell pepper and tomato as ingredient in other products, such as soup, spices, etc.
  - ✓ Apples: direct consumption or as a baking ingredient.
- Intended use of frozen products:
  - ✓ Direct consumption or as ingredient in other products.
- Vulnerable groups:
  - ✓ Dehydrated products: consumers allergic to SO2. Possibility of contamination with SO2.
  - ✓ Frozen products: consumers allergic to celery. The line is used only for celery. Production is done only once.

- The information used for identifying hazards includes scientific literature, likelihood of hazard trends, as well as legislations pertaining to source markets and client requirements.

- Dehydration flow diagram:
  - ✓ Receipt of raw material.
  - ✓ Preparation and storage of raw material, cleaning ad washing.
  - ✓ Optical selection.
  - ✓ Cutting.
  - ✓ Dehydration (CCP1)
  - ✓ Sieving
  - ✓ Optical selection
  - ✓ Visual inspection
  - ✓ Metal detection (CCP 2)
  - ✓ X ray (CCP 3)
  - ✓ Packaging
  - ✓ Storage
  - ✓ Dispatch (CCP 4 of allergen labeling only for apple).

- Frozen flow diagram:
  - ✓ Receipt of raw material
  - ✓ Preparation and storage of raw material, cleaning ad washing.
  - ✓ Chlorine washing (50-100 ppm)
  - ✓ Optical selection.
  - ✓ Cutting.
  - ✓ Optical selection
  - ✓ Visual inspection
  - ✓ Blanching for vegetables (CCP 1)
  - ✓ Magnetic trap
  - ✓ Congelación
  - ✓ Optical selector
  - ✓ Visual inspection
  - ✓ X-ray
  - ✓ Metal detection (CCP 2)

- ✓ Magnetic trap
- ✓ Packaging
- ✓ Storage
- ✓ Dispatch.

- Flow diagrams verified IN SITU by the HACCP team:
  - ✓ Products processed at Foods plant:
    - FO-MN-HACCP-003.1 Apple dehydrates high humidity with sulfite, verified on 15.04.2020.
    - FO-MN-HACCP-003.2 Apple dehydrates low humidity with sulphite, verified on 23.04.2020.
    - FO-MN-HACCP-003.3 Stabilized dehydrated apple, verified on 19.04.2020.
    - FO-MN-HACCP-003.4 Apple dehydrates high humidity segments and rings with sulfite, verified on 21.04.2020.
    - FO-MN-HACCP-003.5 Dehydrated paprika, verified on 15.04.2020.
    - FO-MN-HACCP-003.6 Dehydrated tomato, verified on 21.02.2020.
    - FO-MN-HACCP-003.7 Celery, verified on 27.05.2020.
    - FO-MN-HACCP-003.8 Apple cube color and flavor, verified on 18.04.2020.
    - FO-MN-HACCP-003.9 Apple chips, verified on 18.04.2020.
    - FO-MN-HACCP-003.10 Kale, verified on 15.05.2020.

  - ✓ Products processed at Frozen product plant:
    - F-MN-HACCP-003.1 Frozen peper, verified on 07.02.2020.
    - F-MN-HACCP-003.2 Frozen tomato OM, verified on 18.02.2020.
    - F-MN-HACCP-003.3 Frozen apple, verified on 01.07.2020.
    - F-MN-HACCP-003.4 Frozen OM apple, verified on 01.07.2020.
    - F-MN-HACCP-003.5 Frozen blackberry, verified on 12.01.2020.
    - F-MN-HACCP-003.6 Frozen raspberry, verified on 05.01.2020.
    - F-MN-HACCP-003.7 Frozen blueberry, verified on 23.01.2020.
    - F-MN-HACCP-003.8 Frozen strawberry, verified on 18.01.2020.
    - F-MN-HACCP-003.9 Frozen cherry, verified on 15.01.2020.
    - F-MN-HACCP-003.10 Frozen spinach, verified on 18.01.2020.
    - F-RG-HACCP-003.11 Frozen Kale, verified on 19.11.2019.
    - F-RG-HACCP-003.12 Celery, verified on 02.06.2020.

The HACCP analysis identifies the hazards detailed below:

- Foods plant:
  - ✓ Inadequate thermal treatment that benefits E. coli O157:H7 survival during the drying stage.
  - ✓ Contamination caused by banned or excessive pesticides in raw materials.
  - ✓ Lead in raw materials above established limits.
  - ✓ Migration of monomers.

- Frozen plant:
  - ✓ Raw materials:
  - ✓ Microbiological contamination caused by E. coli O157:H7.
  - ✓ Metal particles larger than 7 mm.
  - ✓ Contamination caused by banned or excessive pesticides in raw materials.
  - ✓ Lead in raw materials above established limits.
  - ✓ Inadequate thermal treatment that benefits E. coli 0157:H7 during the drying stage.

- Hazard assessment:
  - ✓ 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.
  - ✓ The organisation uses the Codex Alimentarius decision tree.

- CCP is determined by using the Codex Alimentarius decision tree.
- Pesticide and heavy metals controls is GAP and contract for vegetable farmers and GLOBAL GAP certification for fruit growers:
  - ✓ All the farmers are analyzed once per year.

- Foods (Dehydrated) plant:
  - ✓ **CCP 1: Dryer**
    - Hazard: inadequate thermal treatment that benefits pathogen survival, such as E. coli 0157:H7 during the drying stage.
    - Critical limit: A stage must be performed at least at 70º C and 80 Hz maximum speed.
    - Monitoring: temperature control and drying time. Visual display control and thermogram analysis whilst monitoring drying temperature. Tasks to be carried out by the laboratory analyst every two hours.
    - Corrective actions:
      - To notify the head of shift.
      - To stop the conveyor belt.
      - To identify bins or pallets as of the latest approved measurement.
      - Microbiological sampling. The product will be released or discarded, depending on detection results.
      - To adjust the drying parameters to comply with operational critical limits.
      - To verify drying parameters 20 minutes later to check that the corrective action was applied accordingly.

  - ✓ **CCP 2: Metal Detector**
    - Hazard: metals.
    - Critical limit: functional metal detector and rejection system.
    - Monitoring by means of parameters per product as follows:
    - High moisture: ferrous 1.5 mm, non-ferrous 1.5 mm and stainless steel 2.0 mm.
    - Low moisture: ferrous 1.0 mm, non-ferrous 1.2 mm and stainless steel 1.5 mm.

- Hourly monitoring by the laboratory analyst. Daily review of CCP 2 sheets by the head of laboratory. Verifying functionality and sensitivity by means of predictive maintenance. Annual calibration.
- Corrective actions: To notify the head of shift against any deviation.

✓ **CCP 3 X Ray detector**

- Hazard: metals.
- Critical limit: functional x ray and rejection system.
- Monitoring by means of parameters per product as follows:
- 2 mm glass balls.
- Aluminium: 2 mm.
- Ceramic: 2 mm.
- SUS304 stainless steel: 0.8 mm.
- Piedra: 2 mm
- Hourly monitoring by the laboratory analyst.
- daily review of CCP 3 sheets by the head of laboratory. Verifying functionality and sensitivity by means of predictive maintenance. Annual calibration.
- Corrective actions: To notify the head of shift against any deviation.

✓ **CCP 4 of labelling:**

- Hazard: sulphite not mentioned in labels.
- Critical limit: correct 'With SO2' labelling.
- Monitoring: to verify light blue label, pallet and box number, as well as the 'With SO2' mark. To be monitored hourly by the laboratory analyst.
- Corrective actions: the packaging supervisor must be informed and labelling must be stopped in order to segregate products as of the latest successful inspection. Newly printed labels will be checked before being placed on boxes.

✓ CCP 4: labels with a 'product with sulphite' notation.
✓ The 4 CCPs apply for apple with sulfites.
✓ For the rest of the species applies 3 CCP. 1 2 and 3.

- Frozen plant:

✓ **CCP 1 Dryer or blanching applicable only to vegetables**

- Hazard: inadequate thermal treatment that benefits pathogen survival, such as E. coli 0157:H7 during the blanching stage.
- Critical limit: temperature must be at least at 80º C and the belt must be running at 63 Hz.
- Hourly monitoring on temperature and blanching machine conveyor belt speed
- Corrective actions: the preparation area supervisor must be informed in order to stop the conveyor belt and identify the product for further segregation as of the last measurement approved. Afterwards, the product must be analysed, microbiological samples must be taken and drying parameters must be adjusted in order to comply with critical limits. Twenty minutes later, blanching parameters must be checked to validate the corrective action.

✓ **CCP 2: metal detector**

- Hazard: metal particles in food.
- Critical limit: ferrous 1.5 mm, stainless steel 2.0 mm and non-ferrous 1.5 mm. Critical limits are defined by the manufacturer on the basis of metal detector sensitivity.
- Monitoring: the CCP monitor must place the test pieces inside the metal detector to ensure the machine works accordingly.

