Part II: Section III

Export and Certification Control

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CHAPTER I. SHIPMENT AUTHORIZATION FOR EXPORT FISHERY PRODUCTS

The fishery and aquaculture products exports must have the authorization of the National Fisheries and Aquaculture Service, before their shipment. For this, the exporter must present a Notification of Shipment of Export Fishery Products (NEPPEX); this authorization will be subject to evaluation of SERNAPESCA to verify the associated technical and administrative requirements, which will depend on the type of product, type of requested certificate (if appropriate), and the country or market of destination.

There are two ways to process the NEPPEX: manually and through the Internet. For manual processing, the exporter must present at the offices of SERNAPESCA located in the port of exit, the NEPPEX form, which can be downloaded from the Service's web page.

Shipments exclusively of salmonids by-products, produced and consolidated in the Los Lagos region, and with customs exit in the region of Biobío are excluded from the previous procedure since these must present their Notification of Shipment at the regional office of Puerto Montt, excluding the certification of origin and the sanitary certification proceedings, which must be requested at the SERNAPESCA office of the jurisdiction of customs port of exit for the goods.

The web proceedings consist of processing the Notification of Shipment of Export Fishery Products through the internet, where the processing establishment authorized for this procedure, directly requests an electronic NEPPEX from the "Ventanilla Empresa" system. This system runs automatic validations to authorize the export accordingly, sending an XML message to the National Customs Service to allow the entry of goods through customs at the primary zone. This procedure does not require the review of the Official Inspector of SERNAPESCA.

If the destination market does not require a sanitary certification, and the exporter declares that it will not need one, SERNAPESCA will authorize the export subject to the compliance with the technical, administrative and sanitary requirements described in this Chapter. If the product to be exported corresponds to bivalve mollusks, echinoderms, tunicates, and gastropods, it must also comply with the sanitary requirements outlined in Item 3 of this Chapter.

If a sanitary certification is required, it must be requested when requesting the NEPPEX, so as to conduct the validation of the sanitary requirements to obtain the certification, before the goods exit through customs. Otherwise, the sanitary certification cannot be granted.

1. ADMINISTRATIVE PROCEDURE

The exporter, the shipping agency or the customs agency representing it, must notify their intent to export to SERNAPESCA, presenting the original version and a copy of the NEPPEX. All the original documents must be presented at the SERNAPESCA office of the place where the customs documents were processed and through where the goods will enter to primary export zones, even when the physical exit of the goods takes place through another border crossing (cabotage). With the exception of exports exclusively of salmonids by-products, produced and consolidated in the region of Los Lagos, which exit through customs at the region of Biobío, where 2 original versions and 1 copy of the NEPPEX must be presented in the region of origin, to then present one original version of the document in the region of shipment.

The NEPPEX authorization will be granted within 24 hours of its reception, provided that all the documentation required has been delivered and that the legal and sanitary requirements established by the Service have been met.

The notification must include all the information required according to the instructions provided on the back of the document. Item B requires the declaration of all the involved producers (name and number of the establishment) and a clear association with the production dates. Only if the space provided in the document is insufficient, a packing list may be attached, keeping the same format of item B. In this case, the Annex must be identified with the corresponding Notification number.

In the case of air shipments of fresh products, if the production dates are not available, the NEPPEX may be presented exceptionally without this information, which must necessarily be completed before its authorization.

Products intended for human consumption and not intended for human consumption must be notified separately.

The official in charge of receiving the Notification must verify that it includes all the requested information, and if applicable, verify that it is sealed and signed by the official of the Control Department providing the authorization, and the description of the corresponding tax documentation. The tax documentation declared in the Notification must be the same that the exporter presents at the Customs Service when entering the primary zone.

2. GENERAL REQUIREMENTS FOR THE SHIPMENT AUTHORIZATION

2.1. LEGAL AUTHORIZATION

The legal origin authorization consists of the review and analysis of tax documentation that accredits that the used resource, as well as the production and commercialization processes, as appropriate, have been conducted in full compliance with the fisheries and aquaculture regulations in force. Having the authorization of legal origin will allow continuing with the export process to obtain NEPPEX.

To grant the authorization of legal origin, the compliance with the requirements outlined in Resolution No 1319/2014 for fishery resources and products, and those outlined in Resolution No 1971/2014 for aquaculture resources and products must be verified. The FIP number for all the aforementioned resources and products will be provided if all the above requirements are met. All salmonids by-products are excluded from this measure.

If the Control Department requests the Foreign Trade Sub-Directorate to verify the compliance with a fisheries regulation, before issuing a certificate of origin or a sanitary certificate, the official responsible for the certification must verify its compliance according to the instructions provided by the Control Department. These instructions must be made available, within a reasonable time, in writing, including the purpose of the measure, the start and end date of the procedure, as well as any necessary details for its proper application.

2.2. SANITARY AUTHORIZATION

To grant the sanitary certification the compliance with the sanitary requirements must be verified, according to the product to be exported and the destination market.

If the certification of origin or the export authorization is required, and sanitary certifications are not, it will be verified that the destination market allows it and that the establishment is part of the List of Companies under SERNAPESCA's Sanitary Control Programs. If it is not part of the list, the exporter must present a copy of the Resolution of the Fisheries and Aquaculture Sub-Directorate or of the National Fisheries and Aquaculture Service, accordingly, authorizing the producer to operate.

If the sanitary certification is required, it must be verified in Chapter IV, Item 2, if the destination market requires the registry of the establishment and/or the product, and also verify that the information on the producer and the batch to be exported declared by the exporter matches the information included in the List of Companies under SERNAPESCA's Sanitary Control Programs.

If the producer is not part of the List of Companies under SERNAPESCA's Sanitary Control Programs, it must accredit to have legal and regulatory authorization to operate, this is, that it complies with the Resolution(s) of the National Fisheries and Aquaculture Service which authorizes the processing of the described products, and must also request to be included in the List as soon as possible. This situation must be informed by the port of exit of the region under whose jurisdiction the processing plant is located.
When checking the NEPPEX, the SERNAPESCA official will assess the type of product, the master table of unfavorable products, the destination market, and if applicable, the required

certificates, and must request from the interested party the guarantees that prove the compliance with the technical and administrative requirements described in Chapters V and VI, as appropriate.

Therefore, the exporter must attach the original sanitary documents that support the authorization, which are the following:

- SMAE (Sampling and Analysis Request for Export) and the Results Report, or the Sensory Evaluation Report in the case of chilled-refrigerated products, for the End Product Control or
- the AOSC (Authorization at Origin for Sanitary Certification) for the Quality Assurance Program or a
- Sworn Declaration of Origin and/or toxins reports issued by the Health Service, as appropriate.

If in the SMAE form presented by the company to SERNAPESCA the exporter is different from the producer or the requester, the tax document that proves the transfer of property of the product must be required.

If not all the required information is presented or if there are any inconsistencies in the information presented, the Notification will be returned to the interested party without processing it.
Once the compliance with the requirements above is verified, the official of SERNAPESCA will log in to http://cerberos.sernapesca.cl/sernapesca/ entering the information of the notification, and the system will provide a unique national number, which must be recorded on the Item No of the NEPPEX, approving the shipment. Afterward, it must be dated, signed and stamped with SERNAPESCA's stamp (figure 1). The original Notification document will be returned to the interested party, and a copy will be filed at the SERNAPESCA office.

The original sanitary supporting documentation must always be filed in the Service together with a copy of the authorized Notification. If they are to be used for other notifications, the original sanitary support documents will be returned to the interested party, to the extent that they have been settled; in whose case SERNAPESCA will leave a copy of the Sampling request and the Results report or the Authorization at origin for the Sanitary certification.
The procedures for the control of settlements are described in Chapter II, Item 4.

Once the Notification number is obtained, the exporter, the shipping agency or the customs agency representing it, must log in to the Customs system to associate the Notification No provided by SERNAPESCA to the Approved item of the Single Exit Document (DUS - SED). The approval of the Notification will be informed internally to the National Customs Service, who will only authorize the entrance to the primary zone of the fishery products exports that have been authorized through the approval of the Notification of Shipment for Export Fishery Products. Each Single Exit Document of the National Customs Service can only be associated with one Notification number, where 1 NEPPEX = 1 DUS. Any DUS amendments made after the authorization of the NEPPEX must be informed to SERNAPESCA.

All documents that are presented to SERNAPESCA to process the NEPPEX, whether a certification is requested or not, must be signed by the legal representative of the company, or who is formally designated for these purposes.

2.2.1 SPECIFIC CONDITIONS AFTER GRANTING THE AUTHORIZATION

If during the transportation of the goods the seals of the containers holding them are violated, or if the cargo has not been kept under proper conditions that assure the preservation of the products' cold chain, their export cannot be authorized to markets that require a QAP. If it is destined to other markets that do not require a QAP, it must comply with the requirements set forth in Section III, Chapter IV, Item 2, with the purpose of accrediting the sanitary integrity of the product. Also, a packing list must be made to accredit the general conditions of the cargo.

If during the transportation of the goods the seals of the container that holds them are violated, before exiting the national territory, the sanitary integrity of the product will be evaluated before authorizing its export to markets that require a QAP.

3. EXPORTING SAMPLES

Samples without any commercial value are those lots of up to 20 kg products that are exported with the purpose of opening new markets, exhibiting Chilean products in international trade shows, for tastings, scientific research or family consumption.

3.1. SAMPLES FOR HUMAN CONSUMPTION

The interested party must comply with the Notification procedures described in Chapter I of this Manual and the requirements of the market described in Chapter IV, Item 2. To grant the sanitary certification, in accordance with the End Product Control, only the sampling and analysis of the product subject to marine toxins, *Vibrio parahaemoliticus* or Norovirus will be required, as set forth in Chapter IV, in the item regarding the specific sanitary requirements for the authorization of shipment notifications of bivalve mollusks, echinoderms, tunicates and gastropods.

If the destination market requires the issuance of a certificate that declares the production under HACCP systems, the corresponding Authorization at Origin for Sanitary Certification will be required. Such markets are listed in Chapter IV, Item 2.

It must be mentioned, that for the issuance of sanitary certificates for samples without commercial value, pro forma invoices may be used.

In the specific case of Brazil, and in accordance with Circular Nr 438/2011/DIPOA, samples without commercial value are exempt from the requirement of approval of the establishment and approval of the labeling of products. However, this regulation does not exempt from the fulfillment of the sanitary requirements applicable to each type of product, therefore the goods must be accompanied by a Sanitary Certificate of the Committee of Argentina, Brazil, Chile and Uruguay, which may be issued according to the compliance with the requirements set forth in Chapter IV, Item 2.3, Brazil.

The certificate must state that the product is sent as a "sample without commercial value" detailing the specific Fair or event in question, in addition to the information that characterizes the goods (weight, number of pieces, etc.).

The delivery of food samples without commercial value to Guatemala, El Salvador, Nicaragua, Honduras and Costa Rica should comply with the procedures established in the Central American Technical Regulation (RTCA 67.01.32: 06), which allows the importation of processed products from establishments that are not approved.

3.2. SAMPLES NOT FIT FOR HUMAN CONSUMPTION

When the sample being sent is intended to be used for purposes other than human consumption (research, laboratory, universities, etc.), the interested party must contact the closest SERNAPESCA office expressing its interest to export these products. SERNAPESCA will evaluate the case, based on the product and the destination market, using a Special Certificate form. The certificate to be issued must always provide information on the use to be given to the product at the destination. If the export and the issuance of the certificate is approved, the product must be properly labeled, stating "product unfit for human consumption," including also the contact address of the consignee at the place of destination.

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CHAPTER II. SANITARY CERTIFICATION

If the exporter requests a sanitary certification, it must comply with the requirements described in Chapter I, and in the case of bivalve mollusks, gastropods, tunicates, and echinoderms, with the analyses described in Chapter IV, Item 1.

The exports of fishery products destined to the markets described in Chapter IV, Item 2 must always be accompanied by the sanitary supporting documentation that allows accrediting the compliance with the requirements described therein.

1. ADMINISTRATIVE PROCEDURE

The issuance of the official sanitary certification for export fishery and aquaculture products will take place after the Notification's authorization, and will require in all cases the execution of the proceedings described in Chapter I, together with the presentation of the documentation described as follows.

Documentation to be presented to request the issuance of a sanitary certificate:

a. The original version of the corresponding Notification of Shipment of Export Fishery Products, that was returned signed and stamped to the interested party before the shipment, which includes the single number assigned by the official when authorizing the export.
b. The Single Exit Document Number provided by the National Customs Service, which must be reviewed by the Inspector issuing the certification on the website made available for these purposes. In the case of air or land shipments, it will be sufficient for the DUS to have been admitted for processing.
c. The corresponding photocopy of the Export Invoice. A proforma invoice will be accepted only for shipments of chilled-refrigerated products. In these cases, the exporter must commit to submitting an original copy of the export invoice as soon as possible.
d. The certificates being requested, 1 original and 2 copies, which must come preprinted, numbered and provided by this Service. They must be identified with the number of the Notification of Shipment of Export Fishery Products.
e. B/L or non-negotiable copy (original or photocopy) issued by the shipping company; air waybill for air shipments or land waybill for land shipments.

Sanitary supporting documentation will not be required in this instance since it was already requested when authorizing the shipment, according to the information described in Chapter I.

The certificates will only address information regarding the safety and sanitary conditions of the products to be exported, not including aspects associated with commercial documents or requirements.

If the exporter requires specific certificates and any additional ones to those required by the destination markets, these must be clearly described in the notification, and therefore all the sanitary supporting documentation must include the requirements of the new certification.

2. GENERAL REQUIREMENTS FOR ISSUING CERTIFICATES

The issuance of sanitary certificates must follow these guidelines:

a. The official SERNAPESCA Inspector issuing a Certificate that accompanies a shipment of fishery products, must always sign the Certificate and make sure that it has the official seals. This requirement is applicable to each one of the pages of the Certificate, in the case of having more than one.
b. Before issuing the sanitary certificate, the official Inspector must verify that the product does not present any unfavorable results, against the unfavorable results table.
c. The ink color used for the stamp and the signature must be different from the color of the ink used in the printed document.
d. The certificates are available in Spanish/English or in the language of the country of destination/English; these must be issued in the official language the country of destination and of the country where the border inspection is conducted, if applicable.
e. The certificates must be presented as follows:
   - Ideally in one single page (the back of the page must be used in case of having to declare production dates).
   - Two or more pages that are part of a single and indivisible document.
   - A sequence of numbered pages, indicating that each one of them is part of a certain sequence (e.g. Page 2 of 4).
f. The certificates must have a single identification number, and if the certificate consists of a sequence of pages, such number must appear in each one of them.
g. Only one original certificate and two copies, including the one to be filed by SERNAPESCA, may be issued, and these must also be stamped with a red stamp with the word "COPY."
h. The issuance of certificate forms for products in transit is allowed to the extent that it is documented, and that the words IN TRANSIT THROUGH [COUNTRY] FINAL DESTINATION [COUNTRY] are included in the Destination item. In the case of products that are transported by a country member of the European Union, the in transit forms will only be issued subject to the full compliance with the regulations of that market.
i. The supporting documentation for the issuance of the certificate must be available for the official Inspector before the shipment exits the control of SERNAPESCA.
j. Spaces left blank in the form must the crossed out.
k. The certificates may not be amended.
l. If a certificate includes products of more than one producer and the form requires including production dates, these must be provided with the details associated with each processing establishment.
m. The certificates to be presented with the shipment are valid for 10 days from the date of their issuance, and if the shipment takes place via land or sea, the term will be extended to the time of the journey.
n. The original version of the certificate must accompany the shipment when entering the country of destination.
o. The certificates must always include the full scientific name of the species for their proper identification. Fantasy names may also be included.

3. CERTIFICATION FOR SHIPMENTS OUT OF OFFICE HOURS

For air shipments that take place out of SERNAPESCA's office hours, an anticipated certification may take place, which consists of the issuance of the official certificates before the arrival of the product at the port of shipment through which its export will take place.

The anticipated certification may be provided within 72 hours before the shipment of the product, having all the necessary original documents at hand.

4. SANITARY CERTIFICATION BALANCE CONTROL

If the sanitary supporting documentation includes more products than those to be exported, the differences will be cleared. To record such balances, the official of the region's Foreign Trade Sub-Directorate in charge of issuing the certification, must write on the back of the SMAE or the AOSC, as appropriate, the quantity of product per production date that is left outstanding for the exporter, stamping its initials, date and associated Notification number ("SERNAPESCA stamp" – Figure 1).

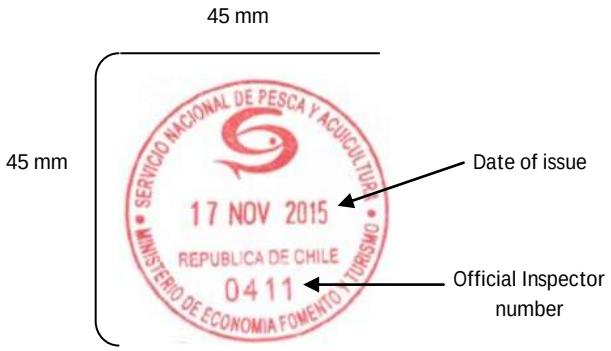

Figure 1: Stamp format of the National Fisheries and Aquaculture Service.

5. SIGNING AND STAMPING SANITARY CERTIFICATES

Once the compliance with the requirements is verified for issuing the certificate, the authorized SERNAPESCA official will sign and stamp the original document and 2 copies, including the one for SERNAPESCA, and use red ink for these purposes. The SERNAPESCA stamp (Figure 1) that identifies him as an "Official Inspector" must be stamped, and also include his signature in the corresponding box of the certificate.

All copies issued must include a stamp or registry number on the upper side, with the word COPY.

The following are the characteristics and requirements of the different types of sanitary certificates; those that can only be issued by an Official Inspector that is a Doctor of Veterinary Medicine are clearly identified.

Name	Description
Sanitary Certificate for fishery and aquaculture products intended for human consumption	Accredits that the export fishery products are fit for human consumption, except for seaweeds and their byproducts. The requirements described in Chapter IV, Item 1 must be met for its issuance. The English/Spanish bilingual format is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Sanitary Certificate for fishery and aquaculture products not intended for human consumption	To be used exclusively in products not intended for human consumption, such as fish meal and oil. The requirements described in Chapter IV, Item 1 must be met for its issuance. The English/Spanish bilingual format is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
HACCP Certificate	Is issued upon request of the processing establishments, and certifies that at the moment of issuance, the company has an HACCP in place for a specific processing line. The production plant must have a QAP certification. This document is available in a bilingual English/Spanish format at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Process Monograph Certificate	Shows that the processing establishment conducts the operational steps detailed in the attached monograph. This certificate can only be signed and sealed by a Doctor of Veterinary Medicine; it is available in SERNAPESCA's web page, and it must be printed in a special format with the official seal of the Service.
Vibrio cholerae Free Zone Certificate	Specific certification for products from *Vibrio cholerae* free zones. The English/Spanish bilingual format is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Certificate for Fishery Products transiting through Argentina	For Chilean fishery products that are transported from one point to another in the country, and that

Name	Description
	have to transit through Argentina; and for products that will be exported to third countries and that transit through the Argentinian territory without a sanitary certification. This certificate is available in SERNAPESCA's web page, and it must be printed in a special form with the official seal of the Service.
Sanitary Certificate for Seaweeds and their by-products intended for human consumption	Certifies that the export of seaweeds and their byproducts is intended for human consumption. The requirements described in Chapter IV, Item 1 must be met for its issuance. The English/Spanish bilingual format is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Sanitary Certificate for Seaweeds and their by-products not intended for human consumption	Export of dry seaweeds and their by-products not intended for human consumption. The requirements described in Chapter IV, Item 1 must be met for its issuance. The English/Spanish bilingual format is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Phytosanitary Certificate	Certifies that the declared export product, complies with the phytosanitary requirements of the National Fisheries and Aquaculture Service, at the moment of shipment. The certificate accredits its fitness for non-human consumption The English/Spanish bilingual format is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Certificate of the Committee for products intended for human consumption	Sanitary Certificate for fish and fishery products (extractive/farm) intended exclusively for human consumption that are commercialized between Argentina, Brazil, Chile, and Uruguay. The requirements described in Chapter IV, Item 2 must be met for its issuance. This certificate can only be signed and stamped by a Doctor of Veterinary Medicine. The Spanish/Portuguese bilingual version is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Certificate of the Committee for products not intended for human consumption	Sanitary Certificate for fish and fishery products (extractive/farm) not intended for human consumption that are commercialized between Argentina, Brazil, Chile, and Uruguay. The requirements described in Chapter IV, Item 2 must be met for its issuance. The certificate can only be signed and stamped by a Doctor of Veterinary Medicine. The Portuguese/Spanish bilingual format is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Sanitary Certificate for the import of fishery products intended for human consumption in the EU	This certificate accredits that the products are fit for human consumption and to be exported to the EU. The requirements described in Chapter IV, Item 2 must be met for its issuance. The document is

Name	Description
	available in PDF format (different languages) in SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Sanitary Certificate for transformed animal proteins not intended for human consumption, including mixes and products different from pet foods that contain them that will be sent to the European Union or that will transit through it	For fish meal exports destined to the EU. This certificate can only be signed and stamped by a Doctor of Veterinary Medicine. The requirements described in Chapter IV, Item 2 must be met for its issuance. It is available at SERNAPESCA's webpage (different languages).
Sanitary Certificate for fish oil not intended for human consumption, used as an ingredient for feedingstuffs or for technical purposes that will be sent to the European Union or that will be transit through it	For fish oil exports destined to the EU and other markets. This certificate can only be signed and stamped by a Doctor of Veterinary Medicine. The requirements described in Chapter IV, Item 2 must be met for its issuance. It is available at SERNAPESCA's webpage (different languages).
Sanitary Certificate for hydrolyzed protein not intended for human consumption in the European Union	Certifies the exports of fish peptones that are destined to the European Union and other markets that have adopted Regulation (EC) 1774/2002, as per the requirements described in Chapter IV, Item 2. The requirements described in Chapter IV, Item 2 must be met for its issuance.
Sanitary Certificate for the import of composite products intended for consumption in the EU	This certificate accredits the fitness of composite products that contain 50% fishery products, or more, to be exported to the European Union. The requirements described in Chapter IV, Item 2 must be met for its issuance. It is available at SERNAPESCA's webpage (different languages) and must be printed in a special format with the official shield logo.
Sanitary Certificate for the import of live marine bivalve mollusks, gastropods, tunicates or echinoderms intended for human consumption in the European Union	This certificate accredits the fitness for exporting live fishery resources intended for human consumption to the EU. The requirements described in Chapter IV, Item 2 must be met for its issuance, and it must be printed in a special format.
Veterinary Certificate for fishery products destined to the Russian Federation	This certificate accredits the export of products intended for human consumption. The requirements described in Chapter IV, Items 1 and 2 must be met for its issuance. The certificate can only be signed and stamped by a Doctor of Veterinary Medicine. The English/Russian version is available at SERNAPESCA's web page, and it must be printed in a special format with the official rhombus-shaped logo.
Veterinary Certificate for meal destined to the Russian Federation	It is used to certify the export of fish meal and oil not intended for human consumption. The requirements described in Chapter IV, Items 1 and 2 must be met for its issuance. This certificate can only be signed and stamped by a Doctor of Veterinary Medicine. The English/Russian version is available at SERNAPESCA's web page, and it must be printed in a special format with the official rhombus-shaped logo.
Sanitary Certificate for Human Consumption in China	Certifies products intended for human consumption destined to China. The requirements

Name	Description
	described in Chapter IV, Items 1 and 2 must be met for its issuance. The certificate can only be signed and stamped by a Doctor of Veterinary Medicine. The Chinese/English bilingual format is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Sanitary Certificate for products not intended for human consumption destined to the Republic of China	Certification for fish meal and oil not intended for human consumption. The requirements described in Chapter IV, Items 1 and 2 must be met for its issuance. This certificate can only be signed and stamped by a Doctor of Veterinary Medicine. The English/Chinese bilingual format is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Sanitary Certificate for fishery and aquaculture products destined to the Republic of Croatia	Certifies the export of fishery products intended for human consumption. This certificate can only be signed and stamped by a Doctor of Veterinary Medicine. The requirements described in Chapter IV, Item 1 must be met for its issuance. The English/Croatian version is available at SERNAPESCA's web page.
Sanitary Certificate for fishery and aquaculture products destined to Tunisia	Certifies the export of fishery products intended for human consumption. The requirements described in Chapter IV, Items 1 and 2 must be met for its issuance. The English format is available at SERNAPESCA's web page.
Sanitary Certificate for raw farmed scallops with gonads destined to Canada	Certifies the export of raw farmed scallops with gonads intended for human consumption. The requirements described in Chapter IV, Items 1 and 2 must be met for its issuance. The English/French/Spanish trilingual format is available at SERNAPESCA's web page.
Sanitary Certificate for fishery and aquaculture products not intended for human consumption for export to Canada	To be used in fish meal and oil. The requirements described in Chapter IV, Items 1 and 2 must be met for its issuance. The English/Spanish format is available at SERNAPESCA's web page.
Official Veterinary Certificate for fishery products destined to Costa Rica	Certifies the export of products intended for human consumption. The requirements described in Chapter IV, Items 1 and 2 must be met for its issuance. The Spanish format is available at SERNAPESCA's webpage.
Sanitary Certificate for fishery and aquaculture products destined to Tahiti	Certifies fishery products intended for human consumption. The requirements described in Chapter IV, Items 1 and 2 must be met for its issuance. The French/Spanish bilingual version is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Sanitary Certificate for fishery and aquaculture products not intended for human consumption for export to Australia	To be used in fish meal and oil. The requirements described in Chapter IV, Items 1 and 2 must be met for its issuance. The English/Spanish format is available at SERNAPESCA's webpage.
Export Certificate for the export of fish meal and	Certifies fish meal and oil destined to Japan. The

Name	Description
oils to Japan	requirements described in Chapter IV, Items 1 and 2 must be met for its issuance. The English version is available at SERNAPESCA's webpage. It must be printed in a special format with the official shield logo.
Veterinary Certificate for aquatic animal feeds destined to New Caledonia	For fish meal with destination to New Caledonia. The requirements described in Chapter IV, Item 2 must be met for its issuance. The English/French bilingual version is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Sanitary Certificate for the export of fish and fishery products destined to Israel	This certificate accredits that the fishery products are fit for human consumption and to be exported to Israel. The requirements described in Chapter IV, Items 1 and 2 must be met for its issuance. The English version is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Veterinary Sanitary Certificate for the export of fishery products intended for human consumption destined to the Republic of Turkey	This certificate accredits that the fishery products are fit for human consumption and to be exported to Turkey. The requirements described in Chapter IV, Items 1 and 2 must be met for its issuance. The English/Turkish bilingual version is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Zoosanitary Certificate for Salmon Culture Products in transit in the Republic of Argentina	This certificate accredits the zoosanitary fitness of chilled-refrigerated or frozen fishery salmonid by-products to transit through the Republic of Argentina. The requirements described in Chapter IV, Item 2 must be met for its issuance. The certificate can only be signed and stamped by a Doctor of Veterinary Medicine. The Spanish version is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Veterinary Certificate for fishery products destined to New Caledonia	For fishery products with destination to New Caledonia. The requirements described in Chapter IV, Item 2 must be met for its issuance. The English/French bilingual version is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Veterinary Certificate for mollusks destined to New Caledonia	For bivalve mollusks with destination to New Caledonia. The requirements described in Chapter IV, Item 2 must be met for its issuance. The English/French bilingual version is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.
Fish Meal Sanitary Certificate for Israel/Fish Meal Plant Certificate	These certificates accredit that the fish meal not intended for human consumption is fit to be exported to Israel. The requirements described in Chapter IV, Items 1 and 2 must be met for their issuance. The English version is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.

Name	Description
Fish Oil Sanitary Certificate for Israel/Fish Oil Plant Certificate	These certificates accredit that the fish oil not intended for human consumption is fit to be exported to Israel. The requirements described in Chapter IV, Items 1 and 2 must be met for their issuance. The English version is available at SERNAPESCA's web page, and it must be printed in a special format with the official shield logo.

6. CERTIFICATES PRICES

According to Decree No147 of 2015, MINECON, the certification prices are the following:

- Sanitary Certificate for samples without commercial value: 0.5 UF
- Sanitary Certificates: 1 UF for shipments with a commercial value equal to or lower than 1,000 net kg. and 4 UF for shipments with a commercial value greater than 1,000 net kg.
- Certificates of Origin: 0.5 UF, regardless of the quantity shipped.
- Special Certificates: 1.5 UF

Any re-issuances of sanitary certificates and certificates of origin due to transcription or typing errors, meaning clerical errors, will not be charged; including those certificates issued under the void and replacement concept, due to formal errors.

Any re-issuances of sanitary certificates and certificates of origin that are due to modifications to essential aspects, for instance: Change in the consignee, destination country, adding commercial information associated with the product, among others, and those certificates issued under the void and replacement concept due to loss, damage, theft or destruction, will be charged as per Decree 147 of 2015.

These fees have a 50% surcharge when requested out of office hours (from 17:30 to 08:30 on the next business day), on Saturdays, Sundays and holidays.

7. SPECIFIC PROCEDURES AND REQUIREMENTS FOR SANITARY CERTIFICATION

7.1. SAMPLING AND ANALYSIS REQUEST FOR EXPORT (SMAE)

Based on the sampling and analysis of the products by production date. To obtain access to this system, the company must be part of the List of Plants under SERNAPESCA's Sanitary Control Programs. The sanitary evaluation of the batch to be exported will be conducted according to the sampling plans and the chemical, physical and microbiological determinations described in Chapter IV, Items 1 and 2, as appropriate, according to the destination market and type of product. For this, the SMAE (Sampling and Analysis Request for Export) form must be used as per the procedures described for collecting samples in Section IV, Chapter 2, Item 1.

The exporter must present the original SMAE, the Sampling Report and the Results Report, including the required analyses, by production type, the category of the establishment, destination and type of certificate required, as described in Chapter IV, Items 1 and 2, as appropriate. The Results Reports must be valid, dated and signed by the Head of the laboratory or another authorized person.

In the case of Results Reports with advanced electronic signature, the interested party may present the corresponding copy whose validity and authenticity must be confirmed by the SERNAPESCA Inspector, where he must:

- Go to the "Analysis Entities" list available at SERNAPESCA's webpage.
- In the "Personal autorizado para firma electrónica avanzada" (Personnel authorized for advanced electronic signatures), verify that the signer's name appears in this column.
- In the "Procedimiento Inclusión Identidad Firmante en PDF" (Procedure to include the identity of the signer in PDF), follow the instructions to include the signer in the "Identidades de Confianza" (Trusted Identities).
- Optionally, those entities that have the "Documento Electrónico Certificado" (Certified Electronic Document) (DEC) option enabled can download the document. For this, the link must be entered in the "Firma Electrónica Avanzada" (Advanced Electronic Signature), and also fill in the fields "Nº Auditoría" (Audit No.) and "Nº Documento" (Document No.) in the Results Report.

In the case of bivalve mollusks, gastropods, tunicates, and echinoderms, the analyses described in Chapter IV, Item 1 are needed.

When the information related to the packaging of the product in the Notification of Shipment of Export Fishery Products does not match the information provided in the Request for Sampling and Analysis for Export, it must be verified that the authorization of repackaging exists and that the instructions provided in Section IV, Chapter 2, Item 1 have been met. In such case, the certificate will only be issued if:

- The Request for Sampling and Analysis for Export and its corresponding Sampling Report include the phrase "repackaging authorized," with the initials and SERNAPESCA stamp (Figure 1) authorizing the procedure.
- The "Report on repacking packed products (primary packaging)" is attached, and it must include the SERNAPESCA stamp when repacking has taken place at a place different from the port of shipment.

7.2. AUTHORIZATION OF ORIGIN FOR SANITARY CERTIFICATION (AOSC)

a. Issuance

The certification under the Quality Assurance Program (QAP), is based on the Hazards Analysis Critical Control Points (HACCP) evaluation in the productive process. To become part of this system the company must join the Quality Assurance Program of our Service. The producer that is part of the program may process the AOSC, Authorization at Origin for Sanitary Certification, form which will serve as a sanitary guarantee at the moment of export.

The issuance of the AOSC document must be requested at the SERNAPESCA office of the corresponding jurisdiction of the processing establishment presenting an original and a copy. The applicant must complete all the information for items I and II of the Authorization, indicating the location and address of storage for the batch identified in it, and including a declaration of compliance with all SERNAPESCA standards for labeling and injuries in salmonids.

If the applicant declared in the AOCS is different from the producer, it must present the tax documentation as proof of the processing or purchase of the product. A company different from the producer may only be consigned when it provides the necessary supporting documentation. All the establishments that may apply to a certification through the QAP must send to the SERNAPESCA Office of the jurisdiction of the establishment a letter signed by the legal representative of the company indicating the people that will be responsible for signing the Authorization at Origin for Sanitary Certification. It is recommended, but not mandatory, for them to be those responsible for the QAP or their surrogates.

It must be noticed that in the AOSC must be declared if the product to be exported was produced with imported raw material, and the original fishery products entry request form (SIPP or SUI) associated with the product must be attached.

When issuing the AOSC, the SERNAPESCA official must confirm that the format corresponds to the current version, that all the information included in the document is correct, and that the establishment complies with the requirements and procedures set forth by SERNAPESCA and the destination market, as appropriate, and that it is considered for the products and markets to which the company in fact exports.

The information provided in the Authorization at Origin for Sanitary Certification is the responsibility of the SERNAPESCA official of the region granting the authorization, and it is the only sanitary supporting documentation that this product will have when applying for the corresponding certification (except as described in the following paragraph).

For the issuance of the Authorization at Origin for Sanitary Certification of products different from those affected by marine toxins, its processing may be accepted 72 hours before the departure of the ship, filling in the minimum required information and under the following conditions:

- The document must have the same company name in the producer and applicant fields.
- Only the partial information corresponding to the manufacturing date, associated lot, number of boxes and expiration date may be pending to be completed.
- The information must be detailed, and that corresponding to the species and the commercial name, type of production and presentation and destination market may not be rectified.

Once the company does the consolidation, it will create a *packing list* providing the details for the missing information on the initial Authorization at Origin for Sanitary Certification. This *packing list* must be assigned the reference number of the Authorization at Origin for Sanitary Certification and must be signed by the person responsible for the establishment with the same format described in item II of the Authorization at Origin for Sanitary Certification. When presenting the notification at the SERNAPESCA Office of the port of shipment, it must be accompanied by the *packing list* and the original Authorization at Origin for Sanitary Certification.

The producer responsible for the procedure must present the *packing list* at the SERNAPESCA Office of origin, on the following business day, indicating the Authorization of Origin for Sanitary Certification to be used as a reference. If after the review conducted by the Office of origin it is detected that the product has been exported to a market for which it is not authorized or if the terms provided are not met, the production company will not be able to use this procedure for new shipments. This procedure may not be applied to exports of bivalve mollusks.

For fishery and aquaculture products affected by marine toxins that access the Authorization of Origin for Sanitary Certification, the applicant must present a Sworn Declaration of Origin (S.D.O.). (Part II, Annexes, Chapter II).

For the products manufactured in establishments with QAP Certification from products susceptible of being affected by marine toxins, the sanitary certification will be issued with the sole presentation of the Authorization at Origin for Sanitary Certification of the corresponding batch, except when the raw material comes from natural banks from the Region of Los Lagos, in whose case a Paralytic Shellfish Poison (PSP) analysis must be conducted for each export batch, in accordance with Section III, Chapter IV, Item 1.2.21. The results reports of the marine toxins complementary analyses must be settled in the place of origin when issuing the Authorization at Origin for Sanitary Certification.

In the case of resources susceptible of being affected by marine toxins from areas that are not part of the BMSP, the raw material monitoring or periodical verifications described in Part II, Section II, Chapter II, Item 1.9.1, must also be applied.

The company must file a photocopy of the S.D.O. as well as of the RET (Records of Extraction and Transportation of Live Bivalve Mollusks) and the way bills, indicating the number of the Authorization at Origin for Sanitary Certification for which they were used. These documents will be filed and must be available at the establishment for their review during the QAP inspection. It must be mentioned that if there are any deficiencies detected during the issuance of the Authorization at Origin for Sanitary Certification (error in production dates or production lots), the establishment must attach all the previously mentioned information.

To issue the Authorization at Origin for Sanitary Certification for fishery establishments that process farmed fish, in regards to pharmaceutical products residues, contaminants, prohibited and unauthorized substances, the production establishment must present the traceability chart shown below, together with the corresponding tax documentation. The Analysis Reports will be filed and must be available at the establishment for their review during the QAP inspection.

It must be mentioned that if there are any deficiencies detected during the issuance of the Authorization at Origin for Sanitary Certification (errors in production dates), the establishment must attach all the previously mentioned information.

Table: *Traceability chart*

Production date or prodcution code	Declaration of Guarantee Number	Transportation Way Bill Number	Pre-harvest Request Number	Pre-harvest Request Date	Analysis Report Number	Analysis Report Number	Farm Number	Cage Number

Note: "The documentation is available at the production establishment for SERNAPESCA to inspect it as needed."

Based on the number of documents needed for the traceability chart, it may be necessary to increase the number of columns.

It must be mentioned that this procedure and the corresponding requirements are valid for primary, secondary and tertiary establishments.

The AOSC will be signed and stamped with SERNAPESCA's stamp by the official of the Service, based on the results of the last supervision that took place at the establishment and it will be provided for each one of the shipments that requires certification in accordance with the QAP.

The original will be provided to the interested party, and the copy will be filed at the SERNAPESCA Office issuing the Authorization.

b. Presentation for Sanitary Certification

The exporter must present the AOSC in original, authorized by SERNAPESCA, in the office of shipment of the products. The SERNAPESCA official will confirm that the AOSC is original, that the format corresponds to the current version, that it has been properly completed, that it is duly signed, stamped, and that the products described are valid.

Similarly, he/she must confirm that the information declared in the AOSC for the description of the product and the destination market matches the information provided in the previously presented Notification and the certificate being requested.

In the case of frozen products, the Authorization at Origin for the Sanitary Certification will be valid only if the product has been stored in the processing plant's facilities or in cold stores authorized by SERNAPESCA. For this, the interested party must declare in the AOSC and in the Shipment Notification of Export Fishery Products, if the product has been stored in a cold store outside of the plant. If this is the case, its name and location must be provided, supporting this information with the corresponding waybills for the product. The SERNAPESCA official must verify that the cold store is part of the List of Companies under SERNAPESCA's Sanitary Control Programs.

If the storage takes place in a cold store not authorized by SERNAPESCA, the certification may be only provided for markets that do not require a QAP, with the end product analyses of the batch, through a Request for Sampling and Analysis for Export, with a number of samples of n=5, c=0, per batch of export. The determinations to be carried out are the following:

- Determination of Total Count of Aerobic Mesophiles - 35 C°
- Organoleptic Physical Analysis

If the producer declares in the AOSC to comply with SERNAPESCA's standards on salmonids injuries, and this information does not match the results of the pre-shipment inspection conducted by SERNAPESCA, the exports from the processing establishment to the intended destination market will be restricted.

As the correct issuance of the AOSC is the responsibility of the SERNAPESCA official of the region granting the authorization, the SERNAPESCA official for the region from where the products are being shipped will only verify that it is duly signed, stamped and valid.

c. Validity of the Authorization at Origin for Sanitary Certification

The validity of the Authorization at Origin for Sanitary Certification will be equivalent to the declared shelf life of the product. The shelf life of the product must be indicated in the item "Authorized batch information," in the "Expiration Date" column of the Authorization at Origin for Sanitary Certification.

7.3. SPECIFIC PROCEDURES AND REQUIREMENTS PER TYPE OF CERTIFICATE

7.3.1. SPECIAL CERTIFICATES

Are those documents that certified special sanitary situations that are not included in official certificates.

For the Special Certificate to be issued, the requested document must be delivered to the SERNAPESCA office of the port of shipment of the product or to the corresponding SERNAPESCA office, accordingly, for its evaluation. If its issuance is authorized, the Notification of Shipment of Export Fishery Products must be presented, attaching the original of the special certificate with the printed text, and any necessary required supporting documentation.

Special Certificates must always include all the necessary identification information with its scope clearly defined.

7.3.2. *VIBRIO CHOLERAE* FREE ZONE CERTIFICATE

The interested party must present a Notification of Shipment of Export Fishery Products, at the SERNAPESCA office assigned to the shipping location of the product.

The Free Zone certification for fishery products may be issued without conducting an analysis or categorization of the plant since Chile is a cholera-free country since 1998.

