Audit Report

Global Standard for Food Safety Issue 7: July 2015

1.Audit Summary			
Company name	COMERCIAL Y SERVICIOS SUR AUSTRAL LTDA	BRC Site Code	1923096
Site name	COMERCIAL Y SERVICIOS SUR AUSTRAL LTDA		
Scope of audit	Heading, Filleting and Portioning of raw aquaculture salmonids. Whole Fish, Fillets, Portions, Pieces, Pulp, Marinated Portions and Salmon Roe. Frozen products bulk packed, or individual bag packed in polyethylene glazed or not; individual vacuum packed or not. Chilled products bulk packed, or individual bag packed in polyethylene. Secondary packaging in cardboard for frozen products and expanded polystyrene for chilled products.		
Exclusions from scope	None		
Justification for exclusion	N/A		
Audit Finish Date	2018-08-07		
Re-audit due date	2019-05-16		

Voluntary modules included		
Modules	Result	Details
Choose a module	Choose an item	
Choose a module	Choose an item	
Choose a module	Choose an item	

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	A	Previous audit date	2017-06-06		

	Fundamental	0

Number of non-conformities	Critical	0
	Major	0
	Minor	10

3.Company Details

Address	RUTA 7 KM 10.5 SECTOR CHAMIZA – PUERTO MONTT		
Country	CHILE	Site Telephone Number	+56 65 2686250
Commercial representative Name	MAURICIO TOIRKENS	Email	M.TORKIENS@SALMONESAUSTRAL.CL
Technical representative Name	MARIO RODRIGUEZ	Email	Mario.rodriguez@salmonesaustral.cl

4.Company Profile

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

Subcontracted processes	No
Other certificates held	BAP, IFS, HACCP SERNAPESCA, KOSHER, HALAL
Regions exported to	Asia North America South America Europe Oceania Choose a region
Company registration number	SERNAPESCA registration N°10884; FDA 14816143098
Major changes since last BRC audit	Change of plant drains. Change of waste disposal system by vacuum suction. Replacement of fillet conveyor belts (plastic modular intralox by thermodrive intralox). Change in facility manager position. Industrial cleaning staff were contracted by Comsur

4.Company Profile

Company Description

Company was created in 1997. In 2013 plant Comsur Ltda. Became part of the Southern Holding SPA Salmon with Trusal SA and Salmones Pacific Star SA. That same year an incident which burns all of its facilities located on Route 5 Sur Km. 12 placed at South from Puerto Montt. The same year Company hired the plant Chamiza to the company Marine Harvest Chile located on Route 7 in the sector Km.10,5 Chamiza placed in Carretera Austral near to Puerto Montt. During 2016, the Chamiza plant was bought by the Holding Salmones Austral. Are Processed in this plant frozen and fresh product for which has a dynamic calibrating in gutted two lines of fillets, 4 continuous sealing machines, a spiral and blast tunnels and a cold storage for frozen products capable of storing 200 tons product.
Its main raw material suppliers are the companies Trusal SA and Salmones Pacific Star SA. COMSUR Ltda. It meets all sanitary requirements, food safety, biosecurity, environmental, labor and social responsibility means, that the authorities demand for which has a plant self-supply and purification of water, treatment plant Riles, infrastructure for the collection and disposal of solid waste, canteen and locker room for staff working in this facility.
Currently the facility processes in 2 shifts from Monday to Friday. The staff of Comsur is made up of 93 employees with roles of Management, Supervision and Supporting areas. Operators for fish processing are subcontracted to 2 companies: AGUA VIVA (85 employees) and CONTINENTAL (85 employees). Plant without process during the months of April and July 2018 (23-April to 11-July). Authorization to carry out the audit after the due date was delivered by Control Union.

5.Product Characteristics

Product categories	04 - Raw fish products & preparations Category Category Category Category Category				
Finished product safety rationale	Frozen at -18ºC. Chilled -1 to 4 °C				
High care	Yes	High risk	No	Ambient high care	No
Justification for area	Finished products need to be refrigerated to its preservation and are intended for consumption cooked or raw				

5.Product Characteristics	
Allergens handled on site	Fish Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	No
Product recalls in last 12 Months	No
Products in production at the time of the audit	Atlantic salmon; fillets and portions

6.Audit Duration Details			
On-site duration	18 man hours	Duration of production facility inspection	9 man hours
Reasons for deviation from typical or expected audit duration	None		
Next audit type selected	Announced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2018-08-06	09:00	18:30
2 (end date)	2018-08-07	09:00	18:30

	Auditor (s) number(s)	Names and roles of others
Auditor Number	098140	HECTOR OJEDA, LA
Second Auditor Number	N/A	

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.9) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
ARTURO RIVERA/Facility manager	X		X	X
EVA CARCAMO/Head of laboratory	X	X	X	X
RODRIGO VALDEBENITO/Head of Industrial cleaning	X	X		X
MAURICIO VALENZUELA/Head of cold storage	X	X		X

Present at audit				
CESAR MUÑOZ/Head of materials storage	X	X	X	X
MAURO LARA/Head of facility	X	X		X
RENE VELASQUEZ/Head of maintenance	X	X	X	X
IVAN BARRIENTOS/Head of Human Safety	X			X
MARITZA SOTO/Head of Norms and certifications	X	X	X	X
MARIO RODRIGUEZ/Deputy Quality Manager	X	X	X	X
MERCEDES MALDONADO/Head of personnel	X		X	X
JORGE CHAMORRO/Head of Quality Assurance	X	X	X	X

Non-Conformity Summary Sheet

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

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

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

Minor							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1	2.2.1	During document review it was noted tha Control of allergens in the HACCP program does not include allergen risk analysis of H1 lubricants	A review of the technical sheet is made to identify if there is presence of allergens in the H1 lubricants.	**Root cause**: The contact with H1 lubricants is not evaluated through risk analysis, as it is considered as a control covered in POS, specifically in the	-Meeting record of HACCP Team -Compliance letter of supplier	2018-09-06	HOJEDA

				Prevention of cross contamination section. Failure to consider this lubricant or any other used in the process in the risk analysis of allergens can cause a consumer to ingest product contaminated with these and generate a serious allergic reaction. **Preventive action**: A review of the hazard analysis is carried out by the PAC team to identify polluting agents or allergens that have not been considered in the initial analysis.			
2	2.10.1	During review of the monitoring procedures it was observed that the format of record of PCC No. 3, metal detector, does not consider control of the equipment at the end of the operation	The personnel in charge of metal detector monitoring are immediately instructed to carry out the check at the end of the process and formal induction is programmed.	**Root cause**: According to what is indicated in the HACCP plan, the metal detector is checked with prisms every 1 hour, however when this frequency was defined it was not considered the shifts that end half an hour after the last check, so that time is outside of control. It can not be guaranteed that the equipment is	-Meeting record of HACCP Team -Training record -Control log HACCP3	2018-09-06	HOJEDA

				working correctly during the entire shift, which may result in the non-detection of a metallic trace that may harm the consumer. **Preventive action**: A review is made by the PAC team of all the controls that are carried out, with a certain frequency during the shift, to the relevant equipment or devices to verify if the control covers the entire shift.			
3	3.4.3	During document review for corrective actions it was noted that the proposed Corrective action to NC 1.1.4 MEETING PLAN was not implemented and does not evidence follow-up	The Non-Conformity detected in said internal audit was monitored.	**Root cause**: A misunderstanding is generated in the assignment of the person who must perform the verification, that is, it was expected that the follow-up would be carried out by the person who did the audit to said department, however, the auditor trusted that the Head of Regulations follow up . By not verifying the corrective or preventive actions, it is not possible to determine if the observation has been lifted	-Record NR RE 012, NC 04 (07-06-2018) -Evidence of communication	2018-09-06	HOJEDA

				and if the action has been effective. If the Non-Conformity is greater, it can affect the whole process. **Preventive action**: The team of internal auditors is informed that the follow-up of the Non-Conformities will be carried out by the person who completed the observation when there is no direct assignment by the plant management.			
4	3.7.2	During document review it was noted that in the Log "REGISTRO DE NO CONFORMIDADES Y ACCIONES CORRECTIVAS(NR-RE-012 V01)" it was not included the assessment of consequences	A section is added in the format "Record of Non-Conformities and Corrective Actions" which indicates that an analysis of the consequence must be developed for each Non-Conformity.	**Root cause**: Due to an error in the interpretation of the BRC norm, the analysis of consequences was not included in the "Record of Non-Conformities and Corrective Actions" format because it was understood that the root cause analysis itself also allowed identifying the consequences of Non-Conformity. When the response format of a nonconformity does not request the analysis of the consequence of the finding, the person responsible for raising said	-Format of Record NR RE 012, REGISTRO DE NO CONFORMIDADES ACCIONES CORRECTIVAS	2018-09-06	HOJEDA