- The same person above must check containers in order to check traces of metal particles and inspection records filled by maintenance staff. Monitoring to be carried out hourly.
- Corrective actions: in case the metal detector alarm is activated, the operator must pass the product three times more in different positions. Should the alarm sounds more than twice, the metal particle will be found and the deviation will be logged on the control record. Afterwards, the product will be passed one more time to confirm that all metal particles have been removed for further packaging. Metal found in containers involve checking maintenance records to verify if any metal deviation was detected. It that is the case, production must be stopped. The amount of reprocessed products equals the time elapsed between the deviation and the last conforming maintenance review. CCP 2 metal detector record.
- Records of inspections have been evidenced and verified by means of signatures, considering control inspection performance, corrective actions taken in case of deviations and generation of non-conforming products.

- Corrective actions are defined in HACCP plans.
- Records reviewed during the audit of January March, April, June, July, August 2020 are reviewed:
  - ✓ No deviation in oven or blanching critical limits.
  - ✓ No deviation in labelling critical limits.

- CCP validations:
  - ✓ Critical point 1 is validated by reviewing the pesticide analysis carried out last year. The parameter is equally applied to the Foods and Frozen plants
    - Foods plant:
      - CCP 1: thermal lethality time calculated on 26.04.2016.
      - CCP 2: re-validation granted on 10.02.2019 by passing each test piece 10 times. Method applicable to high and low-moisture products.
      - CCP 3 X-Ray validation dated from February 28, 2018, practical test with different contaminants, all the contaminants were tested.
      - CCP 4: re-validation granted on 19-06-2014 by checking all labels pertaining to sulphated products.
    - Frozen plant:
      - CCP 1: Final report Process validation of the steam blancher and optimized moisture pasteurization systems. Report date May 20, 2015." Process Validation of the Steam Blancher and optimized moisture pasteurization Systems. Rick Falkenber, Ph D CFS
      - CCP 2: validation granted on 25-01-2016 by passing each test piece 10 times. Method applicable to high and low-moisture products.

- System verifications are considered as detailed below: CCP daily monitoring verification, GMP verification. Finished products are analysed by the head of Quality Assurance and in internal audits.

- Information on last review and date of each HACCP study:
  - ✓ HACCP Foods manual, code FO-MAN-HACCP-001 rev05 dated 10.10.2020.
  - ✓ HACCP Frozen manual, code F-MN-HACCP-001 rev06 dated 10.10.2020.
    - A review is performed annually or whenever there is a change.

Details of non-applicable clauses with justification

Clause/section reference	Justification
N/A	

3. Food safety and quality management system

3.1 Food safety and quality manual

The quality manual meets its intended purpose, as observed in document review and during the audit.

- Quality manual, code I-MN-GEN-001 revision 07, dated from June 09, 2020.
- It is managed within a folder on the intranet, and you have access to the documents including the manual, according to your profile, mostly by way of consultation.
- All documents are legible and available in physical and digital copies for key personnel. Furthermore, the documents are written in Spanish.
- The clauses mentioned on the quality manual are in line with BRC GS 8 in order to ensure that the entire system is communicated.

3.2 Document Control

The organisation controls document effectively, as observed during process review and on documents checked during the audit.

- The document development procedure (I-PR-GDT-001 rev 004 dated from 16-04-2019) includes as listed below:
  - ✓ Document master list, I-RG-GDT-001.
  - ✓ External documentation list, including scientific evidence, client documentation and standards.
  - ✓ History of changes.
  - ✓ Documents are controlled and distributed in PDF in "GRANNY" server the IT area generates backup of the documents on a weekly basis.

3.3 Record completion and maintenance

The organisation has effective procedures to keep records, as observed during process and record review.

- Record control procedure, code I-PR-GDT-002 revision 03 dated from April 16, 2019.
- Record completion and maintenance is mentioned on each system document and control record per area. Also, records are approved per area individually.
- Record amendment control is mentioned in clause 4.4.3 of procedure I-PR-GDT-002.
- Records are kept during product shelf life plus 12 months. 3 years.
- The documents will be stored in a compartment of the cellar, until they are 3 years old. After these they will be destroyed in the same way; When the documents are stored in electronic format, there are certain security conditions, they are authorized to access, they maintain control of modifications, backup copies are made on the server to avoid loss of information.

3.4 Internal audits

- Internal Audit Procedure code I-PR-GEN-002, revision 002, dated 04.09.2018.
- Risk analysis code I-DC-GEN-015, revision 004, 06.08.2020.
- The determined frequency is:
  - ✓ Chapter 1, annual frequency. Audited on 03.03.2020, without deviation.
  - ✓ Chapter 2, annual frequency, Audited on 03.03.2020, without deviation.
  - ✓ Chapter 3, annual frequency, Audited from April 07 to 23, 2020, without deviation.
  - ✓ Chapter 4, semi-annual frequency, Audited from May 14 to 29, 2020, 3 minor non-conformities. Next evaluation November 2020.
  - ✓ Chapter 5, annual frequency. Audited from June 03 to 15, 2020, 1 minor non-compliance.
  - ✓ Chapter 6, annual frequency, Audited from June 13 to 25, 2020. No deviations.
  - ✓ Chapter 7, annual frequency, Audited from 04 to 15 August 2020, 1 minor non-conformity.

- Internal Audit Program:
  - ✓ I-DC-GEN-001, rev 02, dated from April 09, 2018.
  - ✓ Risk analysis is evidenced in document I-DC-GEN-014, dated from March 03, 2019:
  - ✓ It was evidenced risk analysis with conclusion that all the areas must be audited once a year.
  - ✓ Internal audits are scheduled throughout the year for all the clauses of BRCGS.
  - ✓ Auditor team trained and independent from the areas audited:
    - All the auditors have training in BRC GS 8 internal audits:
      - On the 18.06.2020 an update and verification of internal auditors is carried out. There are three groups to ensure the independence of the auditee process.
    - The audits are done to ensure independence.

- Weekly and Daily GMP inspections of the open product areas, patios and warehouse areas dating from the dates below have been evidenced:
  - ✓ Weekly external areas inspection I-RG-GMP-002.
  - ✓ Weekly inspectios of catering and change rooms: I-RG-GMP-010.
  - ✓ Daily inspections of processing rooms conditions: I-RG-GMP-001.
    - Evidence of immediate actions for GMP deviations, observed in records from December 2019 to october 2020.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

- The organisation has an effective system for approving and monitoring raw material suppliers and packaging material suppliers.
  - ✓ Risk assessment of raw materials supplies and food-contact and non-contact materials.
  - ✓ The raw material analysis on fruit originating from fields, supplied and food-contact materials is included in the HACCP hazard analysis and summary of risk assessment dated on 20.03.2020.
  - ✓ Raw material authenticity assessment dated March 18, 2020.
  - ✓ Analysis of hazards due to malicious contamination dated March 18,2020.
  - ✓ All fruit suppliers have been classified as of low risk because all suppliers have Global GAP certification or with on-site auditing, the fields are their own. and all additives and food-contact material suppliers are of low risk.
  - ✓ All suppliers are approved through GFSI certification or on-site audit:
    - Frutera san fernando, approved through an audit carried out on 07.01.2020.

- Agropecuaria Wapri, approved status, Global Gap certificate No. 4049928385178, valid until 03.04.2021.
- Sociedad Agricola el Alamo, Global Gap Certificate No. 4056186878298, valid until 28.12.2020.
- Agrícola San Leon, Global Gap Certificate No. 00084-FNTHX-0002, valid until 08.05.2021.

- Procedure of supplier and raw material management, code I-PR-ADQ-002, revision 07, date 21.03.2019.
  - ✓ Plastic bags supplier:
    - PLASTICOS BIO BIO. FSSC 22000 certificate No. CL14/81841258 valid until December 06, 2020.
  - ✓ Cardboard supplier:
    - "Chile Empack S.A.": IFS PAC secure Certificate, valid 04.02.2021.
    - Cartocor chile S.A, On-site audit report is reviewed on February 13, 2020.
  - Fruit and Vegetables. Global Certification GAP is the requirement to the fields and audits are also carried out. 60% of processed fruit is from its own fields and 40% is from supplier fields.

- The organisation has a department responsible for controlling raw material suppliers.
- Contracts with suppliers:
- Raw material suppliers for 2019 - 2020.
- Brokers:
  - ✓ Fruit and vegetables: no brokers are used.
  - ✓ Citric and ascorbic acid: Broker used is "Navarro y Compañía":
  - ✓ Citric acid:
    - WEIFANG CITY BRC SITE CODE: 2015764.
  - ✓ Ascorbic acid:
    - ZHENGZHOU TUOYANG BRC SITE CODE: 1920096.

- Exceptions are established in procedure I-PR-ADQ-002 revision 07 dated 23.03.2019, considers and will be applied in case of suppliers imposed by clients or purchases from suppliers not included on the list.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

- The organisation has controls in place with the purpose of avoiding the ingress of out-of-specification raw and packaging materials.
  - ✓ Controls of raw materials, food-contact materials and supplies are defined in HACCP plans and other requirements.
    - Supply receipt procedure, code I-IT-BOD, revision 001, date 25.04.2019, revision 03.
    - Procedure for receiving and weighing raw materials, code I-IT-BYC-001, revision 03, date 24.04.2019.
  - ✓ Every truck goes through raw material and is received against specification.
  - ✓ Everything is left within the SAP platform.