7.3.3. CERTIFICATES FOR LIVE SPECIES

Those interested in obtaining the certification must request it to the Aquaculture Department of the Regional Directorate of SERNAPESCA under whose jurisdiction the farm is located, presenting a Notification and indicating the type of certification required, the species and the destination market.

This information must be sent to the Animal Health Department of the National Directorate for its evaluation and to establish the procedures to grant the certification. These will be informed to the interested party with a copy to the Inspectors of the port of exit and the Foreign Trade Sub-Directorate.

7.3.4.CERTIFICATES FOR FEED FOR AQUATIC ANIMALS

Those interested in obtaining this certification must request it at the regional SERNAPESCA office closest to the customs point of exit of the goods.

For the certificate to be issued, the processing establishment or manufacturer of the feed, supplements, formulated additives, and ingredients used in the production of aquatic animal feed must be part of the national list of processing establishments for supplies or feed intended for animal consumption, and of the List Export Establishments for Animal Feed (LEEAA) of the Agriculture and Livestock Service (SAG), as per the requirements and procedures described in www.sag.gob.cl. Likewise they should be up to date with the annual general background statement required for these establishments.

The feed must comply with the following requirements:

- The product must have been produced from marine origin protein, not including protein originated from fish of the Salmonidae family or from ruminants.
- The production conditions must guarantee that the product is not susceptible to contamination after heat processing.
- The product must be packed with new and clean materials.

The compliance with these requirements must be supported by analyses results from an external laboratory or a process monograph (the latter is mandatory if required by the destination market).

The requirements for each destination market described in Item 2 of Chapter IV must also be met.

When the interested party requires the certification of conditions different from those established in this Manual, the information must be presented at the Regional Directorate of SERNAPESCA corresponding to the place of storage or export of the food, indicating the type of certification required and the destination market. This information will be sent to the National Directorate for its evaluation and to establish the procedures that allow the eventual certification.

8. SPECIFIC PROCEDURES AND REQUIREMENTS PER TYPE OF PRODUCT

8.1. CERTIFICATION PROCEDURE FOR CHILLED-REFRIGERATED PRODUCTS

If the packaging of products in primary packages is broken, SERNAPESCA will require the guarantees to consider the issuance of a certificate, and may not issue the certificate to markets that require an HACCP.

For these products, the addition of ice for gel packs will be authorized in the port of shipment,

only when the product is properly protected (primary package) so that the product does not come into direct contact with the added ice or gel packs. When adding ice or gel packs, the process must take place under proper sanitary conditions in a closed area, protected from possible contamination and at a proper temperature that does not affect the cold chain of the product.

In both cases, guarantees may be provided through the application of similar procedures for storage of frozen products in cold stores not authorized by SERNAPESCA, described in Item 7.1 of this Chapter. These procedures must always be informed by the exporter or the shipping agency, to the corresponding SERNAPESCA office of the port of shipment of the product, with the purpose of inspecting the conditions in which they take place.

If the packaging of bulk products is broken, SERNAPESCA will not be able to issue the sanitary certification.

8.2. CERTIFICATION PROCEDURE FOR PRODUCTS FROM REDUCTION PROCESSES

All establishments that conduct reduction processes (fish meal, crustacean meal, oils, peptones, fish protein concentrate, etc.), and that need to export their products with the SERNAPESCA certification, must be part of the List of Companies under SERNAPESCA's Sanitary Control Programs. If the establishment is not part of this list, the interested party must deliver a copy of the "Transformation Fishery Activities Resolution" issued by SERNAPESCA, and that authorizes it to process, where the export and certification may be only authorized once, and only for those markets that are not included for Products Not Intended for Human Consumption in Chapter IV, Item 2.

The company that requires the SERNAPESCA certification must become part of the List of Companies under SERNAPESCA's Sanitary Control Programs

Based on the product to be exported and the destination market, the compliance with the requirements outlined in Chapter IV must be proven.

The procedures described in Chapter I must be followed to processes the certification.

If the certification takes place in accordance with the End Product Control Program, the sampling of the batch to be exported must be conducted as per the instructions provided in Section IV, Chapter II, Items 1 and 2.

If the results of the analyses conducted for exporting purposes show non-compliances with the standard, the production company must record and keep the original documents containing the information that supports the actions taken with the affected product.

When the interested party requires the certification of other requirements different from those set forth in Chapter IV, Item 2, this must be requested at the corresponding Regional Directorate of SERNAPESCA, indicating the type of certification required and the destination market. This information must be sent to the National Directorate for its evaluation and to establish the procedures that allow the eventual certification.

8.3. PARTIALIZATION OF HAKE SHIPMENTS DESTINED TO THE EU

This procedure applies to refrigerated and chilled hake air shipments destined to Europe, which

take place out of office hours of the SERNAPESCA office at the CAMB airport, and where the customs agent or the shipper inform SERNAPESCA the possibility to partialize the shipment. The notice must be sent before the shipment and notified through a letter sent by the shipping company to SERNAPESCA, during office hours.

The companies that wish to apply for a sanitary certification must present the information described herein during office hours.

The shipping company must present two Notifications of Shipment, the first one being binding, which will be processed according to the instructions provided in the previous items, under a regular procedure.

The second Notification of Shipment will be processed simultaneously with its corresponding certificate. The information on the number of containers, their net weight, and gross weight will remain pending to consign, and the Service will provide the interested party the copy of the Notification of Shipment in which the official signing the certificates will write in red ink and in the description item of the product, the maximum quantity of boxes and net weight for the interested party with the pending certificate. Both the original Notification as well as the certificate and its corresponding copies will be filed by SERNAPESCA, in a folder that will be provided at the closure of the Service's office to the official on duty at the apron.

To formalize the second certification, the shipping company must contact in the SERNAPESCA offices, the personnel of the Service working at the airport's apron, at least an hour before the departure of the flight.

The shipping company must provide transportation for the Service's official to the physical area where the product described in the second certificate is being shipped, providing the SERNAPESCA official, in the apron, a copy of the Notification of Shipment of the pending certificate and a copy of the Order Manifest issued by the airline. If the previously described requirements are not met, the certification process may not continue.

The quantity to be shipped may never exceed what has been consigned in the Notification of Shipment provided. The SERNAPESCA staff will be in charge of providing the pending certificate that provides proof of the balance of the cargo shipped. Once the shipment is verified (keys, type of products, net kilograms, etc.), the official will provide the airline the original and the copies of the pending certificate to be filled with the shipped quantities and consigned in the Order Manifest. The airline will fill in the original certificate and its copies in type and in the presence of SERNAPESCA staff, returning the entire set to the Service's staff, who will separate the original from the copies and will proceed to hand them out to the airline cargo coordinator, who must record the acceptance of the certificate in the copy for SERNAPESCA, writing its name, signature, RUT, date and time.

Before starting this procedure, the airlines must provide, and in the format to be provided by the National Fisheries and Aquaculture Service, a List of Air Cargo Coordinators, an official record with the names of the people authorized to conduct the previously described process.

The shipping company must pay the corresponding rates, the next business day after the issuance of the certificate. If the certificates provided in the procedure above are not paid accordingly, the company will not be able to request new certificates.

On the next business day, the authorized SERNAPESCA staff will provide the certifier on duty of

the Foreign Trade Sub-Directorate, the copies of the certificates provided, or in their absence, the folders with the original certificates, copies, and attachments of the shipments that did not effectively take place.

Every time that fishery products coming from shipments that do not take place are entered, the cold store entering the cargo, must provide the following information to SERNAPESCA on the next business day, and before 10:00 AM:

- Number of boxes, production keys and net kilograms of products entered in the cold store.
- Name of the exporting and shipping company.

This information must be sent in writing to the following email address: aeropuertosantiago@sernapesca.cl.

9. DOCUMENTS CONTROL

The official of the Foreign Trade Sub-Directorate issuing a certification must file a copy of all the documents required for the certification.

Together with the Notification, the original or copies of the sanitary documents (Request for Sampling and Analysis for Export, with their corresponding Sampling and Analysis Reports or the Authorization at Origin for the Sanitary Certification, as appropriate), the export invoice, the bill of lading, the Waybill or Air Waybill, accordingly, must be filed, and an identical copy of the issued certificates.

The information must be filed so as to allow for its easy access.

10. PROVISION OF CERTIFICATE FORMS

Every SERNAPESCA office that provides certificates forms to users must keep a record in the "Export Certificates Issuance Logbook" administered by the person in charge at national or regional level, as appropriate, or another type of log that allows tracing of every blank official certificate available at each office.

The person in charge at national level must register in the logbook the following information:

a) Quantity of certificates sent to each regional office
b) Initial and final number of the certificates
c) Shipping date
d) Name of the regional office

When delivering blank certificates to the users the person in charge at regional level must identify:

a) Quantity of blank certificates
b) Initial and final number of the certificates provided
c) Type of certificate
d) Date of delivery
e) Name and RUT of the Customs Agency
f) Name and signature of the person collecting the certificates, amongst other information.

At the moment of giving account of the delivered certificates, the SERNAPESCA official must record in the logbook:

a) Date of accounting
b) Number of annulled certificates
c) Number of deteriorated certificates
d) Conformity or non conformity with the accounted documents
e) Name and signature of the person giving account, amongst other information

The delivery of blank certificates to Customs Agencies will be conducted as stipulated in Exempt Resolution No. 3142 of 07July 2017, through the one-time subscription of a cooperation agreement between the legal representative of the Agency and SERNAPESCA.

As per such agreement the number of certificates should not be limited to the certificates required for a particular operation (i.e., it should not be restricted to a form per NEPPEX) but the fluidity of export operations should be ensured, so that the Agencies must not request a certificate for each operation.

At the time of delivering the certificates it must be noted that the correct use and administration of such documents will be the exclusive charge of the requester to whom they were delivered, in addition to the criminal responsibility that assists him in case of committing in the certificates some of the falsehoods designated in Article 193 of the Penal Code.

11. AMENDMENT OF CERTIFICATES

11.1. AMENDMENTS MADE PRIOR TO THE EXPORT

If an amendment to the information contained in the NEPPEX is required, the interested exporter must file its request at the SERNAPESCA office of the place where the Notification was processed, attaching the original document and the supporting sanitary documentation, if applicable.

If the requested amendment is related to the information included in the SMAE or ACOS sanitary supporting documents, the amendment of such supporting documents must be requested before requesting the amendment of the NEPPEX at the SERNAPESCA office where these were authorized. The NEPPEX amendment request may only be processed with the corresponding authorized sanitary supporting documentation.

11.2. AMENDMENTS MADE AFTER THE EXPORT

a. Change in the destination of exports

An amendment request for the country of destination of the goods will be evaluated on a case-by-case basis, and the request will be analyzed only if the product has not reached the initially informed country of destination. The interested exporter must file its request at the SERNAPESCA office of the place where the NEPPEX was processed, attaching a letter from the exporting company's Management with the following information:

- NEPPEX number.
- The new country of destination.
- Reasons for the request.
- Attach the corresponding supporting documentation, e.g. SMDA (Customs Destination Amendment Request), *tracking* of the ship, new export invoice, new transportation document (Waybill, Air waybill or B/L) and the sanitary supporting documentation updated for the new market, if applicable.
- Originals and copies of the certificates previously issued by SERNAPESCA.

The regional official will conduct the technical evaluation of the information presented and will analyze the requirement for changing the country of destination presented by the exporter, and if applicable, will authorize the request and will issue the corresponding approvals.

b. Other Amendments

If certificates containing information different from that included in the initially processed Notification are requested, the interested party must file a formal request from the Management of the exporting company, describing the causes for the request and addressed to the Regional Directorate of the SERNAPESCA office under whose jurisdiction the shipping office is located. This request must be presented with the authorization of the producers involved, and with all the supporting information for the amendment.

If the amendment refers to the consignee in a Sanitary Certificate, it must present a letter of responsibility from the exporter, clearly indicating the information of the new consignee and its responsibility for the requested change.

If the consignee needs to be amended in a Certificate of Origin, a new export invoice that indicates the information related to the new consignee must be presented.

Once the requested documents for filing the amendments have been presented, SERNAPESCA will conduct a technical evaluation of the associated sanitary aspects and will reply in accordance with the terms provided by law.

c. Returning Certificates

If a shipment for which SERNAPESCA has issued and provided the corresponding certification has been canceled, the interested party must return the original certificates and copies, without any right to be refunded.

d. Revoking and Replacing Certificates

Amendments to certificates will not be accepted, and only a replacement certificate may be issued when the original certificate has been lost, deteriorated, destroyed, stolen, contains errors or when the original information is not up-to-date.

The replacement certificate must be issued with the current date, and must clearly indicate that it is replacing the original certificate, including the number of the original certificate and the date in which it was signed, with the following wording "This certificate revokes and replaces certificate N°XXXXXX, control number XXXXXX, dated on XX-XX-XXXX". The new certificate will be assigned a number based on the original NEPPEX No and the side control number of the new document, leaving a 13 or 14 digit number for authorizations processed by SISCOMEX.

The original certificate must be revoked, and to the extent possible, it must be returned to SERNAPESCA.

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CHAPTER III. INSPECTION AND SAMPLING PROCEDURE FOR FISHERY AND AQUACULTURE PRODUCTS SHIPMENTS DESTINED TO BRAZIL AND THE EEU

This procedure applies to all export fishery and aquaculture products destined to the Eurasian Economic Union (EEU) and to frozen salmonids destined to Brazil.

The party interested in exporting to this market, must request the inspection and sampling service to consolidate the shipment, either at the plant or at the cold store, to a sampling entity authorized by SERNAPESCA, which must be conducted by a EFP Export Fishery Products Sampler authorized by SERNAPESCA, according to the information described in Section IV, Chapter II, Item 2.

Only frozen products that are kept at a temperature of ≤ -18 C° may be exported to this market, and in the specific case of salmonids, these must also comply with the requirement of absence of injuries in all the inspected samples, as outlined in Table 1.

Table: *Sampling plan for the inspection of shipments destined to Brazil and the EEU.*

Parameter	Established Limit	Sampling Plan	
		n	c
Temperature	≤ -18 C°	13[1]	0
Injuries	Absence	13	0

The number of samples must be distributed according to the *packing list* or AOSC. If the shipment is comprised of products from different processing establishments, at least one sampling unit for each one must be considered, distributing the remaining samples according to the distribution of the shipment.

If the container is consolidated partially in different establishments, the inspection service must be requested for each consolidation location, which must fully comply with the requirements set forth by Brazil and the EEU; there must be as many reports as consolidation locations, being complementary to each other, and all documents must be presented when requesting the shipment notification.

After the consolidation, whether it is single or partial, and if it complies with the requirements for the export of products destined to Brazil and the EEU, the authorized sampler will seal the load and issue the inspection and sampling report, which must include at least the aspects set forth in Section IV, Chapter II, Item 1. If required immediately, it may be completed by hand. In addition, the sampling entity must provide a copy to the processing establishments described in the report, which will be filed and made available to the staff of SERNAPESCA for future inspections or audits at the establishment.
The report must be presented at the SERNAPESCA office corresponding to the point of shipment

[1] In the case of salmonids, n=13 includes the control of injuries and temperature measurement.

at the moment of requesting the authorization and certification. The report must indicate the type of reference document used during the inspection, whether it is a packing list or an AOSC. When authorizing the export, the SERNAPESCA official must associate the Notification of Shipment of Export Fishery Products (NEPPEX) and the AOSC number to the original inspection and sampling report.

When Results Reports with advanced electronic signature are used, the interested party may present the corresponding copy whose authenticity must be confirmed by the SERNAPESCA Inspector according to the following steps:

- Go to the "Analysis Entities" list available at SERNAPESCA's webpage.
- In the "Personal autorizado para firma electrónica avanzada" (Personnel authorized to verify advanced electronic signatures), verify that the name of the signer appears in the column.
- In the "Procedimiento Inclusión Identidad Firmante en PDF" (Procedure to include the identity of the signer in PDF), follow the instructions to include the signer in the "Identidades de Confianza" (Trusted Identities).
- Optionally, those entities that have the "Documento Electrónico Certificado" (Certified Electronic Document) (DEC) option enabled can download the document. For this, the link must be entered in the "Firma Electrónica Avanzada" (Advanced Electronic Signature) column, and also fill in the fields "Nº Auditoría" (Audit No.) and "Nº Documento" (Document No.) in the Results Report.

When the inspection and sampling entity finds evidence in the report of some kind of abnormality in the process of load consolidation, or if when conducting the sampling it detects one or more samples with injuries or at a wrong temperature, and in consequence, the shipment does not comply with the requirements to export to the markets of Brazil and the EEU, this situation must be informed within 24 hours to the shipment and origin offices of SERNAPESCA. Additionally, the manufacturer or exporter is responsible for permanently blocking the product that conforms the shipment to be sent to the referred markets.

In the case of air shipments, the NEPPEX may be authorized without presenting the inspection and sampling report, however, it will be a mandatory requirement to provide the sanitary certification.

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CHAPTER IV. REQUIREMENTS FOR OBTAINING THE AUTHORIZATION OF SHIPMENT AND SANITARY CERTIFICATION

Item 1, below, describes the microbiological, physical, chemical, sensory, and toxicological criteria that the export fishery products intended for human consumption, animal consumption or other uses must meet; as well as the applicable sampling plans according to the classification of the processing plant and the presentation of the products.

These standards and sampling plans may be used for the control of end products, or for verification purposes in the Quality Assurance Programs.

The compliance with the following criteria is a necessary condition to obtain the following sanitary certificates, as appropriate:

a. Products intended for human consumption: "Sanitary Certificate for Fishery and Aquaculture Products."
b. Products not intended for human consumption: "Sanitary Certificate for Fishery and Aquaculture Products not Intended for Human Consumption."
c. Seaweeds intended for human consumption: "Sanitary Certificate for seaweeds and their by-products Intended for Human Consumption."
d. Seaweeds not intended for human consumption: "Sanitary Certificate for seaweeds and their by-products not Intended for Human Consumption."

For those markets with a sanitary certification agreement, both the specific criteria and the certificate models are described in Item 2 of this Chapter.

1. MICROBIOLOGICAL, CHEMICAL AND PHYSICAL STANDARDS PER PRODUCT

1.1. FISHERY PRODUCTS INTENDED FOR HUMAN CONSUMPTION

1.1.1. LIVE, CHILLED-REFRIGERATED FISHERY PRODUCTS

a. Sampling Plan

A double sampling plan must be applied according to the following:

- First stage: n = 5
  - If all the analyzed samples comply with the certification standard, the shipment will be certified without the need to continue to the second stage of the sampling (no defects in the lot).
  - If 3 or more analyzed samples do not comply with the evaluated standard, the sample will be rejected without the need to continue to the second stage.
  - If 1 or 2 units are detected to exceed any parameters (defective units), the second part of the sampling may take place.
- Second stage: n = 5
  - If the number of defective units of the first and the second stage is lower than or equal to 2 units, the lot will be certified.
  - If the number of defective units is greater than 2 units, the lot will not be certified.

b. Temperature

Live fishery products and chilled-refrigerated products must not have a temperature exceeding 4 C°; no more than 20% of the samples will be between 4 C° and 6 C°.

c. Sensory Examination

The physical-sensory characteristics to be met by live and chilled-refrigerated products are described as follows.

Table: *Fish*

	External Appearance	Eyes	Gills	Consistency	Abdominal Cavity
Extra Class	Very intense pigmentation. Transparent skin mucus. Medallions and fillets: translucent and pink. Absence of visible parasites.	Convex eyeball. Transparent cornea. Bright black pupil.	Red, bright color, odorless or with a specific odor. Perfectly separated, long and evenly aligned lamellae.	Presence of cadaveric rigidity or signs of this partial disappearance.	Red, bright blood stains. Clear serous membranes. Absence of visible parasites.
Class A	Insignificant loss of pigments. Important loss of pigments due to mechanical factors. Slightly turbid mucus. Absence of visible parasites.	Convex and slightly sunken eyeball. Slightly opalescent cornea. Cloudy black pupil.	Less red (pink) and odorless. Lamellae attached by groups.	Firm, elastic, pressure marks disappear immediately and completely.	Red blood stains. Clear serous membranes. Absence of visible parasites.

	External Appearance	Eyes	Gills	Consistency	Abdominal Cavity
Class B	Minor injuries. Pigmentation becoming discolored and loss of shine. Opaque mucus. Absence of visible parasites.	Flat eyeball. Opalescent cornea. Opaque pupil.	Slightly pale and attached. "Fish" odor. Lamellae attached by groups and of different lengths.	Mechanical marks present. Notably reduced elasticity, minor body deformation.	Traces of brownish red blood. Cloudy serous membranes. Absence of visible parasites.

Super chilling products must be evaluated applying the physical-sensory requirements described in the previous Table, on the internal condition of the muscle.

In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the maximum residual limits allowed for fish meat and skin coming from aquaculture and carry out sampling plans, as per the information provided in Section I, Chapter II.

Table: *Crustaceans*

	Eyes	Musculature	Thoracic-Abdominal Membranes	Odor	Presence of Melanosis
Extra Class (only live)	Reflex reactions at the level of the eyes, antennae, and legs.	Does not apply.	Does not apply.	Does not apply.	Does not apply.
Class A	Turgid bright black.	Firm.	Sturdy, bright and light.	Pleasant or none.	Absent or very scarce.
Class B (Non-certifiable)	Decolored, flaccid, wrinkled.	Relaxed.	Relaxed, flaccid, greenish or blackish.	Putrid at a mouth level.	Strong.

Table: *Cephalopods*

	External Appearance	Odor	Flesh	Tentacles (Only decapods)
Extra Class	Very strong pigmentation with intact chromatophores, smooth, soft and intact skin. Typical color of the species.	Pleasant or none.	White, firm, nacreous.	Firmly attached to the mantle.
Class A	Strong pigmentation, distinguishing itself very well from the chromatophores. Smooth and soft skin and with minor continuity solutions. Typical color of the species, with a tendency to become darker.	Like seafood, not unpleasant.	Firm, muted white color.	Well attached to the mantle.

	External Appearance	Odor	Flesh	Tentacles (Only decapods)
Class B (Non-certifiable)	Natural pigmentation practically disappeared. Highly deteriorated skin, mostly missing. Violet color.	Strong and very unpleasant.	Of scarce consistency, from violet-yellowish to purple.	Lost a good connection to the mantle.

Table: *Bivalve mollusks and gastropods*

	Live Product	Chilled-Refrigerated
General Condition	Live.	Good appearance in general.
Condition of the Shell	Absence of dirt. In one piece and without mechanical damages.	
Reaction to Percussion	Positive.	
Odor	Odorless or with a slight seaweed odor.	Pleasant, characteristic.
Intervalvular Liquid	Presence.	

The resources to be exported must come from a Type An extraction area that is part of the BMSP, or if they must come from a region not affected by marine toxins, they must undergo a biweekly monitoring at reception at the plant for *Vibrio parahaemolyticus*, and monthly for *Escherichia coli*. Resources extracted and processed in the Region of Magallanes are excluded from this microbiological control.

In addition, all the requirements described in the item on marine toxins specific requirements for the sanitary certification of bivalve mollusks, echinoderms, tunicates and gastropods must be met.

Table: *Echinoderms and tunicates*

	External Appearance	Odor	Spicules
Class A	Live, respond to external stimuli, good appearance. Fresh, good appearance.	Pleasant or none.	Mobile and upright.
Class B (non-certifiable)	Dead, immobile mollusks. Fresh, pleasant appearance.	Like seafood, not pleasant.	Immobile and dropped.

The resources to be exported must come from a Type A extraction area that is part of the BMSP, or they must undergo a biweekly monitoring at reception at the plant for *Vibrio parahaemolyticus*, and monthly for *Escherichia coli*. Resources extracted and processed in the Region of Magallanes are excluded from this microbiological control.

In addition, all the requirements described in the item on marine toxins specific requirements for the sanitary certification of bivalve mollusks, echinoderms, tunicates and gastropods must be met.

1.1.2. REFRIGERATED AND PROCESSED FISHERY PRODUCTS

Bivalve mollusks, gastropods, tunicates or echinoderms must also comply with the physical-sensory requirements described in Item 1.1.1, and also with those requirements related to the

control of marine toxins described in Item 1.1.21 of this Chapter.

If the export corresponds to raw product, a bi-weekly monitoring at the reception at the plant for *Vibrio parahaemolyticus* must be conducted.

In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the requirements described in Section I, Chapter II.

a. Sampling Plans and Microbiological Determinations
The sampling plans and certification standards described for the technological process to which these products have been subjected to will be applied.

1.1.3. FROZEN FISH AND CEPHALOPODS

Table: *Sampling plans and microbiological determinations for raw fish and cephalopods*[1]

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Total Count (g)	$5x10^5$	10^6	5	3	5	2	10	2	10	1
Escherichia coli (NMP/g)	100	500	5	3	10	2	10	2	15	2
Salmonella (25 g)	Absence		5	0	5	0	5	0	10	0
S. aureus (ufc/g)	100	500	5	2	10	2	15	1	20	1
L. monocytogenes (ufc/g)[2]	100		5	0	5	0	5	0	10	0

n = sample size m = lower limit c = acceptance number M = upper limit

Table : *Sampling plans and microbiological determinations for frozen cooked fish and cephalopods*[3]

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Total Count (g)	10^5	$5x10^5$	5	3	5	2	10	2	10	1
Escherichia coli (NMP/g)	10	100	5	3	10	2	10	2	15	2
Salmonella (25 g)	Absence		5	0	5	0	5	0	10	0
S. aureus (ufc/g)	10	100	5	1	10	2	15	1	20	1
L. monocytogenes (ufc/g)	100		5	0	5	0	5	0	10	0

n = sample size m = lower limit c = acceptance number M = upper limit

Table: *Sensory examination for frozen fish and cephalopods (raw or cooked)*

Parameters	Certification Standard	Sampling Plan	
		n	c
Species	Corresponds to the one declared by the exporter.	5	0
Presentation	Corresponds to the one declared by the exporter and it must include		

[1] In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the requirements described in Section I, Chapter II.
[2] If the frozen products must be unequivocally cooked before their consumption, and this condition is clearly labeled, the *Listeria monocytogenes* analysis may be skipped.
[3] In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the requirements described in Section I, Chapter II.

	all the aspects described by it (example: bones, skin, type of cut, type of package, among others).
Appearance	The product is well-preserved, with a normal appearance. Does not present dehydration in more than 10% of the product's surface, does not contain any foreign matter or gelatinous alterations in the meat that affect more than 5%, in weight, of the sample.
Parasites	Absence of visible parasites of the Cestoda Classes, Diphyllobothriidae and Nematoda Family, and the Anisakidae Family.
Odor	Normal, characteristic of the species and the presentation. There are not any abnormal odors that could indicate decomposition or rancidity.
Color	Natural, typical color of the species.
Texture	Turgid, firm and tender, typical of the species.

Table :*Chemical parameters for frozen fish and cephalopods (raw or cooked).*

Parameter	Limit	Sampling Plan n	Sampling Plan c	Number of Analyses
Histamine[1]	M = 200 mg/kg (ppm)	5	0	5
Mercury	0.5 mg/kg (ppm)		5	1 (composite)
	1.5 mg/kg (ppm) (Shark, tuna, bonito, swordfish, eel, Patagonian toothfish [*Dissostichus eleginoides*] and ray)		5	1 (composite)
Lead	2 mg/kg (ppm)		5	1 (composite)
TVB-N	30 mg N/100g (Fish except elasmobranchii)	5	0	5
	70 mg/100g (Elasmobranchii)			
	30 mg/100g (Mollusks except for cuttlefish and other squids)			

1.1.4. SURIMI BASE AND SURIMI PRODUCTS

a. Surimi Base

Table:*Sampling Plans and Microbiological Determinations*

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m		n	c	n	c	n	c	n	c
Total Count (g)	$5x10^5$	10^6	5	3	5	2	10	2	10	1
E. coli (NMP/g)	100	500	5	3	5	2	10	1	15	1
Salmonella (25 g)	Absence		5	0	5	0	5	0	10	0
S. aureus (ufc/g)	100	500	5	2	10	2	15	1	20	1

n = sample size m = lower limit c = acceptance number M = upper limit

[1] Fresh fish, fresh-chilled and frozen.

Table: *Sensory Examination*

Parameters	Certification Standard	Sampling Plan	
		n	c
Species	Corresponds to the one declared by the exporter.	5	0
Presentation	Corresponds to Surimi Base.		
Appearance	The product is homogeneous.		
Odor	Characteristic of the species.		
Color	Characteristic of the species.		
Flavor	Characteristic of the species.		

b. Surimi Products

Table: *Sampling Plans and Microbiological Determinations*

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Total Count (g)	$5x10^4$	$5x10^5$	5	1	5	1	10	1	15	1
E. coli (NMP/g)	10	100	5	1	5	1	10	1	15	1
Bacillus cereus (ufc/g)	50	500	5	1	5	1	10	1	15	1
Clostridium perfringens (ufc/g)	50	500	5	1	5	1	10	1	15	1
Salmonella (25 g)	Absence		5	0	10	0	10	0	15	0
Listeria monocytogenes (ufc/g)[1]	100		5	0	10	0	10	0	15	0
S. aureus (ufc/g)	10	100	5	1	5	1	10	1	15	1

n = sample size m = lower limit c = acceptance number M = upper limit

1.1.5. FROZEN CRUSTACEANS

Table: *Sampling plans and microbiological determinations for frozen raw crustaceans*

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Total Count (g)	$5x10^5$	10^6	5	3	5	2	5	2	5	1
Salmonella (25 g)	Absence		5	0	5	0	5	0	10	0
S. aureus (ufc/g)	100	500	5	2	5	2	5	1	10	1
Listeria monocytogenes (ufc/g)[2]	100		5	0	5	0	5	0	10	0
E. coli (NMP/g)	100	500	5	3	5	3	5	1	5	1

n = sample size m = lower limit c = acceptance number M = upper limit

Table : *Sampling plans and microbiological determinations for frozen cooked crustaceans*

[1] If the frozen products must be unequivocally cooked before their consumption, and this condition is clearly labeled, the *Listeria monocytogenes* analysis may be skipped.

[2] If the frozen products must be unequivocally cooked before their consumption, and this condition is clearly labeled, the *Listeria monocytogenes* analysis may be skipped.

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Total Count (g)	$5x10^5$	10^6	5	3	5	2	5	2	5	1
Salmonella (25 g)	Absence		5	0	5	0	5	0	10	0
S. aureus (ufc/g)	10	100	5	1	5	1	5	1	10	1
Listeria monocytogenes (ufc/g)	100		5	0	5	0	5	0	10	0
E. coli (NMP/g)	10	100	5	3	5	3	5	1	5	1

n = sample size c = acceptance number m = lower limit M = upper limit

Table: *Sensory examination for frozen crustaceans (raw or cooked)*

Parameters	Certification Standard	Sampling Plan	
		n	c
Species	Corresponds to the one declared by the exporter.	5	0
Presentation	Corresponds to the one declared by the exporter and it must include all the aspects described by it (example: cut, type of freezing method, type of package, among others).		
Appearance	Normal appearance, well structured. Does not present dehydration in more than 10%, in weight, of the sample and does not present foreign matter.		
Odor	Good, characteristic of the species. There are not any objectionable persistent and unmistakable odors that are a sign of decomposition or rancidity or odors that are not characteristic of the product.		
Color	Natural, typical. There are not any black, green or yellow alterations, either alone or in combination.		

Table: *Chemical parameters for frozen crustaceans (raw or cooked)*

Parameter	Limit	Sampling Plan		Number of Analyses
		n	c	
Mercury	0.5 mg/kg (ppm)		5	1 (composite)
Lead	2 mg/kg (ppm)		5	1 (composite)
TVB-N	60 mg N/100g	5	0	5

1.1.6. FROZEN BIVALVE MOLLUSKS, GASTROPODS, TUNICATES AND ECHINODERMS

These products must also comply with the requirements outlined in Item 1.1.21 of this Chapter.

Table: *Sampling plans and microbiological determinations for frozen raw bivalve mollusks, gastropods, tunicates and echinoderms*

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Total Count (g)	$5x10^5$	10^6	5	3	5	3	5	1	10	2
Escherichia coli (NMP/ g)	100	500	5	3	5	3	5	3	10	0
Salmonella (25 g)	Absence		5	0	5	0	5	0	5	0
S. aureus (ufc/g)	100	500	5	2	5	2	5	1	5	1

Vibrio parahaemolyticus (NMP/g)[1]	10	100	5	1	5	1	10	1	10	1		
Listeria monocytogenes (ufc/g)[2]	100		5	0	5	0	5	0	10	0		
Norovirus[3]	Absence		3	0	3	0	3	0	3	0		

n = sample size c = acceptance number m = lower limit M = upper limit

Table: *Sampling plans and microbiological determinations for frozen cooked bivalve mollusks, gastropods, tunicates and echinoderms*

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Total Count (g)	10^5	$5x10^5$	5	3	5	3	5	1	10	2
Escherichia coli (NMP/g)	10	100	5	3	5	3	5	0	10	0
Salmonella (25 g)	Absence		5	0	5	0	5	0	5	0
S. aureus (ufc/g)	10	100	5	1	5	1	5	1	5	1
Listeria monocytogenes (ufc/g)	100		5	0	5	0	5	0	10	0

n = sample size c = acceptance number m = lower limit M = upper limit

Table: *Microbiological sensory examination for frozen bivalve mollusks, gastropods, tunicates and echinoderms (raw or cooked)*

Parameters	Certification Standard	Sampling Plan	
		n	c
Species	Corresponds to the one declared by the exporter.	5	0
Presentation	Corresponds to the one declared by the exporter and it must include all the aspects described by it (example: with or without a shell, type of freezing method, type of package, among others).		
Appearance	Normal, characteristic of the species. Those frozen products presented in their shell must be clean and free of broken or damaged units. Shucked products must be free of sand, shell remains or other unwanted material.		
Odor	Typical, normal.		
Texture	Firm, characteristic of the species.		

Table: *Chemical parameters for frozen bivalve mollusks, gastropods, tunicates and echinoderms (raw or cooked)*

Parameter	Limit	Sampling Plan		Number of Analyses
		n	c	
Mercury	0.5 mg/kg (ppm)	5		1 (composite)
Lead	2 mg/kg (ppm)	5		1 (composite)
TVB-N	30 mg N/100g	5	0	5

[1] Raw bivalve mollusks, gastropods, tunicates and echinoderms extracted and processed in the Region of Magallanes are excluded from this requirement.
[2] If the frozen products must be unequivocally cooked before their consumption, and this condition is clearly labeled, the *Listeria monocytogenes* analysis may be skipped.
[3] It will be applied to raw oysters. Raw oysters' exports may be authorized, only if they come from an area included in the Bivalve Mollusks Sanitary Program with category A. Also, a sampling of the lots to be exported must be conducted, and it should consider n = 3 per extraction origin and per week of production.

1.1.7. CANNED FISHERY PRODUCTS

Bivalve mollusks, gastropods, tunicates, and echinoderms must comply, apart from the previously described requirements, with those stated in Item 1.1.21 of this Chapter.

In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the requirements described in Section I, Chapter II.

Table : *Microbiological parameters for canned fishery products*

Microbiological Determinations	Limits	Category A		Category B		Category C		Category D	
		n	c	n	c	n	c	n	c
Mesophiles (aerobic and anaerobes)	Absence	5	0	10	0	15	0	20	0
Thermophiles (aerobic and anaerobes)	Absence	5	0	10	0	15	0	20	0

n = sample size c = acceptance number m = lower limit M = upper limit

Table: *Evaluation of tin cans*

Parameters	Certification Standard	Sampling Plan	
		n	c
Type of Package	Describe the type of package used, including its dimensions, use, type of varnish, and type of welding.	5	0
External Appearance	Free of dents, rust or other visible defects.		
Internal Appearance	Free of dark spots due to of discontinuity in the varnishing or other visible defects due to corrosion.		

Table:*Evaluation of flexible containers*

Parameters	Certification Standard	Sampling Plan	
		n	c
Incubation Test	Absence of protuberances.	5	0
Visual Examination of the Seal	Absence of serious defects (when the flexible container has lost its airtight seal (perforations, fractures, puncturing, product leaks, etc.), it represents a problem for public health).	5	0
	Up to 2 minor defects (when the flexible container has not lost its airtight seal, it is a minor defect from the public health point of view).	5	2

Table:*Main defects in packages*

Defect	Description	Serious Defect 1	Minor Defect 2
Abrasion	Scratches in any of the layers of the package.	Abrasion penetrates the outer layer. Samples lose their	Wear in the outer layer.

Defect	Description	Serious Defect 1	Minor Defect 2
		hermetic integrity.	
Blisters	A blister resembles a bubble, or has a raised appearance in the seal.	The width of the continuous seal is reduced to less than 3 mm.	Presence of a blister with a seal width of 3 mm or more.
Channel Leaker	Interruption in the channel of the seal causing the leak of the content through that area.	The product leaks through the channel.	
Contaminated Seal	Contamination trapped in the seal area.	The seal width is reduced to less than 3 mm.	The seal width is greater than 3 mm.
Uneven Seal	Uneven seal juncture.	The width is reduced to less than 3 mm.	
Delamination	The laminate materials separate and may result in a loss of hermetic integrity.	Delamination produces a width of less than 3 mm in the seal.	Outside of the seal area.
Flex Cracks	Presence of small breaks in the surface of the bag, where only one layer is affected.		Presence of cracks.
Fracture	Affects all the layers of the laminate.	Loss of hermetic integrity.	
Leaker	Opening in any part of the bag.	Loss of hermetic integrity.	
Puncture	Mechanical defect that punctures the bag.	Loss of hermetic integrity.	
Hot Fold	A bend in a seal that is produced in the sealing process.		Presence of a bend.
Misaligned Seal	A seal that is not formed in a continuous, straight line.	Loss of hermetic integrity (absence of a seal in a given area).	Does not affect hermetic integrity.
Notch Leaker	A leak occurring at the manufactured notch.	Loss of hermetic integrity.	
Wrinkles	A wrinkle is a material fold on one seal surface, caused when one seal surface is longer than the other.	A fold along the entire seal.	The fold is not located along the entire seal.
Swollen	The pouch bulges due to gas formation from bacterial contamination, or excess internal residual air.	Gas inside the pouch.	
Stringy Seal	Presence of plastic threads showing at the edge of the seal area.	Excessive plastic threads showing at the edge of the seal area.	

Table :*Sensory Examination*

Parameters	Certification Standard	Sampling Plan	
		n	c
Species	Corresponds to the one declared by the exporter.	5	0
Presentation	Corresponds to the one declared by the exporter and it must include all the aspects described by it (example: bones, skin, type of cut, type of preparation, type of packaging, among		

Parameters	Certification Standard	Sampling Plan n c
	others).	
Appearance	Normal, characteristic of the preparation. Does not contain any foreign material or color alterations that may be a sign of decomposition or rancidity, or a blue, brown or black color (in the case of crustaceans), or sulfide taints (in the case of crustaceans and fish).	
Odor and Flavor	Characteristic of the presentation. Objectionable persistent and unmistakable odors must not be detected, for they are a sign of decomposition or rancidity.	
Texture	Typical, firm and tender. Excessively soft or excessive hard meat, that is not characteristic of the product, should not be detected.	

Table :*Chemical parameters.*

Parameter	Limit	Sampling Plan n c	Number of Analyses
Mercury	1.0 mg/kg (ppm)	5	1 (composite)
Lead	2.0 mg/kg (ppm)	5	1 (composite)
Histamine	m = 100 mg/kg (ppm) M = 200 mg/kg (ppm) (Applicable only to cupleidae, scombridae and jack mackerel).	5 2	5

1.1.8. SMOKED FISHERY PRODUCTS

Bivalve mollusks, gastropods, tunicates, and echinoderms must comply, apart from the previously described requirements, with those stated in Item 1.1.21 of this Chapter.

In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the requirements outlined in Section I, Chapter II.

These sampling plans and microbiological determinations must be applied equally to frozen smoked products.

Table:*Sampling plans and microbiological determinations*

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Total Count (g)	10^5	$5x10^5$	5	1	5	1	5	1	5	1
E coli (NMP/g)	10	100	5	1	5	1	5	1	5	1
Salmonella (25 g)	Absence		5	0	5	0	5	0	10	0
S. aureus (ufc/g)	10	100	5	1	10	1	10	1	10	1

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
L. monocytogenes (ufc/g)[1]	10		5	0	5	0	5	0	5	0

n = sample size c = acceptance number m = lower limit M = upper limit

Table: *Sensory examination*

Parameters	Certification Standard	Sampling Plan	
		n	c
Species	Corresponds to the one declared by the exporter.	5	0
Presentation	Corresponds to the one declared by the exporter and it must include all the aspects described by it (example: type of cut, type of package, among others).		
Appearance	Normal, typical. The presence of abnormal taints that indicate contamination is not permitted.		
Parasites	Absence of visible parasites of the Cestoda Classes, Diphyllobothriidae and Nematoda Family, and the Anisakidae Family.		
Odor	Typical, characteristic. Absence of objectionable persistent and unmistakable odors that are a sign of decomposition (acid, putrid odor, etc.) or of contamination with foreign materials (fuel, cleaning products, etc.).		
Flavor	Typical, characteristic.		
Color	Typical, characteristic.		
Texture	Firm to the touch. Water must not exude when pressing with the fingers.		