				observation will not be able to identify how critical it may be in the process and therefore cannot be prioritized regarding other observations whose incidence is lower. **Preventive action**: A revision of the BRC Standard will be carried out in its new version to comply with all the requirements by the Head of Regulations.			
5	3.9.1	During the plant audit, in cold storage for product (Nº4) in transit it was observed 01 product box without label of identification	Box change is made and immediate labeling of the box in question.	**Root cause**: It is not clear that the corrective actions must be carried out immediately, since the box in question broke (it was made of polystyrene) so the label was removed and the packaging person did not react immediately to change the box and the respective label. Not identifying the product by means of a label can cause a serious case of loss of traceability, which will not allow to identify the origin of the product or perform traceability of any	-Training record	2018-09-06	HOJEDA

				kind. This could be serious in the event of a recall since the entire product could not be recovered. **Preventive action**: Induction is done to personnel who work in the area and who make the changes of boxes or labels when appropriate.			
6	3.11.3	In review of the last product recall exercise it was observed that the company did not contact the certification body	The Recall Procedure is updated, including the contact of the certification house.	**Root cause**: When carrying out the Recall exercise, only the inspection entity was informed, since the contact of the certification body in the Recall document was not updated. The certification house must be kept informed of recall exercises since the product that is being withdrawn from the market is certified by this standard, who guarantee the innocuousness, quality and legality of the product, so they must be aware if there is a failure in any of these aspects. **Preventive action**: When a new Recall exercise is carried out, the	-Pre requisite Program. CC-MA-002 D-07	2018-09-06	HOJEDA

				contact details of the certifying house will be verified, for sending the information of the exercise.			
7	4.4.5	During audit on site it was observed a damaged part of the ceiling in the room for box storage (packaging material)	The repair of the interior ceiling in the area of armored boxes is carried out.	**Root cause**: The personnel that assembles the boxes has not received a correct induction in good manufacturing practices. Keeping damaged interior ceiling can cause contamination of packaging materials. These materials could be in direct contact with the product and its safety could not be guaranteed, in addition it could be the entry of a plague focus into the enclosure. **Preventive action**: Training in good practices is carried out for the area of box assembly by direct leadership.	-Training material in GMP -Training record -Photography of repair -Pre requisite Program. CC-MA-002 D-07	2018-09-06	HOJEDA
8	4.9.1.1	During the audit on site it was observed that there is a storage area for chemical products (Divosan Forte) without restricted access	The padlock in the chemical handling area is changed.	**Root cause**: While it is true, the place keeps a lock, it was in poor condition and waiting for change.	-Photography of padlock -Log POS 06 Control in external areas	2018-09-06	HOJEDA

				By not restricting access to the chemicals used in the plant increases the risk of accidents because it is possible that someone without the required preparation can handle them. On the other hand, it increases the risk of an ill-intentioned act, since they can be used to contaminate the product, the water with which one works or the packaging materials. **Preventive action**: It is checked daily that the status of access to chemical warehouses is restricted to unauthorized personnel.			
9	5.4.5	During review of documents it was observed that the Kosher Certificate is expired (06-30-2018)	The Kosher certificate is requested.	**Root cause**: Kosher certification is not managed the same as the rest of the certification that has Comsur plant, since for being food for the Jewish community and for respect to their habits of interaction with the opposite gender, the management was carried out by the Quality Assistant Manager, who	-Certificate Kosher (valid through 06/30/2019) -Evidence of communication	2018-09-06	HOJEDA

				accompanied the Kosher auditor but did not refer the management of the certificate to the Head of Regulations who assumed that the quality assistant manager would do the whole process. By not having the updated certificate, you can incur an important legal breach because it cannot be guaranteed that the product has approved the requirements demanded by the Jewish market and that we may be using a brand without authorization. **Preventive action**: It was defined by the plant management that the management of Kosher and Halal certificates will be managed by the quality department in relation to the visit and by the Department of Regulations, which refers to payment and management of the certificate.			

10	7.3.2	During review of documents it was observed that some records of survey control of visits are incomplete	The format of the "Visitors Registry" NR-RE-013 is modified to facilitate its filling by the visitors.	**Root cause**: Visiting records are in the clothing area, it is in this place that the document must be completed by the external parties that must enter the processing plant, therefore, the person who delivers the clothing is also the one requesting it filling the registry. Carried out the analysis, it has been detected that people in the area of clothing, even when they know that the registration must be filled, do not measure the importance of it, therefore, they do not control that the fields are complete but only that they are signed. By keeping incomplete records, it is possible that someone who has entered the plant has not declared their real condition at the time of entry, which can become a safety hazard for the product if it was found to have an infectious disease or contaminate the product if you did not declare your previous visit to some other installation.	-Training record -NR RE-013 Format. PLANT VISIT CONTROL	2018-09-06	HOJEDA

				Preventive action: The Head of Certification and Norms carries out an induction in the correct filling of the register and the importance of it for the process to the people who work in the laundry sector.			

Comments on non-conformities

Voluntary Modules Non-Conformity Summary Sheet

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

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

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

FSMA Module Non-Conformity Summary Sheet

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

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

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

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

There is a documented food safety policy signed by the Facility Manager – ARTURO RIVERA, POLITICA COMSUR LTDA., (2-5-2018 ver 8).
Policy was included in NR-MA-001 ver 11 MANUAL DE CALIDAD SISTEMA INTEGRADO DE GESTION CALIDAD, INOCUIDAD ALIMENTARIA, MEDIAMBIENTE, SEGURIDAD Y SALUD OCUPACIONAL. PLANTA COMSUR LTDA. 2018. The integrated policy is displayed both at the site entrance and in other key places of the building. Also, the policy is communicated via email to key employees.
Targets are set for food safety, Customer satisfaction, Production, Hygiene, Personnel, Legal requirements, Environment, HS and Communication.

KPI's year 2016 - 2017
KPI 1. Keep cold chain during processing. Target <= 4°C. Trend is evaluated weekly.
KPI 2. Reduce non-conform products regarding raw material. Target <10%.
KPI 3. Maintain good performance in environmental samples. Target At least 95% of samples has to meet with COMSUR standard: C fecal < 0,3 NMP 25cm2, L. monocytogenes Absence.
KPI 4. Reduce the quantity of non-conformities from internal audits. Target <10 NC
KPI 5. Maintain microbiological performance in finished products according COMSUR standard. Target meet 100% of the COMSUR Standard

For 2018 after a KPI assessment carried out by the new Facility Manager and the Management staff it was defined the following facility's objectives:

KPI 1. Maintain good performance in environmental samples. Target At least 95% of samples has to meet with COMSUR standard: C fecal < 0,3 NMP 25cm2, L. monocytogenes Absence, TPC <5000 cfu/g.
KPI 2. Reduce the quantity of non-conformities from internal audits. Target <10 NC.
KPI 3. Maintain microbiological performance in finished products according COMSUR standard. Target meet 100% of the COMSUR Standard.

A formal management review is held every three months. Last review was held in 20-Jan-2018: REVISION GERENCIAS 2do SEMESTRE 2017 (COD GG-IF-001 ver. 00). Evidence SIG NR-RE-005 (20-1-2018). Issues discussed were:

Follow up of previous meetings, Review of objectives 2017, Org chart, review of company's policy, Integrated management system, integral verification of the HACCP plan (including prerequisites and SSOP), Results of audits carried out during the period (internal, second and third part), HSO, Environment, need of resources, customer complaints, incidents, mock recalls, non-conform products and corrective/preventive actions.

Company keeps updated in technical, regulatory and food safety information by access to different information sources: Salmonchile, FDA, Sernapesca and Rosselkhoznadzor (UEE).