3.5.3 Management of suppliers of services

- The organisation has formal agreements with suppliers of services and control measures are defined by means of risk analyses.

- ✓ The procedure for assessing and approving suppliers (I-PR-ADQ-002, revision 07, 21.03.2019) is applied to the services listed below:
  - Plaguisur company in charge of pest control, evaluated on 03.18.2020, with 5.5 approved status. Contract signed on 02.01.2013 is reviewed.
  - GZ Seguridad company, evaluated on 18.03.2020, with 4 approved status. Contract with annex dated 13.04.2019 is revised.
  - Company to point casino services, evaluated on 18.03.2020, with 5.5 approved status. Contract with annex dated 25.05.2020 is reviewed.
  - Company Quality lab analysis laboratory, evaluated on 18.03.2020, with 6.2 approved status. agreement is reviewed
  - CeimiC company, pesticide laboratory, evaluated on 18.03.2020, with 6.3 approved status. agreement is reviewed
  - Rio Negro company, transportation company, evaluated on 18.03.2020, with 4.1 approved status. Contract signed 07.02.2019 is reviewed.
  - Barlovento laundry company, evaluated on 03.18.2020, with 6 approved status, agreement is reviewed.

3.5.4 Management of Out sourced processing

- No outsourced processing.

3.6 Specifications

- Specifications have been defined according to client requirements.
- Accepting and modifying specifications are agreed with clients.
- The company states specifications for raw materials, packaging materials and finished goods. Such specifications are applicable to all products.
- Evidence of specifications of raw materials for 2019 - 2020 season, additives and packaging materials.
  - ✓ Tomato product, code FO-DC-MPR-001, version 05, 15.03.2020.
  - ✓ Apple, code FO-DC-MPR-008, revision 04, 09.03.2020.
  - ✓ Red paprika, code FO-DC-MPR-002, revision 04, 03.04.2020.
  - ✓ Green paprika, code FO-DC-MPR-009, revision 001, date 03.04.2020.

- Final product Specifications reviewed:
  - ✓ Frozen plant:
    - Frozen IQF Green Apple Dice ¼, code F-DC-PRD-019, revision 002, 01.08.2020.
    - Frozen IQF Tomato Dice ½ ", code F-DC-PRD-031, revision 001, 19.02.2019.
    - Frozen IQF Red Bell Pepper Dice 1/4 ", code F-DC-PRD-042, revision 001, date 22.05.2019.
  - ✓ Dehydrated Plant:
    - Low Moisture red apple says ¼ ", not s02; with peel, code FO-DC-PRD-084, revision 001, date 11.09.2018.
    - Red Bell Pepper Granule -10 + 30 mesh, code FO-DC-PRD-085, review 002, date 01.10.2018.
    - Tomato Flake 3/8 ", code F-DC-PRD-066, review 001, date 20.06.2018.

- Specifications are modified based on packaging performance and checked prior to starting the season or due to new client requirements.
  - ✓ Carton box specification, Code I-DC-GEN-017, revision 001, date 22.06.2020.
  - ✓ Specification polyethylene bags, Code I-DC-GEN-018, revision 001, date 22.06.2020.

3.7 Corrective and preventive actions

- The organisation applies corrective actions as a means to solve system deviations and to analyse their effectiveness with the purpose of avoiding recurrence.
  - ✓ Corrective and preventive action procedure, code I-PR-GEN-006 revision 005 dated 08.06.2020.
  - ✓ Closure on non-conformities raised in internal audits.
  - ✓ Corrective actions for non-conformities raised in the previous visit were implemented. For the year 2020, 9 non-conformities have been detected, they are all closed. Mostly they are findings of internal audit and GMP reviews.

3.8 Control of non-conforming product

- The organisation identifies and segregates potentially unsafe products and non-conforming products in order to prevent accidental dispatch. Trend analyses are undertaken with the purpose of taking corrective actions. There have been no non-conforming products during this period.
  - ✓ Procedure for non-conforming products, code I-IT-LAB-008 revision 004 dated 14.07.2020.
  - ✓ Trend analysis of non-conforming products 2019-2020, form part of the KPI of the plants.
    - There have been no non-conforming product events.

    The head of Quality Assurance is the person responsible for handling non-conforming products.

3.9 Traceability

- Procedure for product withdrawal and traceability, code I-PR-PLA-001 revision 11, dated 15.06.2020.
- It has been evidenced that the organisation performs traceability by means of traceability software SAP and printed documents.
- The organisation can identify origin of additives, packaging materials, process help and growers. Also, they perform mass balance successfully.
- Rework:
  - ✓ No perfom rework.
- Traceability is performed in software SAP and can be backed up with paper documents.

- Traceability test carried out by the company, from Final product to raw material:
  - ✓ Product: Manzana verde IQF.
  - ✓ Lot: CPT1003709.
  - ✓ Code: C53100287.
  - ✓ Date of test: 13-10-2020.
  - ✓ Quantity: 761 kg.
  - ✓ Duration: 2 hours and 25 minutes

- Traceability test carried out by the company, from raw material to final product:
  - ✓ Date of test: 15.02.2020.
  - ✓ Raw material: Fresh tomato.
  - ✓ Batch 180042873-01
  - ✓ Quantity:420 kg.
  - ✓ Duration: 1 hours and 55 minutes
  - ✓ Final product: Dehydrated tomato, lot: 08180601.

- During the audit was performed a traceability exercise to product:
  - ✓ Order: 03000000056
  - ✓ Contract: 0115000039
  - ✓ Client: Watts S.A.
  - ✓ Product code: C53100279.
  - ✓ Product: Green apple IQF cube 3/8.
  - ✓ Lot: CPT1003375.
  - ✓ Quantity: 761.88 kg.
  - ✓ Dispatch date 08.14.2020.
  - ✓ Production date: 11.06.2020.
  - ✓ Expiration date: 06.11.2022.
  - ✓ Start time: 11:30.
  - ✓ End time: 13:15.
  - ✓ The respective documents and the respective mass balances are reviewed.

3.10 Complaint-handling

- The organization has effective procedures, as demonstrated by complaint handling and trend analyzes.
  - ✓ The client complaint management procedure (I-MN-ATC-001, Revision 01, from 10.02.2019) established that the head of Quality Assurance is the person responsible for handling complaints.
  - ✓ Procedure for managing customer complaints, code IPr-ATC-001, revision 003, 02/19/2016.
    - Monthly claims analysis, trend sheet, in 2019 there were a total of 2 claims, associated with quality, in one the client complains about the condition of the boxes (dented) and another Client claims that a lot of cubed apple mixed with skin arrived , the owners are closed and the response sent to the client is reviewed. For the period 2020 they have not presented food safety claims. They have presented 1 claim associated with quality, the client asked for a product without skin and it came mixed with skin.
  - ✓ All complaints accepted are handled by means of corrective actions taken by the corporate committee and the Management department.

3.11Management of incidents, product withdrawal and product recall

- The organisation has procedures in place for managing incidents, product recall and withdrawal, as verified by means of exercises. No incidents have been detected for this period.
- The crisis management procedure (I-PR-GEN-007 revision 003 date 11.06.2020 includes the incidents listed below:
  - ✓ Disruption to water and power services.
  - ✓ Accidents involving finished products in dispatch.
  - ✓ Flood.
  - ✓ Fire.
  - ✓ Natural disasters.
  - ✓ Availability of personnel.
  - ✓ Malicious contamination or sabotage.
  - ✓ Cybersecurity
  - ✓ Pandemic
- The recall and traceability procedure (I-PR-PLA-001 rev 09 dated March 21, 2018) includes as follows:
  - ✓ Responsibilities.
  - ✓ Recall types I, II and III.
  - ✓ Process flow for product recall and withdrawal.
  - ✓ External contact list: I-DC-GEN-005.

- The company performed the annual mock recall.
  - ✓ Recall exercise report performed on 13.10.2020 is reviewed, start time 11:00 hrs, problem It is reported that batch CPT 1003709, Organic Green Apple product IQF 3/8, has detected a foreign element of metal greater than 2 centimeters; class I recall, 100% recovered product, respective mass balance is reviewed, total time 2 hours.
- It was concluded that the product complies with all the procedures. The metal detector equipment for the production date worked correctly.
- The procedure defines to contact the certification body prior to 3 days of a real RECALL:
  - ✓ In case of real recall, the organization shall contact SGS Chile Veronica Muñoz (+56 9 92077211). There have been no recall situations to the date.

- Cybersecurity: computers that have Windows XP are removed, fortinet firewall is purchased, the

prohibition is established for some unsafe websites, you cannot navigate in pages like youtube, facebook, dafity, each person has an alphanumeric password (8 characters)), the keys are changed every 90 days, it will be increased to 14 alphanumeric characters including signs. It has GDATA antivirus, it has two databases.

Details of non-applicable clauses with justification

Clause/section reference	Justification
3.5.1.3	No agents or brokers used.
3.5.4	No outsourced processing.
3.9.4	No rework used or reworking operations carried out.