Table: *Chemical parameters*

Parameter	Limit	Sampling Plan		Number of Analyses
		n	c	
Histamine	m = 100 mg/kg (ppm) M = 200 mg/kg (ppm) (Applicable only to cupleidae, scombridae and jack mackerel).	5	2	5
Mercury	0.5 mg/kg (ppm)		5	1 (composite)
	1.5 mg/kg (ppm) (Shark, tuna, bonito, swordfish, eel, Patagonian toothfish [*Dissostichus eleginoides*] and ray)		5	1 (composite)
Lead	2 mg/kg (ppm)		5	1 (composite)

1.1.9. BREADED FISHERY PRODUCTS

Bivalve mollusks, gastropods, tunicates, and echinoderms must comply, apart from the previously described requirements, with those stated in Item 1.1.20 of this Chapter.

[1] If the product is frozen a limit of 100 ufc/g must be applied.

In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the requirements outlined in Section I, Chapter II.

Table: *Sampling plans and microbiological determinations*

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Total Count (g)	$5x10^5$	10^6	5	3	5	1	10	2	10	2
E. coli (NMP/g)	100	500	5	3	5	2	10	1	15	1
Salmonella (25g)	Absence		5	0	5	0	10	0	10	0
S. aureus (ufc/g)	10	100	5	1	10	1	10	2	15	2
L. monocytogenes (ufc/g)[1]	100		5	0	5	0	10	0	10	0

n = sample size c = acceptance number m = lower limit M = upper limit

Table: *Sensory examination*

Parameters	Certification Standard	Sampling Plan	
		n	c
Species	Corresponds to the one declared by the exporter.	5	0
Presentation	Corresponds to the one declared by the exporter and it must include all the aspects described by it (example: type of cut, type of package, among others).		
Appearance	Normal, typical of the presentation. Does not contain any foreign materials. There are not any objectionable alterations in the texture of the flesh, neither a gelatinous condition that affects more than 5%, in weight, of the flesh.		
Parasites	Absence of visible parasites of the Cestoda Classes, Diphyllobothriidae and Nematoda Family, and the Anisakidae Family.		
Odor	Typical, characteristic of the presentation. There are not any objectionable persistent and unmistakable odors that are a sign of decomposition or rancidity or others that are not characteristic of the product.		
Texture	Firm and tender.		

Table: *Chemical parameters*

Parameter	Limit	Sampling Plan		Number of Analyses
		n	c	
Histamine	m = 100 mg/kg (ppm) M = 200 mg/kg (ppm) (Applicable only to cupleidae, scombridae and jack mackerel).	5	2	5
Mercury	0.5 mg/kg (ppm)	5		1 (composite)
	1.5 mg/kg (ppm)	5		1 (composite)

[1] If the frozen products must be unequivocally cooked before their consumption, and this condition is clearly labeled, the *Listeria monocytogenes* analysis may be skipped.

Parameter	Limit	Sampling Plan n c	Number of Analyses
	(Shark, tuna, bonito, swordfish, eel, Patagonian toothfish [*Dissostichus eleginoides*] and ray).		
Lead	2 mg/kg (ppm)	5	1 (composite)
TVB-N	30 mg N/100g (Fish except elasmobranchii)	5 0	5
	70 mg N/100g (Elasmobranchii)		
	30 mg N/100g Crustaceans and mollusks except for cuttlefish)		

1.1.10. READY COOKED MEALS

Only those ready cooked meals produced in Category A and Category B plants will be certified for export.

Bivalve mollusks, gastropods, tunicates, and echinoderms must comply, apart from the previously described requirements, with those stated in Item 1.1.21 of this Chapter.

In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the requirements outlined in Section I, Chapter II.

Table: *Sampling plans and microbiological determinations for mixed ready cooked meals with raw and/or cooked ingredients*

Microbiological Determinations	Limits	Category A	Category B	Category C	Category D
	m M	n c	n c	n c	n c
Total Count (g)[1]	10^5 10^6	5 1	5 1	10 1	15 1
E. coli (NMP/g)	50 500	5 1	5 1	10 1	15 1
Bacillus cereus (ufc/g)[2]	500 5000	5 1	5 1	10 1	15 1
Clostridium perfringens (ufc/g)[3]	50 500	5 1	5 1	10 1	15 1
Salmonella (25 g)	Absence	5 0	10 0	10 0	15 0
Listeria monocytogenes (ufc/g)	10	5 0	10 0	10 0	15 0
S. aureus (ufc/g)	50 500	5 1	5 1	10 1	15 1

n = sample size m = lower limit c = acceptance number M = upper limit

Table: *Sampling plans and microbiological determinations for ready-made meals that necessarily require cooking.*

Microbiological Determinations	Limits	Category A	Category B	Category C	Category D
	m M	n c	n c	n c	n c

[1] Except with fermented ingredients or ingredients matured with bacterial culture.
[2] Only with rice.
[3] Only with meats.

S. aureus (ufc/g)	100 1000	5	2	5	2	10	1	15	1
Bacillus cereus[1] (ufc/g)	500 5000	5	2	5	2	10	1	15	1
Clostridium perfringens[2] (ufc/g)	100 1000	5	2	5	2	10	1	15	1
Salmonella (25 g)	Absence	5	0	10	0	10	0	15	0

n = sample size m = lower limit c = acceptance number M = upper limit

Table: *Sensory examination*

Parameters	Certification Standard	Sampling Plan	
		n	c
Appearance	The products must present the characteristics of the production. There should not be any foreign materials.	5	0
Odor	Characteristic.		
Flavor	Characteristic.		
Color	Characteristic.		

1.1.11. DRIED FISHERY PRODUCTS[3]

Table: *Sampling plans and microbiological determinations*

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Total Count (g)	10^5	10^7	5	2	5	1	5	1	5	1
E. coli (NMP/g)	<3	10	5	2	5	1	10	2	10	1
S. aureus (ufc/g)	10	100	Not required.		5	1	5	1	10	1
Mold and yeast (g)	100	1000	Not required.		Not required.		5	2	10	2

n = sample size m = lower limit c = acceptance number M = upper limit

Table: *Sensory examination*

Parameters	Certification Standard	Sampling Plan	
		n	c
Species	Corresponds to the one declared by the exporter.	5	0
Presentation	Corresponds to the one declared by the exporter and it must include all the aspects described by it (example: type of cut, type of package, among others).		
Appearance	Normal, characteristic. There are not any mycotic areas, foreign materials or burns due to excessive drying, evidenced by viscous or sticky skin.		
Odor	Characteristic. Absence of objectionable persistent and unmistakable odors that are a sign of decomposition (acid, putrid odor, etc.) or of contamination with foreign materials (fuel, cleaning products, etc.).		

[1] Only with rice and cereals.
[2] Only with meats.
[3] Bivalve mollusks, gastropods, tunicates and echinoderms must comply, apart from the previously described requirements, with those stated in Item 1.1.21 of this Chapter.

Parameters	Certification Standard	Sampling Plan n	c
Color	Natural, typical and even. The presence of reddish or greenish taints or yellow or orange-yellowish discolorations is not permitted.		
Texture	Typical, firm and tender. Absence of meat with texture characterized by a generalized cracking in more than two-thirds of the surface, torn or broken.		

Table: *Chemical parameters*

Parameter	Limit	Sampling Plan n	c	Number of Analyses
Moisture	≤ 10% on average	5	0	5
Histamine	m = 100 mg/kg (ppm) M = 200 mg/kg (ppm) (Applicable only to cupleidae, scombridae[1] and jack mackerel).	5	2	5
Mercury	1.0 mg/kg (ppm) (Shark, tuna, bonito, swordfish, eel, Patagonian toothfish [*Dissostichus eleginoides*] and ray).	5		1 (composite)
TVB-N	150 mg N/100g (Fish except elasmobranchii)	5	0	5

1.1.12. SALTED FISHERY PRODUCTS[1]

Table: *Sampling plans and microbiological determinations*

Microbiological Determinations	Limits m	M	Category A n	c	Category B n	c	Category C n	c	Category D n	c
Total Count (g)	10^5	$5x10^5$	5	1	5	1	5	1	10	1
E. coli (NMP/g)	10	100	5	1	5	1	10	2	10	1
S. aureus (ufc/g)	10	100	Not required.		Not required.		5	1	10	1
Mold and yeast (g)	100	1000	Not required.		5	1	10	2	10	1

n = sample size m = lower limit c = acceptance number M = upper limit

Table: *Sensory examination*

Parameters	Certification Standard	Sampling Plan n	c
Species	Corresponds to the one declared by the exporter.		
Presentation	Corresponds to the one declared by the exporter and it must include all the aspects described by it (example: type of cut, type of package, among others).	5	0
Appearance	Normal. Absence of foreign material and halophilic mold.		

[1] Bivalve mollusks, gastropods, tunicates and echinoderms must comply, apart from the previously described requirements, with those stated in Item 1.1.21 of this Chapter. In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the requirements set forth in Section I, Chapter II.

Parameters	Certification Standard	Sampling Plan	
		n	c
Odor	Characteristic, intense. Absence of objectionable persistent and unmistakable odors that are a sign of decomposition (acid, putrid odor, etc.) or of contamination with foreign materials (fuel, cleaning products, etc.).		
Color	Natural, typical and even. A defect is considered to be a visible evidence of red halophilic bacteria.		
Texture	Typical, firm and tender. Absence of meat with texture characterized by a generalized cracking in more than two-thirds of the surface, torn or broken.		

Table: *Chemical parameters*

Parameter	Limit	Sampling Plan		Number of Analyses
		n	c	
NaCl Content	≥ 15%	5	0	5
Histamine	m = 100 mg/kg (ppm) M = 200 mg/kg (ppm) (Applicable only to cupleidae, scombridae[1] and jack mackerel).	5	2	5
Mercury	1.0 mg/kg (ppm) (Shark, tuna, bonito, swordfish, eel, Patagonian toothfish [*Dissostichus eleginoides*] and ray).	5		1 (composite)
TVB-N	150 mg N/100g (Fish except elasmobranchii)	5	0	5

1.1.13. SALTED AND DRIED FISHERY PRODUCTS

Table: *Sampling plans and microbiological determinations*

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Total Count (g)	10^5	10^6	5	1	5	1	5	1	5	1
E. coli (NMP/g)	<3	10	5	1	5	1	10	2	10	1
S. aureus (ufc/g)	10	100	Not required.		Not required.		5	1	10	1
Mold and yeast (g)	100	1000	Not required.		5	1	10	2	10	1

n = sample size m = lower limit c = acceptance number M = upper limit

Table: *Sensory examination*

Parameters	Certification Standard	Sampling Plan	
		n	c
Species	Corresponds to the one declared by the exporter.	5	0

[1] Cupleidae: Menhaden or shad (*Ethmidium maculatum*), Sardine (*Sardinops sagax*); Araucanian herring (*Clupea bentincki*); Anchoveta (*Engraulis ringens*). Scombridae: Yellowfin Tuna (*Thunnus albacares*); Longfin Tuna (*Thunnus alalunga*); Bigeye Tuna (*Thunnus obesus*); Bonito (*Sarda chilensis*); Pacific Chub Mackerel (*Scomber japonicus peruanus*).

Presentation	Corresponds to the one declared by the exporter and it must include all the aspects described by it (example: type of cut, type of package, among others).
Appearance	Normal. Absence of foreign materials, halophile mold and burns due to excessive heating during drying.
Odor	Characteristic, intense. Absence of objectionable persistent and unmistakable odors that are a sign of decomposition (acid, putrid odor, etc.) or of contamination with foreign materials (fuel, cleaning products, etc.).
Color	Natural, typical and even. Absence of pink color, visible evidence of red halophile bacteria and reddish or greenish taints that affect the product.
Texture	Typical, firm and tender. Absence of meat with texture characterized by a generalized cracking in more than two-thirds of the surface, torn or broken.

Table: C*hemical parameters*

Parameter	Limit	Sampling Plan n	Sampling Plan c	Number of Analyses
Water Activity:	< 0.8 on average	5	0	5
Histamine	m = 100 mg/kg (ppm) M = 200 mg/kg (ppm) (Applicable only to cupleidae, scombridae[1] and jack mackerel).	5	2	5
Mercury	1.0 mg/kg (ppm) (Shark, tuna, bonito, swordfish, eel, Patagonian toothfish [*Dissostichus eleginoides*] and ray).	5		1 (composite)
TVB-N	150 mg N/100g (Fish except elasmobranchii)	5	0	5

1.1.14. FISH SAUSAGES[2]

Table: *Sampling plans and microbiological determinations for cooked sausages*

Microbiological Determinations	Limits m	Limits M	Category A n	Category A c	Category B n	Category B c	Category C n	Category C c	Category D n	Category D c
Total Count (g)	$5x10^4$	$3x\ 10^6$	5	1	5	1	5	1	5	1
E. coli (NMP/g)	10	10^2	5	1	5	1	10	2	10	1
Cl. perfringens (g)	10	10^2	5	1	5	1	5	1	5	1
S. aureus (ufc/g)	10	100	5	1	5	1	5	1	10	1
Salmonella (25g)	Absence		5	0	5	0	10	0	10	0

n = sample size m = lower limit c = acceptance number M = upper limit

[1] Cupleidae: Menhaden or shad (Ethmidium maculatum), Sardine (Sardinops sagax); Araucanian herring (Clupea bentincki); Anchoveta (Engraulis ringens). Scombridae: Yellowfin Tuna (*Thunnus albacares*); Longfin Tuna (*Thunnus alalunga*); Bigeye Tuna (*Thunnus obesus*); Bonito (*Sarda chilensis*); Pacific Chub Mackerel (*Scomber japonicus peruanus*).

[2] In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the requirements set forth in Section I, Chapter II.

1.1.15. RAW MATURED SAUSAGES

Table 48
Sampling plans and microbiological determinations for raw matured sausages

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Salmonella (25g)	Absence		5	0	5	0	5	0	10	0
S. Aureus (ufc/g)	10	100	5	2	5	2	5	2	10	2

n = sample size m = lower limit c = acceptance number M = upper limit

Table : *Sensory examination for matured cooked and raw sausages*

Parameters	Certification Standard	Sampling Plan	
		n	c
	The products must present the characteristics of the production. There should not be any foreign materials.	5	0
Odor	Characteristic.		
Flavor	Characteristic.		
Color	Characteristic.		

Table: *Chemical parameters for matured cooked and raw sausages*

Parameter	Limit	Sampling Plan		Number of Analyses
		n	c	
Histamine	m = 100 mg/kg (ppm) M = 200 mg/kg (ppm) (Applicable only to cupleidae, scombridae[1] and jack mackerel).	5	2	5
Mercury	1.0 mg/kg (ppm) (Shark, tuna, bonito, swordfish, eel, Patagonian toothfish [*Dissostichus eleginoides*] and ray).	5		1 (composite)
TVB-N	30 mg N/100g (Fish except) 70 mg N/100g (Elasmobranchii)	5	0	5

1.1.16. FISHERY PRODUCTS PRESERVED IN OIL[1]

a. Sampling plans and microbiological determinations

Fishery products preserved in oil must comply with the requirements of the production process through which they have been previously subjected, applying the sampling plans and microbiological determinations described for each case.

b. Chemical parameters

In addition to those described for the previous technological process, the following parameters

[1] Bivalve mollusks, gastropods, tunicates and echinoderms must comply, apart from the previously described requirements, with those stated in Item 1.1.21 of this Chapter. In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the requirements set forth in Section I, Chapter II.

must be met:

Table: *Chemical parameters*

Parameter	Limit
Peroxide Value	≤ 10% meq oxygen peroxide/kg
Free Acidity	≤ 0.25% expressed as oleic acid

1.1.17. PRESERVED FISHERY PRODUCTS[1]

Table: *Sampling plans and microbiological determinations*

Microbiological Determinations	Limits		Category A		Category B		Category C		Category D	
	m	M	n	c	n	c	n	c	n	c
Mold and Yeast (g)	10^2	10^3	5	1	5	1	10	2	10	1

n = sample size m = lower limit c = acceptance number M = upper limit

Table: *Sensory examination*

Parameters	Certification Standard	Sampling Plan	
		n	c
	The product presents organoleptic features characteristic of the species and the preparation used.	5	0

Table: *Chemical parameters*

Parameter	Limit	Sampling Plan		Number of Analyses
		n	c	
pH	< 4.0 (measured in the meat). (Fermented products and products preserved in vinegar).	5	0	5

1.1.18. CRUDE FISH OIL AND ITS BY-PRODUCTS

a. Sampling Plans

If the sampling unit is comprised of storage tanks, n samples will be collected per tank; if the product is stored in drums, gallons or other standard unit, n drums, gallons or standard units will be sampled.

Table: *Sensory examination*

Parameters	Certification Standard	Sampling Plan	Number of Analyses
		n	
Odor	Characteristic of the assigned product, which must be free of odd or stale odors and flavors.	6	1 (composite)
Flavor	Characteristic of the assigned product, which must be free of odd or stale odors and flavors.		
Color	Characteristic of the assigned product.		

[1] Bivalve mollusks, gastropods, tunicates and echinoderms must comply, apart from the previously described requirements, with those stated in Item 1.1.21 of this Chapter. In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the requirements set forth in Section I, Chapter II.

Table: *Chemical analyses*

Parameter	Limit	Sampling Plan n	Number of Analyses
Butylated hydroxyanisole (BHA)	175 mg/kg (ppm)	6	1 (composite)
Butylated hydroxytoluene (BHT)	75 mg/kg (ppm)		
Tertiary butylhydroquinone (TBHQ)	120 mg/kg (ppm)		
Any combination of BHA, BHT and/or TBHQ	200 mg/kg (ppm)		
Lead	0.1 mg/kg (ppm)		

1.1.19. SEAWEEDS AND THEIR BY-PRODUCTS

Table: *Sampling plans and microbiological determinations*

Parameter	Limit	Sampling Plan[1] n	c	Number of Analyses
Total Count	$m = 10^5$ $M = 5 \times 10^5$	5	2	5
Mold and Yeast	$m = 10^2$ $M = 10^3$			

Table: *Physical parameters*

Parameter	Limit	Size of the export batch (Ton. net)	Sampling Plan[2] n	c	Number of Analyses
Moisture	≤ 20% on average[3]	1 – 50	5	0	5
Impurities	≤ 10% on average[4]	1 – 50	5	0	5

1.1.20. SPECIFIC SANITARY REQUIREMENTS FOR OBTAINING THE AUTHORIZATION FOR SHIPMENT NOTIFICATIONS OF BIVALVE MOLLUSKS, TUNICATES, ECHINODERMS AND GASTROPODS

1.1.20.1. *VIBRIO PARAHAEMOLYTICUS* CONTROL

a. *Vibrio parahaemolyticus* control in live and fresh-chilled resources

To authorize shipments of live or fresh bivalve mollusks, echinoderms, tunicates and gastropods, these must come from Class A areas (BMSP/EU), as per List of Extraction Areas of the BMSP, except when the products have been extracted and processed in the Magallanes Region.

If the resources come from an area other than a BMSP area, the company interested in their

[1] For seaweeds, the n to be sampled is equal to 5 for every 50 tons; for seaweeds by-products, the n to be sampled is per production key.
[2] The n to be sampled is equal to 5 for every 50 tons
[3] This requirement applies only to dry seaweeds.
[4] This requirement does not apply to seaweeds by-products.

export must manifest its intent to SERNAPESCA in advance, so as to arrange a special sampling program in the extraction area, which must be conducted before the export. This monitoring will consist of 2 samples per day for 3 consecutive days (6 samples in total).

b. *Vibrio parahaemolyticus* control in processed resources

To authorize shipments of live or fresh bivalve mollusks, echinoderms, tunicates, and gastropods, these must comply with the requirements outlined in the Quality Assurance Program, or conduct the analyses of the end product according to the sampling plans described in Item 1 of this Chapter.

1.1.20.2. MARINE TOXINS CONTROL

Whenever a batch undergoes biotoxins analyses conducted by the Health Services, these will be considered as part of the analyses required by SERNAPESCA and will be subtracted from the number of samples to collect described in each sampling plan. If the number of analyses issued by the Health Services is equal to or greater than the number of samples required by SERNAPESCA, it will not be necessary to collect any additional samples.

For determinations of biotoxins, the samples will be extracted per batch to be exported, applying the table according to the total net weight. Canned products are excluded from this measure, in whose case the sampling tables will be applied according to the total drained weight of the product.

The Simple Sworn Declaration (Part III, Annexes, Chapter II), must be presented to process the AOSC, SMAE or NEPPEX for products affected by marine toxins.

a. Authorization for Shipment Notifications of live and chilled-refrigerated resources
Only those Shipment Notifications for resources susceptible of being affected by marine toxins, fresh or live, may be authorized, when these come from areas not affected by red tides, otherwise, these resources must come from Class A areas (BMSP/EU), as per the List of Extraction Areas of the BMSP, which must be accredited through a Simple Sworn Declaration (Part III, Annexes, Chapter II). In this case biotoxicological analyses will not be required. Susceptible products are defined as: bivalve mollusks, tunicates, and gastropods.

b. Authorization for Echinoderms Shipment Notifications
Samplings or biotoxins analyses will not be required to obtain the authorization for the Shipment Notification of sea urchins and sea cucumbers, regardless of their presentation. Their origin must only be accredited when the product is destined to the European Union, for which an AOSC must be presented.

c. Authorization for Shipment Notifications of abalones from the BMSP areas
To obtain the authorization for the Shipment Notification of abalones from areas that are part of the Bivalve Mollusks Sanitation Program, their origin must be accredited through a Simple Sworn Declaration (Part III, Annexes, Chapter II). Samplings or biotoxins analyses will not be required, regardless of the region of origin.

d. Authorization for Shipment Notifications under the Quality Assurance Program

The Notification of Shipment for products manufactured in establishments with a valid QAP will be authorized with the sole presentation of the AOSC for the corresponding batch, except when the raw material comes from natural banks of the X region, in whose case the PSP analysis must be conducted for each batch to be exported, as described in the item for resources coming from the II, IV and X regions.

When the interested party requests the Notification of Shipment in the port of exit, it must present the following original documents:

- Notification of Shipment of Export Fishery Products.
- Authorization at Origin for Sanitary Certification (AOSC).

e. Authorization for Shipment Notifications under the End Product Control

For those products that are not manufactured under the Quality Assurance of Program, the following will apply:

1. Processed Resources from the Magallanes Region

To obtain the authorization for the Notification of Shipment, those products coming from the Magallanes Region will require a biotoxins analysis, as outlined in the Item for resources from the XII region.

When the interested party requests the Notification of Shipment in the port of exit, it must present the following original documents:

- Notification of Shipment of Export Fishery Products.
- Sampling and Analysis Request for Export.
- The corresponding Analysis Report.
- Results from the Health Laboratory, when these are used to support authorizations for notifications and/or Sanitary Certifications.

2. Processed Resources from the Region of Aysén del General Carlos Ibáñez del Campo

To obtain the authorization for the Notification of Shipment, those products coming from this region will require a biotoxins analysis, as set forth in the Item for resources from the XI region.

To process the Sampling Request for products affected by marine toxins coming from the Region of Aysén, SERNAPESCA will require the presentation of the Resolution from the Sanitary Authority of the Region of Aysén, which authorizes them for human consumption, which is always supported by laboratory analyses. If the product corresponds to raw material that will be processed in another Region, the resolution authorizing only the transportation of the raw material must be presented, in whose case it is the responsibility of the Sanitary Authority of the region of destination to authorize the products for end consumption.

When the interested party requests the Notification of Shipment in the port of exit, it must present the following original documents:

- Notification of Shipment of Export Fishery Products.
- Sampling and Analysis Request for Export.
- The corresponding Analysis Report.
- Results from the Health Laboratory, when these are used to support authorizations for notifications and/or Sanitary Certifications.

3. Processed Resources from the Regions of Atacama, Coquimbo and Los Lagos.

To obtain the authorization for the Notification of Shipment of products produced with

resources coming from the previously mentioned regions, DPM, PSP and ASP analyses will be required, as appropriate, which must be conducted according to the sampling plans, and as set forth in the Item for resources coming from the III, IV and X regions.

When the interested party requests the Notification of Shipment in the port of exit, it must present the following original documents:

- Notification of Shipment of Export Fishery Products.
- Sampling and Analysis Request for Export.
- The corresponding analysis report.
- Results from the Health Laboratory, when these are used to support authorizations for notifications and/or Sanitary Certifications.

4. Processed Resources from the Regions of Arica y Parinacota, Tarapacá, Antofagasta, Valparaíso, del Libertador Bernardo O'Higgins, del Maule, del Bío-Bío, La Araucanía, and Los Ríos.

The Notification of Shipment will be authorized with the sole presentation of a Sworn Declaration accrediting the origin of the product (Part III, Annexes, Chapter II).

When the interested party requests the Notification of Shipment in the port of exit, it must present the following original documents:

- Notification of Shipment of Export Fishery Products.
- Sworn Declaration of Origin.

1.1.20.3. NOROVIRUS CONTROL IN RAW OYSTERS

Notification of Shipments for raw oysters (live, fresh or frozen) will be authorized only if they come from an area that is part of the Bivalve Mollusks Sanitation Program, with an A category and that guarantees the absence of Norovirus in the lots to be exported, through samplings that consider n=3 per each extraction origin and week of production.

1.1.21. SPECIFIC REQUIREMENTS FOR MARINE TOXINS FOR OBTAINING THE SANITARY CERTIFICATION FOR BIVALVE MOLLUSKS, TUNICATES, ECHINODERMS AND GASTROPODS

The sampling plans established for the control of toxins must be applied separately for each one of the origins that comprise the export batch, also based, on the amount of product for each one of the origins declared in the corresponding SMAE.

If there are two types of product for the same origin, the number of samples of this subgroup will be determined taking into account the sampling plan of the product with the greatest risk. For example:

Table: *Composition of the Export Batch*

Type of Product	Origin	Quantity (kilograms)	Reference to the Sampling Plan of this Chapter	Number of Samples	Toxin
High-Risk Resource	Natural bank - Non BMSP X region	13,000	1.1.21.5 g)	25 25 25	PSP DMP ASP

High-Risk Resource	Farm - BMSP X region	860	1.1.21.5 e)	15 25 15	PSP DMP ASP
Low-Risk Resource	XII region	12,500	1.1.21.3 b)	15	PSP

If subtoxic results are detected, the second stage of the sample will be applied only to the part of the batch that showed positive results.

1.1.21.1. EQUINODERMS

Sea urchins and sea cucumbers, regardless of their origin and presentation, will not require samplings and biotoxins analyses to obtain the sanitary certification.

1.1.21.2. ABALONES FROM BMSP AREAS

Abalones that are extracted or harvested from extraction areas that are part of the Bivalve Mollusks Sanitation Program will not require samplings and biotoxins analyses to obtain the sanitary certification.

1.1.21.3. RESOURCES IN ALL THEIR PRESENTATIONS FROM THE REGION OF MAGALLANES

a. Live or Chilled-Refrigerated Resources

Only those chilled-cooled or live resources coming from Class A areas (BMSP/EU) may be certified, according to the List of Extraction Areas of the BMSP. In this case, biotoxicological analyses will not be required.

b. Low-risk Resources: Gastropods and Southern Scallops

- Paralytic Shellfish Poison (PSP)

Table: *Sampling Plan: DOUBLE, 1st Stage:*

Size of the export batch (Ton. net)	n
< 1	5
1 – 10	10
> 10	15

- If all results show that the product is free of PSP, the product will be certified without continuing with the second stage of the sampling.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have PSP levels between 30 and 80μg/100g of meat, the second part of the sampling will take place.

Table: *2nd Stage*

Size of the export batch (Ton. net)	n
< 1	10

1 – 10	20
> 10	30

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat, the product will be certified.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

c. Higher-Risk Resources

- Paralytic Shellfish Poison (PSP)

Table :*Sampling Plan: DOUBLE, 1st Stage:*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	15
> 10	25

- If all results show that the product is free of PSP, the product will be certified without continuing with the second stage of the sampling.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have PSP levels between 30 and 80μg/100g of meat, the second part of the sampling will take place.

Table: *2nd Stage:*

Size of the export batch (Ton. net)	n
< 1	20
1 – 10	30
> 10	50

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat, the product will be certified.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- The SERNAPESCA office of the Magallanes region will also require the prior compliance with the requirements set forth by the Health Service, as appropriate.

1.1.21.4. RESOURCES IN ALL THEIR PRESENTATIONS FROM THE REGION OF AYSÉN

a. Chilled-refrigerated or live resources

Only those chilled-cooled or live resources coming from Class A areas (BMSP/EU) may be certified, according to the List of Extraction Areas of the BMSP. In this case, biotoxicological analyses will not be required.

b. Low-risk Resources: Gastropods and Southern Scallops

- Paralytic Shellfish Poison (PSP)

Table: *Sampling Plan: DOUBLE, 1st Stage:*

Size of the export batch (Ton. net)	n
< 1	5
1 – 10	10
> 10	15

- If all results show that the product is free of PSP, the product will be certified without continuing with the second stage of the sampling.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have PSP levels between 30 and 80μg/100g of meat, the second part of the sampling will take place.

Table: *2nd Stage:*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	20
> 10	30

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat, the product will be certified.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

c. Higher-Risk Resources

- Paralytic Shellfish Poison (PSP)

Table: *Sampling Plan: DOUBLE, 1st Stage:*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	15
> 10	25

- If all results show that the product is free of PSP, the product will be certified without continuing with the second stage of the sampling.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be

provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

- If 1 or more samples are detected to have PSP levels between 30 and 80µg/100g of meat, the second part of the sampling will take place.

Table: *2nd Stage:*

Size of the export batch (net ton.)	n
< 1	20
1 – 10	30
> 10	50

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80µg/100g of meat, the product will be certified.
- If one or more results exceed 80µg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

- Diarrhetic Mollusk Poison (DMP)
  - Bioassay analysis technique:

Table: *Sampling Plan:* *SIMPLE (c = 0)*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	15
> 10	25

  - Liquid Chromatography with Mass Detector in Tandem (LC-MS/MS) Analysis Technique:

Table: *Sampling Plan:* *DOUBLE, 1st Stage*

Size of the export batch (net ton.)	n
< 1	10
1 – 10	15
> 10	25

- If all results show that the product is free of any of the lipophilic toxins (lower than the Detection Limit informed by the laboratory), the Notification of Shipment will be authorized without continuing to the second stage of the sampling.
- If one or more results exceed the maximum regulatory limits described as follows, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results:
  - Okadaic acid (OA), dinophysistoxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2) which together account for more than 160µg equivalent of okadaic acid/kg of meat (entire body or any edible part separately).
  - Yessotoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX) greater than 3.75 mg

equivalent of yessotoxin/kg of meat (entire body or any edible part separately).
  - Azaspiracids (AZA1, AZA2, and AZA3) greater than 160μg equivalent of azaspiracid/kg of meat (entire body or any edible part separately).
- If 1 or more samples are detected with levels of any of the aforementioned lipophilic toxins in a range that exceeds the Detection Limit (as informed in Section IV, Chapter II, Item 3) to the corresponding maximum regulatory limit, the second part of the sampling will take place. In the specific case of yessotoxins, if one or more samples are detected with levels between 1.9 and 3.75ppm, the second part of the sampling stage continues.

Table: *2nd Stage*

Size of the export batch (Ton. net)	n
< 1	20
1 – 10	30
> 10	50

- If all the results obtained from the samples analyzed in the 1st stage, and those obtained in the 2nd stage, are ≤ to the corresponding regulatory maximum limit of any of the lipophilic toxins, the Notification of Shipment will be authorized.
- If one or more results exceed the maximum regulatory limits described as follows, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results:
  - Okadaic acid (OA), dinophysistoxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2) which together account for more than 160μg equivalent of okadaic acid/kg of meat (entire body or any edible part separately).
  - Yessotoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX) greater than 3.75 mg equivalent of yessotoxin/kg of meat (entire body or any edible part separately).
  - Azaspiracids (AZA1, AZA2, and AZA3) greater than 160μg equivalent of azaspiracid/kg of meat (entire body or any edible part separately).

The Sanitary Certification will be issued if all the requested documentation is presented, and:
- If all the results for PSP obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat.
- In the case of DMP:
  - With bioassay analysis technique: Absence
  - With the LC-MS/MS analysis technique: If all the results obtained from the samples analyzed in the 1st stage, and those obtained in the 2nd stage, are ≤ at the corresponding regulatory maximum limit of any of the lipophilic toxins.
- If all the results for ASP obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 20μg/g of meat.

1.1.21.5. RESOURCES IN ALL PRESENTATIONS FROM THE REGIONS OF ATACAMA, COQUIMBO AND LOS LAGOS

a. Live or Chilled-Refrigerated Resources

Only those chilled-cooled or live resources coming from Class A areas (BMSP/EU) may be certified, according to the List of Extraction Areas of the BMSP. In this case, biotoxicological analyses will not be required.

b. Specific resources (Chilean abalones and processed abalones)

A PSP and ASP analysis with a double sampling and a fixed number of samples will be required for the Sanitary Certification of Chilean abalones and processed abalones, regardless of the size of the export batch.

Table: *1st Stage:*

Number of Units per Sample	n
4	3

- If all results show that the product is free of PSP and ASP, the product will be certified without continuing to the second stage of the sampling.
- If one or more results for PSP exceed 80μg/100g of meat and 20ppm for ASP, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have PSP levels between 30 and 80μg/100g of meat, and 0.5 and 20 ppm for ASP, the second part of the sampling will take place.

Table:*2nd Stage:*

Number of Units per Sample	n
4	6

- If all samples have levels of ≤ 80μg/100g of meat for PSP and ≤ 20μg/g for ASP, the product will be certified.
- If one or more results for PSP exceed 80μg/100g of meat and 20μg/g, for ASP, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

c. Processed Baby Clam from Areas that are Part of the BMSP

A PSP, BMP and ASP analysis will be required for the issuance of the sanitary certification of baby clams coming from natural banks that are part of the BMSP. A PSP and ASP analysis with a double sampling and a fixed number of samples will be required, regardless of the size of the export batch. For BMP, a simple sampling and a fixed number of samples will be applied, regardless of the size of the export batch.

- Paralytic Shellfish Poison (PSP) and Amnesic Shellfish Poison (ASP)

Table: *Sampling Plan:DOUBLE, 1st Stage:*

N
5

- If all results show that the product is free of PSP and ASP, the Notification of Shipment will be authorized without continuing to the second stage of the sampling.
- If one or more results for PSP exceed 80μg/100g of meat and 20 μg/g for ASP, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have PSP levels between 30 and 80μg/100g of meat, and 0.5 and 20μg/g for ASP, the second part of the sampling will take place.

Table: *Sampling Plan: DOUBLE, 2nd Stage*

n
10

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat for PSP and ≤ 20μg/g for ASP, the Notification of Shipment will be authorized.
- If one or more results for PSP exceed 80μg/100g f meat and 20μg/g, for ASP, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

- Diarrhetic Mollusk Poison (DMP)
    - Bioassay analysis technique:

Table: *Sampling Plan: SIMPLE*

N
5

    - Liquid Chromatography with Mass Detector in Tandem (LC-MS/MS) Analysis Technique:

Table: *Sampling Plan: DOUBLE, 1st Stage*

N
5

- If all results show that the product is free of any of the lipophilic toxins (lower than the Detection Limit informed by the laboratory), the Notification of Shipment will be authorized without continuing to the second stage of the sampling.
- If one or more results exceed the maximum regulatory limits described as follows, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results:
    - Okadaic acid (OA), dinophysistoxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2) which together account for more than 160μg equivalent of okadaic acid/kg of meat (entire body or any edible part separately).
    - Yessotoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX) greater than 3.75 mg equivalent of yessotoxin/kg of meat (entire body or any edible part separately).
    - Azaspiracids (AZA1, AZA2, and AZA3) greater than 160μg equivalent of azaspiracid/kg of meat (entire body or any edible part separately).
- If 1 or more samples are detected with levels of any of the aforementioned lipophilic toxins in a range that exceeds the Detection Limit (as informed in Section IV, Chapter II, Item 3) to the corresponding maximum regulatory limit, the second part of the sampling will take place. In the specific case of yessotoxins, if one or more samples are detected with levels between 1.9 and 3.75 ppm, the second part of the sampling stage continues.

Table: *Sampling Plan: DOUBLE, 2nd Stage*

N
10

- If all the results obtained from the samples analyzed in the 1st stage, and those obtained in the 2nd stage, are ≤ to the corresponding regulatory maximum limit of any of the lipophilic toxins, the Notification of Shipment will be authorized.
- If one or more results exceed the maximum regulatory limits described as follows, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results:
    - Okadaic acid (OA), dinophysistoxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2) which together account for more than 160μg equivalent of okadaic acid/kg of meat (entire body or any edible part separately).
    - Yessotoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX) greater than 3.75 mg equivalent of yessotoxin/kg of meat (entire body or any edible part separately).
    - Azaspiracids (AZA1, AZA2, and AZA3) greater than 160μg equivalent of azaspiracid/kg of meat (entire body or any edible part separately).

The Sanitary Certification will be issued if all the requested documentation is presented, and:
- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat.
- In the case of DMP:
    - With bioassay analysis technique: Absence
    - With the LC-MS/MS analysis technique: If all the results obtained from the samples Analyzed in the 1st stage, and those obtained in the 2nd stage, are ≤ at the corresponding regulatory maximum limit
      Of any of the lipophilic toxins.
- If all the results for ASP obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 20μg/g of meat.

d. Low-risk Processed Resources (Gastropods and Southern Scallops) from areas that are part of the BMSP

Processed low-risk resources (except for Chilean abalones and abalones) that come from extraction areas that are part of the BMSP, will require a PSP and ASP analysis in the end product, according to the following sampling plans:

- Paralytic Shellfish Poison (PSP)

Table: *Sampling Plan: DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	3
1 – 10	6
> 10	9

- If all results show that the product is free of PSP, the product will be certified without continuing with the second stage of the sampling.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

- If 1 or more samples are detected to have PSP levels between 30 and 80μg/100g of meat, the second part of the sampling will take place.

Table: *Sampling Plan: DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	6
1 – 10	12
> 10	18

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat, the product will be certified.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

- Amnesic Shellfish Poison (ASP):

Table: *Sampling Plan: DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	3
1 – 10	6
> 10	9

- If all results show that the product is free of ASP, the product will be certified without continuing to the second stage of the sampling.
- If one or more results exceed 20μg/g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have ASP levels between 0.5 and 20μg/g of meat, the second part of the sampling will take place.

Table: *Sampling Plan:DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	6
1 – 10	12
> 10	18

- If one or more results exceed 20μg/g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

The Sanitary Certification will be issued if all the requested documentation is presented, and:
- If all the results for PSP obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat.
- If all the results for ASP obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 20μg/g of meat.

e. Other Processed Resources from Areas that are Part of the BMSP

Other resources from extraction areas that are part of the BMSP EU, included in the List of Extraction Areas of the BMSP will require a biotoxins analysis in the end product, according to the following sampling plan.

- Paralytic Shellfish Poison (PSP)

Table: *Sampling Plan: DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	5
1 – 10	10
> 10	15

- If all results show that the product is free of PSP, the product will be certified without continuing with the second stage of the sampling.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have PSP levels between 30 and 80μg/100g of meat, the second part of the sampling will take place.

Table: *Sampling Plan: DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	20
> 10	30

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat, the product will be certified.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

- Diarrhetic Mollusk Poison (DMP)
    - Bioassay analysis technique:

Table: *Sampling Plan: SIMPLE (c = 0)*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	15
> 10	25

    - Liquid Chromatography with Mass Detector in Tandem (LC-MS/MS) Analysis Technique:

Table: *Sampling Plan: DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	5
1 – 10	10

> 10	15

- If all results show that the product is free of any of the lipophilic toxins (lower than the Detection Limit informed by the laboratory), the Notification of Shipment will be authorized without continuing to the second stage of the sampling.
- If one or more results exceed the maximum regulatory limits described as follows, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results:
    - Okadaic acid (OA), dinophysistoxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2) which together account for more than 160μg equivalent of okadaic acid/kg of meat (entire body or any edible part separately).
    - Yessotoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX) greater than 3.75 mg equivalent of yessotoxin/kg of meat (entire body or any edible part separately).
    - Azaspiracids (AZA1, AZA2, and AZA3) greater than 160μg equivalent of azaspiracid/kg of meat (entire body or any edible part separately).
- If 1 or more samples are detected with levels of any of the aforementioned lipophilic toxins in a range that exceeds the Detection Limit (as informed in Section IV, Chapter II, Item 3) to the corresponding maximum regulatory limit, the second part of the sampling will take place. In the specific case of yessotoxins, if one or more samples are detected with levels between 1.9 and 3.75ppm, the second part of the sampling stage continues.