1.1.8 Authorization to carry out the audit after the due date was delivered by Control Union.

1.2 Organisational structure, responsibilities and management authority

Management team headed by the Facility manager. Reporting areas includes the Processing, Planning, Storage, Human Resources, H&S and Maintenance. Quality Area reports to Quality Sub Manager.
There is a list with description of relevant positions, their responsibilities and substitution. In addition to, for every role there is a job description managed by Human Resources:

Roles were shown in GE-RE-003 ORGANIGRAMA COMSUR, “ORGANIGRAMA HOLDING SALMONES AUSTRAL SPA”. Roles, Responsibilities and surrogacies appear in SIG NR-MA-001.
Roles and Responsibilities were communicated to staff in every Employment Contract. A copy of the contract is held by every employee.

Details of non-applicable clauses with justification

Clause reference	Justification

2 The Food Safety Plan – HACCP

HACCP study was based on Codex Alimentarius. In addition to, the HACCP study includes information from: NCh 2861-NT/N° 158; US-FDA Fish and Fishery Products Hazards and Controls Guidance - Fourth Edition, Chile RSA 977 and in MANUAL DE INOCUIDAD Y CERTIFICACION of SERNAPESCA

2.1 Quality Area led by Jorge Chamorro - Head of Quality Assurance who is trained and experienced with HACCP. Quality team includes the Head of Quality Assurance Program, Head of Quality Shift and Quality Supervisors.
HACCP team includes Facility Manager, Head of Facility, Head of storage of finished products, Head of Environment, Head of Planning and control of production, Head of Maintenance, Head of purchasing, Head of Materials storage, Head of training and Head of Norms and certification.
The team meets monthly and discusses any operational changes and verification results.

2.2 Company has 1 HACCP studies based on the principles of Codex Alimentarius: PROGRAMA DE ASEGURAMIENTO DE CALIDAD COD CC-MA-01 ver D-06. MAYO 2018. Facility Number 10681.

Besides HACCP Plans there are 1 additional manual that includes Prerequisites and SSOP, PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002 D-06 (MAYO-2018). SSOP program that covers: control of water and ice, Cleaning and condition of food contact surfaces, prevention of cross contamination and health of employees, maintenance of facilities for washing hand and toilettes, food protection, labeling-handling and storage of chemicals, SSOP operational controls, pest control. Prerequisite program includes GMP, Product Recall, Traceability, Customer complaints, Calibration, Training, Control of Suppliers (P-ADQ-001 – a corporate procedure), Control of metal detectors and Control of glass and brittle

Maintenance of equipment and building was described in MT-PG-001 REV 0, Control of food allergens is included in the HACCP Study, Food Fraud assessment is described in NR-MZ-002 ver 0.
2.3 and 2.4 COD CC-MA-01 ver D-06, the HACCP study for Aquaculture salmonids study scope includes raw aquaculture salmonids. Coho salmon (*Oncorhynchus kisutch*), Steelhead trout (*Oncorhynchus mykiss*) and Atlantic salmon (*Salmo salar*). All products are based on raw fish as unique ingredient. Frozen Products: Dressed Head On and HG; Fillets and portions. Shelf life 24 months at -18°C. Product is IQF. IBP, IVP or bulk packed, glazed. Packaged in cardboard Chilled Products: Dressed Head On and HG; Fillets and portions. Shelf life 21 days stored bellow 4°C. Product is IBP or bulk packed. Packaged in expanded polystyrene boxes (EPS). Intended Use Raw or Cooked consumption Sensible group: allergic to fish protein, and for raw consumption are elderly, pregnant, immunocompromised and young children. The design of the HACCP study took as reference the following documents: Codex Alimentarius, 2861-NT/N° 158; US-FDA Fish and Fishery Products Hazards and Controls Guidance - Fourth Edition; Manual SERNAPESCA; Chile RSA 977.
2.5 and 2.6 Process Flow Steps were reviewed and updated as detailed on flow chart last verified by HACCP team in May 2018. Customers' codes of practice have been referred to. Products are: Production of chilled and frozen products of raw salmonid species in vacuum packing, Styrofoam boxes and cardboard boxes with plastic sheets. Operational steps include raw material reception, grading, filleting and portioning, primary packaging (bulk, individual bag packed, or individual vacuum packed), chilling or freezing and secondary packaging.
2.7 The identification and analysis of hazards were carried out according Codex. It was identified physical, chemical and biological hazards related to raw materials and processes. From all the hazards identified criteria was used to choose those significant hazards. To select the significant hazards, it was used a matrix that considers probability of occurrence and effect in the consumer. For every significant hazard identified it were defined preventive measures. CCP were defined using the Codex decision tree.
2.8 Significant hazards have been identified as chemical (residuals of aquaculture drugs, environmental contaminants and not allowed substances), biological contamination (Listeria monocytogenes, E.coli and Salmonella) of raw material, loss of traceability and physical contamination by foreign bodies (metal inclusion).
2.9, 2.10 and 2.11 CCPs and critical limits: It was verified the presence of critical limits for each defined CCP. CCPs and critical limits. The team has used a 4 questions decision tree to identify CCPs: Company has set appropriate monitoring system for each CCP. From the HACCP study, the company has defined 05 CCPs:

CCP1: Raw material reception.
Chemical Hazard: Presence of aquaculture drug residues and forbidden substances. CL not allowed raw material without certificates.
Biological Hazard: Growth of pathogens in raw material. CL Core temperature less than 4°C for refrigerated products. Core temperature less than -18°C for frozen products
Monitoring: Every raw material reception Visual control of documents. Control of core temperature of fish and Organoleptic control through visual, smell and texture. It is carried out by the quality assurance supervisor. Sampling plan based on NCh 44 S2 AQL 1,5, n=10. Record Reg HACCP N°1 (CC-RE-101)

CCP2. Packing, Labeling, Re packing.
Chemical Hazard: Wrong or missing information. CL. Not allowed products without traceability information
Monitoring every 1 hour carried out by the quality assurance supervisor, according sampling plan NCh 44 S1 n=5, AQL 1,5 a=0
Reg HACCP N°2 (CC-RE-102)

CCP3. Metal detector:
Physical Hazard: Presence of metal fragments. CL. Equipment must detect metal probes. Fe 4,0 mm, No Fe 5,0 mm, SUS 6,0 mm.
Monitoring before the start of operation and every 1 hour and at the end of operation, carried out by the quality assurance supervisor. Reg HACCP N°3 (CC-RE-101)

2.12 CCP's verification includes daily verification of monitoring records, periodical verification through laboratory testing and integral verification of HACCP study.

Last Integral verification of the HACCP was carried out in 18-07-2018. Verification includes: Non-conformities of HACCP, microbiological results on products, Program of Control of Aquaculture Drugs residuals, SSOP and Prerequisites, microbiological results on food contact surfaces and employees, Pest Control, GMP, building condition, Customer complaints, Incidents, traceability and recalls, Calibration, Internal and external audits, Training, New products and new ingredients.

2.13 Records were retained for 3 years (shelf life of the product is 24 months).

2.14 Annual verification was in place in 18-07-2018.

Details of non-applicable clauses with justification

Clause reference	Justification

3. Food safety and quality management system

3.1 Food safety and quality manual

Main Quality Management System with department specific work instruction manuals available on a shared drive within the company's network system. Ref. NR-MA-001 ver 11 MANUAL DE CALIDAD SISTEMA INTEGRADO DE GESTION CALIDAD, INOCUIDAD ALIMENTARIA, MEDIAMBIENTE, SEGURIDAD Y SALUD OCUPACIONAL. PLANTA COMSUR LTDA. 2018. Quality Management manual

contains company's commitment associated to quality policy, customer focus, food safety and processes relationship.

3.2 Documentation control

Apply Procedure PROCEDIMIENTO DE CONTROL DE DOCUMENTOS NR-PC-002 v07. Folders had limited write access to designated Responsible of Quality and Food Safety management system.
Procedure includes content of documents, records, control of changes and annexes.
In the procedure are defined in different levels of documents: Manuals, Procedures, Programs, Instructive, Records, Specifications, Reports, Signals, Flowcharts, Photography, Maps, Plans, Schemes, Labels, Certificates, Regulation, Contingency plans.
Documents were maintained in Spanish. Every document has a specific code as described in PROCEDIMENTO DE ELABOARION, FORMATOS Y ESITLOS DE DOCUMENTOS, NR-PC-001v04.
Control of changes is indicated in the procedure.
There is a master list for company's document NR-IF-001 LISTADO MAESTRO DE PROCEDIMIENTOS COMSUR LTDA. Technical specification for ingredients, inputs and packaging materials were those provided by each supplier.

