Part II: Section II

Processes Control

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SECTION II. PROCESSES CONTROL

This section establishes the sanitary administrative procedures and technical requirements that must be met by the different establishments that are part of the production chain of fishery and aquaculture products intended for export, this is primary production, processing, and storage.

It must be noted that these establishments must comply with the basic requirement established by SERNAPESCA, of accrediting the legal origin of the hydrobiological resources.

CHAPTER I. APPROVAL OF ESTABLISHMENTS AND FACILITIES

Production establishments may apply to become part of the SERNAPESCA Sanitary Control programs, for which they must accredit to have all the legal and regulatory authorizations for their operation, this is, the Resolutions of the National Fisheries and Aquaculture Service authorizing them to process the described products, sanitary authorizations granted by the Health Service, municipal permits and other relevant authorizations.

Once the above has been accredited, the person responsible for the company must present the Fish Processing Plants and Factory Ships Approval Program Processing Request and request an inspection visit to the establishment applying. The date of the visit must be coordinated so that when it takes place the plant is processing resources or the factory ship is in its landfall, as appropriate for the type of establishment.

1. LIVE BIVALVE MOLLUSKS DISPATCH ESTABLISHMENTS

The procedures and requirements described in this item apply to live bivalve mollusks dispatch establishments that export their products to the European Union.

The representative of a dispatch establishment must request its authorization in writing to the Regional Directorate of SERNAPESCA under whose jurisdiction the facilities are located.

SERNAPESCA Inspector will carry out the inspection at the date agreed with the interested parties. At the moment of the visit, the establishment and/or facilities must comply with all the requirements described in this section, which will be verified applying the Inspection Checklist for Harvest, Distribution and Depuration Centers of the Bivalve Mollusks Sanitation Program (Part III, Annexes, Chapter III).

The approval will be granted only if at the moment of the visit the number of deficiencies detected in the establishment and/or facility does not exceed what is described in the following table:

Table: *Criterion for the approval of dispatch establishments*

Critical	Serious	Minor
0	2	3

One classification for the observed deficiencies has been added (see Part I, Glossary) for each one of the items included in the above checklist, with the purpose of conducting an objective evaluation of each establishment.

The Regional SERNAPESCA Inspector will send the result of the evaluation to the Central Office with all the information on the visit; if the establishment complies with the requirements for a dispatch center, SERNAPESCA will notify the European Union for it to be included in the list of authorized establishments.

Once the confirmation from the European Union is received, the Central Office will notify the corresponding Regional Directorate and the interested party in writing.

If the establishment does not comply with the requirements, the center must apply the necessary measures to solve the noncompliances and request a new visit, following the same procedure.

After obtaining its authorization, the dispatch center must be regularly inspected with unannounced visits during production periods. The frequency of the inspection will be that described in the SERNAPESCA Inspections Program.

The inspections to the centers will be in charge of the Regional SERNAPESCA Inspector, applying the Checklist for Harvest, Distribution and Depuration Centers of the Bivalve Mollusks Sanitation Program (Part III, Annexes, Chapter III).

If during the inspection any critical deficiencies are detected, they must be immediately corrected. Otherwise, the establishment will be suspended until the issue is solved. Similarly, if fouror more new serious deficiencies are detected, the measures to solve them must be applied; otherwise, the center will be suspended.

The SERNAPESCA Inspector will issue a report to the establishment, informing the results of the evaluation.

1.1. GENERAL REQUIREMENTS FOR INFRASTRUCTURE

Shore-based facilities may not be located in areas that are exposed to floods caused by ordinary high tides or the influence of neighboring areas.

Ponds and/or water tanks must comply with the following requirements:

- Their inner surface must be smooth, resistant, impermeable and easy to clean.
- They will be built in such a way that all the water in it can be drained.
- The seawater pumping hole must be located in an area that avoids the contamination of the pumped water.

In addition, the dispatch centers must comply with the requirements set forth in Item 3.2.2 of this Chapter, applicable to fishery establishments.

1.2. HYGIENE CONDITIONS

The companies that have Dispatch Centers must guarantee the compliance of the following requirements:

- Handling of live bivalve mollusks, and especially their conditioning, calibration, packaging, and packing must not contaminate the product or affect its viability.
- Before their dispatch, the shells of the live bivalve mollusks must be washed thoroughly with clean water.

Live bivalve mollusks must come from:

- A Type A production area;
- A relaying area;
- A depuration center or
- Another dispatch center

The previously described requirements must also apply to the dispatch centers located on board a vessel.

1.3. PACKAGING

Live bivalve mollusks will be packed in good hygiene conditions. Containers:

- May not alter the organoleptic characteristics of live bivalve mollusks.
- May not transmit substances that are harmful to human health to live bivalve mollusks.
- Must be sturdy enough so as to properly protect the live bivalve mollusks.

Oysters will be packed with the concave shell downwards.

All the packaging for live bivalve mollusks must be closed, and the company must make sure that they will remain sealed from their exit from the dispatch center until their delivery to the end consumer or retailer.

The shipments will consist of mollusks packed in packages of a proper size for retail sale to restaurants or directly for the consumer.

1.4. PRESERVATION AND STORAGE

In cold stores, live bivalve mollusks will be kept at a temperature that does not impose a negative effect in their quality and viability. The packaging will not be in contact with the floor of the cold store, it must be placed in a clean and raised surface.

Re-immersing live bivalve mollusks in water or sprinkling water over them is prohibited after their packing or exit from the dispatch center.

1.5. LABELING SHIPMENTS

All packages from live bivalve mollusks shipments will have a sanitary mark that allows identifying their dispatch center, during the entire process of transportation, distribution, and delivery to the retailer. The mark must contain the following information:

- Country of dispatch.

- Species of bivalve mollusk.
- Identification of the dispatch center through the authorization number provided by the National Fisheries and Aquaculture Service.
- Packaging date including at least the day and month, and the expiration date may be replaced by the phrase "these animals must be alive at the moment of purchase."
- Clearly indicate the following phrase "Live mollusks intended for immediate human consumption. Unfit for relaying in community waters."

The sanitary mark may be printed on the packaging, on a separate label, attached to it or inside it. It may also be press-fit or stapled, and only irremovable sanitary adhesive labels may be used. Each sanitary mark model may only be used once and will be non-transferable.

The sanitary mark must be resistant and impermeable, and the information included must be legible, indelible and written with clear characters.

When the shipments are directly sent to an importing center approved by the Community, these may not leave such facilities until they have been packed and labeled according to the instructions provided above.

2. SLAUGHTERHOUSES

Those establishments and/or facilities that slaughter fish from aquaculture, either at land or sea, and that supply processing establishments that intend their production for export, must have the sanitary approval provided by SERNAPESCA and be part of the List of Companies under SERNAPESCA's Sanitary Control Programs, for which they must comply with the procedures and requirements set forth in this item.

2.1. APPROVAL PROCEDURES

The person legally responsible for the company interested in obtaining the approval for its facility must present the Slaughtering Establishments and Facilities Approval Request (Part III, Annexes, Chapter II) at the SERNAPESCA Office under whose jurisdiction their establishment is located.

The SERNAPESCA Inspector will coordinate an inspection visit to verify the compliance of the infrastructure and sanitary management conditions, with the requirements set forth in Item 2.2 of this Chapter.

The inspection will be based on the application of the Infrastructure and Health Management Inspection Checklist for Slaughtering Establishments/Facilities (Part III, Annexes, Chapter III).

One classification for the observed deficiencies has been added (see Part I, Glossary) for each one of the items included in the above checklist, with the purpose of conducting an objective evaluation of the facilities. The classification of the deficiencies associated with the different items of the checklist is not final, and it may vary on the field, depending on the nature of the analyzed deficiency.

If during the visit one of the deficiencies detected is solved, the Inspector may evaluate the risk associated with the product and if the deficiency is observed for the first time or if there is a

tendency for it to be repeated. Based on this analysis, a severity level may or may not be assigned, however, it must be recorded in both cases.

When writing the report, the SERNAPESCA official must add up each one of the deficiencies observed during the visit, which will allow determining if the facility is approved or not, based on the following table:

Table: *Classification of the slaughtering establishment based on the deficiencies observed*

CATEGORY	DEFICIENCY		
	MAJOR	SERIOUS	CRITICAL
Approved	≤10	≤4	0
Rejected	≥11	≥5	≥1

The result of the inspection will be communicated to the interested party through a report issued by the Regional Office of the Service, which will be sent via email or fax as the official means of communication and must include the details of the deficiencies observed. If an establishment loses its authorization as the result of an inspection, SERNAPESCA will have 3 business days from the date of the visit to issue the report, and the suspension of the authorization will start on the date in which the document is sent to the establishment. If the establishment is approved, the report must be sent within 15 days.

It must be noted that if the deficiency is repeated over time, its severity may increase in the next inspection.

2.2. APPROVAL REQUIREMENTS

2.2.1 REQUIREMENTS FOR SLAUGHTERING ESTABLISHMENTS

A. IN LAND, THEIR SURROUNDINGS, WATER SUPPLY, AND LIQUID WASTE TREATMENT

The establishment must have transportation roads and pedestrian zones with impermeable surfaces and with a drainage system, that avoids the accumulation of water in the area.

The area in which the establishment is located must be properly delimited and must have an appropriately closed perimeter.

It must have an effective pest control program in place. In addition, the establishment must adopt the necessary measures to avoid the entrance of pests to the facilities.

The establishment must have a sewer system or a liquid waste treatment system, as appropriate, which must comply with what is set forth in EX. RES. 4866 of the National Fisheries and Aquaculture Service "General Sanitary Program for Disinfection Techniques of Affluents and Effluents, their means of control and treatment of organic solid waste (PSG-AE)."

When using seawater, the company must ensure that the water intake point is located far from the coast, in areas that are not exposed to contamination with oily products, effluents or others. It must have the authorization issued by the Undersecretariat of Maritime Affairs, indicating the exact seawater intake point.

Seawater used in the slaughtering process must be previously disinfected with authorized chemicals or any other authorized method such as ozonation, chlorination or ultraviolet light.

The water supply within the establishment must be continuous and sufficient for the operations being carried out.

In the case of using a potable public water supply or water of potable quality, it must be approved by the Competent Sanitary Authority.

Clean potable water will be used for the production of ice, and it must comply with the microbiological requirements established by the Competent Sanitary Authorities.