4. Site standards

4.1 External standards

- It has been evidenced that the organisation controls hazards coming from outside the facilities and their surroundings.
  - ✓ The site is in a rural area.
  - ✓ No evidence of potential contaminants in the surroundings.
  - ✓ External areas have been found in good order, grassed and planted areas are tended and well maintained; no weed has been found.
  - ✓ The building fabric is maintained, contamination sources and pest nesting have not been identified.
  - ✓ The facility has exterior canteens and toilets, exteriors are paved.

4.2 Site security and food defence

- The organization has action plans for potential threats to security, in accordance with clause 3.11.1. No incidents have raised to the date. Items checked below:
  - ✓ The procedure for protection against bioterrorism (I-PR-GEN-003 revision dated April 16, 2019), includes as follows:
    - Annual risk assessment of security measures dated from March 02, 2020.
    - Annual inspection of security measures dated from March 19, 2020.
    - The site map shows areas where finished products are stored.
  - ✓ Control measures were observed as listed below:
    - Handbook of site access control, code I-IT-RRHH-001.
    - Handbook of CCTV control, code I-IT-RRHH-005.
    - I-IT-RRHH-003 Staff permanence in the plant Rev.3
    - I-IT-RRHH-004 surveillance Rev.3

- I-PR-PRP-003 Emergency Plan Rev.3
- Manual water control, code I-MN-LAB-001.

✓ The site has locked intake pipes and enclosed service areas (like water tanks).
✓ Health Ministry food processing license No. 1702 dated 04/08/2009.
✓ FDA registration number 17444062090 dated 12-28-2018, valid until 31.12.2020.

- Cybersecurity: computers that have Windows XP are removed, fortinet firewall is purchased, the prohibition is established for some unsafe websites, you cannot navigate in pages like youtube, facebook, dafity, each person has an alphanumeric password (8 characters)), the keys are changed every 90 days, it will be increased to 14 alphanumeric characters including signs. It has GDATA antivirus, it has two databases.
- Food defence training was held on 10.06 and 10.08.2020.

4.3 Layout, product flow and segregation

- The development design for operations is sufficient to prevent the risk of cross-contamination, in line with applicable legislations. Documents were reviewed as detailed below, dated 15.10.2020:
  - ✓ Map of areas identified with contamination risk:
    - Enclosed product areas.
    - Open product areas. Low-risk areas.
    - Non-product areas.
    - The decision tree for production areas is developed in line with BRC GS v.8.
    - The site layout updated to February 2019 includes as listed below:
    - Routes and access for the movement of personnel.
    - Routes and access of movement for raw and packaging materials.
    - Routes of waste disposal.
    - Reprocess layout.
    - Production flow layout.
    - Facility locations.
    - The linear plant design and separated access to clean and contaminated areas allow sufficient working space to enable all operations to be carried out properly, avoiding cross-contamination between areas.
    - No temporary structures were observed.
    - The personnel entering the site are handed a leaflet containing instructions on procedures for access to premises and the requirements of the areas they are visiting, with special reference to risks and potential product contamination.
    - Contractor supervisors oversee processing areas where services are being provided.
    - The company controls contactors and visits, gives visit cards and applies health questionnaires prior to entering the plant.

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

- The infrastructure intended for operation development complies with private hygiene engineering standards.
  - ✓ Floors are paved and suitably hard wearing to withstand cleaning materials.
  - ✓ There are no drainage design or maintenance issues.
  - ✓ The drainage layout shows that water is disposed of into an aquifer.
  - ✓ Ceilings and overheads are adequate and maintained.
  - ✓ No suspended ceilings or roof voids.

- ✓ There are no windows for ventilation purposes at the production area.
- ✓ The site has air doors to avoid potential infestation.
- ✓ Lighting is controlled by measurements performed by Mutual. The report dated May 2017, shows compliance with Supreme Decrees No. 977 and 594.
- ✓ Lighting is protected.

4.5 Utilities – water, ice, air and other gases

- Hazards have been identified and controls have been determined in production and storage areas.
  - ✓ Water control procedure, I-MN-AGU-001, version 03, dated 07.03.2019.
    - Water is obtained from a 30-metre deep well, chlorinated and stored in tanks.
    - Physicochemical analysis No. QL-145063 carried out by QUALITY-LAB, on February 20, 2020.
      - Evidence of compliance with Chilean Potable water regulation NCH 409.
  - ✓ Microbiological monthly analysis No. No. QL-160833, dated 20.08.2020, carried out by QUALITY-LAB.
    - Total coliforms <1.
    - E. Coli <1.
  - ✓ Microbiological monthly analysis No. No. QL-162598, dated 26.09.2020, carried out by QUALITY-LAB.
    - Total coliforms <1.
    - E. Coli <1.
  - ✓ Map of Location Water network Floor:
    - Dehydrated plant code FO-DC-MAN-002, with 50 sampling points.
    - Frozen code F-DC-LAB-005, with 26 sampling points.
  - ✓ Only potable water is used in processes.
  - ✓ Chlorine inspection levels between 0,2 to 2 ppm in records reviewed of June and July 2020, in record I-RG-LAB-091.
  - ✓ Compressed air has filters for particles, water and oil. Pieces are replaced according to recommendations offered by the manufacturer. Evidence of March 2020 preventive maintenance, the air is used in the sorter's rejection mechanism.
  - ✓ The plant has a multiple fire-tube boiler that operates with food-grade chemicals and a steam filter used before blanching:
    - BW-171 supplier "PRO-QUÍMICA", with approval by the FDA.
  - ✓ The packaging area has a mechanical ventilation system.

4.6 Equipment

- The equipment used for operations is made of materials that minimise the risk of contamination.
  - ✓ The design of equipment ensures it can be effectively cleaned and maintained.
  - ✓ Technical data sheets and food-contact certificates of suitability were checked.

4.7 Maintenance

The maintenance process includes controlling hazards originating from equipment.

- Manual of preventive maintenance (I-MN-MAN-001 revision 004 dated 15-05-2020) includes as listed below:

- ✓ Procedure of calibration and verification I-PR-MAN-001.
- ✓ Predictive and preventive maintenance programme (FO-RG-MAN-001) is planned for each production line in a weekly manner, covering the entire year and including mechanical, electric maintenance, as well as lubrication and cleaning.
- ✓ Preventive maintenance procedure, code I-IT-ACL-008.
- ✓ The following examples of work orders are reviewed:
  - OT 690, 01.07.2020.
  - OT 691, 01.07.2020.
  - OT 694, 02.07.2020.
  - OT 702, 25.07.2020.
  - OT 777, 28.07.2020.
  - OT 778, 28.07.2020.
  - OT 782, 30.07.2020.
  - OT 786, 31.07.2020.
  - OT 775, 31.07.2020.
  - OT 789, 01.08.2020.
  - OT 789, 01.08.2020.
  - OT 790, 01.08.2020.
  - OT 791, 01.08.2020.
  - OT 835, 01.08.2020.

- ✓ Quality and maintenance personnel oversee missing parts and pieces, as well as of any detection in machines. No issues to the date.
- ✓ The cleaning after maintenance is the responsibility of the cleaning staff of the area where the activity is performed.
- ✓ Hygiene inspections documented in each record.
- ✓ Corrective maintenance activities are closed within the shift and logged on the corresponding logbook. No temporary repairs were observed.
- ✓ Each processing area has a tool storage cabinet at its disposal, overseeing mechanics.
- ✓ Food-grade lubricants and oils:
  - Bel Ray No Tox.
  - Bel Ray NT-HD Grease 2 TC. NSF record No. 126376.
  - Bel Ray NT Clear Grease #1 NSF record No. 126355.
  - Bel Ray NT Chain Lube 2500. NSF record No. 126381.
  - Bel Ray NT HD Grease 1 TC. NSF record No.126296.
  - Allergen statement on Bel-Ray No-Tox® Food Grade lubricants, from March 13th, 2015.
- ✓ The workshop is segregated from processing area in order to avoid potential contamination. The handbook of housekeeping and order for the maintenance workshop (I-IT-MAN-046).

4.8 Staff facilities

- The facilities are suitable for the number of workers, controlled by engineering procedures and regulations in order to avoid potential cross-contamination.
  - ✓ There are toilets in enough numbers and segregated from processing areas, in accordance with Supreme Decree No. 594.
  - ✓ Only employees wearing appropriate uniform and carrying no personal effects are allowed to enter processing areas.
  - ✓ Employees have lockers for storing outdoor clothing and receive work clothes before entering the plant.
  - ✓ There are washbasins and advisory signs to prompt handwashing placed prior to

processing areas.

- ✓ The organization has sanitary filters at the entrance of production plants, which have:
  - Posters that remind you to wash your hands.
  - Water in enough quantity and at an appropriate temperature.
  - Faucets of non-manual operation.
  - Soap dried with disposable towels or air dryer and disinfectant.

- ✓ Toilets are segregated from processing areas equipped with cold and warm water, sanitising soap and paper towels.
- ✓ The national legislations states that smoking is not permitted in food processing facilities.
- ✓ The staff canteen is the only place where eating is allowed. Food shall not be brought into the plant.
- ✓ The assessment questionnaire applied to “A Punto” was checked:
  - Weekly inspection record from June and July 2020 were reviewed. Evidence of compliance.