3.3 Record completion and maintenance

Apply Procedure described in "PROCEDIMENTO DE CONTROL DE REGISTROS NR-PC-003 v01".
There is a master list in place with reference to documents and records in use, NR-IF-001.
Documents are maintained in Spanish. Training was performed in Spanish. Records retained for 3 years (shelf life of the frozen product is 24 months).

3.4 Internal audit

Apply procedure: PROCEDIMIENTO DE AUDITORIAS INTERNAS NR-PC-005 v5.
Completed by Internal audit team (competent for IFSv6, BAP and, BRCv7. Annual meetings / discussion of auditor findings between QA department and senior production staff.

Annual plan of internal audits is scheduled to cover the whole quality system through internal audits carried out during the year as indicated in NR-PG-008. Audits were scheduled to cover the whole quality system based on standards BRCv7, IFSv6, and BAP Processing facilities.

Every food standard that company currently have in place (BRCv7, GAA BAP and IFSv6) is full reviewed at least one time per year through internal audits. E.g. FOOD DEFENSE (Jan 2018), BAP – BRC (Jun 2018), IFS (SEP 2018) and control of documents (Oct 2018).

Also, company has an internal audit for their HACCP system. Also, company runs traceability exercises every month and carry out mock recalls two times per year.

The last BRC internal audit was carried out in Jun 2018. It was carried out by internal auditors. Non-conformities are reported to Facility Manager and to every section manager and reviewed at monthly management meetings.

Monthly GMP audits covering fabrication condition, hygiene, and staff practices: Performed by teams of Quality and maintenance.

Last internal audit was carried out by internal auditors competent in BRCv7 (Lead auditor BRCv7 was Mr. Mario Rodriguez). Non-conformities were reported to Facility manager and to every head of and reviewed at monthly management meetings.

There are Monthly GMP audits covering building condition, hygiene, and staff practices, CHECK LIST DE INFRAESTRCUTURA MT-RE-017. Also, daily monitoring of the SSOP program is carried out and the control includes check of building and condition of food contact surfaces.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw materials and packaging

Apply corporative procedure P-ADQ-01v13 (CORPORATIVO).
All suppliers of raw materials, packaging materials and ingredients have to be approved by the Purchasing team (with advice of Quality Area) before they can be used. There is a list of homologated suppliers. LISTADO PROVEEDORES HOMOLOGADOS PRIMARIOS Y SECUNDARIOS 2017-2018 ADQ-11.
New Suppliers from packaging materials are selected according a risk-based assessment that includes hazards identification and risk analysis that includes technical specs, MDS, GFSI certificate (if apply). Certificates of Analysis and laboratory analysis (if apply), Approval for National Sanitary Regulatory authority.
According the fulfilment of requirements, new suppliers are scored to approval or rejection, (suppliers scored below 4 are rejected).
Raw materials and packaging materials have a risk assessment in HACCP study that considers chemical, biological and physical contamination.
In addition to, both raw materials and packaging materials are evaluated for substitution or fraud, Matriz de seguridad alimentaria CC-MZ-001.

3.5.2 Raw material and packaging acceptance and monitoring procedures

Raw materials were assessed on receipt as a CCP. Suppliers of Fish raw material send letters of guarantee and copies of Certificates of analysis/conformance for every site and cage harvested.
CCP1: Raw material reception.
Chemical Hazard: Presence of aquaculture drug residues and forbidden substances. CL not allowed raw material without certificates.
Biological Hazard: Growth of pathogens in raw material. CL Core temperature less than 4°C for refrigerated products. Core temperature less than -18°C for frozen products
Monitoring: Every raw material reception Visual control of documents. Control of core temperature of fish and Organoleptic control through visual, smell and texture. It is carried out by the quality assurance supervisor. Sampling plan based on NCh 44 S2 AQL 1,5, n=10. Record Reg HACCP N°1 (CC-RE-101).

Packaging material is inspected by every batch at receipt. Company works with suppliers BRC certified (e.g. CARTONES SAN FERNALDO, DLC SpA, INDUGEL, ENVASES DEL PACIFICO S.A. (EDELPA) and ENVASES CHILOE.

-Supplier of polyethylene bags. CONFECCIONES LEYAD LTDA. Evaluated H1_2018. Score 6,67

-Supplier of FILM MULTIVAC. Evaluated H1_2018. Score 6,68

-Supplier of gelpack. DLC SPA. Evaluated H1_2018. Score6,79. Certificate BRC (SITE CODE 2185414). CERT 249221-2017-ABRC IOP-ARG-ACCREDIA. EXP 2018-11-14. DNV-GL

-Supplier of cardboard boxes. CARTONES SAN FERNANDO LTDA, Evaluated H1_2018. Score: 6,74. Certificate BRC: CERT 01 184 18295550 VENC 2019-05-31. TÜV RHEINLAND CERT GMBH.

3.5.3 Management of suppliers of services

Services were evaluated once a month. Suppliers of Contracted Services included the following:

Pest control: ESAM. Last evaluation was in H1 2018, score 6,27.
Laundry: COMERCIAL EKS LTDA. Last evaluation was in H1 2018, score 5,24.
Laboratory: AQUAGESTION S.A. Last evaluation was in H1 2018, score 6,37.
Catering. CDR ARAMARK LTDA. Last evaluation was in H1 2018, score 4,38.
Manage of waste: RESITER INDUSTRIAL S.A. Last evaluation was in H1 2018, score 5,06.

3.5.4 Management of outsourced processing and packing

N/A

3.6 Specifications

Specifications for raw material and packaging materials were described in documented procedure provided by the suppliers.
The specifications for raw material include physical, chemical and microbiological relevant parameters, according to applicable legislation and to the target market (e.g. harvest information, transport invoice, farm site name, cage, warranty statement, reports preharvest analysis, analysis of environmental contaminants, microbiological analysis, chemical and organoleptic standards).
For packaging materials are used technical specs provided by the suppliers.
Reception of raw material was considered as CCP1.
During the audit it was checked the specifications: - Raw material from Aquaculture: Salmo salar (Atlantic salmon) provided from authorized farms included in Sernapesca Pharmacological, Not allowed Substances and Contaminants Control Program.
Technical specifications of finished products are updated and are reviewed annually. Specifications are managed (creation, update and control) by the sales area. Technical specifications are available only for reading in the company's server.
The auditor sampled specifications from the product's scope during audit time.
E.g. Finished product. FT-S-118. Atlantic Salmon Frozen Portions (Ruby Tuesday);
E.g. Finished product. FT-S-030. Atlantic Salmon Frozen Fillet Skin Off IVP;
E.g. Finished product. FT-S-056. Atlantic Salmon Chilled Fillet Skin On IBP

3.7 Corrective and preventive actions

Apply PROCEDIMIENTOS ACCIONES CORRECTIVAS Y PREVENTIVAS NR-PC-006 ver 03. Procedure includes corrective actions, preventive actions and improvement actions.
Corrective action log was used across all issues that occurred at the factory. E.g. no conformities of audits, action plans after management reviews, deviation to processes, non-conform products and goals no reached. The action item list included description of root cause analysis, corrections and verification-follow up of the action taken within a specified time frame.

3.8 Control of non-conforming product

It considers both as nonconforming product and non-conformities detected in the process.
Non-conformities regarding CCP and prerequisites program were treated directly in monitoring sheets.
Customer complaints are treated in a different way according specific procedure
Non-conforming procedures for raw materials, products in transit, finished products, ingredients/packaging materials and CCP's deviation considers segregation-identification, quarantine and final disposition (e.g. release, return to supplier, re-packaging, re-work, destruction, etc.). The responsible of release is the quality area.

3.9 Traceability

Traceability system operates through FISHTALK computer systems and paperwork enables trace of raw materials from supplier through processes, to packing and dispatch via lot number. Also, packaging materials traceability is maintained using FINN 700.
Traceability includes rework, re-packaging and re-labeling. Activities and responsibilities are described in procedure PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002 D-06 (MAYO-2018).
The system is tested monthly, including verification of raw materials, final products and packaging materials.
Last traceability exercise was carried out in July 2018. Report Informe de Ejercicio de Trazabilidad CCIF-001. Salmo Salar. Lot TR1820101. Origin QUEULLIN JAULA 9. Raw material: 49915,08 Kg. Packed products: 31691,52 Kg.