B. INFRASTRUCTURE AND MAINTENANCE OF FACILITIES, EQUIPMENT, AND TOOLS

The area intended for receiving the resources must be closed and roofed. Floors must have a slope to facilitate the drainage of liquid waste. In no case, this area of the establishment may be used for washing containers or other services.

Fish slaughtering will take place in closed and roofed facilities. The floor, walls, and roof must be smooth, hard, impervious and easy to clean and disinfect.

The facilities intended for slaughtering must have sufficient ventilation to avoid high temperatures inside. If they have windows, these must have laminated safety glasses with a mosquito net as necessary.

The equipment and tools such as slaughtering tables, bins, machinery (knockers, cooling tanks), knives, among others, must be of sturdy anti-corrosion materials and kept under good maintenance conditions. Their design and location must facilitate the execution of cleaning and disinfection tasks.

C. GENERAL HYGIENE CONDITIONS

The floors, walls, and roofs of the areas intended for the reception and slaughtering of fish must be kept clean, disinfected and rinsed. Only authorized products will be used for disinfection.

Waste and garbage must be piled up and disposed in a proper manner, and must not accumulate in the facilities.

The instruments, tools, and surfaces coming into contact with fish will be regularly washed and disinfected so that they do not become a source of contamination for the resources. The machines preparing the resources must be cleaned at least once per shift.

To carry out the cleaning operations in the facilities, equipment, and materials, the slaughtering establishment must have a cold and hot water supply and a steam supply if necessary.

Disinfectants, sanitizers and similar substances must have the corresponding sanitary authorization. They must be properly labeled and stored in a restricted access area.

D. HANDLING RESOURCES

At the end of the process, the resources will be washed with abundant clean water to eliminate waste from blood and viscera. Afterward, these must be stored in containers with ice or be refrigerated before transferring them to a processing establishment.

While unloading the resources, the establishment must adopt all the necessary measures to avoid their contamination and physical deterioration. All loading and unloading activities will take place, whenever possible, using mechanical means (cranes, mobile hoists, pumps for unloading the resources, loading vehicles, etc.).

E. PERSONNEL

The personnel must wear suitable work clothes for the tasks to be executed.

The personnel in charge of handling the resources must wash their hands at least every time they resume their tasks, this is, after having used the restrooms, after handling contaminated material and whenever necessary.

The company must adopt the necessary measures to avoid the contamination of the product by personnel susceptible to diseases.

Smoking, spitting, drinking, and eating are not allowed in the work areas and in the fish storage areas.

The establishment must have an induction program in place for all its operators, which must be properly registered and must consider at least the minimum requirements for handling the resources and the behavior pattern for the personnel inside the facilities.

F. SANITARY FACILITIES

They must have a proper place for the personnel to change their clothes. Work clothes will be kept separately from off-duty wear.

Restrooms must be clean and in good maintenance conditions. They must have signs that indicate that it is mandatory for the personnel to wash their hands after using the restrooms.

They must have proper areas for cleaning, disinfection, and storage of work equipment and tools. These facilities will be built with anti-corrosion and easy to clean materials.

The entrance area to the slaughtering room must have a proper sanitary filter in place and protected from external conditions.

The establishment must have enough sinks, and these must be properly distributed in the area. These sinks will have a hot and cold water supply, as well as cleaning supplies and a hygienic drying system.

Handling, storage, and transportation of ice must guarantee the preservation of its sanitary quality.

G. TRACEABILITY

The establishment must have documentation on the entrance of fish that allows to reliably determine its origin (declaration of guarantee or sworn declaration for harvesting and nursery centers, waybill, Movement Sanitary Certificate, etc.).

Resources dispatched to processing establishments will be properly labeled and identified so as to ensure their traceability.

2.2.2 REQUIREMENTS FOR SLAUGHTERING NAVAL ARTEFACTS (SHIPS AND PLATFORMS)

A. WATER SUPPLY AND LIQUID WASTE TREATMENT

The structure must have a liquid waste treatment system, as appropriate, which must comply with what is set forth in EX. RES. 4866 of the National Fisheries and Aquaculture Service "General Sanitary Program for Disinfection Techniques of Affluents and Effluents, their means of control and treatment of organic solid waste (PSG-AE)." Alternatively, it may unload liquid waste to be treated in a place authorized for such purpose.

Seawater used in the process must be collected in the same area where the fish are grown and where the slaughtering takes place.

Clean potable water will be used for the production of ice, which must comply with the microbiological requirements established by the Competent Sanitary Authorities.

B. INFRASTRUCTURE AND MAINTENANCE OF FACILITIES, EQUIPMENT, AND TOOLS

The place intended for receiving fish must be closed and kept in good cleaning conditions, minimizing the presence of corrosion. Floors must have a slope to facilitate the drainage of liquid waste. In no case, this area of the establishment may be used for washing containers or other services.

Fish slaughtering will take place in closed and roofed facilities. The floor, walls, and roof must be smooth, hard, impervious and easy to clean and disinfect.

The facilities intended for slaughtering must have sufficient ventilation to avoid high temperatures inside. If they have windows, these must have laminated safety glasses with a mosquito net as necessary. Alternatively, polycarbonate may be used.

The equipment and tools such as slaughtering tables, bins, machinery (knockers, cooling tanks) knives, among others, must be of sturdy anti-corrosion materials and be in good maintenance conditions. Their design and location must facilitate the execution of cleaning and disinfection tasks.

C. GENERAL HYGIENE CONDITIONS

The floors, walls, and roofs of the areas intended for the reception and slaughtering of fish must be kept clean, disinfected and rinsed. Only authorized products will be used for disinfection.

Waste and garbage must be piled up and disposed in a proper manner, and must not accumulate in the facilities.

The instruments, tools, and surfaces coming into contact with fish will be regularly washed and disinfected so that they do not become a source of contamination for the resources. The machines preparing the resources must be cleaned at least once per shift.
Disinfectants, sanitizers and similar substances must have the corresponding sanitary authorization. They must be properly labeled and stored in a restricted access area.

D. HANDLING RESOURCES

If necessary and based on the task conducted, at the end of the process, resources will be washed with abundant clean water to eliminate waste from blood and viscera. Afterward, these must be stored in containers with ice or be refrigerated before transferring them to a processing establishment.

While unloading the resource, the establishment must adopt all the necessary measures to avoid their contamination and physical deterioration. All loading and unloading activities will take place, whenever possible, using mechanical means (cranes, mobile hoists, pumps for unloading the resources, loading vehicles, etc.).

E. PERSONNEL

The personnel must wear suitable work clothes for the tasks to be executed.

The personnel in charge of handling the resources must wash their hands at least every time they resume their tasks, this is, after having used the restrooms, after handling contaminated material and whenever necessary.

The company must adopt the necessary measures to avoid the contamination of the product by personnel susceptible to diseases.

Smoking, spitting, drinking, and eating are not allowed in the work areas and in the fish storage areas.

The establishment must have an induction program in place for all its operators, which must be properly registered and must consider at least the minimum requirements for handling the resources and the behavior pattern for the personnel inside the facilities.

F. SANITARY FACILITIES

They must have a proper place for the personnel to change their clothes. Work clothes will be kept separately from off-duty wear.

Restrooms must be clean and in good maintenance conditions. They must have signs that indicate that it is mandatory for the personnel to wash their hands after using the restrooms.

They must have proper areas for cleaning, disinfection, and storage of work equipment and tools. These facilities will be built with corrosion-resistant and easy to clean materials and must have sufficient water flow for these operations.

The entrance area to the slaughtering room must have a proper sanitary filter in place and protected from external conditions.

The establishment must have enough sinks, and these must be properly distributed in the area. These sinks will have a hot and cold water supply, as well as cleaning supplies and a hygienic drying system.

Handling, storage, and transportation of ice must guarantee the preservation of its sanitary quality.

G. TRACEABILITY

The establishment must have documentation on the entrance of fish that allows to reliably determine its origin (declaration of guarantee or sworn declaration for harvesting and nursery centers, waybill, Movement Sanitary Certificate, etc.).

Resources dispatched to processing establishments will be properly labeled and identified so as to ensure their traceability.

H. TRANSFER OR UNLOADING

Vessels with the necessary disinfection tools and supplies will be used to transfer bins or tanks with resources. When resources are transferred, they must always be accompanied by the documents that support their traceability, as stated in item G.

Bins or tanks must be unloaded in ports of shipments and/or biosafe unloading areas authorized by SERNAPESCA.

3. PROCESSING ESTABLISHMENTS (PRODUCERS)

Processing establishments or facilities that process products fit and unfit for human consumption and that intend their production for export must be part of the List of Companies under SERNAPESCA's Sanitary Control Programs, for which they must comply with the procedures and requirements established in this item.

3.1 APPROVAL PROCEDURES

The person legally responsible for the company interested in obtaining the approval for its facility must present the Fish Processing Plants and Factory Ships Approval Program Processing Request (Part III, Annexes, Chapter II) at the SERNAPESCA Office under the jurisdiction of their establishment, enclosing copy of the following authorizations, in paper or electronic format (.pdf):

- SUBPESCA/SERNAPESCA Resolution – Authorization for processing hydrobiological resources.
- Sanitary Resolution issued by the Ministry of Health.

The SERNAPESCA Inspector will coordinate an inspection visit to verify the compliance of the infrastructure and sanitary management conditions, with the requirements set forth in Item 3.2.2 of this Chapter.

If the entrance of the inspectors to the plant is forbidden or delayed without any justified reasons, the inspector of SERNAPESCA must inform the situation to the person responsible for the plant so as to solve the situation, otherwise a summons for obstruction of a public official in the performance of his or her official duties may be issued.

The inspection will be based on the application of the Infrastructure and Health Management Inspection Checklist for Export Fishery Products Plants for Human Consumption, the Infrastructure and Health Management Inspection Checklist for Factory Ships, or the Infrastructure and Health Management Inspection Checklist for Processing Establishments (Part III, Annexes, Chapter III), as appropriate.

The Infrastructure and Health Management Inspection Checklist for Export Fishery Products Plants for Human Consumption, also consider aspects related to the unloading of fishery products, which are applicable only to those establishments that consider in their production chain an operation at the place of unloading (review, verification, bloodline, etc.).

One classification for the observed deficiencies has been added (see Part I, Glossary) for each one of the items included in the above checklist, with the purpose of conducting an objective evaluation of the plants or vessels.