Table: *Sampling Plan: DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	20
> 10	30

- If all the results obtained from the samples analyzed in the 1st stage, and those obtained in the 2nd stage, are ≤ to the corresponding regulatory maximum limit of any of the lipophilic toxins, the Notification of Shipment will be authorized.
- If one or more results exceed the maximum regulatory limits described as follows, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results:
    - Okadaic acid (OA), dinophysistoxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2) which together account for more than 160μg equivalent of okadaic acid/kg of meat (entire body or any edible part separately).
    - Yessotoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX) greater than 3.75 mg equivalent of yessotoxin/kg of meat (entire body or any edible part separately).
    - Azaspiracids (AZA1, AZA2, and AZA3) greater than 160μg equivalent of azaspiracid/kg of meat (entire body or any edible part separately).

- Amnesic Shellfish Poison (ASP):

Table: *Sampling Plan: DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	5
1 – 10	10
> 10	15

- If all results show that the product is free of ASP, the product will be certified without

continuing to the second stage of the sampling.
- If one or more results exceed 20μg/g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have ASP levels between 0.5 and 20μg/g of meat, the second part of the sampling will take place.

Table: *Sampling Plan:DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	20
> 10	30

- If one or more results exceed 20μg/g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

The Sanitary Certification will be issued if all the requested documentation is presented, and:
- If all the results for PSP obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat.
- In the case of DMP:
  - With bioassay analysis technique: Absence
  - With the LC-MS/MS analysis technique: If all the results obtained from the samples analyzed in the 1st stage, and those obtained in the 2nd stage, are ≤ at the corresponding regulatory maximum limit of any of the lipophilic toxins.
- If all the results for ASP obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 20μg/g of meat.

f. Low-Risk Processed Resources (Gastropods and Southern Scallops) from Areas that are Not Part of the BMSP

Processed low-risk resources (except for Chilean abalones and abalones) that come from extraction areas that are not part of the BMSP will require a PSP and ASP analysis in the end product, according to the following sampling plans.

- Paralytic Shellfish Poison (PSP)

Table: *Sampling Plan:DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	5
1 – 10	10
> 10	15

- If all results show that the product is free of PSP, the product will be certified without continuing to the second stage of the sampling.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

- If 1 or more samples are detected to have PSP levels between 30 and 80μg/100g of meat, the second part of the sampling will take place.

Table: *Sampling Plan:DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	20
> 10	30

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat, the product will be certified.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

- Amnesic Shellfish Poison (ASP):

Table 91
Sampling Plan: DOUBLE, 1st Stage

Size of the export batch (Ton. net)	n
< 1	5
1 – 10	10
> 10	15

- If all results show that the product is free of ASP, the product will be certified without continuing to the second stage of the sampling.
- If one or more results exceed 20μg/g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have ASP levels between 0.5 and 20μg/g of meat, the second part of the sampling will take place.

Table: *Sampling Plan:DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	20
> 10	30

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 20μg/g of meat, the product will be certified.
- If one or more results exceed 20μg/g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

g. Higher-Risk Processed Resources from Areas that are Not Part of the BMSP

Processed higher-risk resources that come from extraction areas that not are part of the BMSP, will require a biotoxins analysis in the end product, according to the following sampling plans:

- Paralytic Shellfish Poison (PSP)

Table: *Sampling Plan: DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	15
> 10	25

- If all results show that the product is free of PSP, the product will be certified without continuing with the second stage of the sampling.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have PSP levels between 30 and 80μg/100g of meat, the second part of the sampling will take place.

Table: *Sampling Plan: DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	20
1 – 10	30
> 10	50

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat, the product will be certified.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

- Diarrhetic Mollusk Poison (DMP)
    - Bioassay analysis technique:

Table: *Sampling Plan:SIMPLE (c = 0)*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	15
> 10	25

    - Liquid Chromatography with Mass Detector in Tandem (LC-MS/MS) Analysis Technique:

Table: *Sampling Plan: DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	5
1 – 10	10
> 10	15

- If all results show that the product is free of any of the lipophilic toxins (lower than the Detection Limit informed by the laboratory), the Notification of Shipment will be authorized without continuing to the second stage of the sampling.
- If one or more results exceed the maximum regulatory limits described as follows, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results:
    - Okadaic acid (OA), dinophysistoxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2) which together account for more than 160µg equivalent of okadaic acid/kg of meat (entire body or any edible part separately).
    - Yessotoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX) greater than 3.75 mg equivalent of yessotoxin/kg of meat (entire body or any edible part separately).
    - Azaspiracids (AZA1, AZA2, and AZA3) greater than 160µg equivalent of azaspiracid/kg of meat (entire body or any edible part separately).
- If 1 or more samples are detected with levels of any of the aforementioned lipophilic toxins in a range that exceeds the Detection Limit (as informed in Section IV, Chapter II, Item 3) to the corresponding maximum regulatory limit, the second part of the sampling will take place. In the specific case of yessotoxins, if one or more samples are detected with levels between 1.9 and 3.75ppm, the second part of the sampling stage continues.

Table: *Sampling Plan:DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	20
> 10	30

- If all the results obtained from the samples analyzed in the 1st stage, and those obtained in the 2nd stage, are ≤ to the corresponding regulatory maximum limit of any of the lipophilic toxins, the Notification of Shipment will be authorized.
- If one or more results exceed the maximum regulatory limits described as follows, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results:
    - Okadaic acid (OA), dinophysistoxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2) which together account for more than 160µg equivalent of okadaic acid/kg of meat (entire body or any edible part separately).
    - Yessotoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX) greater than 3.75 mg equivalent of yessotoxin/kg of meat (entire body or any edible part separately).
    - Azaspiracids (AZA1, AZA2, and AZA3) greater than 160µg equivalent of azaspiracid/kg of meat (entire body or any edible part separately).

- Amnesic Shellfish Poison (ASP):

Table: *Sampling Plan: DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	15
> 10	25

- If all results show that the product is free of ASP, the product will be certified without

continuing to the second stage of the sampling.
- If one or more results exceed 20μg/g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have ASP levels between 0.5 and 20μg/g of meat, the second part of the sampling will take place.

Table :*Sampling Plan:DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	20
1 – 10	30
> 10	50

- If one or more results exceed 20μg/g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

The Sanitary Certification will be issued if all the requested documentation is presented, and:
- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat.
- In the case of DMP:
  - With bioassay analysis technique: Absence
  - With the LC-MS/MS analysis technique: If all the results obtained from the samples analyzed in the 1st stage, and those obtained in the 2nd stage, are ≤ at the corresponding regulatory maximum limit of any of the lipophilic toxins.
- If all the results for ASP obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 20μg/g of meat.

1.1.21.6. PROCESSED RESOURCES FROM THE REGIONS OF ARICA Y PARINACOTA, TARAPACÁ, ANTOFAGASTA, VALPARAÍSO, O'HIGGINS, MAULE, BÍO-BÍO, ARAUCANÍA AND LOS RÍOS

a. Live or Chilled-Refrigerated Resources

The certification for chilled-refrigerated or live resources will be issued if:
- The resources come from Type A areas (BMSP/EU) the according to the List of Extraction Areas of the BMSP or
- A marine toxins weekly sampling is conducted (PSP, BMP, and ASP) per origin when receiving the raw material in the plant.

In both cases, biotoxicological analyses will not be required for certification.

b. Specific Resources (Chilean Abalones and Processed Abalones)

Only a PSP analysis with a double sampling plan and a fixed number of samples will be required for the Sanitary Certification of Chilean abalones and processed abalones, regardless of the size of the export batch.

Table:*1st Stage:*

Number of Units per Sample	n
4	3

- If all results show that the product is free of PSP, the product will be certified without continuing to the second stage of the sampling.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have PSP levels between 30 and 80μg/100g of meat, the second part of the sampling will take place.

Table:*2nd Stage:*

Number of Units per Sample	n
4	6

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat, the product will be certified.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

c. Resources from Farms that are Part of the BMSP

Resources from farms that are part of the BMSP EU, included in the List of Extraction Areas of the BMSP will require a biotoxins analysis in the end product, according to the following sampling plan.

- Paralytic Shellfish Poison (PSP)

Table:*Sampling Plan: DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	3
1 – 10	6
> 10	9

- If all results show that the product is free of PSP, the product will be certified without continuing with the second stage of the sampling.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have PSP levels between 30 and 80μg/100g of meat, the second part of the sampling will take place.

Table: *Sampling Plan:DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	6
1 – 10	12

> 10	18

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80µg/100g of meat, the product will be certified.
- If one or more results exceed 80µg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

- Diarrhetic Mollusk Poison (DMP) (except gastropods)
  - Bioassay analysis technique

Table: *Sampling Plan:SIMPLE (c = 0)*

Size of the export batch (Ton. net)	n
< 1	3
1 – 10	6
> 10	9

  - Liquid Chromatography with Mass Detector in Tandem (LC-MS/MS) Analysis Technique:

Table: *Sampling Plan:DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	3
1 – 10	6
> 10	9

- If all results show that the product is free of any of the lipophilic toxins (lower than the Detection Limit informed by the laboratory), the Notification of Shipment will be authorized without continuing to the second stage of the sampling.
- If one or more results exceed the maximum regulatory limits described as follows, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results:
  - Okadaic acid (OA), dinophysistoxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2) which together account for more than 160µg equivalent of okadaic acid/kg of meat (entire body or any edible part separately).
  - Yessotoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX) greater than 3.75 mg equivalent of yessotoxin/kg of meat (entire body or any edible part separately).
  - Azaspiracids (AZA1, AZA2, and AZA3) greater than 160µg equivalent of azaspiracid/kg of meat (entire body or any edible part separately).
- If 1 or more samples are detected with levels of any of the aforementioned lipophilic toxins in a range that exceeds the Detection Limit (as informed in Section IV, Chapter II, Item 3) to the corresponding maximum regulatory limit, the second part of the sampling will take place. In the specific case of yessotoxins, if one or more samples are detected with levels between 1.9 and 3.75 ppm, the second part of the sampling stage continues.

Table: *Sampling Plan:DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	6
1 – 10	12

> 10	18

- If all the results obtained from the samples analyzed in the 1st stage, and those obtained in the 2nd stage, are ≤ to the corresponding regulatory maximum limit of any of the lipophilic toxins, the Notification of Shipment will be authorized.
- If one or more results exceed the maximum regulatory limits described as follows, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results:
    - Okadaic acid (OA), dinophysistoxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2) which together account for more than 160μg equivalent of okadaic acid/kg of meat (entire body or any edible part separately).
    - Yessotoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX) greater than 3.75 mg equivalent of yessotoxin/kg of meat (entire body or any edible part separately).
    - Azaspiracids (AZA1, AZA2, and AZA3) greater than 160μg equivalent of azaspiracid/kg of meat (entire body or any edible part separately).

The Sanitary Certification will be issued if all the requested documentation is presented, and:
- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat.
- In the case of DMP:
    - With bioassay analysis technique: Absence
    - With the LC-MS/MS analysis technique: If all the results obtained from the samples analyzed in the 1st stage, and those obtained in the 2nd stage, are ≤ at the corresponding regulatory maximum limit of any of the lipophilic toxins.

d. Bivalve Mollusks from other Areas

- Paralytic Shellfish Poison (PSP)

Table 107
Sampling Plan: DOUBLE, 1st Stage

Size of the export batch (Ton. net)	n
< 1	5
1 – 10	10
> 10	15

- If all results show that the product is free of PSP, the product will be certified without continuing to the second stage of the sampling.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have PSP levels between 30 and 80μg/100g of meat, the second part of the sampling will take place.

Table: *Sampling Plan:DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	20
> 10	30

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80μg/100g of meat, the product will be certified.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

- Diarrhetic Mollusk Poison (DMP)
    - Bioassay analysis technique:

Table: *Sampling Plan:SIMPLE (c = 0)*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	15
> 10	25

    - Liquid Chromatography with Mass Detector in Tandem (LC-MS/MS) Analysis Technique:

Table: *Sampling Plan: DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	5
1 – 10	10
> 10	15

- If all results show that the product is free of any of the lipophilic toxins (lower than the Detection Limit informed by the laboratory), the Notification of Shipment will be authorized without continuing to the second stage of the sampling.
- If one or more results exceed the maximum regulatory limits described as follows, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results:
    - Okadaic acid (OA), dinophysistoxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2) which together account for more than 160μg equivalent of okadaic acid/kg of meat (entire body or any edible part separately).
    - Yessotoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX) greater than 3.75 mg equivalent of yessotoxin/kg of meat (entire body or any edible part separately).
    - Azaspiracids (AZA1, AZA2, and AZA3) greater than 160μg equivalent of azaspiracid/kg of meat (entire body or any edible part separately).
- If 1 or more samples are detected with levels of any of the aforementioned lipophilic toxins in a range that exceeds the Detection Limit (as informed in Section IV, Chapter II, Item 3) to the corresponding maximum regulatory limit, the second part of the sampling will take place. In the specific case of yessotoxins, if one or more samples are detected with levels between 1.9 and 3.75ppm, the second part of the sampling stage continues.

Table: *Sampling Plan:DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	10
1 – 10	20
> 10	30

- If all the results obtained from the samples analyzed in the 1st stage, and those obtained in the 2nd stage, are ≤ to the corresponding regulatory maximum limit of any of the lipophilic toxins, the Notification of Shipment will be authorized.
- If one or more results exceed the maximum regulatory limits described as follows, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results:
    - Okadaic acid (OA), dinophysistoxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2) which together account for more than 160µg equivalent of okadaic acid/kg of meat (entire body or any edible part separately).
    - Yessotoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX) greater than 3.75 mg equivalent of yessotoxin/kg of meat (entire body or any edible part separately).
    - Azaspiracids (AZA1, AZA2, and AZA3) greater than 160µg equivalent of azaspiracid/kg of meat (entire body or any edible part separately).

The Sanitary Certification will be issued if all the requested documentation is presented, and:
- If all the results for PSP obtained from the samples analyzed in the 1st stage, plus those obtained in the 2nd stage, are ≤ to 80µg/100g of meat.
- In the case of DMP:
    - With bioassay analysis technique: Absence
    - With the LC-MS/MS analysis technique: If all the results obtained from the samples analyzed in the 1st stage, and those obtained in the 2nd stage, are ≤ at the corresponding regulatory maximum limit of any of the lipophilic toxins.

e. Gastropods and Low-Risk Resources from Other Areas

- Paralytic Shellfish Poison (PSP)

Table: *Sampling Plan:DOUBLE, 1st Stage*

Size of the export batch (Ton. net)	n
< 1	3
1 – 10	6
> 10	9

- If all results show that the product is free of PSP, the product will be certified without continuing with the second stage of the sampling.
- If one or more results exceed 80µg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.
- If 1 or more samples are detected to have PSP levels between 30 and 80µg/100g of meat, the second part of the sampling will take place.

Table: *Sampling Plan: DOUBLE, 2nd Stage*

Size of the export batch (Ton. net)	n
< 1	6
1 – 10	12
> 10	18

- If all the results obtained from the samples analyzed in the 1st stage, plus those obtained in

the 2nd stage, are ≤ to 80μg/100g of meat, the product will be certified.
- If one or more results exceed 80μg/100g of meat, the Sanitary Certification will not be provided, and the situation will be immediately informed to the corresponding Health Service and to the National Directorate of SERNAPESCA, attaching a photocopy of the results.

1.1.21.7. GENERAL CONSIDERATIONS

- Samples will be extracted per batch to be exported, applying the table according to the total net weight.
- Whenever a batch undergoes biotoxins analyses conducted by the Health Services, these will be considered as part of the analyses required by SERNAPESCA and will be subtracted from the number of samples to collect described in each sampling plan.
- The procedures for the application of the sampling plans described in this Chapter can be found in Item 1.1.20.2.

1.2. PHARMACEUTICAL PRODUCTS RESIDUES SPECIFIC REQUIREMENTS FOR CERTIFYING FARMED FISH

In the case of farmed fish, the farm of origin of the species to be exported, must be part of the Residue Control Program of our Service and comply with the Maximum Residual Limits (MRL) based on the Sanitary Food Regulation of the Ministry of Health of Chile, as per the information provided in Section I, Chapter II, Item 3 of this Manual.

1.3. FISHERY PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

1.3.1. FISH MEAL

- Sampling Plans

The sampling plans to be applied are described in detail in Section IV, Chapter II, Item 2, according to the presentation of the meal (in 50 kg. sacks, 1-ton or in bulk), and based on when the sampling will take place (on-line sampling or during the packing).

Table: *Microbiological parameters*

Parameter	Limit
Salmonella spp	Absence in 25 g.
Aspergillus spp	Absence.

Table: *Physico-sensory parameters*

Parameter	Limit
Species	As declared.
Presentation	As declared (bulk, sack, powdered, pellets, etc.).
Color	Natural, typical.
Odor	Characteristic.
Dermestes spp	Absence.

1.3.2. CRUDE FISH OIL AND ITS BY-PRODUCTS

For Sanitary Certification, this product must be processed in establishments under the sanitary control of SERNAPESCA.

1.3.3. SEAWEEDS AND THEIR BY-PRODUCTS

Table: *Physical parameters*

Parameter	Limit	Size of the export batch (Ton. net)	Sampling Plan[1]		Number of Analyses
			n	c	
Moisture	≤ 20% on average[2]	1 – 50	5	0	5
Impurities	≤ 10% on average[3]	1 – 50	5	0	5

1.3.4. BAIT

Table: *Parasitological requirements for labeling and sampling plan*

Parameter	Limit	Sampling Plan*		Number of Analyses
		n	c	
Live or latent parasites	Absence	5	0	5
Labelling	Must indicate "Unfit for Human Consumption."	N.A.		N.A.

1.4. BY-PRODUCTS COMING FROM PROCESSING PLANTS WITH FISHERY PRODUCTS FIT FOR HUMAN CONSUMPTION

A "Sanitary certificate for fishery and aquaculture products intended for human consumption" may be issued for those shipments in which the exporter requests a Sanitary Certification; it is available in a pre-printed format and described in Item 5 of this Chapter. To issue the certificate above, the establishment from which the by-product comes from must be part of the List of Establishments under SERNAPESCA's Sanitary Control Programs. Also, the product must comply with the following standards for the certification:

1.4.1. FROZEN FISHERY BY-PRODUCTS

Table: *Sampling plans and microbiological determinations*

Parameters	Certification Standard	Sampling Plan
		n
Salmonella spp	Absence in 25 g	5

Table: *Sensory Examination*

Parameters	Certification Standard	Sampling

[1] The n to be sampled is equal to 5 for every 50 tons
[2] This requirement applies only to dry seaweeds.
[3] This requirement does not apply to seaweeds by-products.

		Plan	
		n	c
Species	Corresponds to the one declared by the exporter.	5	0
Presentation	Corresponds to the one declared by the exporter and it must include all the aspects described by it (example: bones, skin, type of cut, type of package, among others).		
Odor	Normal, characteristic of the species and the presentation. There are not any abnormal odors that could indicate decomposition or rancidity.		
Color	Natural, typical color of the species.		

1.4.2. DRY-SALTED FISHERY BY-PRODUCTS

Table: *Sampling plans and microbiological determinations*

Parameters	Certification Standard	Sampling Plan	
		n	c
Mold and Yeast	m = 100 M = 1000	5	0

Table: *Sensory examination*

Parameters	Certification Standard	Sampling Plan	
		n	c
Species	Corresponds to the one declared by the exporter.	5	0
Presentation	Corresponds to the one declared by the exporter and it must include all the aspects described by it (example: bones, skin, type of cut, type of package, among others).		
Appearance	Normal. Absence of foreign materials, halophile mold and burns due to excessive heating during drying.		
Odor	Characteristic, intense. Absence of objectionable persistent and unmistakable odors that are a sign of decomposition (acid, putrid odor, etc.) or of contamination with foreign materials (fuel, cleaning products, etc.).		
Color	Natural, typical and even. Absence of pink color, visible evidence of red halophile bacteria and reddish or greenish taints that affect the product.		
Texture	Typical, firm and tender. Absence of meat with texture characterized by a generalized cracking in more than two-thirds of the surface, torn or broken.		

Table: *Chemical parameters*

Parameters	Certification Standard	Sampling Plan
		n
Water Activity:	< 0.8 on average	5

2. COMPLEMENTARY STANDARDS AND OTHER SPECIFIC REQUIREMENTS ACCORDING TO THE DESTINATION MARKET

Below is the description of the specific complementary requirements for fishery and aquaculture products intended or not intended for human consumption that are subject to the verification of SERNAPESCA and required by markets for which the Official Sanitary Certification is mandatory.

For all those markets that are not considered in this document and for which the issuance of a sanitary certification is voluntarily requested, the instructions described in Item 1 of this Chapter will be required, as well as the conditions to be met by the different establishments stated in this Manual.

2.1. ARGENTINA

2.1.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products aimed for this market must be accompanied by the Sanitary Certificate for Argentina, Brazil, and Uruguay, available in PDF format at www.sernapesca.cl. The submission of the certificate is bound to the following requirements[1]:

- The establishment must be authorized to export to such market, in accordance with the requirements outlined in Section II, Chapter I, Item 2.1.
- To authorize a fish processing plant or factory ship to export to the Argentinian market, the establishment must be at least within the "B" category, as per the Infrastructure and Health Management Inspection Checklist for Export Fishery Products Plants Intended for Human Consumption or the Infrastructure and Health Management Inspection Checklist for Factory Ships, as appropriate.
- The establishment will only be able to export to Argentina, once the competent body in Argentina has officially communicated this Service, the incorporation of such company.
- Every time deficiencies that may affect the authorization of this company to enter that market are detected, the interested party and the Central Office must be informed immediately.
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP using an Authorization at Origin for Sanitary Certification (AOSC).
- The establishment must process a process monograph with SENASA for each product destined to this market, also attaching the corresponding conversion factor analyses.
- Live bivalve mollusks must be packaged only in establishments authorized to export to Argentina.
- Bivalve mollusks, echinoderms, tunicates, and gastropods, live or chilled-refrigerated, must comply with the sanitary requirements outlined in Item 1.1.20 of this Chapter.
- The following statement must be added for the export of live bivalve mollusks and gastropods:

  "Conforme a los resultados del Programa Sanitario Específico de Vigilancia de enfermedades de moluscos bivalvos, no existe evidencia de la presencia en Chile, de los

[1] Regardless of the official controls conducted by SERNAPESCA for the authorization of shipments or sanitary certification, manufacturers and exporters are responsible for complying with the standards set by such market, such as: Argentine Food Code; Technical Regulations of Mercosur; National Plan for Residue Control and Food Safety (PLAN CREHA).

agentes causales de las siguientes enfermedades: / In accordance with the results of the Specific Sanitary Program to Monitor Diseases that affect Bivalve Mollusks, there is no evidence of the presence of the causal agents of the following diseases in Chile:
  - *Bonamia exitiosa*
  - *Bonamia ostrae*
  - *Marteillia refringens*
  - *Perkinsus marinus*
  - *Perkinsus olseni*"

The clinical presence of *Mikrocytos mackini* disease has not been detected in Chile.

- The following must be added for live crustaceans intended for human consumption:
  "Las siguientes enfermedades de crustáceos son de notificación obligatoria y no se ha detectado la presencia clínica en Chile / The following diseases in crustaceans are of compulsory notification and their presence has not been detected in Chile:
    - White spot
    - Yellow head
    - Taura syndrome
    - Infectious myonecrosis
    - Infectious hypodermic and haematopoeitic necrosis."

- The Sanitary Certificate requires the signature of a Dr. of Veterinary Medicine.
- The product must comply with the sanitary requirements set by this Service in Item 1 of this Chapter, in accordance with the presentation of the product. In addition, the following microbiological analyses must be conducted according to the following Table:

Table: *Microbiological analyses*

Product	Parameter	Maximum Level
Fishery products in general	*Listeria*	Absence in 25 g
	Escherichia coli	Less than the DL of the technique [1]

- Perform the analysis of Cadmium, Mercury, Lead and Arsenic, according to the following process:
  - Sampling Plan: n = 10 by production date
  - Number of analyses: Sample units must be mixed to create a composite, from which 1 determination must be made.
- In accordance with the National Plan for Residue Control and Food Safety (CREHA PLAN), dated 02.05.13, Version I, the limits for heavy metals are as follows:

Table: *Cadmium*

Product		Maximum Level (mg/kg (ppm))
Fish	Fish in general	0.05
	Bonito, mojarra, eel, grey mullet, jack mackerel, emperor, mackerel, pilchard, tuna, wedge sole, lenguadillo (*Dicologlossa cuneata*).	0.1
	Melba (*Auxis rochei*)	0.2
	Argentine anchovy and swordfish	0.3

[1] <0.3 NMP/g for processed products and <0.2 NMP/g for live products. NCh 3056.Of2007.

Crustaceans	0.5
Bivalve mollusks	2.0
Cephalopods	2.0

Table: *Lead*

Product	Maximum Level (mg/kg (ppm))
Fish	0.3
Crustaceans	0.5
Bivalve mollusks	1.5
Cephalopods	1.0

Table: *Mercury*

Product	Maximum Level (mg/kg (ppm))
Fish other than predators, crustaceans, bivalve mollusks and cephalopods	0.5
Predatory fish	1.0

The following species are considered as predatory fish:
- Bonito (*Sarda sarda*)
- Ray (*Raja sp.*)
- Shark (all species)
- Tope shark (*Galeorhinus vitaminicus*)
- Narrownose smooth-hound (*Mustelus schmitti*)
- Swordfish (*Xiphias gladius*)
- Patagonian toothfish (*Dissostichus eleginoides*)
- Tuna (*Thunnus species*, *Ehuthynnus species*, *Katsuwonus pelamis*)

- For land transportation, the Sanitary Certificate must include the seal number and the identification of the truck.

Other Certificates

- Process Monographies

Any exporter that wishes to send its production to Argentina must file a process monograph with SENASA (Part III: Annexes - Export Certificates) for each product, importer, and brand destined to that market. For this, the interested party must present a Notification of Shipment for export fishery products at the SERNAPESCA Office under whose jurisdiction the processing plant is located, attaching the certificate with the description of the process, including the qualitative and quantitative formulation of the product (with percentages) in numbered sheets.

The information will be authorized if it matches the processes supervised by SERNAPESCA though the Reduction Plants Program (PER - RPP) or the Quality Assurance Program (QAP). If requested, periodical verifications Results Reports and heat treatment studies for processing lines for the corresponding monograph may be attached, as well as the detailed information on the material that makes contact with the product and the one used for packing and packaging.

The official from the Service must review this document to verify that it corresponds to the process conducted at the plant and verify that the company is authorized for such market in the List of Companies under SERNAPESCA's Sanitary Control Programs.

If authorized, the description of the process provided by the plant will be validated with the SERNAPESCA stamp, the stamp, and signature of the Dr. of Veterinary Medicine of SERNAPESCA in all sheets. This document will be attached to the Process monograph certificate, which will be signed and stamped by the Dr. of Veterinary Medicine.

The issuance of monographs for markets other than Argentina will be evaluated by the Foreign Trade Sub-Directorate, based on a request presented at the regional office by the interested party.

- Certificate for Fishery Products Transiting through Argentina

The Certificate for Fishery Products Transiting through Argentina (Part III, Annexes, Chapter I) is requested to transport a Chilean fishery product from one point to another in the country through Argentinian territory, and for products that will be exported to other countries, and that are transported through Argentina without a sanitary certification. The following must be met to obtain this certificate:

- The interested party must present the Notification of Shipment of Export Fishery Products for the product. When the transportation is Chile-Chile, the notification will be processed through the "Ventanilla Empresa" system, in the "NEPPEX Manual Anticipado" (Manual NEPPEX in Advance) tab.
- The interested party must present the completed Certificate with the information on the dispatch of the batch.
- When the transportation is Chile-Chile, the tax document that proves the origin and destination of the product must be presented as well as information on the identification of the means of transport and the driver. This certificate will be free of charge for the requesting company since the associated commercial operation does not correspond to exports.

- Zoosanitary Certificate in Transit

The Zoosanitary Certificate for products in transit must be issued for chilled-refrigerated products and frozen fishery salmonids by-products in transit through the free zone set by Resolution 375/2013 of SENASA, regardless of the destination, including the Chile-Chile transit.

Those products that are not in transit through the free zone will not be subject to the zoosanitary certification. Wet algae are considered risk material according to Resolution 116/2016 of SENASA, therefore shipments of this product must transit exclusively through the sanitary corridor specified in Article 8 of the said Resolution.

To obtain this certificate, the interested party must present the AOSC, a traceability chart or a *packing list* that relate the exported product with the farms of origin.
This certificate must be signed and stamped by a Dr. of Veterinary Medicine, who must review the list of centers positive for ISAv, verifying that the farms of origin of the product to be exported are not included in the aforementioned list.

- Exports by Land

This procedure applies for exporting or transporting fishery products by land in the Argentinian territory. The shipments must have a sanitary certificate or the Certificate for Fishery Products transiting through Argentina, as appropriate, and with a security seal.

To comply with this requirement, a cooperation agreement was subscribed between SERNAPESCA and the Agriculture and Livestock Service (SAG), which established that the officials from SAG, located at the corresponding border crossings, will be in charge of applying the seals provided by SERNAPESCA.

The transporter must present the export invoice and the Sanitary Certificate or the Certificate for Fishery Products transiting through Argentina, as appropriate, to the SAG official located at the border crossing, who will apply the seal and will consign the number of seals applied to the corresponding certificate, as well as the license plate number of the vehicle if it has not been indicated before.

Every quarter, SAG will dispatch the copies of the certificates issued by SERNAPESCA with the numbers of seals applied to the corresponding regional SERNAPESCA office.

2.1.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

To approve a reduction establishment with these type of products for the Argentinian market, it must be included in the SENASA Registry of Argentina, which must be verified in the List of Companies under SERNAPESCA's Sanitary Control Program.

The interested party must register its product, presenting a "Request for Approval and Registration of By-products of Animal Origin to Export to Argentina" at SENASA.

It must be mentioned that the reduction establishment will only be able to export to Argentina, once the competent body in Argentina has officially communicated this Service, the incorporation of such company.

Shipments must be accompanied by a "Single Sanitary Certificate for products, subproducts and/or by-products, obtained from fishing and/or aquaculture intended exclusively as Bait, Animal Feed and other Uses Not Intended for Human Consumption, traded between the Republic of Argentina, The Federative Republic of Brazil, the Republic of Chile and the Eastern Republic of Uruguay", which is available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:

Fish Meal and Oils

- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category D.
- The interested party must register its product, by submitting the Request for Approval and Registration of By-products of Animal Origin to Export to Argentina at SENASA, also attaching a label project in accordance with the Service's requirements.
- The processing establishment must be included in the SENASA Registry of Argentina, which must be verified in the List of Companies under SERNAPESCA's Sanitary Control Program.
- The reduction establishment will only be able to export to Argentina, once the competent body in Argentina has officially communicated this Service, the incorporation of such company.
- The product must comply with the sanitary requirements required by this Service, described in Item 1 of this Chapter, for fishmeal or fish oil, as appropriate.
-

Dry Seaweeds for Industrial Use
The product must comply with the sanitary requirements set by this Service in Item 1 of this Chapter.
The interested party must submit the following documents to the Office of General Quarantine at SENASA:
- Seaweeds process monograph.
- Attach the analysis of moisture percentage for the finished product.

Bait
The product must comply with the sanitary requirements set by this Service in Item 1 of this Chapter.

2.2. AUSTRALIA

2.2.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

If a certification is required, the issuance of the sanitary certification will be bound to the compliance with following requirements:
- The processing establishment must be included in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- Comply with the requirements established in Item 1 of this Chapter and the Sanitary Requirements and Sampling Plans to obtain the Sanitary Certification for Export Fishery Products, in accordance with the product's presentation.
- In addition to what is mentioned in Item 1 of this Chapter, the following requirements must be met:

Table: *Microbiological analyses*

Product	Parameter	n	c	m	M
Bivalve Mollusks other than Oysters	*Escherichia coli* (NMP/g)	5	1	2.3	7

Fish products that are not in a consumer-ready form must be accompanied by the "Health Certificate for Fishery and Aquaculture Products", available in PDF format at www.sernapesca.cl; the fish must be eviscerated, headless and without gills.

Consumer-ready products correspond to: cutlets weighing no more than 450 grams; skinless fillets of any weight; skin-on fillets each weighing no more than 450 grams; eviscerated, headless 'pan-size' fish, each weighing no more than 450 grams; fish that is headless and eviscerated which has been salted, dried or smoked; products that are processed further than the stages described above, including canned products.

In addition, the following sanitary attestations should be included in the item Remarks of the certificate:
- The fish were processed in premises approved by and under the control of the competent authority.
- The fish were eviscerated.
- The fish were subjected to an inspection system supervised by the competent authority.

- The head and gills were removed and internal and external surfaces thoroughly washed.
- The product is free from visible lesions associated with infectious disease.

Restrictions
Exports of chilled-refrigerated or frozen salmonids are prohibited.

2.2.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Shipments of fish oil and fish meal must be accompanied by a "*Health Certificate for fishery products not intended for human consumption for export to Australia,*" available in PDF format at www.sernapesca.cl. The issuance of the certificate is bound to the compliance with the following requirements:

- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category D.
- The product must comply with the sanitary requirements required by this Service, described in Item 1 of this Chapter, as appropriate.

Feeds Intended for Aquatic Species
Shipments destined to this market must be accompanied by the Certificate for feed for aquatic species available at www.sernapesca.cl.

For lots of feed produced with fish meal, the issuance of the aforementioned certificate will be subject to the compliance with, at least, the microbiological standards for fish meal, described in Item 1, Chapter IV. For this, the feed must be sampled prior to the shipment, considering the collection of n=1 for every 50 tons of feed.

The following statement must be included in the certificate:

- During manufacture, the fish meal has been heat-treated at a minimum core temperature of 80 C° for 30 minutes.

Restrictions
Exports of fish meal and fish oil from salmonids are prohibited.

2.3. BRAZIL

2.3.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION (M.05.01.18)

Fishery products destined to this market must be accompanied by the Sanitary Certificate for Argentina, Brazil, and Uruguay, which is available in PDF format at www.sernapesca.cl.

The issuance of the certificate above, which must be signed by a Dr. of Veterinary Medicine, is bound to the following requirements:

- The processing establishment must be included in the Department of Inspection of Animal Origin Products (DIPOA), an entity in charge of authorizing establishments in Brazil, which can be verified in the List of Companies under SERNAPESCA's Sanitary Control Programs.

- To grant an authorization to a fishery plant or factory ship to export to this market, the establishment must send the corresponding request to SERNAPESCA who will send such request to the DIPOA.
- Every time the establishment intends to export a new product to such country, its authorization must be requested to the DIPOA, and this procedure can be processed through SERNAPESCA.
- The establishment will only be able to export its products to Brazil, once the DIPOA has officially communicated this Service, the incorporation of such company.
- Every time deficiencies that may affect the authorization of this company to enter that market are detected, the interested party and the Central Office must be informed immediately.
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP using an Authorization at Origin for Sanitary Certification (AOSC). Also, the establishment must have a category A or B.
- The establishments that manufacture products destined to Brazil may only receive raw materials processed in fishery plants with the corresponding QAP certification for the corresponding line.
- If a product manufactured with imported raw materials is destined to Brazil, it must comply with the requirements outlined in the Raw Materials Import Program.
- For the export of bivalve mollusks, the resources must come from raw materials from extraction areas that are part of the BMSP.
- The product must comply with the sanitary requirements set by this Service in Item 1 of this Chapter, in accordance with the presentation of the product.
- For exports of fish and by-products from extractive fishing, the following animal health attestations must be indicated in a complementary manner in the sanitary certificate, as appropriate to the product: (M.05.01.18)
  - "Os animais utilizados como matéria-prima para fabricação do produto não foram obtidos a partir de cultivo e não apresentaram lesões atribuíveis à doença/infecção no momento da recepção da matéria prima */ The animals used as raw material in the manufacturing of the product were not obtained from farms and do not present injuries attributable to diseases/infections when receiving the raw materials;*
  - Os produtos certificados não incluem espécies de camarão*/ The certified products do not include species of shrimp or prawn;*
  - Os produtos certificados não incluem animais vivos, nem material de reprodução viável*/ The certified products do not include live animals or material of viable reproduction;*."
- The following statement must be added to the export of live bivalve mollusks and gastropods:
  "In accordance with the results of the Specific Sanitary Program to Monitor Diseases that affect Bivalve Mollusks, there is no evidence of the presence of the causal agents of the following diseases in (name of the country):
  - *Bonamia exitiosa*
  - *Bonamia ostrae*
  - *Marteillia refringens*
  - *Mikrocytos mackini*
  - *Perkinsus marinus*
  - *Perkinsus olseni*"
- Salmonids roes: The product must be subjected to a minimum temperature of 70 C° for at least 2 hours.

- The companies' labels must be registered at the DIPOA for each product and presentation, in accordance with the agency's Technical Regulation for Labelling of Packaged Food, as follows: : (M.05..01.18)

REGISTRATION OF LABELS

The registration of all products of animal origin (labels) will take place by electronic means by each processing establishment, in accordance with:
- Decree No. 30691, of March 9, 1952, amended by Decree No.8681 of February 23, 2016.
- Normative Instruction No.1 -2017 SDA-MAPA Registration animal origin products
- Circular letter No. 1 - 2017 DIPOA-SDA-MAP on the procedures to be followed in the Agricultural Management Platform (PGA_SGSIF); Annexes I, II, III and IV Access Manual and Annex V Table with regulated products.

For the purpose of products registration mentioned above, interested parties should use the Agricultural Management Platform (PGA-SIGSIF). For this, it is suggested to use the document "Initial registration procedures in PGA / SIGSIF system for registration, alteration, cancellation of labels of animal origin products in DIPOA / MAPA" prepared by the Agriculture Office of Chile in Brazil.

In order to register the legal representative of the company in the system, SERNAPESCA will issue the declaration " REPRESENTANTE DE ESTABLECIMIENTO ESTRANGEIRO PERANTE A AUTORIDADE SANITÁRIA DO BRASIL", document included in part III: Annexes, Chapter II: Forms.

To issue the above statement:
- The establishments must request it in writing to the office of SERNAPESCA under whose jurisdiction the plant is located, indicating all relevant data.
- It should be checked if this background (name of legal representative, RUT, etc.) corresponds to the information that currently the Service has.
- In case there is no agreement, the company must deliver a certificate that prove the validity of the legal representative and with this endorsement sign the declaration.

Specific Requirements for the Process
In the case of plants processing fish and cephalopod mollusks destined to Brazil (either chilled-refrigerated or frozen) an operational step of "raw material washing" must be included, for the purpose of reducing the surface microbial load in at least 80%, before its processing, according to the provisions of Circular 370/BR.

Furthermore, in the case of plants that process chilled-refrigerated salmonids destined to Brazil, a dynamic endoparasite control system must be implemented.

The establishments that manufacture products destined to Brazil, based on processed products, may only receive raw material from establishments authorized to export to said market and these products must have a valid QAP and be approved by SERNAPESCA. In the case of imported raw materials, the origin establishment must be at least authorized by DIPOA.

Restrictions
For the case of shipments of salmonids, the products must not present any kind of injuries, regardless of their origin. Imperfections in a product as a consequence of the productive process (slaughter, bins toppling over, classification, etc.) will not be considered as injuries.

The export of shrimp in their shell in all its forms and presentations is prohibited.

The export of live salmonids and salmonids with viscera is prohibited.