During audit, a traceability exercise was performed with product from Atlantic Salmon.

Processing LOT: TR1820401, Production date 23.07.2018.
Origin: Farming site: QUEULLIN (SIEP 102930), Cage 9 & 14.

Entrance to processing: 23-Jul-2018.
Total received: 45.787,28 Kg.

Packed: 29.234,58 kg (63,8 %)
Total chilled products: 17226,1 kg
Total frozen products: 12008,48 kg

In frozen stock: 3687,82 kg
D&C: 3318 Kg
COMSUR: 549,82 Kg

Total shipped: 25367 kg
Chilled products: 17319,1 kg

PACKAGING MATERIAL TRACEABILITY:

PAÑAL. LOT 22090. Supplier CINTEC
FUNDA INTERNA. LOT 13581. Supplier LEYAD

3.10 Complaint handling

Complaints logged by sales department are handed to technical area for investigation.
The Customer Complaints Investigation report and is described in PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002. Complaints data was summarized and reported monthly in INFORME MENSUAL DE CALIDAD.
Follow up of customer complaints carried out by the Quality chief according FORMULARIO CC-RE-003 v1.
During 2017 the plant received 14 complaints:

Labeling (6), Organoleptic (2), Metal (1), Foreign body (1), Mix of products (1), Out of spec (1), Packaging material (1), weight (1)

3.11 Management of incidents, product withdrawal and product recall

Management of incident procedure is described in “PLAN DE EMERGENCIA PROTECCION DE LA INOCUIDAD ALIMENTARIA (CC-PC-005 v03)”. Procedure considers incidents as shut down electricity supply, fail in water supply, Earthquakes, Floods, Volcanic Eruptions, Tsunamis, Fires, Explosive Attacks, Robbery, Social Events, Others.
There is a specific procedure for Product Withdrawal/Recall: PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002.
Key team member roles were identified in the recall program including LEADER Facility Manager.
Two times per year it is performed a mock recall to test the system.
E.g. Mock recall 2018-06-28. Presence of E coli in Salmon Fillet Skin On. Recall Class II. No recalls reported during the last year.

3.12 Customer focus and communication

Customer’s relationship is managed by the sales area. Staff is communicated about customer requirements using technical specs that are well controlled.
There is a procedure in place “PROCEDIMIENTO DE COMUNICACIÓN Y ENFOQUE AL CLIENTE P-3-001 v01”.
All communication with suppliers of products and services are carried out by the Purchasing team (with advice of Quality Area). Communications are made through mail, telephone and in person (audits in some cases) with suppliers.

Details of non-applicable clauses with justification

Clause reference	Justification
3.5.4	No outsourced processes

4. Site standards

4.1 External standards

Processing Facility was in a good repair condition.

The facility is located in Chamiza in front of a local road near to the city of Puerto Montt. No near activities that would risk product contamination.

4.2 Security

There is in place a MANUAL DE DEFENSA DE LOS ALIMENTOS NR-MA-002 v02. Manual includes a vulnerability assessment with evaluation on security inside the facility and processing areas, security of storage, security of visitors and employees, security in external areas, security during emergencies.
Enclosed site with guards in 24 hours shifts 7 days per week.
Staff is trained as part of induction and with access limited to hours of work.
There is a restricted access to storage of materials, warehouse, treatment and storage of water. CCTV is in place. Visitors and contractors were required to register at time of arrival and were issued a visitor badge.
There is in place an audit plan to check the Food Defense Program. E.g. AUDITORIA DE FOOD DEFENSE, carried out by Maritza Soto, 100% of compliance

Facility is registered in FDA (Food Facility Register #14816143098).

4.3 Layout, product flow and segregation

The premise is structured on 1 floor with a physically segregated high-care area accessed by staff through a separate footbath and sanitary filter.
Process flow start from intake, gutting, grading and whole fish storage. Then the raw material pass to the high care area and the gutted fish is filleted or filleted-portioned and then is chilled or freeze in static or continuous blast tunnels. Then, after being packaged the product is placed in pallets in warehouse area and is dispatched or kept in frozen or refrigerated storage.
Site layout plans were documented showing product areas, waste, personnel access points and facilities etc. High-care production areas were identified and appropriately controlled.

The following drawings and process flows are verified.
- Fresh and salt water
- Flow of products and raw materials
- Raw materials
- Solid and liquid waste
- Distribution equipment
- Personnel

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

Design and construction of the building and equipment meet the standard. Factory fabric was well maintained. Walls and ceilings were of clad panel construction. Floors were laid with tiles. A factory drainage plan was documented. Drains flowed out of high-care. Doors were well tight in the building. Lighting was of good quality and lights protected against breakage. Off-odors were not detected.

4.5 Utilities – water, ice, air and other gases

Facility is supplied from a water deep well for processing, flow-ice, cleaning, glazing, canteen and toilettes. Employees drink only bottled water. Water, flow ice and flake ice are tested monthly according requirements of National regulatory office that consider requirements of US-EPA, UE 98/83/EC, Chile NCh 409/1 & SERNAPESCA.

MONTHLY VERIFICATION:
- Fresh water and Flow-Ice: External Laboratory AQUAGESTION (ISO 17025, INN LE 640):

E.g. Flow ice: CoA AQ-18-17140 (2-8-18). Tested for Total coliforms and E. coli

E.g. Water: CoA AQ-18-17131 (31-7-18) N=7 (#7, #17, #30, #41, #54, #65, #79). Tested for Total coliforms, E. coli, Smell, Color, Flavor, Conductivity, Turbidity and pH.

Once a year water from every source was tested for compliance with US-EPA, UE 98/83/EC, Chile NCh 409/1 & SERNAPESCA.
ANNUAL VERIFICATION:
- Fresh water from deep well. External Laboratory SGS (ISO 17025, INN LE117, LE118, LE119, LE057, LE 717 Y LE 718).
CoA ES18-11433 (14-3-18). Tested for Pesticides, Heavy metals, chemical Contaminants, Total coliforms, E. coli

4.6 Equipment

Equipment intended for gutting, filleting, pin boning, skinning, portioning, vacuum packaging, boxes strapping and metal detection. Equipment varied in age but was predominantly constructed of stainless steel and was in general in well condition. Equipment and materials are adequate for food industry. Food contact surfaces has guarantee letters from suppliers related to compliance for use food industry.

E.g. CINTAS MODULARES INTRALOX. Materials PE, PP. FDA: 21 CFR 177.2600, EC 1935/2004
E.g. CINTA THERMODRIVE – INTRALOX. Materials POLIPROPILENO (31002), AZUL (35040) 21CFR 177.1520

Processing plant was subject to preventive maintenance at scheduled intervals.

4.7 Maintenance

Preventive maintenance is described in MANTENIMIENTO PREVENTIVO MT-PG-001 v03.
Technicians and maintenance supervisors' staff report to Head of Maintenance.
The design of the maintenance program has as input drivers the equipment's manufacturer recommendations and the experience of the competent staff.
Preventive maintenance is managed in a MS database. Inputs to maintenance schedule are based in Technical specifications provided by the equipment suppliers and experience-competence of maintenance staff. A maintenance calendar was in place including scheduled intervals, weekly, monthly and quarterly: MT-PG-001
E.g. Filleting machine BAADER 581, EQUIPO BA 581 (L1)
Monthly maintenance REGISTRO DE TRABAJO Nº 331 (14-5-18)

E.g. Vacuum sealing machine MULTIVAC R-245
Monthly maintenance REGISTRO DE TRABAJO (11 AL 15 JULIO 2018)

E.g. Metal detector. DET METALES EMPAQUE 2. (SERIE MH308-12648D)
Monthly maintenance ORDEN DE TRABAJO PREVENTIVO Nº6 DEL 6 AL 8 JUNIO 2018.
Yearly maintenance Carried out by the supplier SERTEC (26-2-18)

Food grade lubricants were used. E.g.
NSF 123540, NSF 126377, NSF 144721

4.8 Staff facilities

Personnel facilities included lockers/changing rooms, toilets and canteen. Individual lockers were provided for employees to store their coats. Hand wash facilities were provided with foot operated taps, liquid soap, paper towels and alcohol-gel. Canteen personnel prepare the meals for the employees. Smoking was not permitted in the staff facilities. Eating and drinking were not permitted in staff facilities or outside.