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

4.9.1 Chemical control

- The procedure for toxic components (I-MN-GMP-002, dated February 23, 2017) holds the considerations detailed below:
  - ✓ Approved checklist for purchasing chemical products.
  - ✓ Specifications and safety datasheets in line with Supreme Decree No. 78.
  - ✓ The organisation has documented procedures for preventing cross-contamination:
  - ✓ Chemical control
  - ✓ These procedures are sufficient for preventing chemical and physical hazards.
  - ✓ the chemical products are found with their original label identification, technical data sheets and safety sheets are found, the warehouse is ordered, with controlled access and the products are identified according to their use.
  - ✓ There is evidence of course in the control of chemicals for the warehouse manager.
  - ✓ The technical data sheets and safety sheets of the following chemicals are reviewed:
    - Oxonia Activo 150.
    - TOPAX 66.
    - TOPAX 66.
    - Whisper V.

4.9.2 Metal control

- The documented metal policy is evidenced (I-DC-GEN-001 Policy Revision 001, dated 05.01.2018.).
  - ✓ The use of ingredients or packaging materials containing staples or other foreign body hazard is prohibited.
  - ✓ Control of loose items is by a cord; the only evidence of metal use is scissors, include register of scissors.
  - ✓ They do not use snap off blade knives in the process.
  - ✓ Training carried out to personnel on 03.04.2020 is reviewed.

4.9.3 Glass, brittle plastic, ceramics and similar materials

- Instructive of control of glass and hard plastic contamination risk, code I-IT-ACL-011, revision 002, dated 09.04.2018.

- Control means were checked as detailed below:
- Layout of halogen lamps, fluorescent tubes, windows, mirrors and lubrication instruments. Foods plant – packaging area.
- Layout of halogen lamps, fluorescent tubes, windows, mirrors and lubrication instruments. Foods plant – preparation area.
- Control of optical lenses: I-RG-ACL-009, records of April 2019, of workers with lenses in compliance.
- Layout of halogen bulbs, fluorescent tubes and windows - Frozen product area.
    - ✓ Examples of inspection reports of June and July 2020 in record I-RG-GMP-005:
        - No deviation.
        - There are corrective actions in case of broken glass, in revision to the facilities no broken or broken glass was observed.
- Procedure to handle breakages: I-IT-MAN-008, version 03, 04.09.2020.
- In case of detection, the potentially jeopardized product shall be retained and treated as a non-conforming product. The organization has not had detection issues to the date.

4.9.4 Products packed into glass or other brittle containers

- No glass or brittle containers.

4.9.5 Wood

- Handbook of wood contamination risk, code I-IT-ACL-026.
    - ✓ Evidence of program of control and replacement of wooden pallets and raw material bins.

4.9.6 Other physical contaminants

- Comment on controls in place to prevent contamination of raw materials by raw material packaging, and control of pens in the production facility.
    - ✓ They use detectable pens.

4.10 Foreign-body detection and removal equipment

4.10.1 Selection and operation of foreign-body detection and removal equipment

- The organisation has determined using equipment for removing and decreasing foreign bodies in processing lines.
- The hazard analysis has led to use the equipment below:
    - ✓ Risk assessment of dehydrated products: dated July 01, 2020.
    - ✓ Risk assessment of frozen products: dated October 16, 2020.
        - Metal detectors.
        - X-ray machine.
        - Magnets.
        - Optical sorters.
    - ✓ The company has procedures in place for applying operational control of equipment involved.
    - ✓ Monitoring frequency is determined according to risk analyses and client requirements.
    - ✓ Quality and maintenance personnel oversee missing parts and pieces, as well as of any detection in machines.
    - ✓ Evidence of investigation:
        - No events.

4.10.2 Filters and sieves

- The risk analysis has led to the conclusion that the use of filters or sieves with food safety purposes is not necessary.

4.10.3 Metal detectors and X-ray equipment

- The use of metal detectors and x-ray equipment has been determined as a result of the HACCP risk analysis.
- The equipment has detection alarms.
- Metal detector functioning, code FO-IT-LAB-002, revision 03 dated March 2018.
    - ✓ The company has three metal detectors located at:
        - Packaging 1.
        - Packaging 3.
        - Freefall detector at retail product area.
    - ✓ Metal detection parameters vary based on the type of product as follows:
        - Low moisture: ferrous 1 mm, non-ferrous 1.2 mm and stainless steel 1.5 mm.
        - High moisture: ferrous 1.5 mm, non-ferrous 1.5 mm and stainless steel 2 mm.
        - Freefall: ferrous 2.5 mm and stainless steel 3.5 mm.
    - ✓ Metal detector certificates:
        - The Loma detector (ID 4501371) located at the packaging area 1 was verified on 04.12.2019.
        - The Loma detector (ID 4511371) located at the packaging area 3 was verified on 04.12.2019.
        - The Loma detector (ID 4521371) located at the packaging area 3 was verified on 04.12.2019.
        - The Loma detector (ID 4531371) located at the packaging area 3 was verified on 04.12.2019.
        - The Loma detector (ID 4541371) located at the packaging area 3 was verified on 04.12.2019.
        - The Loma detector (ID 4551371) located at the packaging area 3 was verified on 04.12.2019.
        - The Loma detector (ID 4561371) located at the packaging area 3 was verified on 04.12.2019.
        - The Loma detector (ID 4571371) located at the packaging area 3 was verified on 04.12.2019.
        - The Loma detector (ID 4581371) located at the packaging area 3 was verified on 04.12.2019.
- The last LOMA test pieces verified are used on the freefall detector. Verified on December 2018.
- The rejection mechanism is ejection to a black box locked.
- X-ray management procedure: F-IT-LAB-029, revision 02, from May 2018.
- X-ray equipment:
    - ✓ X-ray machines are used for supporting foreign body control. There are two machines located at packaging areas 1 and 3 and another one located prior to the fruit drying area. validation certificates were checked as follows, verified December 2019.

- The last inspection report No. 094964 was issued on March 2018.
- Test pieces:
  - ✓ 2 mm glass balls.
  - ✓ Aluminium: 2 mm.
  - ✓ Ceramic: 2 mm.
  - ✓ SUS304 stainless steel: 0.8 mm.
- The quality monitor is in charge of checking test pieces passing through the detector.
- The CCP monitoring record includes the rejection system.
- The rejection mechanism is ejection to a black box locked.
- Jeopardised products are handled as non-conforming products.

4.10.4 Magnets

- Magnets located at packaging lines 1 and 3 of dehydration plant and frozen plant line 1 and 2.
  - ✓ Certification of the magnetic profile N ª 1105, magnetic plate, series 0801198, confidence level 95.45%, 13.07.2020 (calibration every 2 years).
- Certification of the magnetic profile N ª4560, magnetic plate, ND series, intensity over 3580 gauss, frozen, 95.00% confidence level:
  - ✓ Example:
    - Frozen magnets over 5000 Gauss.
    - Dehydration plant magnets over 6000 Gauss.
      - Equipment reviewed annually.

4.10.5 Optical sorting equipment

- There are three optical sorters, one located prior to the fruit drying machine and the other two in packaging lines.
  - ✓ Sortechnology company that performs calibration N ª PRI163, dated 11.03.2020.
- Sortex Z is used for apples, controlling foreign bodies, color, skin, calyx, seeds and stem.
- Sortex A is used for peppers, controlling foreign bodies, stems and seeds.
- The Sortex Z equipment is used for tomatoes, covering foreign bodies, color, gray or green placenta, burnt tomatoes, tomatoes bitten by insects, necrosis and stems.

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

- No rigid containers that require cleaning are used.

4.11 Housekeeping and hygiene

- The company has housekeeping programs per area as evidenced below:
- General cleaning procedure: I-IT-H&S-001, rev 04, dated March,2019.
  - ✓ In depth weekly cleaning: FO-IT-L&S-002, rev 02, from March 2019.
  - ✓ Equipment and facilities were observed clean and in good condition.
  - ✓ Housekeeping programme performance:
    - Daily operational cleaning includes sweeping, and cleaning of the packaging area. Cleaning the fruit and vegetable preparation area involves rinsing processing lines, particularly during lunch breaks. The activity was observed in progress during the audit, yet the company does not keep records of it.
    - Check- list Food (dehydrated), Biweekly frequency:
      - The records corresponding to January, February, March, April, May,June,

July, August, September and October 2020 are reviewed.

- Check- list of toilets reception Frozen lines preparation vegetables (weekly).
  - The records corresponding to January, February, March, April, May, June, July, August, September and October 2020 are reviewed.

✓ General cleaning procedures:
- Detergent:
  - TOPAX 66 (Alkaline)
  - OXONIA ACTIVIA 150(Peracetic acid sanitizer).