It must be mentioned that the classification of the deficiencies associated with the different items of the checklist is not final and that it may vary on the field, depending on the nature of the analyzed deficiency. Similarly, if at the moment of inspection other aspects that were not considered in the checklist are observed, these must be included in the remarks/notes section and will be classified according to the previously described definitions.

If during the visit one of the deficiencies detected is solved, the Inspector may evaluate the risk associated with the product and if the deficiency is observed for the first time or if there is a tendency for it to be repeated. Based on this analysis, a severity level may or may not be assigned, however, it must be recorded in both cases.

In regards to the solution alternatives proposed by the processing establishment to correct a deficiency, it is the responsibility of the company to demonstrate that this solution complies with the objective established in the standard.

If any deficiencies in the infrastructure are detected, and their solution requires a mid to long-term period and investment, the company may present an activities schedule to solve those deficiencies at SERNAPESCA for its review and approval.

While the schedule is in place and considering the application of mitigation measures, the deficiencies may be included in the inspection checklist with a reduced severity level. The

SERNAPESCA Inspector must verify the strict compliance with the terms set in the schedule, and if not met it may imply a change in the category of the establishment.

It must be mentioned that the application of schedule charts for deficiencies related to sanitary management, as well as aspects that have a direct incidence on the safety of the product, will not be accepted and must be solved immediately.

It is important to point out that these criteria for the application of work schedules are extensible to the inspections of establishments based on the requirements of the markets, as in the case of the Eurasian Economic Union.

When writing the report, the SERNAPESCA official must add each one of the deficiencies observed during the visit, which will allow classifying the fishery plant or factory ship under one of the following categories: A, B, C, D or Non-Certifiable, based on the following Table:

Table: *Classification of the plants based on the deficiencies observed*

CATEGORY	DEFICIENCY			
	MINOR	MAJOR	SERIOUS	CRITICAL
A	0-6	0-5	0	0
B	≥7	6-10	1-2	0
C		≥11	3-4	0
D			5-7	0
Non-certifiable			≥8	≥1

The category obtained will be communicated to the interested party through a report issued by the Regional Office of the Service, which will be sent via email or fax as the official means of communication and must include the details of the deficiencies observed and the category given to the establishment. That report must be sent within 3 business days from the inspection visit for the establishment whose change of category means a modification with exports, this is, from B to C, from C to B or when a plant is NC. For all other cases, the report must be sent within 15 days. The change in the category will be valid from the date in which the document is sent to the establishment.

It must be noted that if the deficiency is repeated over time, its severity may increase in the next inspection.

The main aspects to be considered in the categorization visit, as well as the basic information to be included in the report, are the following:

1. General Information of the categorization:
   a) Name of the Inspector that conducted the categorization.
   b) Name of the inspectors that were part of the categorization.

c) Name of the person responsible for the establishment with whom the categorization visit took place.
d) Date of the categorization.
e) Name of the establishment (fishery plant, factory ship or processing establishment).
f) Code of the establishment.
g) Process lines involved in the categorization.

2. Information related to the previous categorization.
a) Survey of the deficiencies detected in the previous categorization process.
b) If there is a work schedule, the inspector must verify the compliance of the commitments undertaken by the company.

3. Aspects related to the inspection checklist.
a) The inspection report must include all the items considered in the corresponding checklist, indicating in each case the observation detected (as appropriate) or that deficiencies were not detected:
b) If there is a deficiency that is repeated over time, this condition must be clearly expressed in the report, assigning the corresponding severity level.
c) Any observations not included in the checklist but that the inspector considers relevant must be included in the report indicating the assigned severity level.
d) The observations that were solved during the inspection must be included in the report clearly indicating this condition and the assigned severity level, as appropriate.
e) In those cases in which the Inspector determines to apply a severity level different from those provided in the field checklist, he or she must justify this decision and clearly inform it in the report.

4. Results of the categorization:

The Regional Office of SERNAPESCA will issue a report with the result of the inspection to the establishment, by e mail or any official way, with copy to the Foreign Trade Sub-Directorate, and must include all deficiencies detected. If the change of category means a restriction for specific markets (plants A or B, change to C, d or NC), the report must be send to the plant at least the next working day after the inspection. In other cases, could be send in 5 working days. The change of category applies from the date that report was issued. (M.05.01.18)

It must be mentioned that the categorization must not be conducted only by the inspector in charge of its permanent supervision. To carry out these inspections a regional or national (if necessary) exchange program for inspectors must be in place, and the categorization visit must be coordinated so as to take place with both inspectors. The inspection of these establishments must be conducted with the frequency established by the Service.

When a visit takes place at a company that is already authorized, and it is not operating or is closed, another visit must be coordinated with the person responsible for the company. If it is not possible to comply with the above, an inspection visit must take place at the company within 30 days. If in this new visit it is still not possible to conduct the categorization, the company will be automatically assigned a category Not Certificable. (M.05.01.18)

Any further categorizations for a plant that has been assigned an NC category must be requested by the interested party at the Regional SERNAPESCA Office for that establishment.

When removing an approved establishment from the SERNAPESCA Sanitary Control Program, this will be done through a request in writing from the Regional SERNAPESCA Office or from the person responsible for the establishment.

3.1.1 MEASURES TO BE IMPLEMENTED FOR A CHANGE IN CATEGORY

When a fishery plant or factory ship is authorized to export to a market that requires at least a B category, and it is assigned a lower category, the inspectors in charge must proceed as follows:

- Immediately report the change in the category via fax to the Central Office.
- At the same time, the Regional Office must communicate the plant the category that it was assigned, and the suspension of the authorization to export to the markets with those requirements.
- Once the fishery company is notified of the change in its category, it must present a detailed report of the stock of stored, processed products at the SERNAPESCA Regional Office, indicating the place where they are stored.

When a fishery plant or factory ship obtains a better category in a periodical inspection or in the special request from the company to be categorized again, this change will be informed via fax to the Central Office.

When a fishery plant or factory ship lowers its category to Non-certifiable, the following procedure must take place urgently:

- The Regional Office must immediately inform the Central Office of this change in the category, attaching the report. At the same time, it must communicate this situation to the company and inform that the products processed from that date on will not have a Sanitary Certification for export.
- The Regional Office will notify to the Health SEREMI immediately. (M.05.01.18)
- Those fishery plants that are supplied by third parties must be previously informed about the category of the primary plant from which they are purchasing their products because if it is Non-certifiable, it will not obtain the Sanitary Certification for Export.

The category and the markets for which a fishery plant or factory ship is authorized to export will always be those described on the List of Companies under SERNAPESCA's Sanitary Control Programs, which is published on a periodical basis and is updated through formal communication from the National Directorate.

3.1.2 MEASURES TO IMPLEMENT FOR A CHANGE IN THE REGISTERED NAME OF A COMPANY

To modify its registered name, the company must provide the relevant documentation to the FIP Department, which will also inform the situation to the GIA Department. The GIA Department will officially communicate this change to the Foreign Trade Sub-Directorate, from where the change in the name and/or registry number in the lists of the different markets that require the registry of the establishments will be requested automatically.

Once the change of the registered name has taken place, through the documentation sent by the GIA Department, the company may certify its shipments and label its products with the former

name and/or the processing establishment number for a certain amount of time. To proceed with the aforementioned, the following must be considered:

- The company must send to the Regional Office of SERNAPESCA a summary of the stock of packaging supplies labeled with the former name and/or code of the manufacturing company, as well as the products packed with the former label, prior to the change in the company's registered name. This must be verified by the plant inspector, who must define an estimated date in which the company must start labeling its products with the new name and/or number; this term may not exceed two months from the official recognition of the change in the registered name, which will be informed to the company by the Foreign Trade Sub-Directorate.
- Those shipments destined to countries that have officially recognized the change in the company's name and/or code may not be labeled with the former registered name and/or registry number.
- If the packaging supplies stock labeled with the former registered name of the company originally informed to SERNAPESCA has run out, all the stored products manufactured before or after the official recognition of the change in the registered name must be labeled with the new registered name and/or number of the company, except in those cases in which the confirmation of the change in the registered name by the destination market exceeds the period established.

3.1.3 APPROVALS BASED ON DESTINATION MARKETS AND PRODUCTS

The markets that have specific registry requirements as well as special requirements associated with registry, are detailed in Part II, Section III, Export and Certification Control.

For an establishment to obtain the approval to export to a destination market with specific registry requirements, the company must include in the Destination Market Registration Processing Request (Part III Annexes, Chapter II) a detailed list of the markets and products that it needs to export.

Similarly, when an already authorized establishment wishes to add new fishery products to the exports of the markets that require the registry of plants and factory ship, they must send the Destination Market Registration Processing Request. With this request, the Service will carry out the necessary actions to add these products in the requested markets.

3.2 APPROVAL REQUIREMENTS

3.2.1 MANDATORY REQUIREMENTS AT UNLOADING

The processing establishments that have their own facilities to conduct fishery products unloading activities must comply with the specific requirements described in this section.

The loading and unloading equipment must be made with easy to clean materials and must be kept in good and hygienic conditions.
When loading and unloading fishery products all type of contamination must be avoided, taking special care of the following:

- That loading and unloading operations are executed promptly,
- The fishery products are placed without any delays in a protected environment at a proper temperature based on the type of the product and, if necessary, surrounded by ice in transportation, storage, and sales facilities or in an establishment,

- Materials or handling practices that may deteriorate the edible parts of fishery products must not be used.

After unloading, fishery products must be transported to their place of destination without any delays and in proper transportation conditions, as stated in the Storage and Transportation item of the Mandatory Requirements for Establishments that manufacture products intended for human consumption (Item 3.2.2.1, Letter I).

However, if the fishery products cannot be immediately transported to their destination, cold stores with sufficient capacity and complying with the following requirements must be made available:

- The floor must be impervious, easy to clean and disinfect and sloping sufficiently towards a drain, thus allowing cleaning with water or with a device that allows draining water.
- Walls must have smooth, easy to clean, resistant and impervious surfaces.
- The roof must be easy to clean.
- The doors must be made of a material that does not deteriorate, and that is easy to clean.
- They must have proper lighting.

In such case, fishery products must be stored at a temperature close to the freezing point of ice.

If the products are dispatched directly from the point of unloading to markets that have not officially presented their export requirements, they must be packed under satisfactory hygienic conditions avoiding the contamination of fishery products.