4.9 Chemical and physical product contamination control

Raw material handling, preparation, processing, packing and storage areas

Control of chemical contamination of raw material is part of CCP1 Raw material reception.

-Chemical Hazard: Presence of aquaculture drug residues and forbidden substances. CL not allowed raw material without certificates.

Apply PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002. Procedure includes prevention of cross contamination, food protection and handling-labelling of chemicals for cleaning and disinfection. Glass was not allowed in food storage, processing or packaging areas unless controlled.
Wood was not used in processing areas with exposed products.
Daily monitoring covering facility condition, and review of glass, brittle materials and hard plastics: e.g. POS 8 # 1334 (2-6-17).

4.9.1 Chemical control

Chemicals were well controlled within the factory as all containers properly labelled. Cleaning chemicals were stored in a locked space with restricted access.
A list of approved chemicals used at the facility was maintained for cleaning chemicals.
General Chemical awareness training was given to cleaning and sanitation personnel at induction.
Cleaning chemicals were supplied against specifications by CINTEC. Food suitability was documented for chemicals used on site.
E.g. DIVOSAN FORTE ISP D160-15

4.9.2 Metal control

Knife controls: Knives are managed by every shift supervisor dry stored & clean in a locked toolbox.

A review for knives and utensils was applied and cleaning conditions were observed
Metal detection is considered a CCP.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Apply PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002. Procedure includes prevention of cross contamination, food protection and handling-labelling of chemicals for cleaning and disinfection. Glass was not allowed in food storage, processing or packaging areas unless controlled.
Wood was not used in processing areas with exposed products.
Daily monitoring covering facility condition, and review of glass, brittle materials and hard plastics: e.g. POS 8 # 1716 (23-7-18).

4.9.4 Products packed into glass or other brittle containers

N/A

4.9.5 Wood

Apply SSOP procedure PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002. Wood was not permitted in high care areas. Only it is allowed in area for closed products.

4.10 Foreign-body detection and removal equipment

4.10.1 Foreign-body detection and removal equipment

Foreign body control measures included metal detection in boxes of finished products in already strapped/sealed boxes.

Metal detector testing is a CCP and controls were carried out at start and then every hour and at end of each production batch after product packing. Metal detector was check, e.g. HACCP 3, From # 4433 to #4426 (23-7-2018).

No X-ray equipment used.

4.10.2 Filters and sieves

N/A

4.10.3 Metal detectors and X-ray equipment

Foreign body control measures included metal detection in boxes of finished products in already strapped/sealed boxes.

Metal detector testing is a CCP:

CCP3. Metal detector:
Physical Hazard: Presence of metal fragments. CL. Equipment must detect metal probes. Fe 4,0 mm, No Fe 5,0 mm, SUS 6,0 mm.
Monitoring before the start of operation and every 1 hour and at the end of operation, carried out by the quality assurance supervisor. Reg HACCP N°3 (CC-RE-101). E.g. HACCP 3, From # 4433 to #4426 (23-7-2018).

No X-ray equipment used.

4.10.4 Magnets

N/A

4.10.5 Optical sorting equipment

N/A

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

N/A

4.11 Housekeeping and hygiene

A cleaning team cleans the facility during the non-productive shift.
Process described in Apply PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002, verified specific rooms to clean utensils as trays and bins.
Cleaning Schedules were described. Pre operational and operational of cleaning (process room, once per shift). Cleaning instruction procedures were available for all areas on company server. SSOP procedures include instructions for cleaning of equipment, machine, food contact and non-food contact surfaces, and the all facility.

Production start-up checks included housekeeping and hygiene. Hygiene assessment is carried out by visual inspection.

4.11.7 Cleaning in place (CIP)

N/A

4.12 Waste / waste disposal

Waste materials were well managed on site. Solid food waste was removed from the site by third party contractor. Liquid waste was treated by company effluent treatment system previously evacuation to receiving water body.

4.13 Management of surplus food and products for animal feed

Food waste is used for animal feed. Food waste was retired daily. Through invoice number it is possible to track the food waste to processing and raw materials.

4.14 Pest Control

Apply PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002 D-05 – Pest Control.
The Pest Control activities have a third part company contracted: “ESAM LTDA. (sanitary authorization N° 1662 dated on 2015-04-22) and is well managed. Technical Representative MIRIAM BARTSCH.

Service includes:
-Fortnightly control of rodents.
-Monthly control of insects (fumigation).

A map that identifies all traps (bait stations, insect light traps and others) is available.
Documents of third part company are suitable and actualized.
Verified certificates of services carried out OT#79501 (5-7-18) (for rodents); OT#80593 (15-7-18) (for insects)

Monthly reports are provided by the supplier indicating performance of service and trends. E.g. TR 58311 (3-7-2018). Reviewed Report period June 2018.
In addition to, company carries out a monitoring of pest control activities. E.g. POS06 # 1131 (23-7-2018).

4.15 Storage facilities

Company stores its finished goods in 2 cold storage warehouses with storage capacity of 60 metric tons each one.
The storage rooms were in good maintenance and have automatic temperature monitoring.
Products in transit and semi-finished products were stored in controlled temperature rooms. There is a system to monitoring environmental temperature during storage.
There are defined warehouses for storage of packaging materials. The warehouses are in good state of maintenance and free of access to pests.
Company has a computer system that ensures the proper rotation of materials.

4.16 Dispatch and transport

Final products are dispatched in closed boxes. Each box is identified with a label that contains data of the product, the processor and a box number that allows traceability
Vehicles and goods were subject to formal inspection at dispatch. Records of inspection were maintained.
For transport of frozen finished goods, the set point temperature is -20°C. Every transport has its own temperature chart recorder. In addition to, temperature data loggers were placed in dispatch if requested by the client.
Vehicles and goods were subject to formal inspection at dispatch. Records of inspection were maintained.

Details of non-applicable clauses with justification

Clause reference	Justification
4.3.5 – 4.3.6	No high-risk areas
4.3.7	No ambient high-care areas
4.4.13	No high-risk areas
4.5.3	Non-potable water is not used
4.5.4	Air, other gases and steam are not used directly in contact with, or as an ingredient in, products
4.7.5 – 4.8.4 – 4.8.5	No high-risk areas
4.8.8	Smoking is not allowed
4.9.4.1 – 4.9.4.2 – 4.9.4.3	There are not products packed into glass or other brittle containers
4.10.2.1 – 4.10.2.2	There are not filters and sieves used in processing or in contact with raw materials, semi-finished goods of finished products.
4.10.3	No metal detector or x-ray equipment in use.
4.10.4.1	There is no use of magnets

4.10.5.1	There are no optical sorting equipment or devices
4.10.6.1 – 4.10.6.2	There is no packaging in glass jars, cans and other rigid containers
4.11.7.1 – 4.11.7.2 – 4.11.7.3	There is no CIP cleaning system
4.15.4	No controlled atmosphere storage is required
4.15.5	No storage outside

5. Product control

5.1 Product design/development

Technical specifications were prepared by sales area and were available in SharePoint. When facility only do process service to clients, the technical specs were directly provided by each client.

Every modification to raw material, packaging materials, new suppliers, new products or new processes is assessed by HACCP team and included in HACCP study.

5.2 Product labelling

Product labelling is a CCP. Company files a sample of label of primary and secondary packaging for every product packed.

CCP2. Packing, Labeling, Re packing.
Chemical Hazard: Wrong or missing information. CL. Not allowed products without traceability information Monitoring every 1 hour carried out by the quality assurance supervisor, according sampling plan NCh 44 S1 n=5, AQL 1,5 a=0. Reg HACCP N°2 (CC-RE-102).

There is a specific control of labeling (primary and secondary) at the start of operation carried out by the quality monitors. There is a record file to keep historical information of labels printed and approved by quality and processing areas.

Format of label were available in company's' database. Control of processing area keep updated new requirements about product labeling and is responsible to validate every change in label format or content. Legal compliance is based in the MANUAL DE INOCUIDAD Y CERTIFICACION of SERNAPESCA and specifics requirements from every destiny market. Additional labels are proposed by the client and validated by Facility. Quality assurance area keep updated new requirements about product labeling and is responsible to validate every change in label format or content.