✓ The organisation provides resources for processes in enough numbers.
✓ The company verifies housekeeping aspects prior to starting shifts, defining acceptable limits in the documents listed below:
- Bioluminescence surface sampling manual code F-IT-LAB-019.
  - The records corresponding to January, February, March, April, May, June, July, August, September and October 2020 are reviewed.
  - Each product change, each work stop, bioluminescence test is carried out.
  - Weekly ATP sampling after in-depth cleaning.
  - ATP is measured after in-depth housekeeping validated by Quality staff.
- Also, allergen cleaning is followed by titration tests. After cleaning, after allergens (celery).
  - The records corresponding to August, September and October 2020 are reviewed.
- Listeria monitoring in the frozen plant, once a month (4 in preparation and 4 in packaging), all gave absence to listeria.
  - The following examples are reviewed:
    - ✓ Test report N ª QL.149038 Z1a, absence result, 25.03.2020.
    - ✓ Test report N ª QL.149039 Z2d, absence result, 25.03.2020.
    - ✓ Test report N ª QL.149040 Z2g, absence result, 25.03.2020.
    - ✓ Test report N ª QL.149041 Z3a, absence result, 25.03.2020

✓ The cleaning equipment is in good conditions, clean and colour coded, only used by cleaning staff.

4.11.7 Cleaning in place (CIP)

- No CIP cleaning.

4.11.8 Environmental monitoring

- The frequency of environmental monitoring was defined based on risk, it is reviewed annually, the last review was carried out in March 2020.
- The monthly environmental monitoring programme covers finished product areas and surfaces, with the purpose of detecting pathogens, anaerobes and mesophylls, mould and yeast. The auditor observed that acceptable results have been obtained to the date.
  - ✓ Microbiological analyses are carried out by Quality Lab, Accreditation valid until 30.11.2021.

- No out-of-limits results to the date. In the event of exceeding limits, there are corrective actions established for each pathogen.

4.12 Waste

- The organisation disposes of waste in line with national legislations and internal procedures, with the purpose of minimising risks of contamination and attraction of pests.
  - ✓ Procedure for the disposal of solid and liquid waste, code I-IT-ACL-006.
  - ✓ Liquid residues undergo primary treatment before being poured onto regular water course.
  - ✓ Evidence of compliance of Chilean waste regulation:
    - Transports Rio Negro Ltda. The following guides with withdrawals are reviewed:
      - Guide 2576, 17.09.2020.
      - Guide 2647, 01.10.2020.
  - ✓ Waste containers were found closed.
  - ✓ Trademarked materials are stored for further destruction with client approval, although it has not performed to the date.

4.13 Management of surplus food and products for animal feed

- All client surplus is disposed of as defined in requirement 4.12 or client enquiry. Surplus is not considered in sales or animal feed. The following specifications have been reviewed:
  - ✓ Surplus customer-branded products shall be disposed of in accordance with customer-specific requirements and queries submitted by the sales manager. The organisation has not performed this activity to the date.

4.14 Pest management

- The organisation has an effective preventive pest control programme in place to minimise the risk of infestation as observed in control measures, such as on-site enclosing, waste removal, housekeeping and hygiene programmes, as well as monitoring activities carried out during that period. The following items were reviewed.
- Pest control manual, code I-MAN-PLG-001, dated 07.02.2020.
  - ✓ The company has agreements with Plagisur Ltda, whose authorisation number is N° 694 dated 07.12.2016.
  - ✓ The integrated pest management programme (dated 2019-2020) includes as follows:
    - Rodent control.
    - Disinfection.
    - Insect control.
  - ✓ Weekly visits to insects, birds and rodent control:
    - Brodifacoum for rodent “RODEX”.
    - Cypermethrin “DEMON TC 25”.
    - The technical data sheets of chemicals in use demonstrate suitability.
  - ✓ The provision of services, contract signed on 02.01.2013 is reviewed.
  - ✓ Monitoring devices are allocated as follows, in force in August 2020:
    - 220 stations at the external perimeter- weekly
    - 92 mechanical traps at indoor areas- weekly
    - 24 UV traps - biweekly
    - Desinsectacón- semanal.
  - ✓ Only capture traps are used inside facilities.
  - ✓ Insect traps and pheromone traps are sited correctly and products are not under

contamination risk.
- ✓ Training in pest control, 6.09.2018, conducted by luis troncoso pest control company expert, 10 people
- ✓ Competencies of the pest control company expert are reviewed
- ✓ Infestation thresholds have not been crossed during this period.
- ✓ Pest control reports were checked as listed below:
  - Certificate N ° 011183, dated 15.09.2020.
  - Certificate N ° 011275, dated 30.06.2020.
  - Certificate N ° 010119, dated 25.08.2020.

- ✓ Quarterly report Example: January, February, March 2020, of rodents and insect insects includes recommendations.
- ✓ In depth study:
  - Technical expert head of operations to the pest control company, with different training courses in pest control performed an in-depth study on 11.08.2020.
  - Evidence of recommendations and photographs of the visit to all sites.

- Trend analyses were observed:
  - ✓ Quarterly trend analysis dated from April 16, 2020:
    - Insect levels are within or below historical limits.
    - Rodent levels are normal for the historical limits.

4.15 Storage facilities

- All facilities used for the storage of raw materials, packaging, in-process products and finished goods are suitable for their purpose.
- The control and operation management manual (FO-IT-CAM-003, from March, 09, 2019) includes as follows:
  - ✓ Warehouses are located in outdoor areas and products are stored at room temperature.
  - ✓ Cold storage areas are used solely for finished products and products to be processed.
  - ✓ Quality control personnel are responsible for temperature control, checking parameters in accordance with Supreme Decree No. 977.
  - ✓ Frozen product is stored in 3 chambers:
    - The control sheet records dated January, February and March 2020 show that the temperature in storage areas varies between -22 and -18º C.
  - ✓ No outdoor storage.
  - ✓ Records are used for supplier evaluations.
  - ✓ The material warehouse works under FIFO or FEFO system, as applicable.

4.16 Dispatch and transport

- The facilities used for storing raw materials, packaging materials, products to be processed and finished goods are suitable for their purpose.
- The dispatch control procedure (FO-IT-LAB-007) includes control methods to safeguard temperature in frozen goods, vehicle cleaning, stowage and inspections.
- Shipping orders are carried out at the loading area.
  - ✓ Records were checked as listed below:
    - The control sheet records dated January, February and March 2020, are reviewed.

  - ✓ Drivers are responsible for maintaining and cleaning trucks and inspections are performed prior to loading goods.
  - ✓ Frozen and non-frozen products are dispatched in separate vehicles.

- Frozen dispatch use thermograph, evidence of compliance for dispatch of January, February and March 2020.
- Safety conditions are monitored by means of pictures and thermography records.

✓ The organisation has agreements with transport companies and insurance companies whether contracted by Invertec Foods S.A. or clients.

Details of non-applicable clauses with justification

Clause/section reference	Justification
4.3.5	No temporary structures constructed.
4.4.5	No suspended ceilings or roof voids present.
4.4.6	They do not have elevated walkways.
4.7.3	No temporary repairs evidenced during the audit.
4.9.4	No products packed into glass or other brittle containers.
4.10.2.1	No filters or sieves in place.
4.10.2.2	No filters or sieves in place.
4.10.4.1	No magnets in place.
4.10.6	No products packed into glass jars, cans or other rigid containers.
4.11.7	No CIP.
4.13.3	No products intended for animal feed.
4.14.3	The site doesn't undertake its own pest control.

4.15.4	No controlled atmosphere is required.
4.15.5	No outside storage.
4.16.6	No transport third-party contractors hired.

5. Product control

5.1 Product design/development

- The organization has effective procedures for treating new design and development.
  - ✓ The head of laboratories is the person in charge of the development process.
  - ✓ Head of Quality Management and Assurance, approves It. (Food safety Leader).
  - ✓ The product development manual (I-DC-GEN-016 revision 001 dated June 22, 2020) includes guidelines to define scopes pertaining to product design and development.
  - ✓ The following product development example is reviewed:
    - Development of Cherry tomato cut in half, dated 12.05.2020.
    - Purple Carrot Puree Development dated 19.08.2020.
  - ✓ Shelf-life trials are run on all products, the following reports are reviewed:
    - Test Report No. QL 156396.
    - Test Report No. QL 156398.
    - Test Report No. QL 156400.
    - Dehydrated Apple Shelf Life Evaluation dated 03.01.2020.
    - Shelf Life Evaluation of Red Paprika Flake ¼" dated 14.02.2020.
  - ✓ Evidence of compliance with variables for microbiology, chemical and sensory.
  - ✓ Labelling is done in accordance with target market and client requirements.

5.2 Product labelling

- The organisation has product labelling procedures that ensure compliance with legal requirements and information towards the supply chain.
  - ✓ The labelling control procedure (Labelling control manual, code IT-GEN-004 revision 003 dated March 15, 2019) includes:
    - Label receipt provided by clients.
    - Legal requirement reviews by the quality assurance supervisor and further approval by the head of technical customer service.
    - The head of planning adds labelling information to production orders.
    - Personnel pertaining to laboratories are responsible for:
      - Reviewing labels prior to production.
      - Approving labels.
      - Checking labels during packaging and shipping tasks.
  - ✓ The organisation does not make claims to satisfy a consumer group.

- ✓ Information on labels (provided by clients or third parties) is defined in specification controls, considering language, address or other requirements needed for the target market.
- ✓ Course on labeling, quality control, packaging, on 03.04.2020.