2.3.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Shipments must be accompanied by a "Single Sanitary Certificate for products, subproducts and/or by-products, obtained from fishing and or aquaculture intended exclusively as Bait, Animal Feed and other Uses Not Intended for Human Consumption, traded between the Republic of Argentina, The Federative Republic of Brazil, the Republic of Chile and the Eastern Republic of Uruguay", available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:

- The products must comply with the sanitary requirements set forth by this Service in Chapter IV, Item 1, according to their type (bait or fish meal or other protein by-products and fish oil).
- The establishments that produce fish meal or other fish protein by-products must be part of the List of Companies under SERNAPESCA's Sanitary Control Programs and must be at least in Category D, as set forth in Section II, Chapter I, Item 2.23. Also, such establishments must be authorized by the Livestock Input Inspection Department of the Ministry of Agriculture, Livestock and Food Supply (MAPA/DIPOA) of Brazil.[1]
- Fish meal and other protein byproducts, as well as fish oil, must also be accompanied by a special certificate in Spanish-Portuguese in addition to the sanitary certificate, which must state the following:
- Los animales utilizados como materia prima fueron procesados en un establecimiento bajo supervisión veterinaria oficial y habilitado para exportación / The animals used as raw material were processed in an establishment under official veterinary supervision and authorized for exporting. Os animais utilizados como matéria-prima, foram processados em um estabelecimento sob supervisão veterinário oficial e habilitado para exportação.
- Los productos no contienen proteína de rumiantes en su composición. / The products do not contain ruminants protein. Os produtos não contêm proteínas de ruminantes em sua composição.
- La materia prima fue sometida a una temperatura mínima de 90 C° por un período mínimo de 25 minutos. / The raw materials were subjected to a minimum temperature of 90 C° for at least 25 minutes. A matéria prima foi submetida a uma temperatura mínima de 90 C° por um período mínimo de 25 minutos.[2]
- Los animales nacieron y fueron criados en Chile. / The animals were born and raised in Chile. Os animais nasceram e foram criados em Chile.[3]
- La planta elaboradora no utiliza proteínas de rumiantes en sus productos. / The processing plant does not use ruminants' proteins in its products. A planta fabricante não utiliza proteínas de ruminantes em seus produtos.
- Los productos fueron envasados directamente en la planta de elaboración. / The products were packed directly in the processing plant. Os produtos foram embalados diretamente na planta de fabricação.

Los productos debidamente embalados fueron transportados directamente de la planta elaboradora hasta el lugar del embarque, y acondicionados en un contenedor sellado bajo

[1] The registration must take place directly at DFIP, through the importer in Brazil.
[2] Treatments that do not comply with these conditions, must provide a brief description of their treatment in item 3), indicating the temperature and times for each stage of the process, prior presentation and approval from the *Ministério da Agricultura, Pecuária e Abastecimento* de Brasil (MAPA).
[3] Only in the case of products made from raw materials from aquaculture.

supervisión del Servicio Veterinario Oficial. / The packed products were transported directly from the processing plant to the shipment location, and stored in a sealed container under the supervision of the Official Veterinary Service. Os produtos devidamente embalados foram transportados diretamente da fábrica até o local de embarque e acondicionados em container lacrado sob supervisão do Serviço Veterinário Oficial.

2.4. CANADA

2.4.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Raw Farmed Scallops with Gonads
Each shipment must be accompanied by a "Sanitary Certificate for raw farmed scallops with gonads destined to Canada," available in PDF format at www.sernapesca.cl. The issuance of the certificate is bound to the compliance with the following requirements:

- The extraction areas and the processing establishment must be part of the Bivalve Mollusks Sanitation Program (BMSP).
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP using an Authorization at Origin for Sanitary Certification (AOSC).
- The product must comply with the sanitary requirements outlined in Item 1 of this Chapter.

Farmed Salmonids
To obtain authorization for each Notification of Shipment, the following requirements must be met:

- The processing establishment must be included in the List of Companies under SERNAPESCA's Sanitary Control Program.
- It must comply with the requirements set forth in Chapter IV, Item 1.
- Packaged or eviscerated fish ready for consumption do not require certification.

Restrictions
Exports of raw bivalve mollusks and raw gastropods are not authorized, except for farmed oysters with gonads.

2.4.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Shipments of fish oil and fish meal must be accompanied by a "*Health certificate for fishery products not intended for human consumption for export to Canada*," available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:

- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category D.
- The product must comply with the sanitary requirements required by this Service, described in Item 1 of this Chapter, for fishmeal and fish oil, as appropriate.
- In the case of fish meal, when notifying the shipment, the copy of the results of the determination of moisture content conducted by IFOP, with an informed percentage below 10%, must be attached.
- The company must include the seals of the container on the second sheet of the certificate, in the place specially set for these purposes.

The shipments of fish meal and oil must be accompanied by a copy of the authorization to

import in each delivery, which must be presented at the first point of entry to Canada. For fish meal, the "*CFIA Facility Questionnaire for EXPORT of Rendered Products to CANADA*" must also be presented; this document is valid for a year and must be signed by a Dr. of Veterinary Medicine of SERNAPESCA.

2.5. CHINA

2.5.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by the "*Health Certificate for export of fishery products to the P. R. China*", available in Word format at www.sernapesca.cl.

Live fishery products intended for this market must be accompanied by the "*Health Certificate for aquatic animals intended for export from the Republic of Chile to the People's Republic of China*," available in Word format at www.sernapesca.cl.

The submission of the aforementioned certificates is bound to the following requirements:

- The establishment must be included in the List of Companies under SERNAPESCA's Sanitary Control Program and must be previously registered and authorized to export to this market.
- The establishment will only be able to export to the Republic of China, once the Certification and Accreditation Administration of the People's Republic of China (CNCA), has officially communicated this Service, the incorporation of such company.
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP using an Authorization at Origin for Sanitary Certification (AOSC).
- All fishery products from aquaculture fish must comply with the procedures and requirements set forth in Part II, Section I: Control at origin, Chapter II on pharmaceutical products residues, prohibited substances, unauthorized substances or contaminants control in aquaculture, so as to provide guarantees on the Maximum Residual Limits described therein and required by this market.
- All fishery and aquaculture products must be incorporated in the List of aquatic species and presentations authorized for export to China.
- In addition to what is mentioned in Item 1 of this Chapter, the following requirements must be met:

Table: *Microbiological analyses*

Product	Parameter	Maximum Level
Fishery products in general (raw)	Salmonella	Absence in 25 g
	Vibrio parahaemolyticus	≤100 NMP/g
	Listeria monocytogenes	Absence in 25 g
Fishery products in general (cooked)	Salmonella	Absence in 25 g
	Vibrio parahaemolyticus	≤100 NMP/g
Seaweeds and by-products thereof	Salmonella	Absence in 25 g
	Vibrio parahaemolyticus	≤100 NMP/g

- Sampling Plan

Execution Frequency: Fortnightly checks in establishments with Quality Assurance Programs.

Table: *Contaminants:*

Parameter	Product	Maximum Limit (mg/kg)
Polycyclic Aromatic Hydrocarbons (PAH) Benzo(a)pyrene	Smoked and roasted aquatic products	0.005

n=10 per production date. Sampling units must be mixed creating a composite, from which 1 determination must be made, and which must comply with the limits set for each case.

Restrictions

Only fresh by-products from establishments authorized to manufacture fishery products intended for human consumption can be exported.

The following live species have a restriction on their export to China: Abalones, Japanese oysters, Chilean oysters, and salmonids.

The export of fish oil intended for human consumption is prohibited.

The export of farmed fish with viscera is prohibited.

2.5.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Fish meal and oil

To authorize a reduction establishment to export to the People's Republic of China, the establishment must be part of the List of Companies under SERNAPESCA's Sanitary Control Program, must be at least within the "B" Category and must have presented its Quality Assurance Program at the National Fisheries and Aquaculture Service (approved for validation).

The interested party must request the authorization at the National Directorate of SERNAPESCA assigned to the location of the establishment. In turn, the Regional Office will send this information the Central Office which will process its incorporation through the Ministry of Foreign Affairs.

It must be mentioned that the reduction establishment will only be able to export to the People's Republic of China, once the incorporation of the company has been officially communicated.

Shipments of fish oil and fish meal must be accompanied by a "*Health Certificate for fishery products not intended for human consumption exported to the People's Republic of China*," which is available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:

- The establishment must be included in the List of Companies under SERNAPESCA's Sanitary Control Program and must be previously registered and authorized to export to this market.
- The establishment will only be able to export to the People's Republic of China, once the incorporation of the company has been officially communicated.
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP using an Authorization at Origin for Sanitary Certification (AOSC).

- Comply with the following specific requirements (the sampling must take place as per the instructions provided in Section IV, Chapter II, Item 2:

Table: *Specific Requirements*.

Product	Parameter	Maximum Level
Fish Meal	Mercury (Hg)	≤0.5mg/kg
	Cadmium (Cd)	≤2.0mg/kg
	Lead (Pb)	≤10mg/kg
	Chromium (Cr)	≤8.0mg/kg
	Mold	≤20.000ufc/g
	Salmonella	Absence in 25g
	Shigella	Absence in 25g
	Enterobacteria	n=5, c=2, m=10, M=300ufc/g
	Aerobic Mesophilic Count (AMC)	≤2.000.000ufc/g
	Melamine	≤2.5mg/kg
Fish oil not intended for human consumption (*)	Salmonella	Absence in 25g
	Total Coliforms	≤300NMP/g

Sampling Plan:

- Fish meal: n=5, c=0 for microbiological analyses, except Enterobacteria. For chemical analyses, a composite and 1 determination must be made.
- Fish oil: Microbiological analyses: n=6, c=0, with 6 analyses.
- Execution frequency: For establishments with Quality Assurance Programs (QAP), the determinations of heavy metals and microbiological parameters must be included in the biweekly verifications.

For establishments with QAP, melamine determinations must be made only in SERNAPESCA's verifications.
The determination of malachite green, not described in the previous Table, applies only to farmed fish and is covered by the controls conducted under the Residue Control Program described in Section I, Chapter II. Dioxins analyses, not described in the previous Table, must be conducted on the basis of the Annual Dioxins Control Program.

Seaweeds
Sanitary certification for seaweeds intended for this market must be accompanied by a "Phytosanitary Certificate," available in PDF format at www.sernapesca.cl. The issuance of the certificate is bound to the compliance with the requirements described in Chapter IV, Item 1, in accordance with the presentation of the product.

Feeds Intended for Aquatic Species
Shipments destined to this market must be accompanied by the Certificate for feed for aquatic species, available at www.sernapesca.cl.

The issuance of the aforementioned certificate will be subject to the compliance with, at least, the microbiological standards for fish meal, described in Item 1, Chapter IV. For this, the feed must be sampled prior to the shipment, considering the extraction of n=1 for every 50 tons of feed.

The following statement must be included in the certificate:
- During manufacture, the fish meal has been heat treated at a minimum core temperature of 80 C° for 30 minutes.

Restrictions
Only fishmeal and fish oil manufactured with species harvested in Chilean waters is authorized to be exported.

2.6. COLOMBIA

2.6.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

If certification is required, the issuance of the sanitary certification will be bound to the compliance with following requirements:
- The processing establishment must be included in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP using an Authorization at Origin for Sanitary Certification (AOSC).

Restrictions
The export of whole farmed fish with viscera is prohibited.

2.6.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Feed for aquatic animals

For the export of feed for aquatic animals consumption, the interested party must have an authorization issued by the Colombian Agricultural and Livestock Institute, ICA indicating the specific sanitary requirements to be certified for the product to be exported. Shipments destined to this market must be accompanied by the Certificate of aquatic animal feed which is available at www.sernapesca.cl, in which the additional requirements that the ICA has determined will be incorporated.

The issuance of the certificate indicated above will be subject to compliance with all the requirements established by the ICA.

2.7. KOREA

2.7.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery and Aquaculture Products
The processing establishment must be authorized by the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea to export fishery and aquaculture products to that market; this authorization is valid for two years. The processing company may directly request its registration at the website provided by the authority, through the following procedure:

- Fill in the form at https://impfood.mfds.go.kr/#!CFABB01F010. All fields with red asterisks are mandatory. Consider:

- Only caps should be used, and avoid the use of accent marks or the letter ñ.
- Do not translate the establishment's registered name or its address, since they must match their description in the export documents.
- In the section >Business information >Whether seafood? "Yes" should be selected as the answer. Then, the fields >Business type and >Food category will be filled in automatically.
- In the case of producing fish oil intended for human consumption, in the >Business information >Whether seafood? Section, "No" must be selected, and register it as "Health functional food manufacturing/ processing."

- Click on the "Submission" button.
- You will be provided with the "Receipt Number" at that moment.
- In 2-3 days, the MFDS will send an email informing the applicant that its registration was completed successfully (see image).


De: admin@mail.mfds.go.kr [mailto:admin@mail.mfds.go.kr]
Enviado el: ••••••••••••••••••••••••••••••••••
Para: ••••••••••••••••••••••••••••••••••
Asunto: Notification of Foreign Food Facility Registration

Notification of Foreign Food Facility Registration

Registration code : ••••••••••••••••••••••••••••••••••
Receipt no. of Application : ••••••••••••••••••••••••••••••••••
Date of receipt : ••••••••••••••••••••••••••••••••••
Facility Information : ••••••••••••••••••••••••••••••••••
• Name of facility (••••••••••••••••••••••••••••••••••) • Country (CL)
• Address (••••••••••••••••••••••••••••••••••)

In accordance with Article 5 (1), 5 (2), or 5 (6) of the Special Act on Imported Food Safety Control and Article 2 (1), 2 (2), 2(6), or 2 (9) of the Enforcement Rules of the same Act, this is to certify that the facility concerned is registered as Foreign Food Facility.

Minister of Food and Drug Safety, Republic of Korea

There are two options to verify the status of the registration:

- In the section "*My Civil Petition*" (https://impfood.mfds.go.kr/#!CFBAA01F010), enter the "*Receipt number*" and the email address, select the establishment and *click* on "*Detail views.*"
- In the section "*Petition application*" >*Foreign Manufactures Views* (https://impfood.mfds.go.kr/#!CFAAA01F040), enter one of the search fields *(Code/ Country/ Business name)* and *click* on "*Search.*" The resulting list corresponds only to those establishments that are indeed registered.

If the MFDS does not accept the request, the process must be conducted again. Meanwhile, if you have received an email requesting to correct or add information, it must be done accordingly.

Fish by-products Intended for Human Consumption

A "Sanitary Certificate for Fishery and Aquaculture Products" must accompany every Shipment, the model certificate is available in PDF format at the web page www.sernapesca.cl.

Also, the following sentence must be included in point 4, Item IV (*Remarks*/Observaciones): "*The products are classified as HS Code 03 and are fit for human consumption.*"

According to the Korean regulation, the following are considered as fish by-products intended for human consumption:

- Edible fish heads: Refers to cut fish heads of the species of Adus morhua, Gadus ogac, Gadus macrocephalus, Merluccius australis, tuna and Dissostichus eleginoides, Dissostichus mawsoni, with pectoral and ventral fins.
- The edible parts around the head (collars, cheeks, cocochas) of edible fish (except puffer fish).
- Viscera by-products: Edible hard roe (except puffer fish roe), pollack intestines, cuttlefish gonads and nidamental gland.

The issuance of the certificate is bound to the compliance with the following requirements:

- The processing establishment must be included in the List of Establishments under SERNAPESCA's Sanitary Control Programs and classified at least in category D.
- The establishment must be authorized by the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea to export fish byproducts to that market. The request must be processed through the corresponding Regional Office, filling in the template provided for these purposes.
- The product must comply with the requirements set forth in Item 1 of this Chapter, in accordance with the presentation of the product.
- These by-products must be treated in a hygienic manner, must be fast-frozen at least at -18 C° in the center, and be classified as fit for human consumption.
- In addition, the following requirements must be met:

Table 131
Fish by products intended for Human Consumption

Product	Parameter	Maximum allowed
Frozen Edible Fish Head	*RAM*	< 10^6 ufc/g
	E. coli	< 0.3 NMP/g
	Mercury	≤ 0.5 mg/kg (ppm) (except abyssal fish, tunas and billfishes)
		≤ 1 mg/kg (ppm) (abyssal fish, tunas and billfishes)
	Lead	≤ 0.5 mg/kg (ppm)
	Histamine	≤ 200 mg/kg (ppm) (tunas)
Frozen edible Fish Viscera	*RAM*	< 10^6 ufc/g
	E. coli	< 0.3 NMP/g
	Mercury	≤ 0.5 mg/kg (ppm) (except abyssal fish, tunas and billfishes)
		≤ 1 mg/kg (ppm) (abyssal fish, tunas and billfishes)
	Lead	≤ 0.5 mg/kg (ppm)
		≤ 2 mg/kg (ppm) (cephalopods)
	Cadmium	≤ 3 mg/kg (ppm) (except fish eggs and cephalopods)
		≤ 2 mg/kg (ppm) (cephalopods)
		≤ 1 mg/kg (ppm) (fish eggs)

Source: Ministry of Food and Drug Safety, Food Code 2015

Restrictions

The export of whole fish heads of any species other than southern hake (*Merluccius australis*), tuna, Atlantic cod *(Gadus morhua),* Greenland cod *(Gadus ogac),* Pacific cod *(Gadus macrocephalus*), Patagonian toothfish (*Dissostichus eleginoides*) and Antartic toothfish (*Dissostichus mawsoni*) is prohibited.

2.7.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

The processing establishments that manufacture products intended for industrial use and/or animal consumption do not need to register.

Feeds Intended for Aquatic Species
Shipments destined to this market must present a process monograph and be accompanied by the *Certificate for feed for aquatic species* available at www.sernapesca.cl.

For lots of feed produced with fish meal, the issuance of the aforementioned certificate will be subject to the compliance with, at least, the microbiological standards for fish meal, described in Item 1, Chapter V. For this, the feed must be sampled prior to the shipment, considering the collection of n=1 for every 50 tons of feed.

The following statement must be included in the certificate:
- Durante el proceso, las harinas de pescado han sido procesadas bajo una temperatura mínima de 90 C° por 40 minutos / During manufacture, the fish meal has been heat treated at a minimum core temperature of 90 C° for 40 minutes.

2.8. COSTA RICA

2.8.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION (M.05.01.18)

The establishments must be authorized by the National Service for Animal Health of Costa Rica (SENASA), for which a request must be processed through SERNAPESCA, indicating the establishment and the products that will be destined to that market, attaching the "*General information questionnaire for establishments interested in exporting products or, byproducts of animal origin to Costa Rica for human consumption*", which will be evaluated by SENASA, and will indicate the need for an inspection visit. (M.05.01.18)

Fishery products destined to this market must be accompanied by an "Official Veterinary Certificate" for fishery products destined to Costa Rica, available in PDF format at www.sernapesca.cl. The issuance of the certificate is bound to the compliance with the following requirements:

- The processing establishment must have a Quality Assurance Program (QAP) based on HACCP and must be certified according to the QAP through an Authorization at Origin for the Sanitary Certification (AOSC).
- Fish from farms, farms and processing establishments must be part of the Pharmaceutical Products and Contaminants Residues Control Program.
- Bivalve mollusks must come from extraction areas under the BMSP.
- Comply with the requirements established in Item 1 of this Chapter and the Sanitary Requirements and Sampling Plans to obtain the Sanitary Certification for Export Fishery Products, in accordance with the product's presentation.
- In a complementary manner, the following standards must be met: (M.05.01.18)

Microbiological requirements: (M.05.01.18)

Analyzes for *Listeria monocytogenes* must be performed with a standard of absence in 25 grams in ready-to-eat fishery products, ready-to-eat crustaceans, peel and headless crustacean products and cooked mollusks.

Chemicals requirements: (M.05.01.18)

Chemical contaminants table[37]

Parameter	Products	Maximum level (mg/kg)
Mercury	Crustaceans, cephalopods without viscera and bivalve mollusks	0,5
	Fish in general (with the exception of pilchard (*Sardina* spp) and eel (*Anguila* sp)).	0,5
	Tuna (*Thunnus* spp, *Euthynnus* sp and *Katswounnus pelamis*), Bonito (*Sarda sarda*), eel (*Anguila* spp), Marlin (*Makaira* spp), Ray (*Raja* spp), Sharks (all species), Swordfish (*Xiphias gladius*)	1,0

Parameter	Products	Maximum level (mg/kg)
Cadmium	Crustaceans	0,5
	Fish in general (with the exception of pilchard (*Sardina* spp), eel (*Anguila* sp) and Swordfish (*Xiphias gladius*)).	0,05
	Pilchard (*Sardina* spp) and eel (*Anguila* sp)	0,1
	Bivalve mollusks	1
	Cephalopods without viscera	1
	Swordfish (*Xiphias gladius*)	0,3

Parameter	Products	Maximum allowed (mg/kg)
Lead	Crustaceans	0,5
	Fish in general, with the exception pilchard (*Sardina* spp) and eel (*Anguila* sp))	0,3
	Bivalve mollusks	1,5
	Cephalopods without viscera	1

[37] Detailed Standards for Maximum Microbiological limits and medical residues and contaminates for fishery products for human consumption Regulation. Decree No 34687 - MAG

Histamine: (M.05.01.18)

Determinations of histamine must be performed to all fishery products from fish species associated with high levels of histidine, particularly fish species of the following families: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, and Scombresosidae. For this the following must be applied:

- Sampling plans: n=9; c=2 (n= Number of units that comprise the sample; c = number of sample units with values above the standard that may be accepted).
- Number of analyses: The number of analyses to be conducted must be equal to n.
- Analysis Methodology: The methodology set by this Service will be applied, as described in Section IV, Chapter III, Point 2.
- The result will be considered satisfactory if the following is met:
  - The average observed value is under 100 mg/Kg.
  - A maximum of 2 of the units that comprise the sample have a value above 100 mg/Kg and below 200 mg/Kg.
  - None of the units that comprise the sample has a value above 200 mg/Kg.

Restrictions
The export of whole farmed fish with viscera is prohibited.

2.8.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Feeds Intended for Aquatic Species
Shipments destined to this market must present a process monograph and be accompanied by the *Certificate for feed for aquatic species* available at www.sernapesca.cl.

For lots of feed produced with fish meal, the issuance of the aforementioned certificate will be subject to the compliance with, at least, the microbiological standards for fish meal, described in Item 1, Chapter IV. For this, the feed must be sampled prior to the shipment, considering the collection of n=1 for every 50 tons of feed.
The following statement must be included in the certificate:

- Durante el proceso, las harinas de pescado han sido procesadas bajo una temperatura mínima de 85 C° por 30 minutos. / During manufacture, the fish meal has been heat treated at a minimum core temperature of 85 C° for 30 minutes.

2.9. CUBA

2.9.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Products destined to this market must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products," available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:

- The establishment must be included in the List of Companies under SERNAPESCA's Sanitary Control Programs and must be authorized to export to this market, in accordance with the requirements set forth in Section II, Chapter I, Item 2.1.
- It must be classified at least under category "B," as per the Infrastructure and Health Management Inspection Checklist of SERNAPESCA if it is a farm or a factory ship.
- Also, the following specific requirements must be met:

Frozen Fish
- The product must comply with the sanitary requirements outlined in Item 1 of this Chapter.
- The Sanitary Certificate must include the sentence "This product comes from a *Vibrio cholerae*-free zone," according to the procedure described in Chapter II, Item 7.3.4.
- Include the following parameters in the sensory-physical examination (after thawing) (n=5; c=0).

Frozen Whole Fish
- Gills: Red-pink characteristic color and normal odor.
- Internal appearance: Differentiated viscera, firm parietal regions (free from enzymatic attack) and characteristic odor.
- Mechanical damage: Below 5% of the surface.
- Muscular mass: Firm texture, elastic, characteristic of the species, firmly adhered to spine. Characteristic odor.

Frozen Sliced Fish
- Internal appearance: Firm parietal regions, no viscera.
- Muscular mass: Firm texture, elastic, characteristic of the species, firmly adhered to spine. Characteristic odor.
- Parasites: Absence of live or dead parasites.
- Mechanical damage: Absent.

Canned fish
- The product must comply with the sanitary requirements outlined in Item 1 of this Chapter. The organoleptic physical examination must apply the sampling plan n = 8; c = 1.
- The following parameter must be included in the organoleptic physical examination.
- Appearance: Absence of honey-comb appearance (enzymatic breakdown) in each part of the analyzed can.
- Chemicals (n = 5; c = 0)
  - pH: 4.5-6.5
  - Sodium Chloride: Not exceeding 1.5%

Other Fishery Products
The product must comply with the requirements outlined in Item 1 of this Chapter, in accordance with the presentation of the product.

Labelling Requirements
Submit a sworn declaration in Spanish, stating that the fishery products destined to Cuba are compliant with the following labeling requirements:
- Product name.
- Name of the processing establishment.
- Commercial brand name.
- Content (mass, volume, weight/volume, units, portions, etc.).
- List of ingredients.
- Identification of the lot, coded or written in a clear and easily comprehensible manner.
- Manufacturing date, packaging or freezing.
- Expiration date.
- Storage temperature
- Instructions for use (if appropriate).

2.10. EL SALVADOR

2.10.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products," available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:
- The establishment must be part of the List of Companies under SERNAPESCA's Sanitary Control Program.
- The product must comply with the requirements set forth in Item 1 of this Chapter, in accordance with the presentation of the product.

2.11. UNITED ARAB EMIRATES

2.11.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Products destined to this market must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products," available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:
- The processing establishment must be included in the List of Establishments under SERNAPESCA's Sanitary Control Programs and classified at least in category D.
- The product must comply with the requirements set forth in Item 1 of this Chapter, in accordance with the presentation of the product.
- In addition, the following sentences must be included under Point 4 of Item IV (Remarks/Observaciones), depending on the product to be exported:
  - For products from extractive fishing, the phrase "*Wild Catch*/Captura" must be included.
  - For farm species other than salmonids, the following must be indicated: "Product not fed on animal proteins/Producto no alimentado con proteína animal."
  - The following phrase must be included for salmonids: "In the case of farmed fish, fish has only been fed on feed materials free from pork protein and pork derivatives / En el caso de los peces de cultivo, éstos solo han sido alimentados con materia prima libre de proteína y derivados de cerdo."

The compliance with the requirements for farmed fish will be the responsibility of the processing establishment. Nevertheless, it must be verified by SERNAPESCA as follows:

Those establishments under a Quality Assurance Program (QAP) must include the United Arab Emirates as a destination market in such Program, and must demonstrate by means of a simple sworn declaration issued by the farm or whomever it may concern (food company), that the food used to feed the fish introduced for processing, is free from pork protein or pork derivatives. This declaration will be regularly verified by SERNAPESCA, during the QAP supervisions carried out in the establishment.

Consequently, the compliance with the prior condition will allow the establishment to obtain the Authorization at Origin for Sanitary Certification (AOSC) for that destination.

Those establishments that intend to export to Dubai and do not have a QAP, or have not included the market in their Program, must submit a simple sworn declaration upon processing the Notification of Shipment (NEPPEX) issued by the farm (food company) indicating that the manufactured product to be exported was not fed with pork protein or pork derivatives.

2.12. UNITED STATES OF AMERICA

2.12.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Restrictions
The export of raw bivalve mollusks and scallops with coral is prohibited.

2.12.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

All fish meal shipments must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products not Intended for Human Consumption," which is available in PDF format at www.sernapesca.cl.

The issuance of the certificate above is bound to the compliance with the following requirements:

- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category D.
- The processing establishment must have previously obtained an import permit for the United States provided by the *Animal and Plant Health Inspection Service of the United States (APHIS)*, through the presentation of the *Imported Product Facility Inspection Checklist*. The aforementioned checklist must be completed by the company, reviewed by the official SERNAPESCA Inspector in charge of the establishment, and be signed and stamped by a doctor of veterinary medicine of SERNAPESCA's office of origin.
- The product must comply with the sanitary requirements for fish meal set forth by this Service, described in Item 1 of this Chapter.
- The following statements must be included in Section IV of the certificate:
  1. *" Material was derived only from animals that have not been in any region listed in 9CFR 94.18 (a) (&).*
  2. *Was manufactured in Chile, in a facility which does not receive store, or process any ruminant origin material (except tallow derivatives as defined by 21CFR 589.2001 (b) 6. (&&), milk/milk products, hides, and/or vitamin D3 derived from sheep wool grease sourced from any BSE country/region (&)*
  3. *Was derived from animals that have not been in any BSE country/region (&)*
  4. *Was not otherwise associated with any facility located in any BSE country/region (&)*
  5. *Contains no animal origin ingredient except for materials derived from the following species: fish/shellfish*
  6. *Was not exposed to any other animal origin material*
  7. *(&)Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, the Republic of Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Oman, The Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Switzerland, and the United Kingdom.*
  8. *(&&)Tallow derivative means any product obtained through initial hydrolysis, saponification, or transesterification of tallow; chemical conversion of material*

obtained by hydrolysis, saponification, or transesterification may be applied to obtain the desired product."

2.13. GUATEMALA

2.13.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

To export to Guatemala, the processing establishment must, depending on the type of products that it manufactures, be authorized by the Ministry of Public Health and Social Assistance (MSPAS), for processed food, or by the Ministry of Agriculture, Livestock, and Food (MAGA) in the case of unprocessed food.

The request for authorization for both types of products must be processed through SERNAPESCA, indicating the establishment and the products to be destined to Guatemala. The Guatemalan Authorities will evaluate the documentation and will indicate the need for an inspection visit. The authorization, once delivered will have a duration of 2 years.

The products must be accompanied by the "Sanitary Certificate for Fishery and Aquaculture Products" which is available in PDF format at www.sernapesca.cl

The issuance of the certificate above is bound to the compliance with the following requirements:

- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and authorized by the corresponding competent authority.
- The establishment must have a Quality Assurance Program (QAP) based on HACCP, and it must be certified according to the QAP through an Authorization at Origin for the Sanitary Certification (AOSC).
- Bivalve mollusks must come from extraction areas under the BMSP.
- The product must comply with the requirements set forth in Item 1 of this Chapter, in accordance with the presentation of the product.

2.14. HONDURAS

2.14.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

The establishments must be authorized by the Food Safety Department of the Agriculture and Livestock Secretariat of the National Agricultural Health Service of Honduras (SENASA), for which a request must be processed through SERNAPESCA, indicating the establishment and the products to be destined to that market, attaching the "Health Questionnaire to Admit Import Aquaculture Products" , which will be evaluated by SENASA who will indicate the need for inspection. This questionnaire is available in the section Markets of the SERNAPESCA website and may be sent by those establishments that:

- Are part of the List of Companies under SERNAPESCA's Sanitary Control Programs and
- Have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP using an Authorization at Origin for Sanitary Certification (AOSC).

2.14.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

In order to export these types of products the establishments must be authorized by the Secretariat of the National Agricultural Health Service of Honduras (SENASA),for which a request must be processed through SERNAPESCA, indicating the establishment and the products to be destined to that market. Afterward, SENASA will conduct an inspection visit to those establishments to complete the procedure.

Subsequently, SENASA will carry out an inspection visit to these facilities in which the evaluation checklist "Verification of the application of good manufacturing practices in processing establishments of animal proteins and derived products" will be used, available in the section Markets in the SERNAPESCA website. The costs of this visit will be the responsibility of the applicant.

2.15. HONG KONG

2.15.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Oysters
Shipments of raw oysters (live, chilled and frozen) must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products," available in PDF format at www.sernapesca.cl.

The issuance of the certificate above is bound to the compliance with the following requirements:
- The establishment must be part of the List of Companies under SERNAPESCA's Sanitary Control Program.
- The oysters must come from extraction areas that are part of the BMSP, and that have a Type A or Approved category with monitoring for Norovirus.
- An analysis to detect Norovirus must be conducted, with n=1 (12 units of oysters) by production date and origin, that is to say, if a production date has more than one origin, n=1 will be considered for each origin. The technique to be applied is described in Section IV, Chapter III, Item 6.

Raw Products from Aquaculture
Raw aquaculture products destined to this market must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products," available in PDF format at www.sernapesca.cl, which must also include the following sentence in the "Remarks" section:

> " *The aquatic products have been handled, prepared or processed, identified, stored and transported under a competent sanitary program consistently implemented and in accordance with the requirements laid down in Codex Code of Practice for Fish and Fishery Products*. Los productos acuáticos han sido manipulados, preparados o procesados, identificados, almacenados y transportados bajo un programa sanitario competente implementado coherentemente y de acuerdo a los requerimientos establecidos en el Código de prácticas para el pescado y los productos pesqueros establecidos de Codex."

The issuance of the certificate is bound to the compliance with the following requirements:
- The establishment must be part of the List of Companies under SERNAPESCA's Sanitary Control Program.

- Standards described in Item 1 of this Chapter.

Live Animals from Aquaculture
Aquaculture products destined to this market must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products", available in PDF format at www.sernapesca.cl, which must also include the following sentence in the "Remarks" section:

> "*The aquatic animals have been produced, packed, stored and transported under sanitary condition, which were under the supervision of competent authority and in accordance with the requirements laid down in Codex Code of Practice for Fish and Fishery Products*. Los animales acuáticos han sido producidos, empacados, almacenados y transportados bajo condiciones sanitarias, las que se realizaron bajo supervisión de la autoridad competente y de acuerdo a los requerimientos establecidos en el Código de prácticas para el pescado y los productos pesqueros establecidos de Codex."

The issuance of the aforementioned certificate is bound to the compliance with the following requirements:
- The establishment must be part of the List of Companies under SERNAPESCA's Sanitary Control Program.
- Standards described in Item 1 of this Chapter.

2.16. INDIA

2.16.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Salmonids
Frozen salmonid products destined to this market must be accompanied by a "*Health Certificate for Fishery and Aquaculture Products*", available in PDF format at www.sernapesca.cl, which must also include the following sentence in the "Remarks" section:

The product is free from OIE listed pathogens for aquatic animals viz. diseases of fish, diseases of crustacean and diseases of molluscs in accordance with the type of products.
The above must be understood in relation with Official Active Surveillance Programs of Sernapesca:
-According to the Official Active Surveillance Program: Chile is free of the following OIE diseases and agents thereof Infectious Haematopoietic Necrosis (IHN); Viral Haemorrhagic Septicemia (VHS); Epizootic Haematopoietic Necrosis (EHN), and Infection by Salmonid Alphavirus (SAV).
-According to the Salmon Anemia Surveillance and Control Program: salmon products come from farming sites that are negative for Infectious Salmon Anemia (ISA) virus.

Crustaceans
Frozen crustaceans destined to this market must be accompanied by a "*Health Certificate for Fishery and Aquaculture Products*", available in PDF format at www.sernapesca.cl, which must also include the following sentence in the "Remarks" section:

The product is free from OIE listed pathogens for aquatic animals viz. diseases of fish, diseases of crustacean and diseases of molluscs in accordance with the type of products.
The above can be stated considering that the following diseases have not been detected in Chile

and in accordance the species susceptibility indicated in the Manual of Diagnostic Tests for Aquatic Animals:
- Crayfish plague (*Aphanomyces astaci*)
- Infection with yellow head virus genotype 1
- Infectious hypodermal and haematopoietic necrosis
- Infectious myonecrosis - Necrotising hepatopancreatitis
- Taura syndrome
- White spot disease
- White tail disease
- Acute hepatopancreatic necrosis disease

Mollusks
Frozen mollusks destined to this market must be accompanied by a "*Health Certificate for Fishery and Aquaculture Products*", available in PDF format at www.sernapesca.cl, which must also include the following sentence in the "Remarks" section:

The product is free from OIE listed pathogens for aquatic animals viz. diseases of fish, diseases of crustacean and diseases of molluscs in accordance with the type of products.
The above can be stated considering that the following diseases have not been detected in Chile and in accordance to the species susceptibility indicated in the Manual of Diagnostic Tests for Aquatic Animals or the product has received an effective treatment to inactivate pathogenic agents:
- Infection with *Bonamia exitiosa*
- Infection with *Bonamia ostreae*
- Infection with *Marteilia refringens*
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni*
- Infection with abalone herpesvirus
- Infection with *Xenohaliotis californiensis*

The issuance of the aforementioned sanitary certificates is bound to the compliance with the following requirements:
- The processing establishment must have a Quality Assurance Program (QAP) based on HACCP and its products must be certificated according to the QAP using an Authorization at Origin for Sanitary Certification (AOSC).

Non susceptible species
Frozen products from non susceptible species (*Cilus gilberti, Dissostichus eleginoides, Octopus mimus, Concholepas concholepas*, other species must be enquired case by case) destined to this market must be accompanied by a "*Health Certificate for Fishery and Aquaculture Products*", available in PDF format at www.sernapesca.cl, which must also include the following sentence in the "Remarks" section:

The consigned product is considered free of the diseases listed by the OIE, according to the species susceptibility indicated in the Manual of Diagnostic Tests for Aquatic Animals.

Restrictions
The export of raw abalones is prohibited.

2.17. INDONESIA

2.17.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by a "*Health Certificate for Fish Fishery Product Intended for Human Consumption Exported to The Republic of Indonesia*," available at www.sernapesca.cl.

The issuance of the aforementioned sanitary certificate is bound to the compliance with the following requirements:

- The processing establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must have a Quality Assurance Program (QAP) based on an HACCP; its products must be certificated according to the QAP using an Authorization at Origin for Sanitary Certification (AOSC).
- The product must comply with the requirements outlined in Item 1 of this Chapter, in accordance with the type and presentation of the product.

2.18. ISRAEL

2.18.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by the "*Veterinary Certificate for export of fish and fishery products to Israel*," available in Word format at www.sernapesca.cl.

The issuance of the aforementioned certificate is bound to the following requirements:

- The establishments and the manufactured products must be authorized for export to the European Union, as set forth in the List of Companies under SERNAPESCA's Sanitary Control Program.
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP using an Authorization at Origin for Sanitary Certification (AOSC).
- The extraction area, either a natural bank or farm, must be included in the List of Extraction Areas under the Bivalve Mollusks Sanitation Program (BMSP).
- The Israeli legislation establishes the shelf life of raw fish based on the following table, which must be specified in the label in Hebrew, and also, the original label of the product may be kept. It is the responsibility of the processing establishment to comply with this requirement, which is controlled by the authority at the destination.

Table: *Shelf life of raw fish*

Production Line	Species	Shelf life of the Product	Comments
Chilled-Refrigerated Raw Fish	*Dicentrarchus labrax* *Salmo salar* *Sparus aurata*	7 days	From the date of extraction or harvest
	Other fish	5 days	
Frozen Raw Fish	All fish	12 months	

For farmed fish the harvest date corresponds to the date in which the resource is extracted from the farm; in the cases in which the fish are subsequently destined for a collection center, the

date on which it is extracted from said center will be considered.

Restrictions
The export of fish with organoleptic conditions that are not characteristic of the species, such as wounds, melanosis, hematomas, etc. is prohibited.

2.18.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Fish Meal

The shipments of fish meal must be accompanied by the "*Veterinary Certificate to accompany fish meals intended for export to Israel*" and the "*Official certification of plants producing fish meals intended for export to Israel.*"

The issuance of the aforementioned certificates, available at www.sernapesca.cl, will be bound to the compliance with the following requirements:

- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category B.
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, in accordance with the requirements described in Part II, Section II of this Manual.
- The product must comply with the sanitary requirements established by this Service, described in Item 1 of this Chapter, for fishmeal.
- Also, the compliance with the following standards must be accredited through a laboratory analysis by production lot:

Table: *Specific Requirements.*

Product	Parameter	Acceptance Criterion
Fish Meal	Salmonella	Absence in 25g n=5, c=0, m=0, M=0
	Enterobacteriaceae (ufc)	n=5, c=2, m=10, M=300 in 1g
	Detection of proteins of mammalian origin	Absence

Fish Oil

The shipments of fish oil must be accompanied by the "*Veterinary Certificate to accompany oils and fats for animal feed intended for export to Israel*" and the "*Official certification of plants producing oils and fats for animal feed intended for export to Israel.*"

The issuance of the aforementioned certificates, available at www.sernapesca.cl will be bound to the compliance with the following requirements:

- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category D.
- The product must comply with the sanitary requirements established by this Service,

described in Item 1 of this Chapter, for fishmeal.
- Also, the compliance with the following standards must be accredited through a laboratory analysis by production lot:

Table: *Specific requirements for fish oil.*

Product	Parameter	Acceptance Criterion
Fish Oil	Salmonella	Absence in 25g n=5, c=0, m=0, M=0
	Enterobacteriaceae (ufc)	n=5, c=2, m=10, M=300 in 1g

2.19. JAMAICA

2.19.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products," available in PDF format at www.sernapesca.cl.

The submission of the aforementioned certificate is bound to the following requirements:
- The processing establishment must be included in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- The product must comply with the requirements outlined in Item 1 of this Chapter, in accordance with the presentation of the product.

2.20. JAPAN

2.20.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

- Specific Sanitary Requirements to obtain Notification of Shipment (NEPPEX) Authorizations for Aquaculture Products[1]

Shipment notification authorizations for all products from farmed fish intended for human consumption and destined to this market must, in addition to what is set forth in Chapter I, comply with what is described in Section I, Chapter II, and the MRLs specified for Japan in that Chapter.

- Specific Sanitary Requirements to obtain Sanitary Certification for Fishery and Aquaculture Products.