The label must include the information of the packer and not of the manufacturer. If the products are destined to markets where their requirements are officially known, they must be dispatched to a fishery establishment for their further processing.

3.2.2 MANDATORY REQUIREMENTS FOR ESTABLISHMENTS THAT MANUFACTURE PRODUCTS INTENDED FOR HUMAN CONSUMPTION

3.2.2.1 FISHERY PLANTS

A. SURROUNDINGS

The establishments must be located far from areas that are a source of insalubrity, objectionable odors, smoke, dust or other contaminants and must not be exposed to floods.

Entrance areas and traffic areas within the production plant or in its surroundings must be of hard surface, paved and treated so as to control the presence of environmental dust.

Trash and waste must be properly disposed, and the grass or lawn in the surrounding areas of the buildings or plant must be mowed and cut so as to avoid the presence of pests.
If the area surrounding the plant is out of the control of the company and is not maintained in the way described in the above paragraphs, proper care must be exerted inside the plant through inspections, exterminations or any other means to keep away pests, dirt or any other type of filth that may be a source of contamination for foodstuffs.

B. DESIGN AND CONSTRUCTION

Work areas shall be large enough to carry out work activities in a proper manner and under proper hygiene conditions. Such work areas must be conceived and designed so as to avoid any type of contamination to the product, with a logical flow, and with clearly separated clean and dirty areas, from the arrival of raw materials until obtaining the finished product, allowing the proper movement of staff and fishery products.

In those places where products are handled and processed:

- The floor must be impervious, easy to clean and disinfect and sloping sufficiently towards a drain thus allowing cleaning with water or with a device that allows draining water.
- The walls will have smooth surfaces, without any cracks, easy to clean, resistant and non-toxic with an appropriate height for the operation (1.80 m minimum).
- The ceiling will be easy to clean (its cleanliness must be guaranteed with a monthly cleanup or another method that proves the absence of a risk of contamination of the product).
- The doors must be made of a material that does not deteriorate and is easy to clean.
- A proper ventilation system must be available, and if necessary a steam extraction system. The level of criticality for this will depend on the risk that condensation has on the product and the actions taken by the plant to avoid it and control it.
- There must be proper lighting which must not alter the colors and will allow a proper handling and control of the foodstuffs.
- The lamps that are suspended over the foodstuffs in any of the production phases must be easy to clean and must be protected so as to avoid the contamination of food if they break.
- There must be sufficient hand washing and disinfecting stations, and in the work areas, faucets must not be manual. These stations must have disposable towels or hot air dryers (water control valves designed and built to avoid re-contamination of washed and disinfected hands may be accepted).
- There must be devices available to clean the tools, materials (that enter into direct or indirect contact with the product) and the facilities. During a cleaning procedure, areas must be properly divided, and the contamination of products must be avoided.
- All raised structures and accessories must be installed so as to avoid the direct or indirect contamination of foodstuffs, raw materials, surfaces in contact with foodstuffs or packing material, from condensation from water steam and dripping, and in a way that does not hinder any cleaning tasks.
- Storing substances that may contaminate the foodstuffs or placing clothes or personal objects in the food handling areas is not allowed.
- All the windows that are in the processing rooms, primary and secondary packaging warehouses or in any other place where the product or the surface in contact with the product may be contaminated must have laminated safety glasses or anti-shatter or protection.
- In the case of establishments producing fish oil, the aforementioned items will be applicable only if they refer to structures, materials or procedures that are in direct contact with the products or that affect any stage of the process.
- There must be proper protections installed against the unwanted presence of animals such as insects, rodents, birds, etc.

For those establishments that have isothermal chambers to store fishery products:

- The floor must be impervious, easy to clean and disinfect and sloping sufficiently towards a drain thus allowing cleaning with water or with a device that allows draining water.
- Walls must have smooth, easy to clean, resistant and impervious surfaces.
- The ceiling must be easy to clean.
- The doors must be made of a material that does not deteriorate and is easy to clean.

- There will be proper lighting.
- It must have a thermometer or a temperature recording device that shows the exact temperature inside the chamber, and whose sensor is located in the area with the highest temperature in the chamber.
- It must have a cooling system to keep the products under the temperature conditions defined in this Standard.
- Storing products on the floor is not allowed. As an exception, wood pallets may be used to facilitate airing.
- Meat, products, and by-products may not be placed simultaneously in the same cold store without the authorization of SERNAPESCA. Frozen meat, products, and by-products fit for human consumption packed in airtight and inviolable packages are excluded from this measure.

If bins with raw material are toppled over, the area assigned for this task must be a closed place, not necessarily hermetic, unless there is a direct communication with the plant and there is also evidence of pests that may contaminate the product.

C. EQUIPMENT AND TOOLS

Work devices and tools such as cutting tables, containers, conveyor belts and knives must be made with anti-corrosion and easy to clean and disinfect materials.

The design, construction, and use of the tools must avoid the contamination of the foodstuffs with lubricants, fuel, metal fragments, contaminated water and any other type of contaminants.

Reusable containers must be made of materials that allow to be cleaned easily and thoroughly (with the exception of primary packages).

The containers used for toxic material must be identified and may not be used for foodstuffs.

The joints in the surface that comes into contact with foodstuffs must be soft and maintained so as to reduce the accumulation of food particles, dirt, organic particles and reduce the possibilities of developing undesirable microorganisms.

There must be proper equipment available for cleaning and disinfecting transportation devices. Fishery plants that work with live animals such as crustaceans, mollusks or fish must have a suitable area to keep them alive in the best possible conditions with water that does not transmit organisms or harmful substances to the animals.

They must have proper areas for cleaning, disinfecting and storing work equipment and tools. These facilities will be built with corrosion-resistant and easy to clean materials and must have a sufficient hot and cold water flow for these operations. The possibility for the plant to test its detergent acting properly with cold water must also be evaluated.

The use of wood pallets will only be allowed in the warehouse and the packing room, and in the finished products chambers, to the extent that they are always in good conditions.

D. GENERAL HYGIENE CONDITIONS APPLICABLE TO PREMISES AND MATERIALS

The floors, walls, roofs and partition walls of the premises and the materials and tools used to work with fishery products must be kept in good hygienic and operation conditions so that they do not constitute a source of contamination for such products.

The countertops where foodstuffs are handled must be of washable and disinfectable materials while the structures that support them must be in proper maintenance conditions, regardless of their material.

Devices for transporting harvesting, collection or capture products as raw materials to processing plants must be kept clean, and whenever necessary, they must be properly disinfected after cleaning the equipment, containers, boxes, vehicles, and vessels used.

When cleaned during the manufacturing process, the foodstuffs must be protected. All surfaces coming into contact with food must be washed and disinfected before and after every interruption of the tasks where they may have been contaminated. When equipment and tools are used in a continuous production operation, their contact surfaces will be cleaned and disinfected as many times as necessary.

Disinfectants, sanitizers and similar substances must be authorized by the corresponding health authority and must be used so that the equipment, materials, and products are not affected by them. They must be properly labeled and stored in a restricted access area.

Any residues of disinfectants used must be eliminated in order to avoid the possibility of contaminating the foodstuffs.

There must be a proper pest control system in place (rodents, insects or any other parasites) in the outer perimeter of the plant. It is recommended to place lures around the perimeter and sticky traps in the warehouses. If the pest control procedures are carried out by authorized external companies, these must guarantee to the plant that the processes applied are suitable, and if otherwise, the pest control is in charge of the company's trained staff the rat and insect poison, disinfectants and other potentially toxic substances must be stored in locked rooms or closets. Regardless of whom carries out these processes, the products used must be used in a way that prevents the risk of contamination of the products. When Insect-O-Cutors are used, they must be placed in areas that do not impose a risk to the product.

Guard or guide dogs may be allowed in some areas of the plants to the extent that their presence does not contaminate the foodstuffs, the surface in contact with the foodstuffs or the packing materials for the foodstuffs.

The premises, work tools, and materials must only be used for handling fishery products.

Garbage and any other waste will be transported, stored and disposed in a way to minimize the development of odors, avoid for the waste to become an attractive area for pests, avoid the contamination of foodstuffs, surfaces in contact with the foodstuffs, water supply, and the land surface.

Fishery products not intended for human consumption (by-products or waste) will be stored in special anti-corrosion collection containers, and there must be premises intended to store such containers if they are not emptied, at least at the end of each work day.

Unless there are facilities for their ongoing disposal, the waste placed outside of the plant must be kept in containers with a lid that are easy to clean and disinfect. If there are garbage bins located inside the plant, these must have a lid, and a bag must be used when they are intended for collecting organic waste. Those that use inorganic material may be used without a lid and a bag.

All garbage containers must be non-manual.

Waste must not be piled in work areas. They will be emptied continuously once they have been filled or at least at the end of every workday, in special corrosion-free containers or in a premise intended to store such containers if they are not emptied, at least at the end of each work day.

The bins, containers and/or premises intended for waste will be cleaned thoroughly and will be disinfected as needed after each use.

The waste stored must not constitute a source of contamination for the plant or disrupt the environment.

Fishery products may not be placed under cold devices unless they are protected to avoid their contamination.

E. SANITARY FACILITIES

For the process, a facility with a supply of clean spray water with a proper quantity and temperature must be provided. Chemical and physical parameters analyses for any kind of eater (potable or drinking water or sea water) must be conducted once a year according to Chilean Standard 409/Of 2005.

The microbiological parameters for any type of water (potable and/or drinking water, seawater and/or brackish water) will be analyzed on a monthly basis. The plant must send water samples for *Escherichia coli* and total coliforms analyses: In both cases, the acceptance limits are the following:

Table: *Microbiological parameters for water*

Parameter	Maximum admissible concentration (number/100 ml)
Escherichia coli	0
Total coliforms	0

The determinations for radioactive elements included in the mentioned Chilean standard must only take place when radioactive contamination is suspected.
The establishments may require potable water supply companies a certificate that accredits the compliance with the chemical parameters of Chilean Standard 409/1 Of 2005.

All the water used in the processing plant, except for the water used for desanding mollusks must have a residual effect disinfectant. Nevertheless, a non-potable water supply system will be authorized exceptionally to produce steam, fight fires or cool cooling equipment to the extent that the connections installed for that purpose do not allow the use of such water for other purposes or that present a risk of contamination for the products.