5.3 Management of allergens

- The organisation has risk analyses and control measures in place for managing catering allergens. Furthermore, raw materials and packaging materials do not contain allergens.
  - ✓ The allergen management manual (I-MN-ACL-001 issue 003 dated 12.06.2020) includes as follows:
    - Allergen policy
    - Allergens identified in accordance with target markets, including Europe, Chile, USA, Japan, Australia and Canada. Annex I, code I-REG-ALE-001.
    - The analysis carried out by the organisation demonstrated that there are no allergens in, co-helpers.
    - Contact and non-contact materials.
    - The only allergen presents are:
      - Sulphite.
      - Celery.

- The risk assessment is applied per area based on qualitative performance related to control measures in place.
- Rework:
  - ✓ All the rework manufactured contains SO2 warning labels.
  - ✓ All products processed at the Foods plant (dehydrated) contain SO2 warning labels.
  - ✓ No allergens found at the Frozen plant.
  - ✓ Due to the processes carried out at the Foods plant (dehydrated) allergen cross-contamination cannot be avoided, so:
  - ✓ All products processed at the Foods (dehydration) plant contain SO2 warning labels.
  - ✓ The organisation does not make claims about product suitability.
  - ✓ Allergen cleaning is followed by Sulphites titration tests.
  - ✓ Celery: The organization performs 1 or 2 productions per year of celery, after wich the plant performs a full cleaning process and the only product in production in the plant is celery.
    - Evidence of Cleaning Validation study of celery removal from the lines after cleaning:
      - Validation study date: April, 05, 2018.
- Course on labeling, quality control, packaging, on 03.04.2020.

5.4 Product authenticity, claims and chain of custody

- There is evidence of a risk analysis and control measures to ensure that all product descriptions and statements are legal and adequate. The following items have been reviewed:
  - ✓ Vulnerability analysis (I-RG-GEN-011) of raw materials performed on March18, 2020, including as follows:
    - Possible substitutions:
    - Organic product: high risk.
  - ✓ Assessment criteria:
    - Historical evidence of substitution or adulteration.
    - Economic factors which may make adulteration or substitution more attractive.
    - Ease of access to raw materials through the supply chain.
    - Sophistication of routine tests to identify adulterants.
    - Origin of raw materials.
  - ✓ Information sources about adulteration or substitution obtained from Government institutions, ASOEX and clients. Sources considered:
    - www.food fraud.org
  - ✓ In case of suspecting adulteration, the company takes samples for further analysis or denying ingress to the plant.
  - ✓ Labelled finished goods include information about country of origin, variety, type and other client requirements, as checked whilst visiting facilities.
  - ✓ Statements about production methods and raw materials:
    - ORGANIC USA and EU valid until February 2021.
    - KOSHER PAREVE “JAFETZ JAIM”, valid until August 2021.
  - ✓ Process flows included in HACCP and production planning are considered for product statements.
  - ✓ Evidence of traceability and effective segregation for the organic product:
  - ✓ Organic Management Plan: I-IT-GEN-001.
  - ✓ Green colour is exclusive for the organic product.

5.5 Product packaging

- The organisation has effective procedures for packaging products as detailed below:
  - ✓ Requirements are checked by means of design and development processes and then communicated to suppliers by means of purchase orders.
  - ✓ All the direct contact packaging is from the supplier “Plásticos BioBio”.
    - Plasticos Biobio S.A: FSSC 22000 certificate No. CL14/81841258 valid until January 11, 2021.
    - COC: issued by Plasticos Bio Bio compliance with FDA 21CFR 177.1520, MERCOSUR and UE.
- Containers are stored in an exclusive warehouse and delivered in a controlled manner.
- Frozen products are packaged in white or blue bags.
- Procedure for the disposal of solid and liquid waste, code I-IT-ACL-006.
  - ✓ The management of obsolete packaging is defined.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

- The organisation carried out inspections and analyses with the purpose of confirming product safety, legality and quality.
  - ✓ Analysis programme, covering in-house and external tests, documented in laboratory documents, example:
  - ✓ Microbiology manual I-MN-LAB-001:
    - Surface: 1 per month. Internal
    - Water: 1 per month. External
    - Ambient: Every 15 days. Internal
    - Food handlers: 1 per month. Internal
    - Finished product:
      - 1 per lot. External
  - ✓ Pesticide and heavy metals controls is GAP and contract for vegetable farmers and GLOBAL GAP certification for fruit growers:
  - ✓ All the farmers are analyzed once per year, example:
  - ✓ Specifications are analysed and monitored by the quality control by means of microbiological analyses performed by the ISO/IEC 17025 accredited LABSER laboratory.
  - ✓ Trend and microbiological analyses were checked.
  - ✓ Evidence of compliance with variables for microbiology, chemical and sensory.
    - Pesticide test records N ° 68059 for Dehydrated Celery Granule 0-3mm, date 15.07.2020. Not detected.

5.6.2 Laboratory testing

- No pathogen testing done on site
- The microbiology laboratory is segregated from processing areas and its design allows for ensuring analyses, personnel protection and products.
- Analyses performed by the ISO/IEC 17025 accredited CEIMIC laboratory.:
  - ✓ DAKKS accreditation (EA, ILAC and IAF), ISO/IEC 17025.
- Analyses performed by the ISO/IEC 17025 accredited QUALITY LAB laboratory.
- Analyses performed by the ISO/IEC 17025 accredited CESMEC BUREAU-VERITAS laboratory.
  - ✓ INN accreditations:
    - LE 391: physicochemical analysis of water.
    - LE 254: microbiological analysis of water.
    - LE 255: microbiological analysis of food.
    - OI 125: sampling for microbiological analyses on utensils, handlers and environment.
- Internal laboratory has internal procedures based in AOAC, Chilean standards and BAM, example of analysis done in 25.01.2018:
  - ✓ Humidity test at vacuum: FO-IT-LAB-002, from May 20, 2016.
  - ✓ Sulphite analysis FO-IT-LAB-023.
- Sampling of surfaces and ambient I-PR-LAB-012. Rev 02, from April, 04, 2012

5.7 Product release

- The organisation has effective procedures for releasing products as detailed below:
- Only products that meet specifications and HACCP monitoring are released by laboratory staff

evidenced on INVERTEC internal software.

5.8 Pet Food

- Not Applicable

Details of non-applicable clauses with justification

Clause/section reference	Justification
5.1.3	Trials are not necessary for the product(s) produced.
5.2.3	No claims made to satisfy a consumer group (no nutritional claims).
5.2.5	No cooking instructions provided
5.3.5	No rework used or reworking operations carried out
5.3.6	No allergen cross contamination risks
5.3.7	No claims made regarding suitability for allergy or food sensitivity sufferers
5.6.2.2	No on-site lab
5.6.2.4	No on-site lab
5.8	No Pet Food manufactured by the site.

6. Process control

6.1 Control of operations

- The organisation has documented procedures to ensure that operational controls meet specifications relevant to legal and safe products.
  - ✓ All the food safety hazards are controlled through CCP, according to HACCP chapter 2.
  - ✓ Equipment settings are completed by authorised trained personnel only, quality monitors carry out this activity.
  - ✓ Quality issues are managed by the quality control laboratories of each plant.
  - ✓ Process control involves using quality standards per each product.
  - ✓ Processes observed during the audit:
    - Celery Granule No So2, Code D50100030, Lot FPT1002296.
  - ✓ Laboratory staff and head of lines monitor product specifications.
  - ✓ The organisation does not have in-line measurements.
  - ✓ In case of variations in processing equipment, the company considers validations obtained by means of results of microbiological analyses and on-site tests per batch.
  - ✓ Jeopardised products are monitored by the maintenance department and treated in accordance with procedure for rejection and non-conforming products.
  - ✓ Jeopardised products are treated as non-conforming products.

6.2 Labelling and pack control

- The organisation has procedures that ensure labelling and packaging control.
  - ✓ Labelling control manual, code I-IT-GEN-004 revision 003 dated February 2019.
  - ✓ The sales department verifies that labels are printed according to product specification and target market legal requirements.
  - ✓ Each box has a unique code.
  - ✓ Laboratory staff checks labels.
  - ✓ Dispatch control of finished products, code F-RG-LAB-023.
  - ✓ Control for retail in I-RG-GEN-012, “Labeling and packaging control”:
  - ✓ Including inspection at the start and finish of the conditions of the room “Free of packaging material”.
  - ✓ Laboratory staff also performs process controls as listed below:
    - Labelling instructions established in production orders.
    - Control of finished product boxes, code F-RG-LAB-007.
    - At the beginning, every pallet and at the end or change.
    - Evidence of inspection of labeling of the bags and the boxes, control sheet records dated January, February and March 2020, are reviewed.
- Compliance with requirements such as label printing check, inkjet programming and production during the audit was performed the same product for the same client.
- No in-line vision equipment is used for monitoring labels.
- Course on labeling, quality control, packaging, on 03.04.2020.
- Labeling control record, control sheet records dated January, February and March 2020, are reviewed.

6.3 Quantity, weight, volume and number control

The organisation has defined effective weight control as explained below:

- Quantity control is realised by means of production reports and processes.
- The organisation controls box weight hourly, testing at least 1 box per product size.
- Weight control (FO-IT-LAB-011) was observed during the audit and record F-RG-LAB-044, example:
  - During the visit the packaging process is observed, Celery Granule No So2, Code

D50100030, Lot FPT1002296.
- Weight control control sheet records dated January, February and March 2020, are reviewed.