If a sanitary certification is required for this market, the products must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products," which is available in PDF format at www.sernapesca.cl and must comply with the following requirements:
- Those set forth in Item 1 of this Chapter, in accordance with the presentation of the product.
- The certificates may not include "*to Order*" in the consignee item, or any additional statements in the Remarks section.

[1] Regardless of the additional controls conducted by SERNAPESCA to authorize shipments or to grant sanitary certifications, both producers and exporters will be responsible to comply with the Japanese standard "*Specifications and Standards for Foods Additives, Under the Food Sanitation Law*".

- For by-products of farmed fish, these requirements are additional to those set forth the previous item.

2.20.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Shipments must be accompanied by a "*Certificate for fish meal and fish oil for animal feed for products destined to Japan*," which is available in PDF format at www.sernapesca.cl. The issuance of the certificate is bound to the compliance with the following requirements:

- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category D.
- The product must comply with the sanitary requirements required by this Service, described in Item 1 of this Chapter, for fishmeal or fish oil, as appropriate.

2.21. LEBANON

PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Feeds Intended for Aquatic Species
Shipments destined to this market must present a process monograph and be accompanied by the *Certificate for feed for aquatic species* available at www.sernapesca.cl.

For lots of feed produced with fish meal, the issuance of the aforementioned certificate will be subject to the compliance with, at least, the microbiological standards for fish meal, described in Item 1, Chapter IV. For this, the feed must be sampled prior to the shipment, considering the collection of n=1 for every 50 tons of feed.
The following statement must be included in the certificate:

- Durante el proceso, las harinas de pescado han sido procesadas bajo una temperatura mínima de 85 C° por 30 minutos / During manufacture, the fish meal has been heat treated at a minimum core temperature of 85 C° for 30 minutes.

2.22. MORROCCO

Shipments must be accompanied by the "Veterinary Certificate to export fishery or aquaculture products intended for human consumption to the Kingdom of Morocco," available at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:

- Must be included in the List of Establishments under SERNAPESCA's Sanitary Control Programs.
- Comply with the sanitary requirements for exports destined to the European Union.

2.23. MEXICO

2.23.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

- Crustaceans

The shipments of raw crustaceans must be accompanied by the "Sanitary Certificate for Fishery and Aquaculture Products," available in PDF format at www.sernapesca.cl, and must include the following statement in the remarks section:

"The products are free of Yellow Head Virus (YHV), White Spot Syndrome (WSSV), *Penaeus vannamei Nodavirus* (PvNV) infections and Infectious Myonecrosis Virus (IMNV)."

The shipments of cooked crustaceans must be accompanied by the "Sanitary Certificate for Fishery and Aquaculture Products," and must include the following statement in the remarks section:

"The products have received heat treatment until reaching an internal temperature of at least 70 C°, for at least 5 minutes."

2.23.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Fish Meal, Crustaceans and Mollusks and Mixes

Shipments must be accompanied by the "Sanitary Certificate for Fishery and Aquaculture Products not Intended for Human Consumption," which is available in PDF format at www.sernapesca.cl.

The issuance of the aforementioned certificate is bound to the compliance with the following requirements:

- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category D.
- The product must comply with the sanitary requirements for fish meal set forth by this Service, described in Item 1 of this Chapter.
- The product must comply with the following conditions:
    - Absence of *Salmonella spp*. and *Shigella spp*.
    - Moisture lower than 10%.
    - Absence of mammalian bones and chips, insects or foreign materials.
    - The meal was subjected to heat treatment (cooking) reaching a minimum of 70 C° for 5 minutes or equivalent time/temperature combinations that prove to inactivate viral agents.
- The following statements must be added to Section IV of the "Sanitary Certificate for Fishery and Aquaculture Products not Intended for Human Consumption":
    - The product and raw materials correspond to the country described as the country of origin in this document.
    - The plant in which the product to be exported was manufactured, does not process proteins of ruminant origin.

2.23.3. ANTICIPATED ISSUANCE OF CERTIFICATES FOR IMPORT PERMITS IN MEXICO

- This procedure consists of the issuance of the sanitary certificate before the shipment and is required by the Mexican market, which considers an authorization to import fishery products.
- In this case, the sanitary certificate may be issued without all the official information needed for the sanitary certification. The interested party must present the

Notification of Shipment for export fishery products directly at the Foreign Trade Sub-Directorate at the port of exit of the shipment, attaching the certificate to be issued in original and two copies.
- The SERNAPESCA official will issue the certificate, keeping the original document and providing the duly processed Notification and a copy of the certificate with the phrase: "This certificate is issued only to set forward customs formalities before the corresponding Mexican authorities."
- The Notification will be assigned a number through the "Ventanilla Empresa" system, in the "NEPPEX Manual Anticipado" (Manual NEPPEX in Advance) tab." At the moment of export, when the final certificate is processed, the official must go to the "Autoriza NEPPEX anticipado" (Authorize NEPPEX in Advance) tab, with the issued notification number, to access and enter the FIP number for the export.
- Both the copy issued in advance, as well as the final certificate, must keep the same format, content, control number, stamps, signatures and reference number, and they must only differ in the dates of issuance of the certificate, production dates, number of boxes and kilograms of the products, which will be required in the final certificate. To collect the original, the interested party must present the corresponding sanitary and tax-related supporting information.

Certificates to be issued in advance for markets other than the Mexican will be evaluated by the Foreign Trade Sub-Directorate, based on a request presented at the regional office by the interested party.

2.24. MOLDAVIA

2.24.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by the "*Health Certificate for imports of fishery products intended for human consumption*," available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:
- Must be included in the List of Establishments under SERNAPESCA's Sanitary Control Programs.
- Comply with the sanitary requirements described in this item, for exports destined to the European Union.

2.25. NORWAY

2.25.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by the "*Health Certificate for imports of fishery products intended for human consumption*," available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:
- Must be included in the List of Establishments under SERNAPESCA's Sanitary Control Programs.

- Comply with the sanitary requirements described in this item, for exports destined to the European Union.

2.25.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

All fish meal and oils intended for animal consumption must be accompanied by the following certificates, respectively; "Sanitary Certificate for transformed animal proteins not intended for human consumption, including mixes and products different from pet food that contain them, that will be sent to the European Union or that will transit through it" and the "Sanitary Certificate for fish oil not intended for human consumption, to be used as an ingredient for feed or with technical purposes to be sent to the European Union or that will transit through it." These PDF forms are available in different languages at www.sernapesca.cl.

The issuance of the certificates above will be subject to compliance with the requirements described in this item, for exports destined to the European Union.

2.26. NEW CALEDONIA

2.26.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products intended for this market must be accompanied by the "Veterinary Certificate for products intended for human consumption destined to New Caledonia," available in PDF format at www.sernapesca.cl.
The issuance of the certificate above is bound to the compliance with the following requirements:

- The establishment must be part of the List of Companies under SERNAPESCA's Sanitary Control Programs.
- The product must comply with the requirements set forth in Item 1 of this Chapter, in accordance with the presentation of the product.
- In the case of crustaceans, it must also be accredited that they were subjected to the following heat processes:
  - Procedure at least equivalent to a heat treatment of 50 C° in the core of the product, for at least 60 minutes or
  - Procedure at least equivalent to drying in an oven at 50 C°, for at least 90 minutes or
  - Procedure at least equivalent to full drying at 30 C°, for at least 1 hour or
  - Heat treatment reaching 90 C° in the center for 20 minutes or
  - Heat treatment reaching 80 C° in the center for 30 minutes.

Restrictions
The export of whole farmed fish with viscera, live bivalve mollusks and raw crustaceans is prohibited.

2.26.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Fish Meal
Shipments of fish meal must be accompanied by the "*Veterinary Certificate regarding food for aquatic animals exported to New Caledonia*," available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:

- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category D.
- The product must comply with the sanitary requirements for fish meal set forth by this Service, described in Item 1 of this Chapter.
- In the case of crustacean meal it must be accredited that it was subjected to the following heat treatments:
  - Procedure at least equivalent to a heat treatment of 50 C°, for at least 60 minutes or,
  - Procedure at least equivalent to drying in an oven at 50 C°, for at least 90 minutes or
  - Procedure at least equivalent to full drying at 30 C°, for at least 1 hour.

2.27. NEW ZEALAND

2.27.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Transformed or frozen bivalve mollusks, as well as eviscerated-refrigerated pectinidae destined to this market, must be accompanied by a "Sanitary Certificate for bivalve mollusks destined to New Zealand." This certificate must be printed in a special format, and its issuance is bound to compliance with the following requirements:

- The establishments and the manufactured products must be authorized for export to the European Union, as set forth in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP by means of an Authorization at Origin for Sanitary Certification (AOSC).
- The extraction area, either a natural bank or farm, must be included in the List of Extraction Areas under the Bivalve Mollusks Sanitation Program (BMSP).
- In the case of natural banks, the processing establishment must be part of the Bivalve Mollusks Sanitation Program (BMSP), which can be verified in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- Scallops without coral are excluded from this requirement and may be exported without the above certificate.

Restrictions

- Exports of chilled-refrigerated or frozen salmonids are prohibited.
- Exports of live and/or refrigerated bivalve mollusks are prohibited. Except for eviscerated pectinidae.
- Re-exports of bivalve mollusks that have been imported to the Chilean territory are prohibited.

2.27.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Feeds Intended for Aquatic Species

Shipments destined to this market must be accompanied by the *Certificate for feed for aquatic species* available at www.sernapesca.cl.

For lots of feed produced with fish meal, the issuance of the aforementioned certificate will be subject to the compliance with, at least, the microbiological standards for fish meal, described in Item 1, Chapter IV. For this, the feed must be sampled prior to the shipment, considering the collection of n=1 for every 50 tons of feed.

The certificate must include the corresponding statements for the type of component:

1) Feed Produced with Poultry By-products

- Byproducts are completely produced with poultry and do not contain proteins from ruminants.
- The poultry byproducts used do not come from poultry that has been slaughtered as an official measure to control diseases.
- The poultry byproducts used were processed in establishments under the supervision of the competent authority.
- The poultry byproducts used have been subjected to an industrial process, subjecting the product to an internal temperature of at least:
  - 80 C° during 1364 minutes or
  - 85 C° during 500 minutes or
  - 90 C° during 184 minutes or
  - 95 C° during 68 minutes or
  - 100 C° during 25 minutes or
  - 105 C° during 10 minutes or
  - 110 C° during 4 minutes or
  - 115 C° during 2 minutes or
  - 120 C° during 1 minute.

2) Feed Made with Fish Meal and Fish Oil

- Fish oil and/or fish meal was not obtained from animals that were slaughtered as an official measure to control diseases.
- Fish oil and/or fish meal come from animals that did not show any clinical signs of diseases at the moment of slaughtering.
- Fish oil and/or fish meal have been treated at a minimal core temperature of 80 C° for at least 20 minutes.
- During the production quality control measures have been put in place to guarantee the absence of cross-contamination.

2.28. PANAMA

2.28.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery and aquaculture products intended for this market must be accompanied by the "Sanitary Certificate for Fishery and Aquaculture Products," available in PDF format at www.sernapesca.cl. The issuance of the certificate is bound to the compliance with the following requirements:

- The processing establishment must be included in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- The product must comply with the requirements set forth in Item 1 of this Chapter, in accordance with the presentation of the product.

2.28.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Fish Meal

All shipments of fish meal not intended for human consumption must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products not Intended for Human Consumption," which is available in PDF format at www.sernapesca.cl.

The issuance of the aforementioned certificate is bound to the compliance with the following requirements:

- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category D.
- The product must comply with the sanitary requirements required by this Service, described in Item 1 of this Chapter.

Seaweeds
All shipments of seaweeds not intended for human consumption must be accompanied by a "Sanitary Certificate for Seaweeds not Intended for Human Consumption", which is available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the sanitary requirements established by this Service, described in Item 1 of this Chapter.

Feeds Intended for Aquatic Species
Shipments destined to this market must be accompanied by the *Certificate for feed for aquatic species* available at www.sernapesca.cl.

For lots of feed produced with fish meal, the issuance of the aforementioned certificate will be subject to the compliance with, at least, the microbiological standards for fish meal, described in Item 1, Chapter IV. For this, the feed must be sampled prior to the shipment, considering the collection of n=1 for every 50 tons of feed.

Also, the processing establishment must document and implement a Hazards Analysis Critical Control Points (HACCP) system and must be approved by the Food Safety Authority of Panama, as stated in Resolution 092-2007, Resolution 060-2013 and Resolution 046-2014.

The following statement must be included in the certificate:

- Durante el proceso, las harinas de pescado han sido procesadas bajo una temperatura mínima de 80 C° por 30 minutos / During manufacture, the fish meal has been heat treated at a minimum core temperature of 80 C° for 30 minutes.

For the case of medicated feed, it is a requirement to have a Prescription from a Dr. of Veterinary Medicine (PMV - PVM) for producing and obtaining the export certification of the lots. The PMV must be readily available for the inspector in charge of the certification.

2.29. PAPUA NEW GUINEA

PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery and aquaculture products intended for this market must be accompanied by the "Sanitary Certificate for Fishery and Aquaculture Products," available in PDF format at www.sernapesca.cl. The issuance of the certificate is bound to the compliance with the following requirements:

- The processing establishment must be included in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- The product must comply with the requirements outlined in Item 1 of this Chapter, in accordance with the presentation of the product.

In addition, the following statements must be included in item V of the sanitary certificate:

- According to the Official Active Surveillance Program, Chile declares itself free from the following OIE diseases and agents thereof; Infectious Haematopoietic Necrosis (IHN); Viral Haemorrhagic Septicaemia (VHS); Epizootic Haematopoietic Necrosis (EHN), and Infection by Salmonid Alphavirus (SAV).
- The lots of salmon products come from farming sites that are negative to the virulent strains of Infectious Salmon Anemia (ISA) virus, according to the Infectious Salmon Anemia Surveillance and Control Program of SERNAPESCA.
- Fish harvested for export are not derived from a population slaughtered as an official disease control measure.

Restrictions

Only eviscerated, headless and gutless salmon may be exported.

2.30. PERU

2.30.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products," available in PDF format at www.sernapesca.cl.

The issuance of the certificate above is bound to the compliance with the following requirements:

- The establishment must be part of the List of Companies under SERNAPESCA's Sanitary Control Programs. Whole chilled-refrigerated fish from extractive fishing that are not subjected to transformation are excluded from this requirement.
- The product must comply with the requirements set forth in Item 1 of this Chapter, in accordance with the presentation of the product.
- Products intended for reprocessing and/or re-export to the European Union must come from establishments authorized by SERNAPESCA to export to the EU. In this case, the sentence "The establishment indicated in Item II complies with Regulations 852/2004, 853/2004 and 854/2004 of the European Union", must be included in the "Remarks" section of the sanitary certificate.
- In the case of bivalve mollusks that will be re-exported to the EU, in addition to complying with the aforementioned, they must come from extraction areas authorized for the EU.

Issuance of Sanitary Certificates for Chilled-Refrigerated Products Destined to Peru

- The sanitary certificates for exporting fishery products destined to Peru must comply with the procedures described in Item 1, Chapters III and IV of this Manual. In the case of chilled-refrigerated products, the original and the copy of the sensory evaluation report must be presented at the regional office of SERNAPESCA, together with the NEPPEX and the sanitary certificate of SERNAPESCA, within one business day from the sensory evaluation, at the regional office, during business hours. The SERNAPESCA inspector will assign a number to the NEPPEX and will issue a Sanitary Certificate including the time and date stated in the report.

2.30.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Shipments must be accompanied by the "Sanitary Certificate for Fishery and Aquaculture Products not Intended for Human Consumption," which is available in PDF format at www.sernapesca.cl.

The issuance of the certificate above is bound to the compliance with the following requirements:

- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category D.
- The product must comply with the sanitary requirements required by this Service, described in Item 1 of this Chapter.

Bait

The bait destined to Peru must be accompanied by the "Sanitary certificate for fishery and aquaculture products not intended for human consumption," available in PDF format at www.sernapesca.cl.

The product must comply with the sanitary requirements set forth by this Service in Item 1 of this Chapter, and must include the following statements in the "Remarks" section of the certificate:

- At the moment of inspection, conducted for sanitary certification purposes, these did not present any visible external or internal injuries compatible with any diseases.
- The product was manufactured with species from extractive fishing.
- The species are not intended to be destroyed for sanitary purposes.
- The containers and/or means of transportation are new or have been cleaned and disinfected before loading.
- The species that comprise this shipment are not susceptible to any diseases of compulsory notification to the OIE.

Feeds Intended for Aquatic Species

To obtain the Certificate for feed for aquatic species (available at www.sernapesca.cl), the requirements described in Item 8, Chapter II must be met, and in the case of lots produced with fish meal, at least the microbiological standards for fish meal described in Item 1, Chapter IV must be met. For this, the feed must be sampled prior to shipment, considering the collection of n = 1 for every 50 tons of feed.

The following statement must be included in the certificate:

- Durante el proceso, las harinas de pescado han sido procesadas bajo una temperatura mínima de 80 C° por 30 minutos / During manufacture, the fish meal has been heat treated at a minimum core temperature of 80 C° for 30 minutes.

Restrictions

The export of species intended for bait susceptible to diseases of compulsory notification to the OIE, for instance, bait made from *Sardinops sagax* is prohibited.

2.31. SERBIA

2.31.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

All fishery products intended for human consumption and destined to this market must be accompanied by a "Sanitary Certificate for import of fishery products intended for human consumption," in Serbian and English, printed in a special format. The issuance of the certificate is bound to the compliance with all technical, administrative and sanitary requirements applicable to establishments and products, outlined in the section related to the European Union, in Item 1 of this Chapter.

2.32. SINGAPORE

2.32.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products," available in PDF format at www.sernapesca.cl.

The issuance of the aforementioned certificate is bound to the compliance with the following requirements:

- The establishment must be part of the List of Companies under SERNAPESCA's Sanitary Control Programs.
- Comply with the sanitary requirements set by this Service, as described in Item 1 of this Chapter. The Sanitary Certificate must include the phrase "*The product was harvested from an area free of marine biotoxins*" in the Remarks section.
- Bivalve mollusks, gastropods, tunicates and echinoderms, in any presentation, must come from extraction areas that are part of the BMSP, or otherwise, comply with the requirements established for sampling and analysis of biotoxins as described in Item 1.1.21 of this Chapter.

Restrictions
Exports of chilled-refrigerated oysters are prohibited.

2.33. SWITZERLAND

2.33.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by the "Sanitary Certificate for the import of fishery products intended for human consumption", available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:

- Must be included in the List of Establishments under SERNAPESCA's Sanitary Control Programs.
- The product must comply with the sanitary requirements described for the European Union, and in Item 1 of this Chapter.

2.34. TAHITI (FRENCH POLYNESIA)

2.34.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by the "Sanitary Certificate for the import of fishery and aquaculture products destined to Tahiti," available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:
- The processing establishment must be included in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- The product must comply with the requirements set forth in Item 1 of this Chapter, in accordance with the presentation of the product.
- Comply with the sanitary and zoosanitary declarations included in the sanitary certificate.

Restrictions

The exports of raw decapods and whole frozen abalone with shell (*Haliotis sp.*) are prohibited.

2.34.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Shipments must be accompanied by a "Sanitary Certificate for fishery and aquaculture products destined to Tahiti," available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:
- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category D.
- The product must comply with the sanitary requirements required by this Service, described in Item 1 of this Chapter, as appropriate.
- Comply with the sanitary and zoosanitary declarations included in the sanitary certificate.

2.35. THAILAND

2.35.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

The products intended for transformation in Thailand and for further export to the European Union must be accompanied by the "Sanitary Certificate for fishery and aquaculture products" available in PDF format at www.sernapesca.cl. The issuance of the aforementioned certificate is bound to the compliance with all technical, administrative and sanitary requirements, applicable both to establishments and products, as described in the section on the European Union, in Point 2 of this Chapter. Also, the following statements must be included in item V of the sanitary certificate:

For fish and fishery products:
I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the fishery products described above were produced in accordance with those requirements, in particular that they:

- come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;
- have been caught and handled on board vessels, landed, handled and where appropriate prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters I to IV of Annex III to Regulation (EC) No853/2004;
- satisfy the health standards laid down in Section VIII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;
- have been packaged, stored and transported in compliance with Section VIII, Chapter VI to VII of Annex III to Regulation (EC) No 853/2004;
- have been marked in accordance with Section I of Annex to Regulation (EC) No 853/2004;
- the guarantees covering live animals and products thereof, if from aquaculture origin, provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled; and
- have satisfactorily undergone the official controls laid sown in Annex III to Regulation (EC) No 854/2004.
- have been caught and handled on board vessels, landed, handled and where appropriate prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters I to IV of Annex III to Regulation (EC) No853/2004

For bivalve mollusks products:

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the fishery products described above were produced in accordance with those requirements, in particular that they:

- come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;
- have been harvested from the production area(s) thas as 8have) been classified in accordance with Regulation (EC) No 854/2004;
- satisfy the health standards laid down in Section VIII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;
- have been packaged, stored and transported in compliance with Section VIII, Chapter VI to VII of Annex III to Regulation (EC) No 853/2004;
- the guarantees covering live animals and products thereof, if from aquaculture origin, provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled; and
- have satisfactorily undergone the official controls laid sown in Annex III to Regulation (EC) No 854/2004.

The production area(s) for this consignment was (were) …. [Indicate area]

2.36. TAIWAN

2.36.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

The products intended for transformation in Taiwan and for further export to the European

Union must be accompanied by the "Sanitary Certificate for fishery and aquaculture products" available in PDF format at www.sernapesca.cl. The issuance of the aforementioned certificate is bound to the compliance with all technical, administrative and sanitary requirements, applicable both to establishments and products, as described in the section on the European Union, in Item 2 of this Chapter. Also, the following statements must be included in item V of the sanitary certificate:

> 4. Were processed in (an) establishment(s), implementing a program based on HACCP principles in compliance with the exporting country regulatory requirements and European Union regulatory requirements; Fueron procesados en un establecimiento(s) que tiene implementado un programa basado en HACCP en cumplimiento con los requisitos del país exportador y de la Unión Europea;
> 5. Have been caught and handled on board vessels, landed and appropriately prepared, processed, frozen and thawed hygienically in compliance with the exporting regulatory requirements and European Union regulatory requirements; Fueron capturados y manipulados a bordo de buques, desembarcados y preparados adecuadamente, procesados, congelados y descongelados higiénicamente en cumplimiento con los requisitos del país exportador y de la Unión Europea;
> 6. Satisfy the health standards and have been packaged, stored and transported in compliance with the exporting country's regulatory requirements and the European Union's requirements; Satisfacen los estándares sanitarios y fueron empacados, almacenados y transportados en cumplimiento con los requisitos del país exportador y de la Unión Europea;
> 7. Originate from (an) establishment(s) approved to the European Union. Provienen de un establecimiento (s) aprobado para la Unión Europea.

The shipments of raw mollusks by-products that are accompanied by the "Sanitary Certificate for fishery and aquaculture products," must include the following declarations in item V of the certificate, indicating the name of the extraction area of the resources included in the Sworn Declaration of Origin, and its code, if applicable:

- The products were elaborated from mollusks originating from [*area name*], [*area code*].
- Los productos fueron elaborados a partir de moluscos procedentes de [*nombre del área*], [*código del área*].

Restrictions
The export of whole farmed fish with viscera is prohibited. In addition, exports of roes or products manufactured from internal organs are also prohibited.

2.37. TUNISIA

2.37.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by the "Sanitary Certificate for fishery and aquaculture products destined to Tunisia," available in PDF y format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:

- The establishment and its manufactured products must be authorized to export, as indicated in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP using an Authorization at Origin for Sanitary Certification (AOSC).
- In the case of farmed fish, the farm and the processing establishments must be part of the Pharmaceutical Products and Contaminants Residues Control Program, which may be verified in the List of Companies under SERNAPESCA's Sanitary Control Programs.

2.38. TURKEY

2.38.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by the "*Veterinary Health Certificate for Exports of Fishery Products Intended for Human Consumption to the Republic of Turkey*," available in Word format at www.sernapesca.cl.

This certificate must be issued separately for each producer.

The issuance of the certificate is bound to the compliance with the following requirements:
- Must be included in the List of Establishments under SERNAPESCA's Sanitary Control Programs.
- Comply with the sanitary requirements described in this manual, for exports destined to the European Union.

2.38.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Shipments of fish meal must be accompanied by the "*Veterinary Health Certificate for the importation of processed animal protein not intended for human consumption, including mixtures and products other than pet food containing such protein into the Republic of Turkey.*"

Shipments of fish oil must be accompanied by the "*Veterinary Health Certificate for the importation of processed animal protein not intended for human consumption, including mixtures and products other than pet food containing such protein into the Republic of Turkey.*"

The issuance of the certificates above, available at www.sernapesca.cl, will be bound to the compliance with the following export requirements for fish meal and oil not intended for human consumption and destined to the European Union.

The certificates issued to this market must include the phrase: "The certificate is valid for 90 days from the date of issuance."

2.39. EURASIAN ECONOMIC UNION (EEU)

2.39.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

AUTHORIZATION OF ESTABLISHMENTS

The establishments that intend to export to this market must deliver the processing form, together with the list of its importers at the destination (both in hard copies and electronic format). Such list will be updated on a monthly basis, as requested by the exporting companies, which will be responsible to timely inform the Foreign Trade Sub-Directorate, the National Directorate, of the incorporation of its new Russian importers, by digital means.

To authorize the fishery plant or a factory ship to export to the countries of the Eurasian Economic Union (Russia, Belarus, Kazakhstan, Armenia, Kyrgyzstan), the processing establishment must have an A or B category, and a Quality Assurance program (QAP) in place for the products to be exported.

In addition, the establishment must undergo a special inspection, applying the "Infrastructure and Health Management Inspection Checklist for plants that produce fishery and aquaculture products intended for human consumption and export them to the Eurasian Economic Union." Once the establishment is Approved, SERNAPESCA will request in writing to Rosselkhoznadzor, its incorporation into the list of Chilean establishments authorized for exporting to the EEU.

It must be mentioned that the fishery plant or factory ship will only be able to export to the Eurasian Economic Union, once the competent body of the market has officially communicated this Service, the incorporation of such company.

It is important to note that it is a requirement of the EEU for the establishments and slaughterhouses that slaughter farmed fish and for cold store establishments that store these products, to also be authorized and registered in that market.

SANITARY CERTIFICATION

Regardless of the official controls conducted by SERNAPESCA for the authorization of shipments or sanitary certification, manufacturers and exporters are responsible for complying with the standards set by such market, such as:

- SANPIN 2.3.4.050-96 Production and sale of fishery products.
- SANPIN 2.1.4.1175-02 Hygiene requirements applicable to the quality of water for non-centralized supply. Sanitary protection of sources of water.
- SANPIN 2.1.4.1074-01 On potable water and the supply of water to populated areas.
- SANPIN 2.3.2.1078-01 On the application of sanitary standards.
- RT 005-2011 On Packaging Safety.
- RT 021-2011 On Food Safety.
- RT 022-2011 On Food Product Labeling.
- RT 029-2011 Safety Requirements for Food Additives, Flavorings, and Technological Aids.
- Decision 317 on the application of sanitary and veterinary measures.
- Decision 299 on the application of sanitary measures (includes pages 1-25, 25-35, 96-118 and 358-435).
- Decision 607 On unified veterinary certificate models for goods subject to control exported from third countries to the customs territory of the Customs Union.
- Sanitary regulations for cold stores
- Sanitary and parasitological appraisal methods for fish, mollusks, crustaceans, amphibians, reptiles, and products made from them. Methodological recommendations.

Fishery products destined to this market must be accompanied by the "*Veterinary Certificate for fish and seafood (fishery products) and products of their processing intended for human consumption, exported from the Republic of Chile into the Russian Federation*," available in PDF

format at www.sernapesca.cl.

The issuance of the certificate above is bound to the compliance with the following requirements:

- The establishment must be authorized to export to such market, in accordance with the previously described requirements.
- The establishment will only be able to export to the Eurasian Economic Union, once the competent body the market has officially communicated this Service, the incorporation of such company.
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP using an Authorization at Origin for the Sanitary Certification (AOSC).
- For the export of bivalve mollusks, the resources must come from raw materials from extraction areas that are part of the BMSP.
- All fishery products from farmed fish must comply with the procedures and requirements set forth in Part II, Section I: Control at origin, Chapter II on pharmaceutical products residues, prohibited substances, unauthorized substances or contaminants control in aquaculture, so as to provide guarantees on the Maximum Residual Limits described therein and required by this market.
- The product must comply with the requirements outlined in Item 1 of this Chapter, in accordance with the presentation of the product.
- In addition to what is mentioned in Item 1 of this Chapter, the following requirements must be met:

Table: *Contaminants and residues*

Parameter	Product	Maximum Limit (mg/kg)	
Lead***	Fish, raw, refrigerated, frozen, ground, fillet	1.0	
	Canned fish	2.0	Tuna, swordfish
	Fish, dried, smoked, salted, seasoned, marinated, fish preparations, other ready-made fish products.		
	Caviar and fish roe, their by-products.	1.0	
	Cod liver oil*****	1.0	
	Mollusks, crustaceans and other invertebrates.	10.0	
	Seaweeds	0.5	
Arsenic***	Fish, raw, refrigerated, frozen, ground, fillet	1.0	Freshwater
	Canned fish	5.0	Sea water
	Fish, dried, smoked, salted, seasoned,		

Parameter	Product	Maximum Limit (mg/kg)	
	marinated, fish preparations, other ready-made fish products.		
	Caviar and fish roe, their by-products.	1.0	
	Cod liver oil*****	1.0	
	Mollusks, crustaceans and other invertebrates.	5.0	
	Seaweeds	5.0	
Cadmium***	Fish, raw, refrigerated, frozen, ground, fillet	0.2	
	Canned fish		
	Fish, dried, smoked, salted, seasoned, marinated, fish preparations, other ready-made fish products.		
	Caviar and fish roe, their by-products.	1.0	
	Cod liver oil*****	0.2	
	Mollusks, crustaceans and other invertebrates.	2.0	
	Seaweeds	1.0	
Mercury***	Fish, raw, refrigerated, frozen, ground, fillet	0.3	Freshwater
	Canned fish	0.6	Freshwater predators
	Fish, dried, smoked, salted, seasoned, marinated, fish preparations, other ready-made fish products.	0.5	Sea water
		1.0	Tuna, swordfish
	Caviar and fish roe, their by-products.	0.2	
	Cod liver oil*****	0.3	
	Mollusks, crustaceans and other invertebrates.	0.2	
	Seaweeds	0.1	
Histamine***	Fish, raw, refrigerated, frozen, ground, fillet	100.0	Tuna, mackerel, salmon, herring

Parameter	Product	Maximum Limit (mg/kg)	
	Canned fish		
	Fish, dried, smoked, salted, seasoned, marinated, fish preparations, other ready-made fish products.		
2,4-D acid, its salts, and esters*	Fish, raw, refrigerated, frozen, ground, fillet	Absence (fresh water)	
	Canned fish		
DDT and its metabolites*	Fish, raw, refrigerated, frozen, ground, fillet	0.2	Sea water
		0.3	Freshwater
	Canned fish	2.0	Sturgeon, salmon, fatty herring
	Fish, dried, smoked, salted, seasoned, marinated, fish preparations, other ready-made fish products.	0.4	
		2.0	Fish fillet, fatty herring
	Caviar and fish roe, their by-products.	2.0	
	Cod liver oil*****	0.2	
HCH (α,β,γ-isomers)*	Fish, raw, refrigerated, frozen, ground, fillet	0.2	Sea water
		0.03	Freshwater
	Canned fish		
	Fish, dried, smoked, salted, seasoned, marinated, fish preparations, other ready-made fish products.	0.2	
	Caviar and fish roe, their by-products.		
	Cod liver oil*****	0.1	
Dioxines (PCDD/PCDF)***	Fish, raw, refrigerated, frozen, grinded, fillet	0.000004	
	Canned fish		
	Fish, dried, smoked, salted, seasoned, marinated, fish preparations, other ready-made fish products.		
	Cod liver oil*****	0.000002	mg/kg of fat

Parameter	Product	Maximum Limit (mg/kg)	
PCB (Polychlorinated biphenyls)***/****	Fish, raw, refrigerated, frozen, grinded, fillet	2.0	
	Canned fish		
	Fish, dried, smoked, salted, seasoned, marinated, fish preparations, other ready-made fish products.		
	Cod liver oil*****	3.0	
Radionuclides Caesium-137	Fish and fishing products	130	Bk/kg
	Dried and cured fish	260	Bk/kg
Radionuclides Strontium 90	Fish and fishing products	100	Bk/kg
Nitrosamines: Sum of N-Diethylnitrosamine and N-Diethylnitrosamine (NDMA and NDEA)***	Live fish, fresh fish, chilled, frozen, ground fish meat, fillet, marine mammal meat	0.003	
	Canned and preserved fish		
	Dried, cured, smoked, salted, spicy, marinated, fish culinary, other ready-made fish products.		

* These parameters will be controlled through the Residues Annual Plan of SERNAPESCA.

** Histamine: n=9, the number of analyses to be conducted will be equal to n.

*** Heavy metals, Dioxins and PCB and Nitrosamines (n-Diethylnitrosamine-NDEA and n-Diethylnitrosamine-NDMA): n=10 per production date. Sampling units must be mixed creating a composite, from which 1 determination must be made, and which must comply with the limits set for each case. This does not apply to liver or cod oil.

**** Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180.

***** sampling n and number of analyses, as outlined in Part II, Section IV, Chapter II of this Manual.

****** Radionuclide's control is performed once a year by SERNAPESCA.

Parasites

In addition, a parasite control must be conducted in the raw material and the manufactured product.

Table: *Parameters*

Product	Maximum Limit

	RAM[1](ufc/g)	Total coliforms[2]	*S. aureus*[3]	*Listeria monocytogenes*
Raw, chilled-refrigerated and frozen fish, crab and similar, and other invertebrates (cephalopods, echinoderms, gastropods)	≤1x10^5	Absence in 0.001g	Absence in 0.01g	
Hot-smoked frozen fish	≤1x10^4	Absence in 1g	Absence in 1g	
Whole cold-smoked frozen fish	≤1x10^4	Absence in 0.1g	Absence in 1g	
Cold-smoked frozen fish fillets, portions and slices	≤3x10^4	Absence in 0.1g	Absence in 1g	
Cut fish, mild smoke, lightly salted, vacuum packed	≤5x10^4	Absence in 0.1g	Absence in 0.1g	Absence in 25 g
Raw, chilled-refrigerated and frozen bivalve mollusks	≤5x10^4	Absence in 0.1g	Absence in 0.1g	
Bivalve mollusks, crustaceans, crab and similar, and other invertebrates (cooked-frozen cephalopods, echinoderms, gastropods)	≤2x10^4	Absence in 0.1g	Absence in 1g	
Frozen raw roe	≤5x10^4	Absence in 1g	Absence in 1g	
Dry seaweeds	≤5x10^4	Absence in 1g	-	

- The products exported to this market must display the label attached to the packaging, so that it may not be opened without violating its integrity, to avoid its reuse (Decision N°317 of the Customs Union).
- Signature of the Doctor of Veterinary Medicine.

Specific Requirements for the Process

The establishments that manufacture products destined to the EEU, based on processed products, may only receive raw material from establishments authorized to export to said market and these products must have a valid QAP approved by SERNAPESCA.

For products other than salmonids, the establishments must include in their QAP the statement "Product dispatch does not comply with the requirements of the Eurasian Economic Union," as a significant danger, due to which the operational step of "Dispatch" must always be considered as a CCP. The products that do not comply with the requirements of the market, for the shipping lot (*packing list*) and the traceability of the establishment may not be dispatched.
In the case of salmonids, in addition to the above, if the QAP of the establishment has incorporated the EEU, it must guarantee that raw material with lesions is not processed for that market.

[1] Count of mesophilic and optional anaerobic microorganisms (GOST State Standard 10444.15-94)
[2] GOST State Standard 52816-2007
[3] ISO Standard 6888-3 and GOST State Standard 31746-2012

The company should consider the danger of "Processing of fish with injuries intended for the Eurasian Economic Union" which will be part of the "Classified" CCP. In addition, it must be guaranteed through the computer traceability systems of each plant that manufactured products that do not comply with the requirements of the market are duly identified and blocked for that destination.

Restrictions
The export of salmonids with viscera is prohibited.

Shipments of salmonids destined to this market may only include products that do not show any visible signs of injuries.

The export of products made with imported raw material prohibited.

2.39.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Fish meal
Shipments of fish meal must be accompanied by the "*Veterinary Certificate for fodder fish meal, exported from the Republic of Chile into the Russian Federation*," available in PDF format at www.sernapesca.cl.

The issuance of the certificate above is bound to the compliance with the following requirements[1]:
- The processing establishment must be included in the registry of this market, which must be verified in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP using an Authorization at Origin for the Sanitary Certification (AOSC).
- The product must comply with the requirements outlined in Item 1 of this Chapter, in accordance with the presentation of the product.

2.40. EUROPEAN UNION[2]

2.40.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

All fishery products intended for this market must be accompanied by a "Sanitary Certificate for imports of fishery products intended for human consumption." This model is available, in the corresponding languages, in PDF format at www.sernapesca.cl.

For exports of live bivalve mollusks, gastropods, tunicates or echinoderms, the "Sanitary Certificate for Imports of Live Marine Bivalve Mollusks, Echinoderms, Tunicates and Gastropods intended for Human Consumption," is available in PDF format at www.sernapesca.cl.
The certificates must be written in at least one of the official languages of the member states of

[1] Regardless of the official controls conducted by SERNAPESCA for the authorization of shipments or sanitary certification, manufacturers and exporters are responsible for complying with the standards set by such market, such as Decision No. 317, of June 18, 2010 of the Customs Union Commission, and its amendments.
[2] Germany, Austria, Belgium, Bulgaria, Cyprus, Croatia, Denmark, Slovakia, Slovenia, Spain, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latonia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, United Kingdom, Czech Republic, Rumania, Sweden.

the EU in which the inspection takes place at the border post and the destination member state. In addition, they must contain all the information concerning the consignee, and it must not include the phrase "to order" since the product will be rejected by the competent authority at the destination.

The sanitary guarantees that support the certification of the products destined the European Union must take place prior or on the same date of shipment of the product, according to the requirements of that market. For this, the interested party must present, before or on the same day of the shipment, together with the Notification of Shipment of Export Fishery Products and the required sanitary certificate, the Authorization at Origin for Sanitary Certification.

In the commercial documents accompanying the batch, the compliance with the consumer information requirements outlined in Regulation 2065/2001 EC must be verified, including:

- For extractive fishing products: Commercial name, scientific name, and harvest area (as defined by the FAO).
- For extractive fishing products in freshwater or farmed: Commercial name, scientific name and the word Chile.

The issuance of the aforementioned certificate is bound to the following requirements:

- The establishment and its manufactured products must be authorized for export to the European Union, as set forth in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- To obtain the authorization, the interested party must file a request in the Regional Directorate of SERNAPESCA of the location of the fishery plant or the arrival port of the ship. In turn, the Regional Office will send this information to the Central Office, which will process its incorporation through the Ministry of Foreign Affairs.
- This incorporation process will only start when the establishment is classified under category A or B, and its Quality Assurance Program has been approved for validation.
- These establishments may only receive processed raw material from plants and ships authorized to export to such market, that is to say, establishments that have a QAP certification for the corresponding line.
- These requirements must also be met by the establishments exporting live crustaceans, bivalve mollusks, gastropods, tunicates, and echinoderms.
- The incorporation of the establishments exporting live crustaceans, bivalve mollusks, gastropods, tunicates, and echinoderms will take place once it has been verified that they comply with the requirements for Distribution or Dispatch Centers and once their Quality Assurance Program has been approved for validation.
- The approval from the European Authority considers the communication to all the Member States, before incorporating the establishment in the official list published on the web page of the EU. It must be mentioned that the establishments requesting this authorization may only export once the entire process has been completed, or once the consolidated list of the EU comes into force, and to the extent that its Quality Assurance Program is validated.
- In regards to the continuity of the companies in the list of companies authorized to export to the EU, this will be based on the results of the supervisions conducted by the Regional SERNAPESCA, according to the procedures and frequencies established in the Enforcement Annual Plan.
- The establishments under category B must present a schedule chart at the corresponding SERNAPESCA office, with the purpose of solving all the deficiencies detected in the inspection. The term to solve each deficiency may be set depending on the sanitary risk of the product.