Non-potable water connections must be clearly distinguished from those used for clean water, it must be supplied through separate pipes identified with colors, without a cross-connection or back-siphoning with the tubes that carry clean water.

The water used by desanders and by establishments that keep live crustaceans must comply at least with the microbiological requirements set forth in Table "Microbiological parameters for water" above for seawater or brackish water.

There must be enough sinks located conveniently and intended to wash hands. These sinks must have cold running water, and when the establishment also manufactures products destined to Europe, they must have hot water or water at a temperature that allows to comfortably wash your hands and also hygienic cleaning and drying materials or systems. These hand washing stations must be available in all rooms were foodstuffs are handled. If necessary, the facilities intended for washing foodstuffs must be separated from those intended for handwashing.

Ice used in direct contact with the foodstuffs must be made with the type of water described in this standard, and it must be treated, stored and handled to protect it from contamination. The ice falling from the silo must be properly stored, and all necessary measures must be adopted to avoid its contamination. The tools used to move the ice, such as shovels, are to be exclusively used for this task and must be stored in the bins together with the ice.

Water steam used in direct contact with the foodstuffs must not contain any substances that may contaminate the foodstuffs.

There must be a wastewater disposal device with the proper hygienic conditions.

There must be enough changing facilities and restrooms, with walls and floors with smooth surfaces, impermeable and washable according to the Table "Number of sanitary fixtures required based on the number of operators". These must not communicate directly with work areas.

When there are more than one hundred workers per shift, there will be one toilet and one sink added for every fifteen people and one shower for every ten people. In the case of replacing individual sinks for multi-station sinks, an equivalent of one faucet per individual fixture will be considered.

In men's restrooms 50% of toilets may be replaced by individual or multi-station urinals, and for the latter, the equivalence must be of a length of 60 centimeters per urinal.

The sinks in the restrooms must have products for washing and disinfecting hands and disposable towels or hot air hand dryers. Faucets must not be opened with the hands. Valves to control water flow designed and built to avoid re-contamination of washed and disinfected hands may be accepted.

When the establishment also manufactures products destined to the European Union, it must a have a hot water supply or otherwise water at a temperature that allows to comfortably washing your hands.

Table: *Number of sanitary fixtures required based on the number of operators*

Number of operators	Toilets	Sinks	Showers
1-10	1	1	1
11-20	2	2	2
21-30	2	2	3
31-40	3	3	4
41-50	3	3	5
51-60	4	3	5
61-70	4	3	7
71-80	5	5	8
81-90	5	5	9
91-100	6	6	10

Changing facilities, restrooms, entrance halls and yards located in the surroundings of the plant and those that are part of it must always be clean and properly maintained.

Restrooms and changing facilities must be adequately lit, ventilated and protected against insects.

Work clothes must not be mixed with everyday garments in the changing facilities, neither must other items (such as food or kitchenware or silverware) be stored in those areas.

Restrooms must have signs that remind employees that they must wash their hands after using them.

F. PERSONNEL

The personnel must wear proper and clean work clothes and a clean cap that completely covers the hair, especially when handling fishery products that may become contaminated.

The personnel in charge of handling and preparing such products must wash their hands at least every time they resume their tasks (after using the restrooms, handling contaminated material and whenever necessary).

Smoking, spitting, drinking, and eating are not allowed in the work areas and in the storage areas for fishery products.

The personnel must not use any embellishments while handling foodstuffs and they must keep their nails short, clean and without any nail polish.

Business owners must take all the necessary measures to avoid having staff that may contaminate fishery products when working with and handling them until their fitness to do so without any risks is demonstrated.

If gloves are used when handling fishery products, they must be in perfect condition and clean. Gloves must be made of impermeable material. The use of gloves will not exempt the operator from washing his/her hands properly.

G. SPECIAL REQUIREMENTS FOR MANUFACTURING FISHERY PRODUCTS

Product will be understood to be manufactured in a fishery establishment when the handling process used in the raw materials (whatever its nature) implies a sanitary risk for the product.

According to the General Fisheries and Aquaculture Law, processing fishery activities will not be understood as the sole evisceration of captured fish, neither their preservation in ice or the application of other techniques only intended for the preservation of hydrobiological species.

Some of the processes that may be considered as product's processing are following:

Table : *Processes considered as product's processing*

Raw Material	End Product
Refrigerated-chilled product	Products in any presentation frozen, canned, salted or dry-salted.
Frozen products	Canned, smoked, salted, filleted or frozen products (all with a thawing process).

In the manufacturing process only raw materials and ingredients in good condition, properly identified and without any levels of microorganisms that may produce food poisoning or other diseases for humans may the used.

Only clean water must be used in the manufacturing process.

- Requirements for Live Crustaceans, Bivalve Mollusks, Gastropods, Tunicates, and Echinoderms

These live resources will correspond to primary products. Primary products will be protected from any source of contamination.

In the case of live bivalve mollusks, gastropods, tunicates and echinoderms the establishments must comply with the requirements set forth in Chapter I, Item 1 of this section.

- Requirements for Chilled-Refrigerated Products

If unconditioned refrigerated products are not immediately distributed, dispatched, prepared or processed after their arrival at the plant, they must be stored and preserved with ice in the plant's cold stores. Ice will be added as many times as necessary, and use of properly covered isothermal bins with the correct amount of ice may be accepted.

Pre-packed chilled products must be refrigerated with ice or with a mechanical system that allows keeping a similar temperature.

Operations such as filleting and slicing will be conducted to avoid any contamination, especially to the de-heading and eviscerating operations and must be conducted in a different place.

Fillets and slices may not remain on the work tables for more time than the necessary for their preparation and must be protected from all sources of contamination with a proper packaging.

The viscera and the parts that may represent a hazard to public health will be separated as soon as possible and will be kept away from products intended for human consumption.

The containers used to dispatch or store chilled fishery products must be designed to protect them from all types of contamination, and to keep them in satisfactory conditions.

- Requirements for Frozen Products

Plants must have a freezing equipment capable of subjecting products to a quick temperature reduction that allows reaching a temperature inside of at least -18 C° after its thermal stabilization.

Plants must have refrigeration equipment capable of keeping products in storage areas not exceeding a temperature of -18 C°, regardless of the outside temperature. However, due to imperative reasons related to temperature and linked to the freezing method and to the handling process for these products, for whole salted-frozen fish intended to be canned, higher temperatures than those described in this Standard may be allowed, but they must not exceed -9 C°.

Frozen or ultra-frozen products that are refrigerated must also comply with all the requirements described above for chilled-refrigerated products.

The plant must guarantee that previously mentioned items are compliant by checking their temperatures logs.

Cold stores must be equipped with an easy-to-read temperature log system. The temperature sensor must be placed in the area with the highest temperature.

The charts of the temperatures recorded during the entire process must be made available to SERNAPESCA.

- Requirements for Thawed Products

Thawing fishery products will take place under proper hygiene conditions, this is, all types of contamination must be avoided, and there must be an efficient ice-water slurry discharge system.

The temperature of the products must not increase excessively during thawing.

After the thawing process, the products must be handled according to the requirements set forth in this Manual. If they take place, preparation or processing operations must be conducted as soon as possible.

- Requirements for Processed Products

Chilled-refrigerated, frozen or thawed products used in processing operations must adjust to each one of the requirements for the type of product.

If a treatment to inhibit the proliferation of pathogenic microorganisms is applied, or if this treatment is important to preserve the product, it must be scientifically recognized.

The person responsible for the plant must keep a record of the treatments applied. Based on the treatment used, the time and temperature, the salt concentration, the pH and water content of the heat treatments must be recorded. These records must be made available to SERNAPESCA for a period at least equal to the period of preservation of the product.

Those products whose preservation is guaranteed only for a limited period of time after applying treatments such as salting, smoking, drying or marinating must clearly describe their storage conditions in their packaging.

The expiration of manufactured frozen products made with frozen raw materials must be established based on the date of the first freezing.

It must also comply with the following requirements:

- Canning

The water used for preparing canned products must be clean.

A heat treatment will be applied employing a proper procedure, defined according to criteria such as heating time, temperature, filling, container size, etc. and a record will be kept.
The heat treatment must be capable of destroying or inactivating any pathogenic germs and all spores of pathogenic microorganisms.

The fishery establishment must comply with all requirements described in Item 3.2.4, Letter C of this Chapter for each one of the heat processes applied, in accordance with the requirements set forth in the program.

If there is a deviation in the process or if there is evidence in the production logs that the critical factors are outside of those established in the process, alternative processes proposed by the Process Authorities must be applied, or they must be reprocessed, this is, that all the product involved in the production with the deviation must be sterilized again, keeping full records of the reprocessing conditions applied or alternatively, the affected lots must be segregated so as to be evaluated for their potential risk to public health, according to Item 3.2.4 letter C of this Chapter.

The heat treatment equipment must have a control device to verify that the containers have been subjected to a proper heat treatment (thermograph).
After the heat treatment, the containers will be cooled with clean water, without detriment to the presence of possible chemical additives used according to the best technology best practices to avoid the corrosion of the equipment and the containers.

To prove that the containers have been subjected to a proper heat treatment, the manufacturer will conduct probing controls through the following:

- Incubation tests. Incubation will take place at 37 C° for seven days or any other equivalent combination. In the case of flexible containers (sterilizable bags), the incubation will take place at 25 C° for two weeks.
- Microbiological examinations of the content and of the seals of the containers in the laboratory authorized by SERNAPESCA.

In order to guarantee the efficiency of the sealing or any other airtight closing method, the samples of the daily production will be taken at previously set intervals, and proper equipment must be available to examine the crosscuts of the joints of the closed containers.

Controls will be carried out to verify that the containers are not deteriorated.

All the containers that have been subjected to a heat treatment under practically identical conditions will have a lot identification mark.

The production date will be stamped in one of the lids of the container embossed or with automatic printing equipment with permanent ink, before the treatment.

- Smoking

Smoking operations must take place in a separate premise or location so that, if necessary, it may use a ventilation system that avoids for fumes and heat from combustion to affect the other premises or locations where fishery products are prepared, processed or stored.

The materials used to produce smoke for smoking fish must be stored away from the smoking area and must be used in a way that does not contaminate the products.

Materials used for the production of smoke by combustion made of wood that has been painted, varnished, glued or that has undergone any chemical treatment for its preservation must be prohibited.

After being smoked, the products must be quickly chilled at the temperature needed for their preservation before they are packed.