6.4 Calibration and control of measuring and monitoring devices

- The procedures in place ensure that measuring and monitoring devices are calibrated or verified, as demonstrated below:
- The calibration and verification procedure (N-PR-MAN-001 v01 dated 04-05-2011) includes as detailed below:
  - ✓ Metal detector certificates:
    - The Loma detector (ID 4501371) located at the packaging area 1 was verified on 04.12.2019.
    - The Loma detector (ID 4511371) located at the packaging area 3 was verified on 04.12.2019.
    - The Loma detector (ID 4521371) located at the packaging area 3 was verified on 04.12.2019.
    - The Loma detector (ID 4531371) located at the packaging area 3 was verified on 04.12.2019.
    - The Loma detector (ID 4541371) located at the packaging area 3 was verified on 04.12.2019.
    - The Loma detector (ID 4551371) located at the packaging area 3 was verified on 04.12.2019.
    - The Loma detector (ID 4561371) located at the packaging area 3 was verified on 04.12.2019.
    - The Loma detector (ID 4571371) located at the packaging area 3 was verified on 04.12.2019.
    - The Loma detector (ID 4581371) located at the packaging area 3 was verified on 04.12.2019.

- Certificate of calibration SMA -85603 of 25.06.2020, mass patron 100 GRS.
- Certificate of calibration SMA -85605 of 25.06.2020, mass patron 1 KG.
- Certificate of calibration SMA -85606 of 25.06.2020, mass patron 100, 500 GRS, 1 Kg

- Verification of packaging balance. control sheet records dated June, July, August and September 2020, are reviewed.
- Verification 2 times per week analytical balance control sheet records dated June, July, August and September 2020, are reviewed.
- Portable verification 2 times per week ph meter. control sheet records dated June, July, August and September 2020, are reviewed.
- External companies calibrate test pieces and reference equipment.
- In case of instruments whose calibration is above error rate, the HACCP leader shall be notified in order to decide replacement or repair, besides taking actions for potentially jeopardised products.

Details of non-applicable clauses with justification

Clause/section reference	Justification

6.1.4	No in-line monitoring devices in place
6.2.4	No on-line vision equipment used to check product labels and printing
6.3.2	No bulk quantities packed
6.3.3	No online check weighers

7. Personnel

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

- Procedure for training personnel, code I-MN-CAP-001, issue 02 from January, 12, 2018.
- Pre-employment training inductions on quality and food safety for the employees detailed below have been evidenced:
  - ✓ Induction to new prsonal, on fulfilling the requirements of quality assurance, product safety, GMP regulation, HACCP, BRC,APL, Sensitization and manipulation of allergens and measures that should be adopted in case of suffering infectious diseases, 1 hour, supervisor of GMP, to new staff, 03.04.2020.
  - ✓ It has been evidenced that CCP monitors of dehydration plant attended to training about CCP monitoring in 06.09.2020.
  - ✓ Course of management of allergens 03.04.2020.
  - ✓ Course of food defense,by head of laboratory, 03.04.2020.
  - ✓ Course on labeling, quality control, packaging, on 03.04.2020.
  - ✓ The training program has been evidenced for the 2020 season:
    - For all the employee of the organization, evidence of tests for compliance and effectivenes verification.
    - Evidence of effectiveness through tests, evidence for compliance for participants of:
      - All the trainings have records with duration, participants and teacher information.
      - Competence assessment:
    - The assessment of key job positions includes grading from 1 to 4, is performed quarterly, was reviewed the first quarter of 2020.

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

- Personnel hygiene Instructive, code I-IT-ACL-007, issue 03 from November, 2018.
  - ✓ The prohibition of wearing pendants has been informed at inductions and on the internal regulations.
  - ✓ Daily inspection per shift:
    - Daily inspections of hair, gloves, lenses and band aids in record I-RG-GMP-013: Evidence of records of from April to january 2020. Were reviewed.

- Sanitary facilities and their proper use were observed during the visit. Besides, the staff is permanently monitored on this matter.
- The steps to follow in case of cuts consist of taking the injured to the Mutual Association Company, disposing of jeopardised products and cleaning the area; scratches are covered with blue plasters. The organisation has not encountered this issue to the date.
- The plant has a nursery supported by trained personnel.
- Instructive for the review of metal plasters: I-IT-ACL-010, rev 02, from March, 15,03.2019, Frozen y FOOD.
- The verification of metal detectable plasters (100 plasters) was evidenced: I-RG-GMP-011, evidence of band aids control of Evidence of records of from April to January 2020. Were reviewed.
- It was evidenced that the paramedic are trained on administering medicines.
- Band aids control: in daily health control record done by authorized policlinic.
  - ✓ Evidence of records of from April to January 2020. Were reviewed.
- Medicines are taken by the staff in the change rooms.

7.3 Medical screening

- Effective control measures to avoid contamination sources caused by ill employees were evidenced.
- Personnel health and security procedure, code I-MN-SSO-001.
- The paramedic examines every new employee, following the job application record. Information from 2020 was checked, example:
  - Hired personnel, contractors and visits will answer the health questionnaire prior to entering the plant. This control procedure was evidenced as being applied accordingly. The health questionnaire for personnel from June, July, August and September 2020, was reviewed.
- Auditor perform health declaration.
- Microbiological control of 10 workers per month:
  - Report of manipulative microbiological results I-RG-LAB-002, once a month:
    - Evidence of records dated June, July, August and September 2020, are reviewed.
- Employees who have any symptoms shall notify the corresponding direct supervisor.

7.4 Protective clothing: employees or visitors to production areas

- The organisation has effective procedures for ensuring the delivery of protective clothing to be worn in processing areas.
  - ✓ The handbook of hygiene and personal presentation (Personnel hygiene Instructive, code I-IT-ACL-007, issue 02 from April 09, 2018, includes as follows:
- Hygiene control and personal presentation.
- Operators are responsible for washing their uniforms.
- Operators wearing clean uniforms were observed.
- The organization has defined the use of a laundry.
- Employees transport clean clothing from their homes to the company in closed bags provided by the organization.
- Clothing:
  - ✓ White cotton: Processing areas.
  - ✓ Gray cotton: Cleaning staff.
  - ✓ Blue cotton: Maintenancce staff.
- The organisation provides aprons, hair nets and masks for employees.

- No high-risk or high-care areas were identified in the risk analysis.
- According to risk analysis Work wear is changed daily.
  - ✓ Gloves used:
    - Nitrile, blue disposable gloves “IPRO”, in compliance with 21 CFR177-2600, and Directive 2002/72/EC Directive.
- Daily visual control of clothing for each processing room per shift:
  - ✓ Daily inspections of clothing in record I-RG-GMP-013:
    - Evidence of records dated June, July, August and September 2020, are reviewed.
- The organisation dictates the use of gloves (if required by the activity) that shall be replaced when necessary.
- The organisation has washable clothes, hair nets and masks are disposable items.

Details of non-applicable clauses with justification

Clause/section reference	Justification
7.4.6	No items of personal protective clothing that are not suitable for laundering are provided.

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 reference	Justification
N/A	

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	

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	

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

SGS

12.8 Product inspection and laboratory testing

N/A

Module 13 FSMA Preventive Controls Preparedness Module

Version 2 July 2018

Item no.	Clause	Module item	Conforms (Y/N) or Not Applicable (NA)	Comments
1	13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.	N/A	
2	13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
3	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 maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus		

		minimize the opportunity for growth of microorganisms and allergen cross-contact.		
4	13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.		
5	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.		
6	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 packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety		
7	13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine “hazards requiring a preventive control” (i.e., significant hazards).		
8	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.		SGS
9	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 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		
10	13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.		
11	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).		
12	13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production. Validate allergen, sanitation and		

		supply-chain controls as appropriate to the nature of the hazard, control and facility.		
13	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.		
14	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 • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
15	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		
16	13.1.16	Devices used to verify preventive controls must be calibrated.		
17	13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		
18	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		
19	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.		
20	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 within 24 hours with the exception of the food safety plan, which must remain onsite.		
21	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.		SGS
22	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 temporary basis from unapproved suppliers.		
23	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.		
24	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-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.		
25	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.		
26	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 • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		
27	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 operation was or was not identified as an actionable process step.		SGS
28	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.		
29	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.		
30	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 correcting a lack of implementation • Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective		

		actions		
31	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 • Frequency for verification activities • Recordkeeping requirements of all verification activities		
32	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		

33	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 conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
34	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.		
35	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.		
36	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 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.		

37	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.		
38	13.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier. Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.		
39	13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.		
40	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.		
41	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 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		
42	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		
43	13.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.		
44	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.		
45	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		
46	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 equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment		
47	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.		
48	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.		
49	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.		
50	13.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce. Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.		
51	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.		
52	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.		
53	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 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.		
54	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.		
55	13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce.		
56	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.		
57	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.		
58	13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.		
59	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.		
60	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.		
61	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) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are samples collected) • Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food		

		contact surfaces) The plan shall describe aseptic methods for sample collection and testing according to FDA's ‘‘Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples,’’ Version 1, October 2015 (or equivalent).		
62	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 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		