- It must be noticed that if the deficiency is repeated over time, its severity may increase in the next inspection.
- The elimination of establishments from the official list of the EU will take place using the same procedure set for the incorporation, that is to say, informing via fax, and notifying the European Union through the Ministry of Foreign Affairs. This will be done through the Central Office when the establishment ceases to comply with the requirements for categories A or B and/or does not have the corresponding QAP certification is not processing or is closed. For this purpose, the information will be reviewed with the official in charge of the Regional Foreign Trade Sub-Directorate and with the official in charge of the Quality Assurance program of the Foreign Trade Sub-Directorate. Prior to eliminating the establishment, the Central Office will notify the company in writing.

- In the case of exports of bivalve mollusks, tunicates and echinoderms, the extraction area, whether a natural bank or farm, must be part of the List of Extraction Areas under the Bivalve Mollusks Sanitation Program (BMSP), which must be accredited through the presentation of the "Single Model of Sworn Declaration of Origin for fishery and aquaculture products affected by marine toxins", (Part III, Annexes, Chapter II) when processing the AOSC of when processing the temporary AOSC. The official must verify that production process agrees with the classification of the declared extraction area (type A, B, C) and that the information provided agrees with that list.
- In the case of natural banks, the processing establishment must be part of the Bivalve Mollusks Sanitation Program (BMSP), which can be verified in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- In the case of live gastropods that do not come from an extraction area included in the BMSP, they must comply with the specific sanitary requirements set forth in Item 2.1.34.1. as follows.
- In the case of farmed fish, the farm and the processing establishments must be part of the Pharmaceutical Products and Contaminants Residues Control Program, which may be verified in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- Marine gastropods and pectinidae from natural banks must comply with the requirements set forth in Part II, Section II; Processes Control, Chapter II; Quality Assurance Program, item 1.9.1 E.

2.40.1.1. SPECIFIC SANITARY REQUIREMENTS

- Live crustaceans, bivalve mollusks, gastropods, tunicates, and echinoderms

The establishments that export live crustaceans, bivalve mollusks, gastropods, tunicates, and echinoderms must comply with the following sanitary requirements:

Table: *Live crustaceans*

Product	Parameter	Maximum Level
Live Crustaceans	Lead	0.5mg/kg
	Cadmium	0.5mg/kg
	Mercury	0.5mg/kg

Sampling Plan: n = 3 by production date
Number of analyses: Sample units must be mixed to create a composite, from which 1 determination must be made.

Samplings to determine the presence of these substances must be performed by means of a Sampling and Analysis Request for Export (SMAE), with a frequency of 1 every 15 shipments to the UE.

- Live bivalve mollusks, gastropods, tunicates and echinoderms

The following requirements apply to gastropods that do not originate from an extraction area under a Bivalve Mollusks Sanitation Program, and to bivalve mollusks, tunicates and echinoderms when the dispatch center or processing establishment that conducts the preparation and packaging, does not have a Quality Assurance Program for these resources, in other processing lines (freezing, canning, etc.).

Table: *Live bivalve mollusks, gastropods, tunicates and echinoderms*

Product	Parameter	Maximum Level
Live bivalve mollusks, gastropods, tunicates and echinoderms	Paralytic Shellfish Poison	800µg/kg STX equiv.
	Amnesic Shellfish Poison	20mg/kg
	Lipophilic Toxins	Absence
	Escherichia coli	230NMP/100 g
	Salmonella	Absence in 25 g

Sampling Plan: n = 1 for every reception of raw material.

Samplings to determine the presence of these compounds must be conducted by means of a Sampling and Analysis Request for Export (SMAE) prior to the shipment of each product.

Table: *Live bivalve mollusks, gastropods, tunicates and echinoderms*

Product	Parameter	Maximum Level (mg/kg (ppm))
Live bivalve mollusks, gastropods, tunicates and echinoderms	Lead	1.5
	Cadmium	1.0
	Mercury	0.5
	Benzo(a)pyrene	0.005
	Sum of benzo(a)pyrene, benzo(a)anthracene, benzo[b]fluoranthene and chrysene	0.03

Sampling Plan: n = 3 by production date
Number of analyses: Sample units must be mixed to create a composite, from which 1 determination must be made.

Samplings to determine the presence of these substances must be performed by means of a Sampling and Analysis for Request for Export (SMAE), with a frequency of 1 every 15 shipments to the UE.

- Fishery Products

Manufacturing companies must ensure the compliance with the following sanitary requirements through Quality Assurance Programs:

- Food Additives: All processed products must only contain authorized additives, which must be used in accordance with the community regulations in place: Directive 95/2/EC on food additives other than colors and sweeteners.

- Organoleptic examinations: Must be conducted to verify the compliance with the freshness criteria.
    - Sampling plans: n = 5; c = 0 (n = Number of units that comprise the sample; c = number of sample units with values above the standard that may be accepted).
    - Number of analyses: The number of analyses to be conducted must be equal to n.
    - Analysis methodology: The sensory evaluation will include the determination of those parameters described in Item 1 this Chapter, according to the presentation of the product.
    - The results will be considered to be satisfactory if they comply with the previously mentioned standard.

- Determination of Total Volatile Basic Nitrogen (TVBN) (freshness indicator). (Regulations (EC) Nº 854/2004 and 2074/2005): Only in refrigerated or frozen products, without additional treatment).
    - Sampling plans: n=5; c=0
    - Number of analyses: The number of analyses to be conducted must be equal to n.
    - Analysis methodology: The methodology set by the service will be applied, as described in Section IV, Chapter III, Item 2.
    - Limit values for specific categories: Un-processed fishery products included in the following species categories are considered unfit for human consumption when the organoleptic examination is unfavorable, or the chemical analysis shows that the following TVBN limits have been exceeded:
        - 25 mg of nitrogen/100 g of meat in the case of the following species: *Sebastes spp.*, *Helicolenus dactylopterus* and *Sebastichthys capensis* (cape redfish).
        - 30 mg nitrogen/100 g of meat in the case of the Pleuronectidae family species (except for halibut: *Hippoglossus spp.*).
        - 35 mg nitrogen/100 g of meat in the case of Salmo salar, species of the Merlucciidae family and species of the Gadidae family.

Table: *Merlucciidae and Gadidae family species manufactured and exported by Chile:*

Common Name	Scientific Name	Family
South Pacific hake	*Merluccius gayi gayi*	Merlucciidae
Patagonian grenadier	*Macruronus magellanicus*	Merlucciidae
Southern hake	*Merluccius australis*	Merlucciidae
Southern blue whiting	*Micromesistius australis*	Gadidae

- Trimethylamine Nitrogen Determination (TMAN) (an indicator of freshness): Only in raw and dry salted products of marine origin:
    - Sampling plans: n = 5; c = 0 (n = Number of units that comprise the sample; c = number of sample units with values above the standard that may be accepted).
    - Number of analyses: The number of analyses to be conducted must be equal to n.
    - Analysis methodology: The methodology set by this Service will be applied, as described in Section IV, Chapter III, Item 2.
    - The results will be considered to be satisfactory if the following limits are combined:

Table: *Trimethylamine Nitrogen Determination (TMAN)*

Product	Maximum Level (mg/100 g)
Fish	15
Crustaceans and mollusks except for cuttlefish and squid	5
Cuttlefish and squid	15
Salted and dried products	50

- Histamine Determination (Regulation (EC) No. 2073/2005): Determinations of histamine must be conducted to all fishery products from fish species associated with high levels of histadine, particularly fish species of the following families: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, and Scombresosidae. For this, this following should be applied:
    - Sampling plans: n = 9; c = 2 (n = Number of units that comprise the sample; c = number of sample units with values above the standard that may be accepted).
    - Number of analyses: The number of analyses to be conducted must be equal to n.
    - Analysis Methodology: The methodology set by this Service will be applied, as described in Section IV, Chapter III, Item 2.
    - The result will be considered to be satisfactory if the following is met:
        - The average observed value is under 100 mg/Kg.
        - A maximum of 2 of the units that comprise the sample have a value above 100 mg/Kg and below 200 mg/Kg.
        - None of the units that comprise the sample have a value above 200 mg/Kg.

However, fish from such families that have undergone an enzyme ripening treatment in brine may have higher histamine levels, but not more than twice the above values.

Table: *Species from the following families manufactured and exported by Chile: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae and Scombresosidae*

Common Name	Scientific Name	Family
Yellowfin Tuna	*Thunnus albacares*	Scombridae
Longfin Tuna	*Thunnus alalunga*	
Bigeye Tuna	*Thunnus obesus*	
Black skipjack	*Auxis spp.*	
Bonito	*Sarda chiliensis*	
Chub Mackerel	*Scomber japonicus*	
Shipjack Tuna	*Katsuwonus pelamis*	
Pacific Menhaden	*Ethmidium maculatum*	Clupeidae
Falkland sprat	*Sprattus fuegensis*	
South American pilchard	*Sardinops sagax*	
Araucanian herring	*Strangomera bentincki*	
Anchoveta (Peruvian anchovy)	*Engraulis ringens*	Engraulidae
Common dolphinfish	*Coryphaena hippurus*	Corphaenidae
		Pomatomidae[1]
King gar	*Scomberesox saurus scombroides*	Scombresosidae

- Residues of pharmaceutical products and prohibited substances: All fishery products from aquaculture fish must comply with the procedures and requirements set forth in Part

[1] This family does not have catch, processing or export statistical records in Chile.

II, Section I: Control at Origin, Chapter II on Pharmaceutical products residues, prohibited substances, unauthorized substances or contaminants control in aquaculture, so as to provide guarantees on the Maximum Residual Limits described therein and required by this market. (Directive 96/23/EC, April 1996; Measures to monitor certain substances and residues; Directive 96/22/EC concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of ß-agonists; Regulation (EC) No. 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin; Regulation (EU) No. 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin).

- Contaminants: Determinations for Heavy Metals (Lead, Cadmium, and Mercury) and Polycyclic Aromatic Hydrocarbons (PAH) - (Benzopyrenes) must be conducted, to verify the compliance with the criteria required by Regulation (EC) No. 1881/2006 and its amendments, setting maximum levels for certain contaminants in foodstuffs. For the purpose of efficiently protecting public health and in accordance with what is stated in the previously mentioned Regulation, those products that contain contaminants and levels that exceed maximums, in this case, oils of marine origin, may not be mixed so as to dilute the detected contaminant to acceptable levels. For this, the following must be met:
    - Sampling plan: n = 10 by production date.
    - Number of analyses: Sampling units must be mixed creating a composite, from which 1 determination must be made, and which must comply with the limits set for each case.
    - Analysis Methodology: The methodologies set by this Service and described in Section IV, Chapter III, Item 2, Maximum contents allowed, will be applied:

Table: *Lead*

Product	Maximum Level mg/kg (ppm) Fresh weight[1]
Fish meat[2]	0.3
Crustaceans[3]	0.5
Bivalve mollusks[4]	1.5
Cephalopods without viscera[5]	0.3
Fish oil	0.1

Table: *Cadmium*

Product	Maximum Level mg/kg (ppm) Fresh weight

[1] Fresh weight not applicable to fish oil.
[2] Where fish are intended to be eaten whole, the maximum level must apply to the whole fish. It includes the following categories: a) live fish, b) fresh or refrigerated fish except for fillets and other fish meat specified in d; c) Frozen fish, except fillets and other fish meat specified in d; d) fillets and other fish meat (including chopped) fresh, refrigerated or frozen.
[3] Crustaceans, including peeled, live, fresh, refrigerated, frozen, dry, salted or in brine; unpeeled crustaceans, cooked in water or steamed, including, refrigerated, frozen, dry, salted or in brine; meal, flour and pellets of crustacean fit for human consumption. Ready-made or canned crustaceans.
[4] Includes: a) Bivalve mollusks, including those separated from their valves, live, fresh refrigerated, frozen, dry, salted or in brine, and b) ready-made or canned bivalve mollusks. In the case of echinoderms, gastropods and tunicates, and considering the absence of harmonized standards, the levels required for bivalve mollusks must be applied.
[5] Includes ready-made or canned.

(a) Fish meat[1][2][3], except for the species mentioned in letters b, c, and d.	0.05
(b) Meat from the following fish[1][2][3]: chub mackerel (*Scomber species*), tuna (*Thunnus species, Euthynnus species, Katsuwonus pelamis*) and bichique (*Sicyopteurs lagocephalus*)	0.1
(c) Meat from the following fish[1][2][3]: frigate tuna (*Auxis species*)	0.15
(d)Meat from the following fish[1][2][3]: Anchovy (*Engraulis species*) Swordfish (*Xiphias gladius*), Pilchard (*Sardina pilchardus*)	0.25
(e)Crustaceans [4] (meat from the appendix and abdomen). The meat of the appendix for crab and similar crustaceans (Brachyura and Anomura).	0.5
(f)Bivalve mollusks [5][6]	1.0
(g)Cephalopods (without viscera)[7]	1.0

Table: *Mercury*

Product	Maximum Level mg/kg (ppm) Fresh weight [8]
(a)Fishery products[9]	0.5
(b)Crustaceans (meat from the appendix and abdomen)[10]	0.5
(c)Fish meat [11][12], excluding the species listed in item d.	0.5
(d)Meat from the following fish [12][12]: Anglerfish (*Lophius species*), Atlantic catfish (*Anarhichas lupus*), Bonito (*Sarda sarda*), Eel (Anguilla species), emperor, orange roughy, rosy soldierfish (Hoplostethus species), grenadier (*Coryphaenoides rupestris*), halibut (*Hippoglossus hippoglossus*), kingklip (*Genypterus capensis*), marlin (Makaira species), megrim (Lepidorhombus species) mullet (Mullus species), pink cusk eel (*Genypterus blacodes*), pike (*Esox lucius*), plain bonito (*Orcynopsis unicolor*), poor cod (*Trisopterus minutus*), pailona (*Centroscymnus coelolepis*), rays (Raja species), redfish (*Sebastes marinus*, *S. mentella*, *S. viviparus*), sail fish (*Istiophorus platypterus*), scabbard fish (*Lepidopus caudatus*, *Aphanopus carbo*), seabream or pandora (*Pagellus species*), shark (all species), snake mackerel or butterfish (*Lepidocybium flavobrunneum*, *Ruvettus pretiosus*, *Gempylus serpens*), sturgeon (Acipenser species), swordfish (*Xiphias gladius*), tuna (Thunnus species, Euthynnus species, *Katsuwonus pelamis*)	1.0

[1] If the fish is intended to be eaten whole, the maximum content will apply to the whole fish.
[2] Fish indicated in this category, as defined in category a, excluding fish liver included in the list of article I of Regulation (EC) No. 104/2000.
[3] It includes the following categories: a) live fish, b) fresh or refrigerated fish except for fillets and other fish meat specified in d; c) Frozen fish, except fillets and other fish meat specified in d, and d) fillets and other fish meat (including chopped) fresh, refrigerated or frozen.
[4] Foodstuffs included categories c and f of the list of article I of Regulation (EC) No.104/2000, as appropriate (species listed in the corresponding entry). Includes: a) Crustaceans, including peeled, live, fresh, refrigerated, frozen, dry, salted or in brine; unpeeled crustaceans, cooked in water or steamed, including, refrigerated, frozen, dry, salted or in brine; meal, flour and pellets of crustacean fit for human consumption. Ready-made or preserved crustaceans and b) ready-made or canned crustaceans.
[5] Includes: a) Bivalve mollusks, including those separated from their valves, live, fresh, refrigerated, frozen, dried, salted or in brine, aquatic invertebrates, except crustaceans and mollusks, live, fresh, refrigerated, frozen, dried, salted or in brine; meal, flour and pellets of aquatic invertebrates, except crustaceans, fit for human consumption. In the case of *Pecten maximus*, the maximum content applies only to the adductor muscle and the gonads and b) ready-made or canned bivalve mollusks.
[6] In the case of echinoderms, gastropods and tunicates, and considering the absence of harmonized standards, the levels required for bivalve mollusks must be applied.
[7] Includes ready-made or preserved.
[8] Fresh weight not applicable to fish oil.
[9] Includes a) mollusks in general, included those separated from the valves, live, fresh, refrigerated, frozen, dried, salted or in brine; b)aquatic invertebrates, live, fresh, refrigerated, frozen, drive, salted or in brine and c)ready-made or canned mollusks and other invertebrates.
[10] Includes: a) Crustaceans, including peeled, live, fresh, refrigerated, frozen, dry, salted or in brine; unpeeled crustaceans, cooked in water or steamed, including, refrigerated, frozen, dry, salted or in brine; meal, flour and pellets of crustacean fit for human consumption and b) ready-made or canned crustaceans.
[11] Where fish are intended to be eaten whole, the maximum level must apply to the whole fish.
[12] It includes the following categories: a) live fish; b) fresh or refrigerated fish except for fillets and other fish meat specified in d; c) Frozen fish, except fillets and other fish meat specified in d, and d) fillets and other fish meat (including chopped) fresh, refrigerated or frozen.

If the product is destined to Italy, the following conversion factors must be applied to the results obtained in the determination of mercury, as per the publication of Gazzetta Officiale Nº21/1994:

Salted products (wet)	0.5
Salted products (dry)	0.4
Smoked products	0.4
Canned products	0.7
Cooked products	0.6

The result of the multiplication will be compared with the community standard.

Table: *Polycyclic Aromatic Hydrocarbons (PAH) - Benzopyrenes* [1]

Products	Maximum level Benzo(a)pyrene (mg/kg (ppm))	Maximum level Sum of benzo(a)pyrene, benzo(a)anthracene, benzo[b]fluoranthene and chrysene (mg/kg (ppm)
Smoked fish meat[2] [3] .	0.005 (until 08.31.2014) 0.002 (from 09.01.2014)	0.03 (until 08.31.2014) 0.012 (from 09.01.2014)
Smoked fishery products[4] fishery products listed items c, d and e.	0.005 (until 08.31.2014) 0.002 (from 09.01.2014)	0.03 (until 08.31.2014) 0.012 (from 09.01.2014)
Smoked crustaceans (meat from the appendix and abdomen).	0.005 (until 08.31.2014) 0.002 (from 09.01.2014)	0.03 (until 08.31.2014) 0.012 (from 09.01.2014)
Bivalve mollusks[5]	0.005	0.03
Smoked bivalve mollusks[6]	0.006	0.035
Fish oil	0.002	0.01

When applying the maximum levels set out in the Annex to foodstuffs which are dried, diluted, processed or composed of more than one ingredient, the following must be taken into account:

- Changes of the concentration of the contaminant caused by drying or dilution processes;
- changes in the concentration of the contaminant caused by processing;
- the relative proportions of the ingredients in the product; and
- the analytical limit of quantification.

The specific concentration or dilution factors for the drying, dilution, processing and/or mixing operations concerned or for the dried, diluted, processed and/or compound foodstuffs concerned must be provided and justified by the food business operator when the competent authority carries out an official control.

[1] Used as markers for the occurrence and effect of carcinogenic PAH.
[2] Where fish are intended to be eaten whole, the maximum level must apply to the whole fish.
[3] Smoked fish, including cooked before or after smoking.
[4] Includes all types of aquatic invertebrates.
[5] Fresh bivalve mollusks, refrigerated, frozen, dried, salted or in brine and canned.
[6] In the case of echinoderms, gastropods and tunicates, and considering the absence of harmonized standards, the levels required for bivalve mollusks must be applied.

The aforementioned will apply to the extent that there have not been specific maximum content established for these foodstuffs which are dried, diluted, processed or composed of more than one ingredient.
If there were any changes in the concentration to justify in a certain production line, the companies may present a study conducted by a laboratory authorized by SERNAPESCA, which clearly establishes the correction factors to be applied.

Such study must be presented at the corresponding Regional Office of the jurisdiction of the establishment for its approval and is applicable only for unfavorable verification control purposes for the Quality Assurance Program (release of the product given unfavorable results).

The presentation of such factors to the corresponding Member State according to the entrance of the load to the EU and its final destination within it will be the responsibility of each company. In addition, it must be taken into account that the European authorities may evaluate the correct application of the presented correction factors, thus being able to reject the study if deemed appropriate.

Table: *Melamine and its structural analogs*

Product	Maximum Level (mg/kg (ppm)
Foodstuffs	2.5

Table: *Dioxins (PCDD/PCDF) and PCB*

Products	Sum of dioxins (EQT PCDD/ PCDF-OMS)[1]	Sum of dioxins and dioxin-like-PCBs (EQT PCDD/ PCDF-PCB-OMS) [1]	Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180[1]
Fish meat and fishery products, and by-products[2,3,4]	3.5 pg/g fresh weight	6.5 pg/g fresh weight	75 ng/g fresh weight
Fish liver and its by-products	————————	20.0 pg/g fresh weight[5]	200 ng/g fresh weight[5]
Marine oil (fish oil, fish liver oil, and oil from other marine organisms intended for human consumption)	1.75 pg/g fat	6.0 pg/g fat	200 ng/g fat

Dioxins correspond the sum of Polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs). The sum of dioxins and dioxin-like-PCBs correspond to the sum of dioxin-like-PCDDs, PCDFs and PCBs. The concentrations are expressed as WHO toxic equivalents, using the toxic equivalency factors of the mentioned organization (WHO-TEQ), which are detailed in Regulation 1881/2006. Non-dioxin-like PCBs correspond to the sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180.

1 Upperbound concentrations: Upperbound concentrations are calculated on the assumption that all the values of the different congeners below the limit of quantification are equal to the limit of quantification.

2 Where fish are intended to be eaten whole, the maximum level must apply to the whole fish.

3 Foodstuffs falling within this category, as defined in categories a), b), c), e) and f) of the list in Article 1 of Regulation (EC) No 104/2000: Live fish; Fresh or refrigerated fish; Frozen fish; Fillets and other fresh, refrigerated or frozen fish meat (including chopped); Dried fish, salted or in brine; smoked fish, including cooked before after smoking; meal, flour and pellets of crustacean fit for human consumption; Crustaceans, including peeled, live, fresh, refrigerated, frozen, dried, salted or in brined; unpeeled crustaceans cooked in water or steamed, including refrigerated, frozen, dried, salted or in brine; meal, flour and pellets of crustaceans fit for human consumption; Mollusks, including separated from the valves, live, fresh, refrigerated, frozen, dried, salted or in brine; aquatic invertebrates; ready-made or canned fish; caviar and its substitutes made with fish roe; Ready-made or canned crustaceans, mollusks and other aquatic invertebrates.

4 The maximum level for crustaceans applies to the meat of the appendix and the abdomen. In the case of crab and similar crustaceans (Brachyura and Anomura), it applies to the meat of the appendix.

5 For canned fish liver, the maximum level applies to the entire content of the can intended for consumption.

Table: *Microbiological requirements: Food safety and hygiene criteria for processes (Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs).*

Food category	Microorganisms, their toxins, metabolites	Sampling Plan [1]		Limits		Interpretation of the results
		n	c	m	M	
Ready-to-eat frozen foods able to support the growth of *L. monocytogenes* [2] [3]	*Lysteria monocytogenes*	5	0	100ufc/g		Satisfactory: If all the values observed are ≤ to 10 or 100ufc/g, according to the presentation of the product. Unsatisfactory: if the presence of the bacterium is detected in any of the sample units in levels > a 10 or 100ufc/g, according to the presentation of the product.
Ready-to-eat fresh or smoked foods able to support the growth of *L. Monocytogenes* [3]	*Lysteria monocytogenes*	5	0	10ufc/g		
Cooked crustaceans and mollusks	Salmonella	5	0	Absence in 25 g		Satisfactory: If all the values observed indicate the absence of the bacterium. Unsatisfactory: If the presence of the bacterium is detected in any of the sample units.
Cooked crustaceans and mollusks peeled and headless products [4]	*E. coli*	5	2	1NMP/g	10 NMP/g	Satisfactory: If all the observed values are ≤ to m or if a maximum of c over n values are between m and M and the rest of the observed values are ≤ m. Unsatisfactory: If one or several values observed are > M for more than c over n values are between m and M.
	Coagulase-positive staphylococci	5	2	100 ufc/g	1000 ufc/g	Satisfactory: If all the observed values are ≤ to m or if a maximum of c over n values are between m and M and the rest of the observed values are ≤ m. Unsatisfactory: If one or several values observed are > M for more than c over n values are between m and M.

In addition, the microbiological analyses described in Item 1 of this Chapter must be conducted, in accordance with the presentation of the product.

- Parasites: Fishery products that are clearly contaminated with parasites will be not placed in the market for human use. (Regulation (EC) No. 853/2004, laying down specific hygiene rules for food of animal origin).

[1] n = number of units that comprise the sample; c= number of sampling units with values that exceed the limit that can be accepted or number of sampling units with values between m and M.
[2] It must be guaranteed that the limit of 100ufc/g is not exceeded at the end of the shelf life.
[3] This category considers those foodstuffs that do not comply with the following criteria: i) products which have received heat treatment or other processing efficient to eliminate *L. monocytogenes*, when re-contamination is not possible after this treatment (e.g. Products heat treated in the final package) and in live bivalve mollusks and ii) products with pH ≤4.4 or aw ≤0.92, products with pH ≤5.0 and aw ≤0.94, and products with a shelf life of less than five days.
[4] The test results demonstrate the microbiological quality of the analyzed process.

- Toxins harmful to human health: Fishery products derived from poisonous fish of the following families must not be placed on the market: Tetraodontidae, Molidae, Diodontidae, and Canthigasteridae (These families do not have catch, processing or export statistical records in Chile).
  Fishery products containing biotoxins such as ciguatoxin or muscle-paralyzing toxins must not be placed on the market.
  Fishery products derived from bivalve mollusks, echinoderms and tunicates may be exported if they have complied with the procedures and technical requirements laid down in Section I, Chapter I. Marine gastropods and natural bank pectinidae are excluded from this requirement.
  Also, bivalve mollusks, echinoderms, tunicates, and gastropods must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:
  - Paralytic Shellfish Poison: PSP, 800 μg per kilogram;
  - Amnesic Shellfish Poison, ASP), 20), 20 milligrams of domoic acid per kilogram;
  - Okadaic acid, dinophysistoxins and pectenotoxins together, 160 μg of okadaic acid equivalents per kilogram;
  - Yessotoxins, 3.75 milligrams of yessotoxins per kilogram, according to the biological method or with alternative detection method, and
  - Azaspiracids, 160 μg of azaspiracid equivalents per kilogram.

  To guarantee the compliance with the section "Toxins harmful to human health," in the case of marine gastropods from farms, the company must conduct periodical verifications of the finished product. If the origin of the products is gastropods or natural bank pectinidae, a marine toxins control must be conducted per export batch, in accordance with the sampling plans of Item 2.1.1.20 of this Chapter.

2.40.1.2. REQUIREMENTS APPLICABLE TO RAW MATERIALS TO PRODUCE FISH OIL INTENDED FOR HUMAN CONSUMPTION

The fish must be kept refrigerated until entering the plant, or otherwise, they must be processed within 36 hours from its capture.
In the case of receiving whole fish, it must be demonstrated through a chemical analysis that the levels of TVBN do not exceed 60mg/100gr. A sampling of raw materials must be conducted immediately after entering the process, in accordance with Section IV, Chapter II, Item 2.
The method to be used to control the limits of TVBN must be the one described in Section IV, Chapter III, Item 2. For the supply of primary plants, these must be authorized to export to the European Union, and the raw materials must be fit for human consumption, as set forth in the QAP document of the supplying establishment.

2.40.1.3. APPROVAL REQUIREMENTS

The approval from the European Authority considers the communication to all the Member States, prior to incorporating the establishment in the official list published on the web page of the EU. It must be mentioned that the establishments requesting this authorization may only export once the entire process has been completed, or once the consolidated list of the EU comes into force, and to the extent that its Quality Assurance Program is validated.
In regards to the continuity of the companies in the list of companies authorized to export to the EU, this will be based on the results of the supervisions conducted by the Regional

SERNAPESCA, according to the following procedure for establishments with manufactured products or live resources.

- An in-depth inspection must be conducted at least once a year, for which the Infrastructure and Health Management Inspection Checklist for Export Fishery Products Plants Intended for Human Consumption or the Infrastructure and Health Management Inspection Checklist for Factory Ships must be used, as appropriate. The results of this inspection must be sent to the interested party detailing each and every one of the deficiencies observed. In addition, the corresponding Visit Regional Report must be submitted to the Central Office.
- A monthly inspection whose purpose is verifying the maintenance of the conditions provided for authorization and the proper operation of the Quality Assurance Program, for which the Inspection Checklist for Establishments with Quality Assurance Programs will be used.
- A biannual inspection visit at the establishments that export live bivalve mollusks, gastropods, tunicates, and echinoderms, whose purpose is verifying the maintenance of the conditions provided for authorization and the proper conditioning of the resources, for which the Inspection Checklist for Harvest, Distribution and Depuration Centers of the BMSP will be used.
- All deficiencies detected in these supervisions must be recorded in the inspection book of SERNAPESCA, which must be available in every plant or factory ship.

The establishments under category B must present a schedule chart at the corresponding SERNAPESCA office, with the purpose of solving all the deficiencies detected in the inspection. The term to solve each deficiency may be set depending on the sanitary risk for the product.

It must be noticed that if the deficiency is repeated over time, its severity may increase in the next inspection.

The elimination of establishments from the official list of the EU will take place using the same procedure set for the incorporation, that is to say, informing via fax, and notifying the European Union through the Ministry of Foreign Affairs. This will be done through the Central Office when the establishment ceases to comply with the requirements for categories A or B and/or does not have the corresponding QAP certification is not processing or is closed. For this purpose, the information will be reviewed with the official in charge of the Regional Foreign Trade Sub-Directorate and with the official in charge of the Quality Assurance program of the Foreign Trade Sub-Directorate. Prior to eliminating the establishment, the Central Office will notify the company in writing.

2.40.1.4. LABELING REQUIREMENTS

- Labeling as per Regulation No. 16/2012 amending Annex II of Regulation (EC) No. 853/2004:

This regulation applies to frozen products intended for human consumption, both from fishery and aquaculture. In accordance with the mentioned Regulation, "Production date" is understood as the date of harvesting or catching, in the case of fishery products and harvesting in the case of farmed species.

Currently, the freezing date must be included in the information of the label if it corresponds to the processing date of the product. Such date is defined as "manufacture date," as indicated in Section II, Chapter, Item 2.2. The establishments manufacturing those products must guarantee that the information on the production date and/or freezing date is communicated to the operator of the food company to which the foodstuff is being supplied.

The processing establishment will be able to choose the way in which it will communicate the production date to whom it is supplying the foodstuffs. However, this information must be communicated in a clear and unequivocal manner. The compliance with this requirement will be the sole responsibility of the manufacturer. The process determined by the processing establishment must be established in the QAP.

It is noteworthy to mention that the information above will be required at random by SERNAPESCA, under the framework of the periodical provisions for QAP audits, and therefore, must be available for its verification.

It is important to mention that the communication of the production date must not take place through the issuance of sanitary supporting documentation for sanitary certificates.

- Labeling in accordance with Regulation No. 1169/2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004:

    - The operator of the food business responsible for the information is the operator under whose name or registered name the food is commercialized.
    - For packed food, the mandatory information must appear in the package or on a label adhered to it, and in the case of unpacked food, the food information must be provided to the operator receiving the food, so that it can be provided to the end consumer as required.
    - The mandatory food information for packed foodstuffs corresponds to: Name of the food, the list of ingredients, substances that cause allergies or intolerance, quantity of certain ingredients, net quantity of the food, the date of minimum durability or the 'use by' date, any special storage conditions and/or conditions of use, the name or business name and address of the food business operator, country of origin, instructions of use, alcoholic strength and a nutrition declaration.
    - A mandatory labeling on nutrition declaration for most processed foods is introduced. The mandatory nutrition declaration must include the following: Energy value, the amounts of fat, saturates, carbohydrate, sugars, protein, and salt; all these elements must be displayed the same visual field. The nutritional labeling regulations will apply from December 13, 2016.
    - The freezing date is mandatory in the labeling of non-frozen and processed fishery products, only if they are packed. The Member States may decide to extend this requirement to unpacked goods.
    - In the case of foods which are highly perishable and are therefore likely to constitute an immediate danger to human health, the date of minimum durability must be replaced by the 'use by' date.

- Where the food has been glazed and is intended for direct consumption (food in the commercialization stage), the declared net weight of the food must not include the weight of the glaze.
- When the country of origin is mentioned, and it is different from the one of its primary ingredient, the country of origin of the primary ingredient will be indicated, or it will be indicated that the country of origin of the primary ingredient is different from the country of origin of the foodstuff. This is of special relevance in those situations in which products manufactured with imported raw materials are destined to the EU.
- In the case of unpacked food, it is mandatory to indicate what is set for in letter c, number 1, article 9 of the Regulation:
- "c) any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of food and is still present in the finished product, even if in an altered form;"
- In the case of crustaceans and products thereof, fish and products thereof, as well as mollusks and products thereof, the following must be considered: "In the absence of national measures, the provisions of the Regulation on packed food are applicable to unpacked who in terms of labeling of substances or products that cause allergies or intolerances. Therefore, this information must be easily visible, clearly written and be irremovable. This means that the information on the substances or the products that cause allergies or intolerances must be displayed in writing and the extent that the Member States have not adopted measures".

2.40.1.5. COMPOSITE PRODUCTS

Composite products, which are those that contain processed products of animal origin and products of vegetable origin, in which half or more of their substance is processed fishery products, must be accompanied by sanitary certificate as per the sanitary certificate model (Part III, Annexes, Chapter I), and provided with the previously described requirements. The issuance of the certificate is bound to the compliance with the following requirements for the sanitary certification.

Restrictions
The export of the whole aquaculture fish with viscera, except Turbot (*Scopthalmus maximus*) and Coho salmon (*Oncorhynchus kisutch*) is prohibited.

2.40.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Authorization
To authorize a reduction establishment to export to the EU, the establishment must be part of the List of Companies under SERNAPESCA's Sanitary Control Programs, be at least within the "B" Category and have presented its Quality Assurance Program at the National Fisheries and Aquaculture Service (approved for validation).

The interested party must request the authorization at the corresponding Regional Directorate of SERNAPESCA for the location of the plant. In turn, the Regional Office will send this information to the Central Office, which will process its incorporation through the Ministry of Foreign Affairs.

It must be mentioned that the reduction establishment will only be able to export to the EU, once the incorporation of the company has been officially communicated to the Member States.

Certification
All fish meal and oils intended for animal consumption must be accompanied by the following certificates, respectively; "Sanitary Certificate for transformed animal protein not intended for human consumption, including mixes and products different from pet food that contain them, that will be sent to the European Union or that transit through it" and the "Sanitary Certificate for fish oil not intended for human consumption, to be used as an ingredient for feed or with technical purposes to be sent to the European Union or that will transit through it."

These PDF forms are available in different languages at www.sernapesca.cl. The certificates must be written in at least one of the official languages of the member states of the EU in which the inspection takes place at the border post and the destination member state. Nevertheless, those Member States may authorize the use of other languages, if necessary, with an official translation.

The issuance of the certificates above is bound to the following requirements:
- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category B.
- Fish meal and oil reduction plants must be registered as authorized establishments to export to the European Union, as set forth in the List of Companies under SERNAPESCA's Sanitary Control Programs.
- The specific case of France, Italy, and Greece, the establishment must be part of the list of authorized establishments, required by such countries.
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, in accordance with the requirements described in Section II, Chapter II of this Manual.
- The packaging or container of the product must be labeled indicating: fish meal or oil (as appropriate), lot number, production date, registry number of the plant, the word Chile and phrase "unfit for human consumption." Such packaging or container must also be displayed in a visible and irremovable way, a green sticker with a high content of blue to guarantee that is clearly distinguished from the other colors.
- In the case of fish meal intended to be used as feed for non-ruminant farm animals, different from, fur-bearing animals, the commercial document accompanying the fish meal, as well as any packaging containing these products, must be clearly marked with the phrase "Contains fish meal." "Unfit to be used as feed for ruminant animals:

2.40.2.1. SPECIFIC SANITARY REQUIREMENTS

Fish meal and oil reduction plants must prove the compliance with the following sanitary requirements, the periodical verifications considered in their respective Quality Assurance programs:

- Microbiological requirements for fish meal
- Salmonella: n=5 c=0 M=0 (Absence in 25g)
- Enterobacteriaceae: n=5 c=2 m=10 M=3x10^{2}ufc/g.

  Where:
  n: Number of units that comprise the sample;
  m: Threshold value of the number of bacteria; the result is considered to be satisfactory

if the number of bacteria in all samples is not greater than m;
M: Maximum value of the number of bacteria; the result is considered to be unsatisfactory if the number of bacteria in one or more samples is equal to or higher than M;
c: Number of sample units whose bacterial count may be between m and M, considering that the sample will continue being acceptable if the bacterial count of the other units of the sample is equal to or lower than m.

- Level requirements for undesirable chemical substances for fish meal and oil

As established in Directive 2002/32/EC, the products intended for animal feed whose content of an undesirable substance exceeds the maximum content set in this document, may not be mixed for dilution purposes, with the same product or with other products intended for animal feed.