- Salting

Salting operations must take place in different locations and far away from other areas where the rest of the operations are conducted.

The salt used in the preparation of fishery products must be completely clean, properly labeled and stored in a way that avoids any risks of contamination.

Salt must not be used more than once.
The containers used in the salting process must be made to avoid the contamination of the products during this operation.

The containers and areas intended for salting must be cleaned before conducting the task.

- Cooking Mollusks, Crustaceans, Fish, and Cephalopods

The fishery establishment must comply with what is set forth in Item 3.2.5, Letter B, for each one of the cooking processes applied to manufactured products.

Cooking processes must be immediately followed by refrigeration. The water used for such purpose must be clean. If no other means of preservation are used, refrigeration must be used until reaching the ice melting temperature.

The operations for separating the valves and skinning the fish must take place in a hygienic manner avoiding any type of contamination to the product. When these are done by hand, workers must pay special attention to hand washing, and all the work surfaces must be thoroughly cleaned. If machines are used these must frequently be cleaned and disinfected at the end of each shift.

After the valves separation and fish skinning operations, the cooked products must be immediately frozen or refrigerated at a temperature that avoids the development of pathogenic germs, and they must be stored in suitable premises.

- Fish Pulp

The mechanical separation process must take place without any undue delays after the filleting process, using raw materials without viscera.

If whole fish is used, it must be previously eviscerated and washed.

The machines will be cleaned from solid residues frequently and, at least, every two hours.

After the manufacturing process, the pulp must be frozen as soon as possible or be added to a product intended for freezing or to a stabilizing treatment.

- Requirements Regarding the Presence of Parasites

During the production and before their dispatch for human consumption, fish and fishery products must be subjected to a visual control to detect and remove any visible parasites.

The products intended for consumption without prior processing such as:

- Fish and products intended for consumption, raw or practically raw, products treated with cold smoking where the temperature inside the fish is lower than 60 C° (for instance herring, chub mackerel, sprat, and wild Pacific or Atlantic salmon).
- Marinade and/or salted fish, when this process is not sufficient to kill the larvae of the nematodes.

They must also be subjected to a freezing treatment, at a temperature equal to or lower than -20 C° inside the fish for at least 24 hours. Such freezing treatment must be applied to the raw or finished product.

H. PACKAGING AND LABELING

Packing must take place under satisfactory hygienic conditions avoiding the contamination of fishery products.

The containers that preserve refrigerated products in ice must be impermeable and avoid the contact of ice-water slurry with the products.

The packaging materials and the products that may enter into contact with fishery products must comply with all hygiene standards, and specifically:

- May not alter the organoleptic characteristics of the fish preparations and fishery products.
- May not transmit substances that are harmful to human health to them.
- Will be sturdy enough to guarantee the efficient protection of fishery products.

The primary packaging material may not be used more than once, with the exception of certain types of special packaging of impermeable material, smooth, corrosion-resistant, easy to wash and disinfect, that may be used again after being cleaned and disinfected. The second-use cardboard boxes may be used for products that will be repacked before their final dispatch.

Any unused packaging material must be stored in a separate area from the production area and must be protected from dust and contamination.

The primary and secondary packaging must include at least the following information:

- SERNAPESCA authorization number for the fishery plant or factory ship.
- Chile.
- Production date (date in which the raw material or product was processed) or product code.
- Expiration date or shelf-life.

If the already manufactured product is repacked, the following considerations must be taken into account:

- If the repackaging process is for primary packaging, the initial production date of the product must be maintained, and a lot code or number must be assigned to identify the repackaging process.
- If the repacking takes place at an establishment different from that of the original manufacturer and the primary package is changed, the establishment doing the repackaging must appear as the manufacturer.
- If the repackaging process is only for secondary packaging, the identification of the original manufacturer will be kept in the entire packaging. The establishment that does the repackaging must have traceability records that support this procedure.
- The expiration date of the product will correspond to that assigned in the first processing operation.

When the product is destined to the European Union, Section III, Chapter IV, Item 2 with additional requirements must be referred to.

When the products are introduced in large packages, in bulk and are not intended to be sold directly to the consumers, but will undergo additional processing or reprocessing operations, they may be exempted from labeling this information in the primary packaging, except for canned products.

In the place of storage of the finished product, the packaging must include the previously described information.

The information included in the identification mark of the product must be legible, irremovable and easily understandable in such a way as not to mislead the consumer, mainly in terms of the common name, scientific name, production or expiration date, etc. In addition, it must allow identifying with a visible and unequivocal mark those products that have some kind of market restriction.

If the restriction takes place while the product is at the manufacturing establishment, the involved product must be immediately labeled with the corresponding mark. For this, each establishment must define the way in which the restricted product will be identified.

I. STORAGE AND TRANSPORTATION

During their storage and transportation, fishery products will be kept at the temperatures described in this Standard. Specifically:

- Fresh or thawed fishery products, as well as products from cooked and refrigerated crustaceans and mollusks, will be kept at ice-melting temperature.
- Frozen fishery products, with the exception of frozen fish in brine and intended for canning, at a stable temperature of -18 C° or lower in all the points of the product, eventually with brief fluctuations of a maximum of 3 C° up during transportation.
- Live fishery products (crustaceans) will be kept at a temperature and will be transported in a way that does not negatively impact their safety or viability.

SERNAPESCA may authorize exceptions to what is stated in the previous item if the frozen fishery products are transported from a cold store to an authorized establishment to be thawed at their arrival to be prepared or processed and that the distance to be traveled is short and does not exceed 50 km or one hour.

If the products are preserved in ice, the contact of the water slurry with the products must be avoided.

The products may not be stored or transported with other products that may affect their safety or may contaminate them if they are not packed in a way that guarantees their protection.

Vehicles used for transporting fishery products will be manufactured and equipped to be able to keep the temperatures required in this Manual during the entire transportation process.

The surfaces of the means of transportation will be smooth, easy to clean and disinfect and will not affect the safety of fishery products.

The means of transportation used for fishery products may not be used to transport other products that may affect or contaminate them, except if they are thoroughly cleaned and disinfected to guarantee the absence of contamination to fishery products.
Fishery products may not be transported in vehicles or containers that are not clean and that have not been disinfected.

The transportation conditions of fishery products that are to be sold alive must not impose any negative effects on these products.

J. PRODUCT TRACEABILITY

The purpose of this procedure is to set up a strategy that allows reconstructing the production process, from capture to harvest, with the aim of being able to identify and separate a lot with problems.

All fishery establishments must have a documented Traceability system in place as described in item 5.3 of this Chapter.

K. SPECIAL REQUIREMENTS FOR SENDING BY-PRODUCTS/WASTE TO PROCESSING ESTABLISHMENTS

The establishments that destine their by-products or waste, either heads, viscera, pin bones, skin or others to processing establishments must have procedures in place to collect them along the processing line, so as to ensure the separation of those by-products or waste that enters into direct contact with the floor, or have been exposed to another type of contamination source.

It should be noted that by-products/waste used to produce fishmeal and/or fish oil intended for export to the EU, must come from raw material or products which comply with the health requirements of this market (e.g. MRLs for pharmaceutical residues). Consequently, in the event of an unfavorable result, the processing plant of origin must communicate this situation to the destination plant so that it can take the corresponding measures.

3.2.2.2 FACTORY SHIPS

A. REQUIREMENTS RELATED TO CONSTRUCTION AND EQUIPMENT

Factory ships must have at least:

- An area intended to receive fishery products on board, designed and distributed in large enough areas to be able to separate their consecutive arrivals. It must be designed in such a way that the products are protected from the sun or harsh weather conditions, as well as from any other sources of dirt and contamination. This reception area and its detachable elements must be made to be cleaned easily.
- A hygienic transportation system for fishery products, from the reception area to the work areas.
- Areas with enough space to hygienically conduct the preparation and processing of fishery products. They will be designed and planned to avoid the contamination of the products.
- Storage areas for the end products with enough space and easy to clean.
- A separate storage area for storing by-products or waste if there is a waste treatment unit onboard.
- A storage premise for packaging material, separated from the product's preparation and processing premises.
- Special equipment to evacuate fishery products unfit for human consumption either to the sea or if circumstances require so, to a container reserved for this use.
- If this waste is treated or stored on board for its sanitation, there must be separate premises available for this.
- A facility with a supply of potable water or clean spray seawater. The seawater pumping hole must be placed so that the quality of the pumped water is not affected by the evacuation of waste water, waste and engine cooling water into the sea.

- A proper number of dressing rooms, sinks, and toilets where the latter may not connect directly with the premises where fishery products are prepared, processed or stored.
- Sinks must have hygienic means for washing and drying and sufficient cold water flow, and when the establishment also manufactures products destined to Europe, it must have a hot or warm water supply; the faucets may not be manual. (Valves to control water designed and built to avoid re-contamination of washed and disinfected hands may be accepted).
- The lamps that are suspended over the foodstuffs in any of the production phases must be easy to clean and must be protected to avoid the contamination of food if they break.
- All raised structures and accessories must be installed to avoid the direct or indirect contamination of foodstuffs, raw materials, surfaces in contact with foodstuffs or packing material from condensation from water steam and dripping, and must not hinder any cleaning tasks.
- They must have proper areas for cleaning, disinfecting and storing work equipment and tools. These facilities will be built with corrosion-resistant and easy to clean materials and must have a sufficient hot and cold water flow for these operations.

The following will be required where preparation and processing operations of fishery products take place:

- An anti-sliding floor, easy to clean and disinfect with devices that allow an easy evacuation of water.
- The structures and devices installed on the floor must have scuppers of proper size so that they are not clogged with fish waste and that allow an easy draining.
- Walls and roofs that are easy to clean, especially in the areas of the piping, chains, and electrical conduits.
- All the windows that are in the processing rooms, primary and secondary packaging warehouses or in any other place where the product or the surface in contact with the product may be contaminated must have laminated safety glasses or anti-shatter or protection.
- The hydraulic circuits must be arranged or protected in a way that a possible oil leak will not contaminate fishery products.
- Sufficient ventilation and, if applicable, a good steam extracting system.
- Proper lighting.
- Devices to clean and disinfect tools, materials, and systems.
- Hand washing and disinfecting facilities, where the faucets may not be operated manually, with disposable paper towels or hot air dryers and a sufficient hot and cold water flow. (Valves to control water designed and built to avoid re-contamination of washed and disinfected hands may be accepted).
- Work devices and tools such as cutting tables, containers, conveyor belts, eviscerating and filleting machines must be made with seawater anti-corrosion and easy to clean and disinfect materials and must be kept in good conditions.