5.3 Management of allergens

Apply PROGRAMA DE ASEGURAMIENTO DE CALIDAD COD CC-MA-01 ver D-06.
No other allergen different than fish (farm raised salmonids).
Company identifies through labeling the fish content in all of the packaged boxes.
Company has a risk matrix for evaluation of allergen cross contact risk. Fish content is indicated in labels as described in HACCP study.

5.4 Product authenticity, claims and chain of custody

Through the HACCP study the company has carried out a risk assessment of raw materials, ingredients and packaging materials for chemical, physical and biological hazards.
Facility maintains certifications for BAP that include procedures for traceability, identification and segregation of raw materials, product in transit and finished products. A periodical verification of mass balance is carried out to check coherence between quantities received and packed, and to check absence of misbranding or bad assignation of lots.
A risk assessment for food fraud is included in MATRIZ DE EVALUACION DE RIESGOS NR-MZ-002.

5.5 Product packaging

Packaging materials were appropriate for the range of operations undertaken and comprised PE/PA film, PE bags and films.
Declarations of food contact compliance were available for packaging materials as part of specifications or as separate documents. Packaging materials were stored in a designated area of the warehouse.

E.g. PAÑAL LOT 22090. Supplier CINTEC. PULPA DE CELULOSA PRENSADA
TELA DE POLIPROPILENO Y POLIETILENO. CoA MIGRACION GLOBAL LABEN E164/15 (15-5-15)

E.g. FUNDA INTERNA LOT 13581. Supplier LEYAD. POLIETILENO. CoA MIGRACION GLOBAL LABEN E163/16 (19-5-2016).

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Sampling and analysis plan: the analysis plan adopts the recommendations of SERNAPESCA Manual de Inocuidad y Certificacion. Analyses regarding critical controls are performed by the external laboratories, AQUAGESTION and Universidad de Chile according to APHA, AOAC and include microbiological, chemical, physical and sensorial analyses.
The periodical analyses were carried out on fortnightly basis an include microbiological, physical, chemical and sensorial analysis.
E.g. External Laboratory AQUAGESTION (ISO 17025, INN LE 641; 905; 348; 639). CoA AQ-18-09015 (24-4-18); period from 23-3-18 to 10-4-18. Atlantic Salmon FILETE CONGELADO CON PIEL SIN ESCAMAS, LOT TR 1809601. Tested for TPC 35ºC; E. coli; S. aureus; Salmonella; L. monocytogenes (P/A); L. monocytogenes (cfu/g): V. parahaemolyticus; S. aureus for UEE; Total coliforms for UEE; TPC 30ºC for UEE; NVBT; N-TMA; Hg; Cd; Pb; As; Histamine; Organoleptic.

Also, once a month raw material is tested for verification of drugs residues.

E.g. External Laboratory FAVET (ISO 17025, INN LE 537; 183; 184; 1112). CoA. 9.376 (03-08-2018). Cage 9 & 14. Farming site QUEULLIN (SIEP 102930). Tested for tetracyclines, aflatoxin, deltamethrin cypermethrin, fluoroquinolones, neomycin spectomycin.

5.6.2 Laboratory testing

Accredited external laboratories perform 100% analyses regarding critical controls on finished product, surfaces, manipulators, water and ice.
External laboratories are accredited by SERNAPESCA under ISO 17025.
E.g.
Laboratory AQUAGESTION (INN LE 641; 905; 348; 639)
Laboratory UNIVERSIDAD DE CHILE – FAVET (INN LE 537)
Laboratory Universidad Austral de Chile (INN LE 274; 275; 276)

When a deviation in testing results is reported, the Head of quality assurance is responsible to carry out corrective actions according company's procedure.

5.7 Product release

Procedure for the release of finished goods is verified. Process described in Process described in the HACCP study PROGRAMA DE ASEGURAMIENTO DE CALIDAD COD CC-MA-01 ver D-06.
Once a non-conforming product is found, it is blocked using a block label. Possible destinies of non-conforming products are. Correction (re-processing), other destiny (client or country) when there are no food safety or food fraud issues, destruction, return to supplier
The release of non-conforming products is responsibility of the head of quality assurance.

Details of non-applicable clauses with justification

Clause reference	Justification
5.3.2. 5.3.3, 5.3.4, 5.3.5, 5.3.6, 5.3.7, 5.3.8	There are no different food allergens apart from the inherent ones of the product.
5.4.4	Specie is declared on all labels.
5.4.5.	There is no statement about certified production method.

6. Process control

6.1 Control of operations

The production operation included temperature-controlled storage finished products (automatic checks). Parameter of control is mainly product temperature during packing, storage and dispatch. For frozen products the temperature must be equal or lower than -18 ° C.
Packing is a CCP and in this operational step is controlled labelling.

6.2 Labelling and pack control

Activities and responsibilities are described in HACCP Plan and Pre-requisites Plan (Chp. Traceability) procedure.
Packaging of final product is defined as defined as CCP controlling
CCP2. Packing, Labeling, Re packing.
Chemical Hazard: Wrong or missing information. CL. Not allowed products without traceability information
Monitoring every 1 hour carried out by the quality assurance supervisor, according sampling plan NCh 44 S1 n=5, AQL 1,5 a=0
Reg HACCP N°2 (CC-RE-102)

Adherence to packaging allocation procedure was observed during product changeover ensuring pack clearance before starting up and documented label and packaging checks.
Company files a sample of label of primary and secondary packaging for every product packed. Product labelling is an internal control of labelling in an hourly basis. Limits are: proper labeling and fulfillment of specifications according technical spec for each product.

The labels are previously designed by production control area. The format of the labels in printed during packaging, completing with the variable fields. From the system the packaging operator can select the purchase order (which associates the species, product, quality, size, etc.) and the LOT.

6.3 Quantity, weight, volume and number control

Product was packed to fixed net weight. Net weight and Quantity were verified manually at the rate of 1 product per lane every 1 hour. Records of quantity verification indicated satisfactory control
The legal requirements for amount control are met by calibrated measuring devices.
Quantity checking was carried out on a daily basis and every during traceability test (2 times per year).
Last traceability exercise was carried out in July 2018

6.4 Calibration and control of measuring and monitoring devices

Calibration and contrastation Process described in the documented procedure of PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002 D-05 (02-11-2016. Calibrated measuring devices met the legal requirements for amount control. Calibration was traceable to National standards, with supporting documentation where applicable.

It was verified the following records:
THERMOMETERS
E.g. REGISTRO CONTRASTACION DE TERMOMETROS PPR01 CONTROL TERMOMETROS (Fortnightly) FOLIO 98 (30-7-18) and FOLIO 97 (20-07-18)

THERMOMETER OF REFERENCE. External Laboratory CESMEC, ISO 17025, INN LC006 (A) SERIE 510334891605, Certificate SMD 59020 (2018-04-17)

(B) SERIE 31160302/209, Certificate SMD 57731 (2017-09-29)

SCALES
REGISTRO CONTRASTACION DE BALANZAS (Daily). PPR2 # FOLIO 2712 (23-7-18) and FOLIO 2711 (23-7-18), at the start of every shift

REFERENCE MASS
External Laboratory. CESMEC, ISO 17025, INN LC 002

500g Certificate SMA 77835 2017-09-29
1 kg Certificate SMA 77837 2017-09-29
1 kg Certificate SMA 77836 2017-09-29

External Laboratory. PESAMATIC, ISO 17025, INN LC 042

100 g. Certificate S.PST-50901 (29-6-18)
5 kg. Certificate S.PST-50902 (29-6-18)

Details of non-applicable clauses with justification

Clause reference	Justification
6.2.4	There is no on-line vision equipment used to check product labels and/or printing
6.3.2	No bulk packed products

7. Personnel

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

Training program was included in procedure PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002 D-06. There is an annual planning for training of employees.

All trainings are registered.
It was verified training records for: GMP, POS, HACCP, Work Instructions, and HACCP team.
For HACCP coordinator were verified training records of BRC, HACCP.
Those records include time, instructor, contents and signs of each participant.