Table: *Maximum levels of heavy metals and nitrates for fish meal*

Product	Parameter	Maximum Level (mg/kg (ppm)) (standardized weight 12% moisture)
Fish meal	Lead	10.0
	Mercury	0.5
	Nitrates	30.0 (expressed as sodium nitrate)
	Cadmium	2.0

Table: *Maximum levels of heavy metals for fish oil*

Product	Parameter	Maximum Level (mg/kg (ppm)) (standardized weight 12% moisture)
Fish oil	Lead	10.0
	Mercury	0.5
	Cadmium	2.0

Table: *Maximum levels of organochlorines for fish meal*

Product	Substance	Maximum Level (mg/kg (ppm)) (standardized weight 12% moisture)
Fish Meal	Aldrin (alone or combined expressed as dieldrin)	0.01
	Camphochlor (toxaphene) (sum of the CHB 26, 50 and 62 indicator congeners)	0.02
	Chlordane sum of cis and trans isomers and of oxichlordane expressed as clordane)	0.02
	DDT (sum of the isomers of DDT, DDD, and DDE expressed as DDT)	0.05
	Endosulfan (sum of alpha and beta isomers and endosulfan sulfate, expressed as endosulfan)	0.10
	Endrin (sum of endrin and deltacetoendrin, expressed as endrin)	0.01
	Heptachloride (sum of heptachloride and heptachlorepoxide, expressed as heptachlor)	0.01
	Hexachlorocyclohexane (HCH) alpha isomers	0.02
	Hexachlorocyclohexane (HCH) beta isomers	0.01

Product	Substance	Maximum Level (mg/kg (ppm)) (standardized weight 12% moisture)
	Hexachlorocyclohexane (HCH) gamma isomers	0.20

Table: *Maximum levels of organochlorines for fish oil*

Product	Substance	Maximum Level (mg/kg (ppm)) (standardized weight 12% moisture)
Fish oil	Dieldrin (alone or combined expressed as dieldrin)	0.1
	Camphochlor (toxaphene) (sum of the CHB 26, 50 and 62 indicator congeners)	0.2
	Chlordane sum of cis and trans isomers and of oxichlordane expressed as clordane)	0.05
	DDT (sum of the isomers of DDT, DDD, and DDE expressed as DDT)	0.5
	Endosulfan (sum of alpha and beta isomers and endosulfan sulfate, expressed as endosulfan)	0.1
	Endrin (sum of endrin and deltacetoendrin, expressed as endrin)	0.05
	Heptachloride (sum of heptachloride and heptachlorepoxide, expressed as heptachlor)	0.2
	Hexachlorocyclohexane (HCH) alpha isomers	0.2
	Hexachlorocyclohexane (HCH) beta isomers	0.1
	Hexachlorocyclohexane (HCH) gamma isomers	2

Table: *Maximum levels of Dioxins, dioxin-like, and non-dioxin-like PCBs for fish meal*

Product	Substance	Maximum content in ng EQT PCDD/F OMS/kg (ppm) (1) in feed calculated on the basis of a 12 % moisture content.
Fish meal	Dioxins[1]	1.25
	Sum of dioxins and dioxin-like PCBs[1]	4.0
	Non-dioxin-like PCBs (sum of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 y PCB 180)[2]	30

Table: *Maximum levels of Dioxins, dioxin-like and non-dioxin-like PCBs for hydrolyzed fish proteins that contain more than 20% fat and crustacean meal.*

Product	Substance	Maximum content in ng EQT PCDD/F OMS/kg (ppm) (1) in feed calculated on the basis of a 12 % moisture content.
Hydrolyzed fish proteins containing	Dioxins[1]	1.75
	Sum of dioxins and dioxin-like PCBs[2]	9.0[3]

[1] Sum of Polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs)] expressed in toxic equivalents (TEQ) of the World Health Organization (WHO-TEQ), using the toxic equivalency factors of the mentioned organization (WHO-TEQ, 2005).
[2] Upperbound concentrations: Upperbound concentrations are calculated on the assumption that all the values of the different congeners below the limit of quantification are equal to the limit of quantification.
[3] Does not include crustacean meal.

more than 20% of fat and crustacean meal.	Non-dioxin-like PCBs (sum of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 y PCB 180)[2]	50[3]

Table: *Maximum levels of Dioxins, dioxin-like and non-dioxin-like PCBs for fish oil*

Product	Substance	Maximum content in ng EQT PCDD/F OMS/kg (ppm) (1) in feed calculated on the basis of a 12 % moisture content.
Fish oil	Dioxins[1]	5.0
	Sum of dioxins and dioxin-like PCBs[1]	20.0
	Non-dioxin-like PCBs (sum of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 y PCB 180)[2]	175

2.40.2.2. SPECIAL SANITARY REQUIREMENTS

- Special sanitary requirements to export to France

In addition, shipments of fish meal and fish oil destined to France must be accompanied by a special certificate with additional statements, depending on the use of the product at the point of destination. The following are the possible uses with their respective sanitary statements:

- Products intended as feed for pets

Le sous-produit animal ne contient pas et n'est pas dérivé de matériels d'origine bovine, ovine et caprine autres que ceux provenant d'animaux nés, élevés en permanence et abattus dans un pays ou une région classé comme présentant un risque d'ESB négligeable par une décision arrêtée conformément à l'article 5, paragraphe 2.
«Le produit désigné ci-dessus ne contient pas et n'a pas été préparé à partir:

- *de tout ou partie du crâne, y compris les yeux mais à l'exclusion de l'encéphale, d'ovins et de caprins âgés de moins de six mois;*
- *de tout ou partie du crâne, y compris l'encéphale et les yeux, d'ovins et de caprins âgés de six mois et plus;*
- *d'amygdales d'ovins et de caprins quel que soit leur âge;*
- *de la moelle épinière des ovins et caprins âgés de douze mois et plus;*
- *de tout ou partie du crâne, y compris l'encéphale et les yeux, et d'amygdales d'ovins et de caprins nés ou élevés au Royaume-Uni.»*

- Products intended as feed for ruminants:

Les produits contenant ou préparés à partir de matières d'origine animale destinés à l'alimentation ou à la fabrication d'aliments des animaux d'élevage ne contiennent pas ou n'ont pas été préparés à partir:
a) De protéines et de phosphates d'origine animale interdits par le règlement (CE) n° 999/2001;
b) De graisses de ruminants autres que:

- *les graisses collectées avant la fente de la colonne vertébrale des carcasses de ruminants*
- *les graisses collectées après la fente de la colonne vertébrale des bovins âgés de moins de 12 mois;*
- *les graisses collectées après la fente de la colonne vertébrale des bovins âgés entre 12 et 24 mois, sous réserve de la réalisation du retrait de la moelle*

épinière préalablement à la fente longitudinale de la carcasse selon les modalités définies à l' annexe XI de l' arrêté du 17 mars 1992;
- *les graisses issues de la transformation des os de ruminants destinés à la production de gélatine de qualité alimentaire humaine, sous réserve de l' exclusion des os de la colonne vertébrale de petits ruminants de plus de 6 mois ou dont le poids net de la carcasse est de 12 kg et plus;*
- *les graisses contenant ou préparées à partir d' autres tissus osseux, sous réserve de l' exclusion des os de la colonne vertébrale de petits ruminants de plus de 6 mois ou dont le poids net de la carcasse est de 12 kg et plus.*

- Products intended as feed for non-ruminant farm animals

Les produits contenant ou préparés à partir de matières d' origine animale destinés à l' alimentation ou à la fabrication d' aliments des animaux d' élevage ne contiennent pas ou n' ont pas été préparés à partir:
a) De protéines et de phosphates d' origine animale interdits par le règlement (CE) n° 999/2001;
b) De graisses de ruminants autres que:
- *les graisses collectées avant la fente de la colonne vertébrale des carcasses de ruminants*
- *les graisses collectées après la fente de la colonne vertébrale des bovins âgés de moins de 12 mois;*
- *les graisses collectées après la fente de la colonne vertébrale des bovins âgés entre 12 et 24 mois, sous réserve de la réalisation du retrait de la moelle épinière préalablement à la fente longitudinale de la carcasse selon les modalités définies à l' annexe XI de l' arrêté du 17 mars 1992;*
- *les graisses issues de la transformation des os de ruminants destinés à la production de gélatine de qualité alimentaire humaine, sous réserve de l' exclusion des os de la colonne vertébrale de petits ruminants de plus de 6 mois ou dont le poids net de la carcasse est de 12 kg et plus;*
- *les graisses contenant ou préparées à partir d' autres tissus osseux, sous réserve de l' exclusion des os de la colonne vertébrale de petits ruminants de plus de 6 mois ou dont le poids net de la carcasse est de 12 kg et plus.*

- Specific requirements for the control of Bovine Spongiform Encephalopathy (BSE)

The interested party must conduct a microscopy analysis for each consignment for exportation to guarantee the absence of terrestrial animal proteins, in accordance with Regulation (EC) No. 999/2001. SERNAPESCA will not require this supporting information for the authorization of the shipment and further sanitary certification. Nevertheless, the exporter must ensure that these results are available to be presented at the destination at the moment of entry if required.

2.41. URUGUAY

2.41.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Fishery products destined to this market must be accompanied by the Health Certificate for Argentina, Brazil, and Uruguay, which is available in PDF format at www.sernapesca.cl.

In addition, it must include the phrase "Absence of *Vibrio parahaemolyticus*," for which it is necessary to comply with the requirements set forth for this purpose in the SERNAPESCA standards.

The submission of the certificate is bound to the following requirements:
- The processing establishment must be authorized to export to Uruguay (DINARA).
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP by means of an Authorization at Origin for the Sanitary Certification (AOSC).
- It must comply with the sanitary requirements set by this Service in Item 1 of this Chapter, in accordance with the presentation of the product.
- The establishment must file a process monograph with DINARA for each product destined to this market. Monographs must be processed in accordance with the information provided in Chapters 1 and 2.
- Signature of the Doctor of Veterinary Medicine.

The following zoosanitary statements must appear in the sanitary certificate, as appropriate, for each product:
- "Os animais utilizados como matéria-prima para fabricação do produto não foram obtidos a partir de cultivo e não apresentaram lesões atribuíveis à doença/infecção no momento da recepção da matéria prima */ The animals used as raw material in the manufacturing of the product were not obtained from farms and do not present injuries attributable to diseases/infections when receiving the raw materials;*
- Os produtos certificados não incluem espécies de camarão*/ The certified products do not include species of shrimp or prawn;*
- Os produtos certificados não incluem animais vivos, nem material de reprodução viável*/ los productos certificados no incluyen animales vivos ni material de reproducción viable;*"

- The following statement must be added for the export of live bivalve mollusks and gastropods:

"In accordance with the results of the Specific Sanitary Program to Monitor Diseases that affect Bivalve Mollusks, there is no evidence of the presence of the causal agents of the following diseases in (name of the country):
- *Bonamia exitiosa*
- *Bonamia ostrae*
- *Marteillia refringens*
- *Mikrocytos mackini*
- *Perkinsus marinus*
- *Perkinsus olseni*

2.41.2. PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Fish meal and oil

Shipments must be accompanied by a "Single Sanitary Certificate for products, subproducts and/or by-products, obtained from fishing and/or aquaculture intended exclusively as Bait, Animal Feed and other Uses Not Intended for Human Consumption, traded between the Republic of Argentina, The Federative Republic of Brazil, the Republic of Chile and the Eastern Republic of Uruguay", which is available in PDF format at www.sernapesca.cl. The issuance of the aforementioned certificate is bound to the compliance with the following requirements:
- The establishment must be included in the List of Participating Companies under SERNAPESCA's Sanitary Control Programs and must be classified at least in Category D.
- The product must comply with the sanitary requirements required by this Service, described in Item 1 of this Chapter, as appropriate.

Bait
The product must comply with the sanitary requirements set by this Service in Item 1 of this Chapter.

2.42. VIETNAM

2.42.1. PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Products intended for this market must be accompanied by a "Sanitary Certificate for Fishery and Aquaculture Products," available in PDF format at www.sernapesca.cl.

The issuance of the certificate is bound to the compliance with the following requirements:
- The processing establishment must have a Quality Assurance Program (QAP) based on an HACCP, and its products must be certified in accordance with the QAP by means of an Authorization at Origin for the Sanitary Certification (AOSC).
- The establishment manufacturing fishery products intended for human consumption must be authorized by the Ministry of Agriculture and Rural Development of Vietnam to export to that market. The request must be processed through the corresponding Regional Office, providing document *Appendix 3*, which must be requested in the same office, including all the information on the process requested on it, only in English. This document must be reviewed, signed and stamped by the SERNAPESCA inspector in charge of the plant and submitted to the National Directorate for its further delivery, in original, to Vietnam.
- The establishment may only export to this market once the competent body in that country includes the requesting company and its web list.
- For products that are not intended for internal consumption in Vietnam, such as the case of shipments that will be re-exported (intended or not intended for reprocessing) or that are in transit, the registration of the processing establishment in the Vietnamese list is not mandatory. In this case, the exporter must present a simple statement that accredits that the product will not be consumed in Vietnam when presenting the supporting documentation for the sanitary certification (AOSC or SMAE).
- The product must comply with the requirements set forth in Item 1 of this Chapter, in accordance with the presentation of the product.
- To incorporate new species or products in the Vietnamese list, the company must send new documentation (Appendix 3) for each process line that it wishes to include.

PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

Feeds Intended for Aquatic Species
Shipments destined to this market must present a process monograph and be accompanied by the *Certificate for feed for aquatic species* available at www.sernapesca.cl.

For lots of feed produced with fish meal, the issuance of the aforementioned certificate will be subject to the compliance with, at least, the microbiological standards for fish meal, described in Item 1, Chapter IV. For this, the feed must be sampled prior to the shipment, considering the collection of n=1 for every 50 tons of feed.

The following statement must be included in the certificate:

- Durante el proceso, las harinas de pescado han sido procesadas bajo una temperatura mínima de 90 C° por 40 minutos/During manufacture, the fish meal has been heat treated at a minimum core temperature of 90 C° for 40 minutes.

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CHAPTER V. CERTIFICATION OF ORIGIN

The purpose of the certification of origin is to accredit that the origin of the export product is Chilean and that it complies with the rules of origin described in the corresponding agreement, for the tariff reductions that it has obtained in the negotiation process.

1. ADMINISTRATIVE PROCEDURE

The General Directorate of International Economic Relations of the Ministry Foreign Affairs is the official public institution in charge of certifying the origin of the goods manufactured and produced in Chile from January 1, 1993, as stated in Decree 1295 of November 1992 of the Ministry of Foreign Affairs.

The General Directorate of International Economic Relations, in the exercise of its functions and complying with the relevant legal requirements, determined by exempt Resolution 827 of the Ministry of Foreign Affairs, that the National Fisheries and Aquaculture Service will be in charge of conducting verifications of origin of export fishery products and of providing the corresponding certification.

The purpose of the certification of origin is to accredit that the origin of the export product is Chilean and that it complies with the rules of origin described in the corresponding agreement, for the tariff reductions that it has obtained in the negotiation process.

Markets such as United States, Canada, Mexico, Costa Rica, El Salvador, Guatemala, Honduras, South Korea, P4 (Singapore, New Zealand, and Brunei), Panama and Australia are self-certified, therefore do not require the certification of origin issued by National Fisheries and Aquaculture Service.

For the markets of the European Union, Colombia, EFTA, China and Turkey, the certification of origin is issued by the Ministry of Foreign Affairs with the support of Chamber of Commerce and Sofofa.

The certification of origin is optional and is issued upon the request of the interested party, who must proceed in accordance with the instructions provided in Chapter II of this Section.

If a company requests a certification of origin and the product is destined to markets with which there is a mandatory for sanitary certification agreement in place, it must be verified in the List of Companies under SERNAPESCA's Sanitary Control Programs, that the processing establishment is authorized to export to that market, and that the agreed sanitary certification is being requested.

To obtain a certificate of origin, the interested party must present the following documentation at the SERNAPESCA Office assigned to the place where the product is shipped:

- Notification of Shipment of Export Fishery Products authorized by SERNAPESCA in original.
- B/L or a non-negotiable copy of the B/L (original or photocopy). This document may be replaced by the Air Waybill for air shipments, or by the CMR Waybill, for road transportation.
- Export Invoice, original copy. A proforma invoice will be accepted only for shipments of chilled-refrigerated products. In these cases, the exporter must commit to provide the original export document as soon as possible.

- Original and copy of the Certificates of Origin being requested, which must be printed, numbered and provided by this Service.

The SERNAPESCA official will verify that the information provided in the certificates matches the information provided in the DUS and in the Export Invoice or proforma and that the certificates include all the requested information. The number of the Notification of Shipment for Export Fishery Products must appear in the upper right corner of the certificates. The commercial name of the product and its full scientific name must always be indicated.

1.1. SIGNATURE AND STAMP OF CERTIFICATES OF ORIGIN

To certify the origin, the official of SERNAPESCA, with his signature registered both at ALADI (Asociación Latinoamericana de Integración) as in the SGP (Sistema Generalizado de Preferencias), must stamp the seal SERNAPESCA and his signature in the corresponding box, in accordance with the format of the certificate.

It must also include the name of the official for the certification of origin of ALADI and for Form A, using the stamp "Official Inspector."

1.1.1. CHAPTERS OR TARIFF HEADINGS TO BE CERTIFIED BY SERNAPESCA

Chapter 3	Complete, except for item 0307.6000
Chapter 12	Only items 1212.2010, 1212.2020, 1212.2090
Chapter 13	Only item 1302.3100
Chapter 16	Only items 1603.0000, 1604.0000, 1605.0000
Chapter 23[1]	Only items 2301.1000, 2301.2000

It must be verified that the exporter identified in the certificate of origin always corresponds to the issuer of the Export Invoice.

It must be mentioned that the issuance of certificates of origin for products with specific requirements such as Marine toxins, *Vibrio parahaemolyticus* or norovirus, must comply, in addition to the commercial requirements, with the sanitary requirements described in Chapter 2 of this Section.

1.1.2. TECHNICAL REQUIREMENTS

All certificate of origin forms for export fishery products are available at SERNAPESCA's web page, which are listed as follows:

- Certificate of Origin - Chile: Accredits that the product is of Chilean origin, available in bilingual English/Spanish format. It may not be used for tariff reductions and to obtain it is only necessary to present the NEPPEX, the Single Exit Document (DUS) and the Export Invoice in original.
- Certificate of Origin - ALADI: Accredits that the product is of Chilean origin and allows to apply for preferential tariffs at the destination market, member of ALADI. It must be signed by the exporter and include the name of the importing country, the NALADISA codes and

[1] This Chapter does not apply for the certification of origin under the framework of ALADI.

Chilean harmonized, export invoice number and the Economic Agreement subscribed between Chile and the country of destination.

- Certificate of Origin - Mercosur: Accredits the Chilean origin for markets that are part of Mercosur. The certificate must include a description of the goods with the NALADISA code, FOB price and the sworn declaration of the Mercosur Certificate of Origin (Part III, Annexes, Chapter II) of the exporter with the information that proves the compliance with requirements. The certificate may be issued within five business days after presenting the NEPPEX and within 10 days after the shipment. The certification date may not be prior to the date of issuance of the invoice.
- Certificate of Origin - ALADI Venezuela: Accredits the Chilean origin fishery products destined to Venezuela. It only requires the presentation of NEPPEX, DUS and export invoice.
- Certificate of Origin - ALADI Peru: Accredits the Chilean origin fishery products destined to Peru. The following must be presented for its issuance: NEPPEX, DUS, export invoice and Simple Sworn Declaration, Certificate of Origin - ALADI Perú (Part III, Annexes, Chapter II) of the exporter with the information that proves the compliance with the requirements. It must be issued within seven days from its request, the certification date may not be prior to the issuance date of the invoice and is valid for 180 days.
- Certificate of Origin - Form A: Certifies the Chilean origin and it allows to apply to duty-free entries of developed countries under the framework of the Generalized System of Preferences (GSP). It must include: The signature of the exporter, the invoice number, and date; its format is yellow.
- Certificate of Origin ACE 65: Accredits that the product is of Chilean origin, and as such, it can apply to preferential tariffs granted by the market of Ecuador under the Economic Complementation Agreement (No.65), signed between Chile and Ecuador, according to the technical specifications described in Chapter IV. It must be signed by the exporter in the area assigned for this purpose.

There are different specific technical requirements for each certificate format, which are described as follows:

1.2. CERTIFICATES OF ORIGIN - ALADI

This certificate accredits that the product is of Chilean origin and that as such, can apply to preferential tariffs granted by the ALADI market in accordance with the following rules.

1.2.1. RULES OF ORIGIN

1st Are from countries that have subscribed an agreement in accordance with the 1980 Montevideo Treaty:

a) The goods have been manufactured entirely in their territories when in their manufacturing processes only materials from the country participating in the agreement are used.

b) The goods included in the items of NALADISA, by the mere fact of being produced in their territories.
   For such purposes, the following will be considered as produced:
   - Goods from the mineral, vegetable and animal kingdoms (including hunting and fishing), extracted, harvested or collected, formed in their territory or in territorial, patrimonial waters and in exclusive economic zones.
   - Marine goods extracted outside of territorial, patrimonial waters and exclusive economic zones, by ships with their flags or rented by companies legally established in their territory, and

- The goods from operations or processes carried out in their territory by those who acquire the final form in which they will be commercialized, except for operations and processes considered in the second paragraph of letter c).

c) The goods manufactured in their territories using materials of countries not participating the agreement, to the extent that they are the result of a transformation process conducted in some of the participating countries and that grant them a new individuality characterized by the fact of being classified in NALADISA in a batch different from that of such materials.
The goods obtained through processes and operations for which they acquire a final form in which they will be commercialized, will not be original from the participating countries, when in such processes materials from non-participating countries are used and consist only of simple assemblies or mountings, packaging, lots fractioning, pieces or volumes, selection, and classification, marking, composition of goods assortments and other operations that do not imply a substantial transformation process as vivid description of the first paragraph of this letter.

d) The goods that come from assembly or mounting operations, conducted in the territory of a participating the country using materials from the countries participating in the agreement and of for countries, when the CIF price at the port of destination or the CIF of the maritime port of the materials originating from third countries does not exceed 50 (fifty) percent of the FOB export price of such goods.

e) The goods that, in addition to being manufactured in their territory comply with the specific requirements set forth in Annex 2.

2nd In the cases where the requirement set forth in letter c) of the article 1 cannot be met because the transformation process employed does not imply a change in the position of the batch in the NALADISA, it will be sufficient for the CIF price at the point of destination or for the CIF price of the maritime port of materials from countries not participating in the agreement to not exceed 50 (fifty) percent of the FOB export price for the goods.

3rd For the countries with lower relative economic development, the percentage established in letter d) of article 1 and article 2, will be 60 (sixty) percent. This regime, reaches equally those agreements in which the concessions agreed between the participating countries are automatically extended to the countries with lower relative economic development, without providing compensations and independent from the negotiation or adhesion with them.

4th For the originating goods to benefit from preferential treatments, these must have been issued directly from the exporting country to the importing country. For such purposes, direct issuance is considered as:

a) The goods transported without passing through the territory of a certain country that is not part of the agreement.

b) The transported goods in transit through one or more non-participating countries, with or without transshipment or temporary storage, under the surveillance of the competent customs authority in such countries, to the extent that:
   - The transit is justified by geographical reasons or considerations relative to transportation requirements;
   - Are not intended for commercialization, use or employment in the country of transit; and
   - Are not subjected to, during their transportation and deposit, any operation different from loading and unloading to keep them in good conditions or ensure their preservation.

5th For the purposes hereof the following must be considered:
a) That the expression "territory" comprises the duty-free zones located within the geographical boundaries of any of the participating countries; and
b) That the expression "materials" comprises raw materials, intermediate products and the parts used in the production of the goods.

6th The countries participating in agreements of partial scope may establish specific requirements for the products negotiated in the mentioned agreements. Such requirements may not be less demanding than those that would have been established with the application of this resolution unless referring to the qualification of the products originating from the countries with lower economic development.

7th For the goods to be exchanged to obtain the benefit of the preferential treatments agreed by the countries participating in an agreement subscribed in accordance with the Montevideo Treaty of 1980, such countries must accompany the export documents, in the form adopted by the Association, with a declaration that accredits the compliance with the corresponding requirements of origin as set forth in the previous Chapter. Such declaration may be issued by the end producer or the exporter of the goods.

8th The description of the goods included in the declaration that accredits the compliance with the requirements of origin set forth by the provisions in force, must agree with the one corresponding to the negotiated goods classified in accordance with the NALADISA and with which it is registered in the commercial invoice that accompanies the documents presented for the customs clearance.

In the cases where the goods have been negotiated with a nomenclature different from that of NALADISA, the code and the description of the nomenclature registered in the agreement will be indicated.

9th When the goods to be exchanged are invoiced by an operator of a third country, member or non-member of the Association, the producer or exporter of the country of origin must indicate in the respective form, in the "Remarks" section, that the goods of the Declaration will be invoices from a third country, indicating: "Operation in charge of a third operator", identifying the name, denomination or registered name and commercial address of the operator that will finally invoice the operation at destination.

In the situation referred to in the previous paragraph and, exceptionally, if at the moment of issuing the certification of origin, the number of the commercial invoice issued by an operator of a third country is unknown, the corresponding area of the certificate must not be filled. In this case, the importer will present at the corresponding customs administration, a sworn declaration that justifies the fact, which must indicate, at least, the names and dates of the commercial invoice and of the certificate of origin that support the import operation.

10th The declaration referred to in Chapter 7 must be certified in all cases by an official institution or a trade organization with legal personality, authorized by the Government of the exporting country.

For ALADI certificates, these must be issued within 7 days from the presentation of the respective request.
The certificates of origin issued for the reductions regime will be valid for 180 days, from the date of certification by the competent entity or body of the exporting country.

Notwithstanding the validity referred to in the previous paragraph, the certificates of origin may not be issued before the date of issuance of the commercial invoice of the operation, but on the same date or within the next 60 days, except for what is set forth in the second paragraph of Article 9.

11th The member countries, through their Permanent Representations, will communicate the General Secretariat the relationship of the official departments and trade organizations authorized to issue the certification referred to in the previous paragraph, with the list of authorized officials and their corresponding autographic signatures.

When authorizing trade organizations, the member countries must see that they are organizations that act with national jurisdiction, thus being able to delegate attributions in regional or local entities, always keeping the direct responsibility for the veracity of the certifications being issued.

The communications will be published and immediately made known in the Permanent Representations, by the General Secretariat.

12th The General Secretariat will keep an updated registry of the official departments and trade organizations authorized by the member countries to issue certifications of origin, as well as the lists of authorized officials and their corresponding autographic signatures.

13th The member countries, through their Permanent Representations, will communicate to the General Secretariat any modifications for official departments and trade organizations authorized to issue certificates of origin, as well as in the lists of authorized officials and their corresponding autographic signatures.

The member countries will use the "Registry of Authorized Signatures to issue Certificates of Origin" form, to communicate any new registries of authorized signatures to issue certificates of origin, as well as any updates on the previously registered signatures.

The modifications made in the registry, both in terms of signatures and official departments and trade organizations authorized to issue certificates of origin, will be in force fifteen calendar days after the General Secretariat has communicated the Permanent Representations, and the registries prior to the modification will be valid until then.

Such communications will be published and immediately made known in the Permanent Representations, by the General Secretariat.

14th The certificates of origin must be issued in accordance with the regulations set forth in this Regime.

In consequence, they must be issued in the single form adopted by the Representative's Committee (available in SERNAPESCA's web page) to qualify the origin of the goods being exchanged, duly stamped and signed by the official departments or trade associations authorized for their issuance. Together with the seal of the authorized official department or trade organization, the name of the authorized party must be registered in print.
15th If a participating country considers that the certificates issued by an official department or trade organization authorized in the exporting country, does not adjust to the provisions set forth in this Regime, it will communicate so to the referred exporting country so that it adopts

the measures that it deems necessary to solve the stated problems.

In no case, the importing participating country will stop the import proceeding for the goods included in the certificates referred to in the previous paragraph, but it may, in addition to requesting the additional information corresponding to the governmental authorities of the exporting participating country, adopt the measures that it deems necessary to ensure the compliance with tax laws.

16th The provisions of this General Regime and any amendments, will not affect the goods shipped at the date of their adoption.

17Th This Regime will be applied in general terms to the regional agreements subscribed based on this Resolution and will be applied as a supplement of the partial scope agreements in which specific standards for origin are not adopted unless otherwise decided by its signatories.

1.2.2. FILLING IN THE CERTIFICATES

a) It must be signed by the exporter or its representative (authorized with a power of attorney) in the place assigned for this.
b) The name of the country where the goods will be exported must be included in the box "Importing country."
c) In the NALADISA column, the item of the product to be exported must be filled in, expressed in the NALADISA code and in the Chilean Harmonized code, as per the ALADI agreement and the detailed name of the product in the "Denomination of the goods" column.
d) In "Declaration of origin" the corresponding commercial invoice number must be included, and the agreement under which the negotiated product is subscribed.
e) The export invoice must have been issued within 60 days prior to the issuance of the certificate. Otherwise, it must be expressly stated in the box "Standard (3)" that the product has an overdue export invoice.
f) The standard corresponding to the agreement for such product must be entered in the box "Standard (3)"
g) It is not necessary to include the FOB price.

1.2.3. OTHER CONSIDERATIONS

a) The ALADI Certification of Origin is not required for Mexico, in accordance with the Chile - Mexico Free Trade Agreement.
b) In the specific case of Ecuador, Peru and Venezuela, the issuance of certificates of origin ACE Nº65, ACE Nº38 y ACE Nº23, is required, respectively.
c) In the case of Certificates of Origin Chile (SERNAPESCA format), ALADI, Venezuela and ALADI Peru, only the documentation and supporting documentation described in item i) will be required. In the case of ALADI Peru, also a Specific Sworn Declaration (available at the Service's web page) of the exporter with the documented information that demonstrates that the goods comply with the requirements must be attached.

Under the framework of ALADI, our country has four instruments in force, through which exports can take place, where the rest of the partners of such association benefit from tariff reductions, these are:

1) Partial Renegotiation Agreements of the Preferences granted in the 192/1980 period (AAPR).

Table 157
Economic Complementation Agreement (ACE)

Country	ACE
Bolivia	No. 22
Cuba	No. 42
Ecuador	No. 65
Mercosur	No. 35
Peru	No. 38
Venezuela	No. 23

2) Market Openness Regional Agreements (ARAM).

3) Free Trade Agreements:
Chile/Australia
Chile/Canada
Chile/Central America
Chile/Colombia
Chile/China
Chile/South Korea
Chile/EFTA (Iceland, Liechtenstein, Norway and Switzerland)
Chile/United States
Chile/Malaysia
Chile/Mexico
Chile/Panama
Chile/Turkey
Chile/Vietnam

1.3. MERCOSUR CERTIFICATE OF ORIGIN

This certificate is issued for the markets that are part of Mercosur based on the Chile-Mercosur Economic Complementation Agreement, ACE No. 35.

1.3.1. RULES OF ORIGIN

1° Goods manufactured entirely in the territory of one or more of the Signatory Parties, when in their manufacturing, only and exclusively originating materials of the Signatory Parties have been used.

2° Goods from the mineral, vegetable and animal kingdoms, including those from hunting and fishing, extracted, harvested, born and raised in the territories of the Signatory Parties or within or outside of their patrimonial territorial waters and exclusive economic zones, by ships of their flags or rented by companies established in their territories and processed in their economic zones, even when they have been subjected to primary processes of packaging and preservation, necessary for their commercialization.

3rd Goods produced on board factory ships from fish, crustaceans and other marine species, obtained from the sea by ships registered by one of the Signatory Parties and that carry their flag.

4th Goods obtained by one of the Signatory Parties or by one person of the Signatory Parties, from the seabed outside of territorial waters, to the extent that this Party or person has the right to use that seabed.

5th Goods obtained from the extraterrestrial space to the extent that they have been obtained by one of the Signatory Parties or by one person of the Signatory Party and that are processed in some of such parties.

6th Paragraph 1 - Goods manufactured with non-originating materials, to the extent that they derive from a transformation process, conducted in the territories of the Signatory Parties assigning a new individuality. This individuality is present in the fact that the goods are classified in a consignment different from the materials (four first digits of the NALADISA).

6th Paragraph 1. Appendix No. 1 (B) Goods manufactured with non-originating materials, for which it has been considered, in addition to the change in tariff heading referred to in the previous paragraph, a regional content, in which the CIF price of the port of destination or the CIF price of the maritime port of the non-originating materials does not exceed 40% of the export FOB price of the end goods.

7th Goods manufactured with non-originating materials that do not comply with the requirement set forth in number 6. Paragraph 1 because the transformation process does not imply a change in tariff headings, but the CIF price of the port of destination or the CIF price of the maritime port of the non-originating materials does not exceed 40% of the export FOB price of the final goods.

8th Goods resulting from mounting or assembly operations conducted within the territory of one of the Signatory Parties, regardless of complying with the change on tariff headings, using non-originating materials, the CIF price of the port of destination or the CIF price of the maritime port of these materials does not exceed 40% of the export FOB price of the end goods.

1.3.2. FILLING IN THE CERTIFICATES

a) The description of the goods must agree with the description of the NALADISA code and with the one registered in the commercial invoice.
b) A Simple Sworn Declaration (Part III, Annexes, Chapter II) of the exporter with the documented information that demonstrates that the goods comply with the requirements must be attached.
c) The declaration must manifest the complete compliance with the provisions on the origin of the agreement. This declaration will be valid for 180 days and may be presented in this period every time shipments of the same characteristics take place.
d) It must include the FOB price of the goods to be exported.
e) All the fields of the certificate must be duly completed. Otherwise, the certificate will not be valid. Field 3 may only be crossed out when the importer and the consignee are the same, as well as field 14, if appropriate.

1.3.3. OTHER CONSIDERATIONS

a) The certificate must be issued, within five (5) business days from the presentation of the

respective Notification of Shipment for Export Fishery Products and will be valid for 180 days from its issuance.

b) The certificates of origin may not be issued before the date of issuance of the commercial invoice of the operation, but on the same date or within the next 60 days.
c) The certificates may be issued within 10 business days after the effective shipment of the goods that they certify. Those products destined to trade shows or promotional events sponsored by competent bodies are exempted from this measure, and only what is set forth in the previous paragraph applies.
d) If the incorporation of tariff codes different from those declared in the corresponding agreements is required, this information may be detailed in the "Remarks" box of the certificate, understanding that the agreed codes are declared in the "Tariff code" box.

1.4. FORM A CERTIFICATE OF ORIGIN

Certifies that the product is Chilean and allows to apply for duty-free entries in certain developed countries under the framework of the Generalized System of Preferences (GSP).

1.4.1. RULES OF ORIGIN

The main purpose of the rules of origin is to limit the preferential tariff agreement of the Generalized System of Preferences (GSP) only to products authentically extracted, harvested, produced or manufactured in the exporting countries that obtain preferences. The benefits of the GSP may not be claimed for those products whose origin is from third countries, for instance in countries providing preferences and that are simply in transit through a country that obtains preferences, or that only undergo a slight or superficial manufacturing process in that country.

In general, each item of an export tariff heading must comply with the standards of origin established by the country of destination providing the preferences.

The products exported from a country receiving the preferences may be divided into two groups:

a) The products that have been entirely farmed, extracted from the ground or harvested in the exporting country, or that have been manufactured exclusively from any of these products. Such products that are "entirely obtained" comply with the requirements of the GSP in terms of origin for not having used any imported component or material or of unknown origin.

   The criterion for the product entirely obtained in the beneficiary country is interpreted in a strict sense. A minimum trace of imported parts, materials or components in their content does not allow for the product to have the condition of being "entirely obtained."
   All the countries granting preferences admit the following product categories considering them as "entirely obtained" in a country receiving preferential treatment:
   1. The mineral products extracted from the soil or their sea-beds.
   2. Products of the vegetable kingdom harvested in the country.
   3. Live animals born and raised in the country.
   4. Products obtained from live animals in the country.
   5. Products from hunting or fishing in the country.
   6. Fishery products and other products extracted from the sea by ships in the country.
   7. Items produced on board factory ships exclusively with the products mentioned in

Item (6).
8. Used items that can only be used for recovering raw materials.
9. Waste from manufacturing operations conducted in the country.
10. Products obtained in the country exclusively from the products listed in sections (1) to (9).

b) Products made from imported materials, parts or components, that is to say, that have been manufactured, entirely or in part, from raw materials, parts or components that have been imported to the country receiving preferential treatment from the exporter (or that are of unknown origin). These products, called "products that contain imported supplies," comply with the requirements only if they have subjected to "manufacturing in other sufficient forms" in the country receiving the preferential treatment from the exporter.

In accordance with these basic definitions, each scheme of the GSP describes the "sufficient production or transformation" standards that must be met so that the goods can be part of the GSP agreement.

The products that have been manufactured in a country receiving preferential treatment entirely or partially with imported materials, parts or components, are considered to be originating from that country of those materials, parts or components have been subjected to sufficient production or work in the country. In general terms, a work or production process is considered to be sufficient if it substantially transforms the nature and characteristics of the used materials. Each country granting preferential treatment defines this general concept in detail.

1.4.2. CRITERIA FOR MANUFACTURING AND PERCENTAGE

The concept of "sufficient work or manufacturing" has been defined in different ways. However, there are two main criteria, and each is used by some countries granting preferential treatment. These criteria are called "manufacturing criterion" and "percentage criterion."

1.4.2.1. MANUFACTURING CRITERION

It is considered that the imported materials, parts or components ("non-originating supplies") have been subjected to a sufficient work or manufacturing process if the finished product is within a tariff heading of four figures in the Harmonized System, different from that of those materials, parts or components used in the process ("change in headings of the HS"). However, the change in the headings of the HS does not always imply a change in the sufficient work or manufacturing or vice versa; therefore, the countries granting preferential treatment have created a "Single List" which outlines the works or manufacturing processes that the non-originating materials must be subjected to, to consider the finished product as originating. The conditions specified in the single list can refer to:

a) The requirement that some of the materials used in the production process must be originating from the exporting beneficiary country.
b) The requirement that only certain non-originating supplies can be used as raw materials.
c) A combination of a) and b).
d) The requirement that the non-originating supplies used have a certain level of manufacturing which is generally low.
e) The requirement that the non-originating supplies used must not exceed a certain percentage of the factory price of the finished product.
f) The possibility of using non-originating supplies from the same four-digit headings of the

Harmonized System than the exported product.

Several products mentioned in these lists must comply with the condition that the price of the imported products does not exceed a certain percentage of the finished products so as to calculate if such percentage is respected:

- The price of the imported supplies is defined as its customs price when importing it to the country receiving preferential treatment, or in the case of supplies of undetermined origin, the first verifiable price paid by them in that country; and
- The price of the products obtained is the factory price of the products, deducting indemnifiable or internal indemnifiable taxes when conducting the export.

1.4.2.2. PERCENTAGE CRITERION

Some countries state that imported (or of unknown origin) materials, parts, and components may be used in the manufacturing of export products, whose price does not represent more than a certain maximum percentage. Other countries require the use of materials, manufacturing process, etc., of internal origin in the manufacturing of the exported product, whose price does not represent less than a certain minimum percentage of that product.

Minimum processes that do not constitute origin for most of the granting countries:

a) Operations that ensure the preservation of the products in good condition during transportation and storage (ventilation, cooling, salting, immersion in sulfur dioxide or other aqueous solutions, removal of damaged parts, among others).
b) Simple operations that consist of removing dust, sieve, sift, select, classify, create sets of items, wash, paint, or chop.
c) Changing packages and fragmenting and gathering shipments.
d) Simple placement in bottles, jars, sacks, cases, boxes, on cards or cardboard boxes and other simple packing operations.
e) Placing brands, tags or other similar distinctive signs on the products or their packages.
f) The simple mix of products, whether or not from different classes when one or more components of the mix do not comply with the conditions set forth in the standards to be considered as originating products.
g) The simple assembly of parts of products to form a single product.
h) A combination of two or more of the previously mentioned operations.
i) Animal slaughtering.

1.4.3. FILLING IN THE CERTIFICATES

a) It must be signed by the exporter or its representative (authorized with a power of attorney) in the place assigned for this.
b) That expressly indicates the export invoice number and its date.
c) That all the information required in this form has been included, such as the weight of the product, the order number, and the brands, as appropriate.
d) That it expressly indicates "signed or issued a posteriori," as appropriate, in box No. 4.
e) That box No. 8 relative to the criteria of origin, includes the correct code and that these are different depending on the country.
f) That the certificates issued to the Eurasian Economic Union indicate in box No. 11, over the lower line: National Fisheries Service, CITY (where the certificate is issued), CHILE.
g) That the form to be issued is yellow.

1.5. CERTIFICATE OF ORIGIN ACE 65

Accredits that the product is of Chilean origin, and as such, it can apply to preferential tariffs granted by the market of Ecuador under the Economic Complementation Agreement (No.65), signed between Chile and Ecuador.

Under the framework of this Agreement, the re-issuance of the certificates of origin under the concept of void and replacement is not permitted.

1.5.1. FILLING IN THE CERTIFICATES

a) The certificate must be printed in white paper, without a logo or a pre-printed background, in a legible manner.
b) The certificate must be printed on the front side of the same sheet, and it is considered that the "Instructions for filling in the certificate of origin" are part of the same.
c) The number given to the document will correspond to the number of the Notification of Shipment for Export Fishery Products.
d) The purpose of this certification is to obtain a preferential tariff treatment for fishery products that comply with the criteria of origin (a), (b) or (c), described in the back of the certificate. Therefore, its issuance does not apply in the case of imported raw materials. Similarly, in the case of incorporating supplies that are not of Chilean origin, the cases will be evaluated in accordance with the criteria described in the Agreement in Item 11.
e) Exporting country item: CHILE
f) Importing country item: ECUADOR
g) Field 1: Indicate the full legal name, address (including city and country) and the tax registry number (Taxpayer's ID-RUT).
h) Field 2: Indicate the full legal name, address (including the city and country) and the tax registry number (Tax Identification Number RUC - TIN) of the importer. If the importer is unknown, please enter "UNKNOWN."
i) Field 3: Please provide a full description of each item. It must be sufficiently detailed so as to enter the description in the 2007 Naladisa system and the description of the goods included in the invoice. The Naladisa 2007 description can be downloaded at http://www.aladi.org/NSFALADI/NALADI07.NSF/VNALADISAWEB.
j) Field 4: For each item described in Field 3, provide the corresponding eight digits in the Naladisa 2007 system.
k) Field 5: Provide the corresponding criterion (a, b, or c) for each item described in Field 3. The rules of origin can be found in Chapter 4 and Annex 4.1 of the Agreement. Preferential Criterion:
    1. The goods are entirely obtained or produced in the territory of one or the other Parties, as per article 4.26; (applies to products 100% manufactured in Chile from 100% Chilean raw materials, without using supplies from non-Chilean origin).
    2. The goods are produced in the territory of one or the other Party, exclusively from materials that qualify as original, as per the provisions of this Chapter; (applies to products 100% manufactured in Chile from 100% Chilean raw materials, using supplies from non-Chilean origin, e.g. canned goods where the container is originated in Ecuador, Chile, Bolivia, Colombia or Peru).
    3. The goods are produced in the territory of one or the other Party, from non-originating materials that come from a production or transformation process giving it a new individuality characterized by a change in the tariff classification, a

price of regional content or other requirements as set forth in Annex 4.1 of this Agreement (applies to products manufactured in Chile from non-Chilean raw materials, from Ecuador, Bolivia, Colombia or Peru, which have been subjected to transformation, to determine the use of this certification alternative, the regional content price must be calculated, and therefore it must always be requested).

l) Field 6: Indicate the number and date of the commercial invoice.
m) Field 7: Indicate the gross weight in kilograms (kg) or other measurement units as volume or number of products that indicate exact quantities.
n) Field 8: Indicate any information referring to the verification of origin of the goods. In the case of invoicing from an operator of a non-Party country, indicate the phrase "Operation invoiced by an operator of a non-Party country," in such case an invoice must be provided at the moment of issuance.
o) Field 9: To be filled in by the exporter, indicating COUNTRY: CHILE and adding its signature.
p) Field 10: To be filled in by SERNAPESCA, including the stamp of the Official Inspector, the stamp of the Service, its signature, the location and the date in which it took place.

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