Factory ships that freeze fishery products must have:

- A freezing equipment capable of subjecting products to a quick temperature reduction that allows reaching a temperature inside of at least -18 C° after its thermal stabilization.
- A refrigeration equipment capable of keeping products in storage areas at a temperature below -18 C°. Storage warehouses must have a temperature log system located in an area where it is easy to be seen.

B. HYGIENE REQUIREMENTS FOR MANUFACTURING AND STORING FISHERY PRODUCTS ON-BOARD

The floors, walls, roofs and partition walls of the premises and the materials and tools used to work with fishery products must be kept in good hygienic and operation conditions so that they do not constitute a source of contamination for such products.

All rodents, insects and any other parasites must be systematically exterminated in the premises or materials. Rat and insect poison, disinfectants and other potentially toxic substances must be stored in rooms or areas locked with a key and must be used in a way that does not represent a risk for contaminating products.

The premises, work tools, and materials must only be used for handling fishery products.

Clean water will be used for all purposes. Nevertheless, a non-potable water supply system will be authorized exceptionally to produce steam, fight fires or cool cooling equipment to the extent that the connections installed for that purpose do not allow the use of such water for other purposes or that present a risk of contamination for the products.

Disinfectants, sanitizers and similar substances must be authorized by the corresponding health authority and must be used so that they do not affect the equipment, materials, and products. They must be properly labeled and stored in a restricted access area.

Operations such as eviscerating and de-heading must take place in a hygienic manner, and the products will be washed with abundant clean water immediately after these operations.

Operations such as filleting and slicing will be conducted to avoid any contamination, especially to the de-heading and eviscerating operations and must be conducted in a different place.

Fillets and slices may not remain on the work tables for more time than the necessary for their preparation and must be protected from all sources of contamination with a proper packaging.

The viscera and the parts that may represent a hazard to public health will be separated as soon as possible and will be kept away from products intended for human consumption.

C. REQUIREMENTS FOR THE STAFF

There must be a person on board the factory ship responsible for the correct manufacturing practices of fishery products, with the necessary authority to enforce the provisions set forth in this Standard.

The personnel must wear proper and clean work clothes and a clean cap that completely covers the hair, especially when handling fishery products that may become contaminated.
The personnel in charge of handling and preparing fishery products must wash their hands every time that they resume their tasks.

Smoking, spitting, drinking, and eating are not allowed in the work areas and in the storage areas for fishery products.

The company must apply all the necessary measures to avoid having staff that may contaminate fishery products when working with and handling them until their fitness to do so without any risks is demonstrated.

If gloves are used when handling fishery products, they must be in perfect condition and clean. Gloves must be made of impermeable material. The use of gloves will not exempt the operator from washing his/her hands properly.

D. REQUIREMENTS RELATED TO PROCESSING

The requirements established in letter G, item 3.2.2.1 above must be met.

E. PACKAGING AND LABELING

Finished products (blocks, HG, whole) frozen on board, must be properly packed before unloading.

Finished products stored in bulk in the ship's storage rooms must have primary packaging.

In addition, the requirements established in letter H, item 3.2.2.1 above must be met.

F. STORAGE AND TRANSPORTATION

The requirements described in item 3.2.2.1, letter I of this Chapter must be fulfilled.

G. SPECIAL REQUIREMENTS FOR SENDING BY-PRODUCTS/WASTE TO PROCESSING ESTABLISHMENTS

The establishments that destine their by-products or waste, either heads, viscera, pin bones, skin or others to processing establishments must have procedures in place to collect them along the processing line, so as to ensure the separation of those by-products or waste that enters into direct contact with the floor, or have been exposed to another type of contamination source.

It should be noted that by-products used to produce fishmeal and/or fish oil intended for export to the EU, must come from raw material or products which comply with the health requirements of this market. Consequently, in the event of an unfavorable result, the processing plant of origin must communicate this situation to the destination plant, so that it can take the corresponding measures.

3.2.3 SPECIFIC REQUIREMENTS FOR PROCESSING ESTABLISHMENTS (NOT INTENDED FOR HUMAN CONSUMPTION)

A. SURROUNDINGS

1) Processing plants must be located in areas far from sources of insalubrity and other contaminants and not exposed to floods.
2) Processing plants must not be in the same area as the slaughterhouses or the facilities that process by-products of non-marine origin unless they are located in a completely separated building (the part that refers to these type of products is deleted).

3) Entrance areas and traffic areas within the reduction plant or in its surroundings must be of hard surface, paved and treated to control the presence of environmental dust. Unauthorized people or animals must not have access to the premises.
4) Trash and waste must be properly disposed, and the grass or lawn in the surrounding areas of the buildings or plant must be mowed and cut to avoid the presence of pests.

B. DESIGN AND CONSTRUCTION OF THE ESTABLISHMENT

1) Work areas must be large enough to carry out work activities in a proper manner and under proper hygiene conditions. The establishment must have a clean and a dirty area, properly separated and with sanitary barriers for disinfecting the shoes and hands of the operators.
2) The entrances to the clean area must be properly designed and must be clearly marked to assure the correct use of the corresponding sanitary filters.
3) The dirty area must have a covered area to receive the raw materials and be built in such a way that is easy to clean and disinfect; the floors will be built in such a way that it is easy to drain liquids.
4) Processing plants must have the capacity to produce hot water and steam for processing raw materials.
5) Plants must have the following for heat treatment (the operational stage where processing takes place):
   - Measurement devices to control temperature over time.
   - An ongoing monitoring system for temperature measurements.
   - A suitable safety system to avoid insufficient heating.
6) To avoid the recontamination of finished products with raw materials from the outside, there must be a clear separation between the part of the plant reserved for unloading the material intended to be processed and those reserved to process of that product and to store the already processed product.
7) Production establishments must have proper facilities for cleaning and disinfecting containers in which raw materials are received and those vehicles that transport them, except for vessels.
8) There must be areas available for disinfecting the wheels of vehicles every time they enter the clean areas. This area must be located or designed to avoid the risk of contamination of the processed products.
9) All processing plants must have a waste water evacuation system that complies with the conditions set forth by the competent environmental authorities.
10) They must have a device to check the presence of metallic objects in the raw materials. The presence of foreign matter must be checked before starting the processing operations, and if detected it must be immediately removed.
11) If a reduction plant manufactures meal from salmonids' raw material and from extractive fishing in the same process line, it must guarantee that the meal manufactured with midwater species does not contain remains of salmonid species. For that, the establishment must have a procedure in place that allows to control this risk and make available to SERNAPESCA the means of verification that prove the effectiveness of the procedure.
12) The reduction establishments must guarantee that the meal manufactured and destined to the European Union market (category 3 material) is not processed simultaneously with material of other conditions (categories 1 and 2), in accordance with Regulations (EU) No 142/2011 and (EC) No 1069/2009. It must also have a procedure in place that guarantees that the products of different categories are not mixed.

C. GENERAL HYGIENE CONDITIONS

1) Raw materials must be processed as soon as possible after their arrival. They must be properly stored until they are processed.
2) Fish silage must be stored in corrosion-resistant air-tight containers.
3) There must be records that support the pH measurements of fish silage, and those results must always be lower than or equal to 4 (pH ≤ 4).
4) Containers and vehicles used transporting raw materials must be cleaned in an area assigned for such purpose.
5) People that work in the dirty area must not enter the clean area without having undergone a shoe disinfection process. Equipment and tools must not be moved from the dirty to the clean area unless they are disinfected first. There must be a procedure in place to control the traffic of staff between the different areas and to determine the correct use of sanitary filters.
6) Wastewater coming from dirty areas must be depurated to avoid the contamination with pathogenic agents.
7) Any rodents, insects or any type of parasites must be exterminated systematically and preventively from all premises or materials. For this, a documented pest control program must be used. Rat and insect poison, disinfectants and other potentially toxic substances must be stored in rooms or areas locked with a key and must be used in a way that does not represent a risk for contaminating products.
8) Guard or guide dogs may be allowed only in some areas of the establishment to the extent that their presence does not contaminate the processed products, the surface in contact with them or their packing materials.
9) Trash or any other type of waste must be transported, stored and handled in a way that minimizes odors, that does not allow it to attract pests, that avoids the contamination of processed products, contact surfaces, water supplies and the land's surface.
10) Cleaning procedures must be established and documented for all areas within the plant. Cleaning devices and supplies must be provided for these purposes.
11) Hygiene control must include periodical inspections of the surroundings and the equipment. Inspection programs and their results must be documented and filed for at least two years.
12) The facilities and equipment must be kept in good condition, and the measurement equipment must be calibrated every year.
13) Transformed products must be handled and stored in the plant in a way that avoids their re-contamination. Preventive measures must be in place to guarantee that products are not mixed with land animal proteins.

D. SANITARY FACILITIES

1) There must be enough changing facilities and restrooms, with walls and floors with smooth surfaces, impermeable and washable (see Table "Number of sanitary fixtures required based on the number of operators"). These must not communicate directly with work areas.
2) The sinks in the restrooms must have products for washing and disinfecting hands and disposable towels or hot air hand dryers.
3) Changing facilities, restrooms, entrance halls and yards located in the surroundings of the plant and those that are part of it must always be clean and properly maintained.
4) Restrooms and changing facilities must be adequately lit, ventilated and protected against insects.
5) Work clothes must not be mixed with everyday garments in the changing facilities, neither must other items (such as food or kitchenware or silverware) be stored in those areas.

6) Restrooms must have signs that remind employees that they must wash their hands after using them.

E. PERSONNEL

1) The personnel must wear suitable and clean work clothes.
2) Smoking, spitting, drinking, and eating are not allowed in the work areas and in the storage areas for fishery products.
3) The personnel must not wear any jewelry or accessories when handling food and must keep their fingernails clean and trimmed.