Verified training records for interviewed employees:

CHRIS REYES (Packing supervisor)
-HACCP: 14-5-18. OTEC QUELLON CAPACITA LTDA.
-RECALL Y TRAZABILIDAD: 18-5-18. OTEC QUELLON CAPACITA LTDA.

MELISSA CONTRERAS (Operator, labeling of product. Packing)

REGLAMENTO INTERNO 06-07-2018.
-INDUCCION INTERNA 5-7-2018. (2 HRS) POLITICA, BPM, LAVADO DE MANOS, PCC, FOOD DEFENSE, NRMATIVA RUSA

JORGE CARRASCO (Quality Supervisor)
-HACCP 22 Y 23 MAYO 2018 (16 HRS) DELPHINUS CAPACITACIONES LTDA.
-POS 16 MAYO 2018 (8 HRS) DELPHINUS CAPACITACIONES LTDA.
-RECALL Y TRAZABILIDAD: 18-5-18. OTEC QUELLON CAPACITA LTDA.

RICHARD VERA (ARMADO DE CAJAS – CONTINENTALES)
-BPM – FOOD DEFENSE. 4-7-18. MBA CAPACITCION (8 HRS)

CAROLINA DEL VALLE (Contractor SUPERVISOR, AGUA VIVA)
-REGISTRO DE INDUCCION. ASEG CALIDAD 30-6-2018. AGUA VIVA SPA
-REGISTRO DE INDUCCION. FOOD DEFENSE 30-6-2018. AGUA VIVA SPA
-BPM-FOOD DEFENSE-HACCP-POS 30-6-18. MBA CAPACITACION (8 HRS)

CARLOS PEREZ (worker of industrial cleaning – COMSUR)
SEGURIDAD YMANEJOS PRODUCTOS QUIMICOS Y SUSTANCIAS PELIGROSAS D&C CAPACITACIONES SPA. 9-5-18 (8 HRS)

ROMINA TRIMPAI (Quality supervisor)
-FUNDAMENTOS HACCP 22 Y 23 MAYO 2018. (16 HRS) DELPHINUS CAPACITACIONES LTDA.
- POS 16 MAYO 2018 (8 HRS) DELPHINUS CAPACITACIONES LTDA.

FABIOLA QUINCHAMAN (Fish grading – quality, Contractor AGUA VIVA)
--BPM-FOOD DEFENSE-HACCP-POS 30-6-18. MBA CAPACITACION (8 HRS)

LILIANA VERA (Fish grading – quality, Contractor CONTINENTALES)
-BPM-FOOD DEFENSE 4-7-18. MBA CAPACITACION (8 HRS)

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

The hygiene standards for staff (internal and external) are defined in PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002 D-06.
It was verified that training to all staff regarding personal hygiene and GMP is carried out during the induction for first time employees.
Policy trained out to staff during induction and well managed through daily supervisor checks. No issues seen regarding compliance to documented hygiene policies. The requirements for personnel hygiene are established and during the audit all the personnel observed was compliant (e.g. no jewelry, no food/smoking, protective clothing, hand washing).
The hand washing practices was observed during site visits. The control frequency is done in each entrance and exit.
The hand washing system has warm water, disinfectant soap, alcohol gel, drying system with forced air.
Personnel hygiene is checked on a daily basis at entrance of every shift (visual inspection) using record POS 02 HIGIENE Y PRESENTACION PERSONAL #1504 (23-7-2018). The audit confirmed the correct application by staff and visitors.

7.3 Medical screening

Process described in the documented procedure PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002 D-06.
Verified availability and control of curative blue plastic, supplier Difenpharma. Blue patches are verified at 100% in metal detector. It is confirmed that through inductions to staff the employees are informed of the symptoms of infection, sickness or relevant disorders. A worker suffering these symptoms is prevented from being in contact with food.

Testing for Employees hands are carried out every two weeks as requested by regulatory agency Sernapesca:
Manipulators fortnightly analyses include E. coli and S. aureus in hands.
E.g. External Laboratory AQUAGESTION CoA # AQ-8-17137 (2-8-18), n=5. Tested for S. aureus and fecal coliforms in hands. Results showed absence to these parameters.

7.4 Protective clothing: employees or visitors to production areas

Apply procedures of Prerequisites PROCEDIMIENTOS OPERACIONALES DE SANEAMIENTO Y PROGRAMA PREREQUISITOS CC-MA-002 D-06.

All personnel entering the plant receive working clothes. The design is appropriate, including pants, jacket, hair covers, masks, disposable gloves, no external pocket and without metal fasteners. Verified in record POS 02 HIGIENE Y PRESENTACION PERSONAL #1504 (23-7-2018).

Frequency of control is daily. All employees in areas of product exposed uses plastic covers. There are no high-risk zones identified.
Disposable plastic gloves are used for employees in direct contact areas and were controlled appropriately. Gloves color is different from the product. Metallic gloves (PPE) are used to prevent injuries in zones when knives or cutting elements are used. Metallic gloves are cleaned and sanitized once per shift and were controlled appropriately.

There was an external laundry and company has procedures of control and verification.

Details of non-applicable clauses with justification

Clause reference	Justification
7.4.4	No high-risk areas

Module 8 - Traded Goods	
Scope	
8.1 Approval and performance monitoring of manufacturers/packers of traded food products	
8.2 Specifications	
8.3 Product inspection and laboratory testing	

8.4 Product legality
8.5 Traceability

Module 9: Management of Food Materials for Animal Feed

Scope	
9.1 Management Commitment	
9.2 HACCP	
9.3 Outsourced Production	

9.4 Specifications
9.5 Traceability
9.6 Chemical and Physical Product Contamination Control
9.7 Labelling
9.8 Training

Module 11: Meat supply chain assurance

Scope	

11.1 Traceability

11.2 Approval of meat supply chain

11.3 Raw material receipt and inspection

11.4 Management of cross-contamination between species

11.5 Product testing

11.6 Training

Module 12: AOECS Gluten-free Foods

Scope	

12.1 Senior management

12.2 Management of suppliers of raw materials and packaging

12.3 Outsourced production

12.4 Specifications

12.5 Management of gluten cross-contamination

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

Module 15 FSMA Preventive Controls Preparedness Module

Item no.	Clause	Module item	Conforms (Y/N)	Comments
1	117.20	Handwashing areas, dressing and locker rooms, and bathrooms must have adequate lighting.		
2	117.37	The water distribution system must prevent backflow from, or cross-		

		connection between, piping systems that discharge waste water or sewage.		
3	117.40	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	117.80	Ice used in contact with food must be manufactured in accordance with the good manufacturing practice (GMP) requirements of 21 CFR § 117.		
5	117.110	Where defect action levels (DALs) 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	117.130 (a)	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 that affect food safety.		
7	117.130 (b)	All identified, known, or reasonably foreseeable hazards must be evaluated to determine 'hazards that require a		

		preventive control' (i.e., significant hazards).		
8	117.135	Establish one or more preventive control(s) for each identified 'hazard that require 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.		
9	117.139	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 of recalled product (i.e., destroy, divert, repurpose).		
10	117.145	Establish monitoring activities and a written procedure for each preventive control in a manner consistent with the requirements of BRC section 2.10.		
11	117.150	Establish corrective action procedures when preventive controls are not implemented in a manner 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	117.160	Validate all established process controls prior to implementation of the food safety plan, upon changes		

		requiring revalidation 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	117.165 (a)	The PCQI (or authorized designee) reviews the 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 their authorized designee) reviews the verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record has been created.		
14	117.165 (b)	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 an analysis • corrective action procedure where a pathogen is detected.		
15	117.165 (c)	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 the analysis • corrective action procedure where a pathogen is detected.		
16	117.165	Devices used to **verify** preventive controls must be calibrated.		
17	117.180	Identify a PCQI responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training or qualifications via job experience.		
18	117.305	All records required by 21 CFR § 117 must include: • the date and time of the activity being documented • signature/initials of individual performing the activity or conducting the record review • information to identify the facility (e.g., name and location) • the identity of the product and lot code where applicable.		
19	117.310	The owner, operator or agent in charge of the facility must sign and date the written food safety plan initially and again upon any changes following reanalysis.		
20	117.315	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	117.405	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.		
22	117.420	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	117.430	One or more supplier verification activities (as defined in 21 CFR § 117.410(b)) must be conducted for each supplier **before** using raw materials and ingredients **and** periodically thereafter at an adequate frequency.		