F. PROCESSING METHOD

1) In the case of conducting the processing operation, the processing establishment must use a method approved by SERNAPESCA. At the beginning of the authorization process for such method, the Office of the Service must be informed about the jurisdiction to which the production plant belongs. For such approval, samples of the transformed product must be taken from a production batch every day for 30 consecutive days. The samples must comply with the following microbiological standards:
   a) Samples of the product taken directly at the exit of the processing stage that the plant has defined as a critical control point. If the processing establishments manufacture products from fish silage, the samples must be taken at the exit of the cooker and once the temperature is stabilized.
      Clostridium perfringens absence in 1 g of product n=5, c=0, m=0, M=0
   b) Samples of the product taken during the storage or at the end.
      Salmonella absence in 25 g: n=5, c=0, m=0, M=0
      Enterobacteriaceae: in 1 g: n=5, c=2, m=10, M=300

   Where:
   n= number of samples to be analyzed.
   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 samples whose bacterial content ranges between m and M; the sample will continue being considered as acceptable if the bacterial content of other samples is equal to or lower than m.

   The collection of samples for this purpose will take place in accordance with Section IV, Chapter II, Item 2.
2) The 5 samples indicated in items a) and b) must be collected and sent to the laboratory in separate containers, complying with the total volumes and the number of necessary increments per lot, if appropriate, according to the presentation of the product, based on the sampling procedures stated in Section IV, Chapter II, Item 2.
3) The samples of the product for the approval of the processing method, described in Letter F, Item 1, letters a and b, must be collected from the same production lot. However, the sample corresponding to the storage may not be collected the same day of the product's manufacturing. The samples must be collected and analyzed by samplers and laboratories accredited by SERNAPESCA, in accordance with Section IV, Chapter I, Item 1. The analyses will be conducted according to the techniques described in Section IV, Chapter III, Item 6

4) The company must record and keep originals of the information that supports the compliance with this requirement. A copy of this documentation must be provided to the SERNAPESCA Office under the jurisdiction of the processing plant. The SERNAPESCA official will analyze the information provided, and if all the results are compliant, the Regional Director of SERNAPESCA will issue a letter to the company authorizing the processing method.
   On the contrary, if during the analysis process, there are results that do not comply with the terms; the company must re-validate its method authorization process. In such case, the company must inform the Service the corrective measures adopted for such purposes.
5) The company must also inform, within the supporting information for the processing method, the continuous temperature logs and declare the minimum residence times that were used in the drying stage during the period established for this study.
6) This method will be valid until there is a significant change in the transformation process or in the equipment used. If the change takes place, the company must report it to the corresponding SERNAPESCA office and conduct a new validation for the processing method.
7) If the processing establishment considers the export of fish oil to the European Union, it must ensure that the product is also subjected to a transformation process approved by SERNAPESCA, in accordance with items 1 to 6 described above.
   Fish oil refineries exporting their product to this market may validate a processing method or supply with raw material from reduction facilities that have their own validated method for fish oil intended for the EU. In this case, as a backup for each reception of raw material they must have a declaration issued by the reduction facility of origin, indicating that it complies with the requirements for being exported to the EU.

G. PACKAGING, STORAGE, AND TRANSPORTATION

1) Packaging must take place under proper sanitary conditions, avoiding the contamination of products.
2) The transformed product must be packed and stored in new or sterilized bags, or it must be stored in silos or warehouses intended for that purpose.
3) Sufficient measures must be adopted to reduce condensation to a minimum level within the silos, warehouses, conveyors or elevators.
4) Products will be protected from accidental contamination in the conveyors, elevators, silos and in packing areas.
5) The equipment for handling transformed products must remain clean and dry, and there must be proper inspection points available to verify the cleanliness of the equipment. All storage facilities must be cleared and cleaned on a regular basis, as required by production specifications.
6) The transformed product must be kept dry or in the optimum storage conditions defined for each product. Leaks and condensation must be avoided in the packing and storage areas.
7) Any unused packaging material must be stored in a separate area from the production area and must be protected from dust and contamination.
8) The necessary measures to identify products, to keep them separated, and to continue identifying them must be adopted during the packing and transportation of products.
9) The label must display at least the name of the product, the production date, the production lot, the registry number of the manufacturing establishment and the word Chile.
10) The production establishment indicated on the label must be that which conducts the meal and oil processing process. In the case of meal mix or oil refining, the establishment where these processes were conducted must be indicated on the label, regardless of the lots or batches of

origin, preserving their traceability at all times. A new batch is generated when a mixture is conducted, which acquires the new production date, but maintains the expiration date of the oldest fishmeal used for the mixture.

11) In the case of meal heat re-processing, the date of the last treatment applied must be indicated. In the case of chemical treatments, the production date must not be modified.
12) When a lot is comprised of a product with different production dates without any mixes, the subunits that comprise the lot must be labeled so as to preserve the traceability of each one, always associated to the production date of these subunits.
13) In all previous cases, there must be a proper traceability system in place, associated with the production date and that allows identifying all the sources and processes applied to the product.
14) In the case of reduction establishments that include the European Union as one of their possible destination markets, the phrase fish meal or oil "unfit for human consumption" must be clearly indicated on a label attached to the vehicle, containers, boxes or other packing materials during transportation.
15) The raw materials and processed products must be collected and transported in air-tight and anti-corrosion vehicles or containers (derived from fish silage), intended exclusively for the transportation of fish and marine animals, so as to avoid the contamination of a product with others different from fishery origin.
16) Reusable vehicles or containers, as well as any other reusable parts of the equipment or instruments that come into contact with raw materials or transformed products, must be:
    - Cleaned and disinfected after each use,
    - Kept in clean conditions, and
    - Cleaned and dried before their use.
17) Reusable vehicles and containers must only be used for the transportation of raw materials and materials from marine animals, to avoid the contamination of products with others of a source different than fishery (land animal proteins).
18) In the case of processing establishments whose products may be destined to the European Union, these may not be destined to the production of fish meal and oil, fish or fish parts from mortalities or diseases or that at the moment of slaughtering present signs animal-transmissible diseases. Similarly, they must not receive in their facilities any transformed products of this origin.
19) Raw materials must be transported under proper temperatures so as to avoid any risks to animal or public health.
20) In the case of processing establishments that may be destined to the European Union, the raw materials intended for the production of fish meal or oil must be transported refrigerated or frozen, except if processed within 24 hours from their departure from their place of origin.
21) Vehicles intended for refrigerated transportation must be designed in a way that allows maintaining the required temperature during the entire transportation process.
22) Fish oil, as well as products derived from silage, must be packed in new and clean containers, and all the necessary precautions must be taken to avoid their contamination. If the product is planned to be transported in bulk, the tubes, pumps and barrels, as well as any other bulk transportation containers or bulk liquid carrier trucks used to transport products from the manufacturing plant or directly to the vessel or the coast's storage areas or directly to the plants, must have been inspected and considered to be clean before being reused.
23) Category 3 fish meal and oil must not be stored simultaneously with category 1 and 2 fish meal and oil, except when it complies with the following conditions approved by SERNAPESCA:
    - There are separate and clearly identified delimited areas for storing the products of different categories.

- The products must be stored in closed containers and not in bulk.
- Demonstrate to have a traceability system that guarantees the compliance of the previously described items.

The exception described does not apply to meal and oil derived from salmonids that do not comply with the standards set by the European Union and their corresponding LMRs for fish flesh and skin, described in Part II, Section I, Chapter II of the Food Safety and Certification Manual, regarding the control of pharmaceutical products residues, prohibited substances, unauthorized substances and contaminants. These must be stored in separate facilities.

H. CONDITIONS FOR VERIFYING THE ABSENCE OF CONTAMINATION WITH PROTEINS DIFFERENT FROM FISHERY ORIGIN

1) The manufacturing establishment must obtain raw materials, process, and store products of aquatic origin exclusively, so as to avoid the contamination of the product with land animal proteins, complying with the definition of fish meal.
2) Reception, processing, storage and delivery records for raw materials must be kept for at least 2 years.
3) Fish meal and oil processing establishments and those that process derivatives from fish silage, must collect quarterly samples of a finished product from at least one production lot with n=5, to carry out determinations on the components of animal origin in meal, in accordance with what is described in Section IV, Chapter III, Item 2. The 5 samples must be collected and sent to the laboratory in separate containers, in accordance with the total volumes and the number of increments required per lot, based on the presentation of the product (sacks, bulk, jumbo, etc.), as per the sampling procedures described in Section IV, Chapter II, Item 2.
4) The results for these verifications must be:

   Regarding the presence of components coming from land animals:
   - The microscopic examination of the collected sample has not detected any components coming from land animals.
   - The microscopic examination of the presented sample has detected components derived from land animals.

   Regarding the presence of fish meal:
   - The microscopic examination of the collected sample has not detected the presence of components coming from fish.
   - The microscopic examination of the collected sample has detected the presence of components coming from fish.

I. CONDITIONS FOR FISH MEAL STORAGE AREAS

The storage premises or facilities must not be located in the same area of those used for storing processed products from materials of different origin than fishery products. These premises, whether they are located in the plant or outside of it, must comply with the following requirements:

1) They must have a covered area to receive the products, or they must have some kind of collection system that protects them from harsh weather conditions or from any source of contamination.
2) They must be built in a way that makes their cleaning and disinfection process easy; floors must be built in a way that makes drainage easy.
3) They must have suitable restrooms, changing facilities and sinks for the staff.

4) They must have proper protection devices against pests such as insects, rodents, and birds.
5) They must have proper facilities for cleaning and disinfecting containers in which the products are received and those vehicles that transport them, except for vessels. There must be proper facilities for disinfecting the staff's footwear and the vehicle's wheels.
6) Products must be stored properly until the freight is forwarded.

J. VERIFICATION CONDITIONS FOR DIOXINS, DIOXIN-LIKE AND NON-DIOXIN-LIKE PCBs FOR FISH MEAL AND OIL EXPORTED TO THE EU

The processing establishments that export to the European Union must conduct a dioxins, dioxin-like and non-dioxin-like PCBs control in accordance to what is established in Section III, Chapter IV, Item 2. European Union.

In the case of fish meal, the samplings and analyses will be conducted once a year per establishment. For raw fish oil, the lots to be sampled must not exceed 1,000 tons, and for refined fish oil, the lots to be sampled must not exceed 2,000 tons.

K. CONDITIONS FOR SUPPLYING BY-PRODUCTS/WASTE COMING FROM ESTABLISHMENTS THAT MANUFACTURE PRODUCTS INTENDED FOR HUMAN CONSUMPTION.

Reduction establishments that supply raw materials (by-products/waste) coming from establishments that manufacture products intended for human consumption or cold storages, must have procedures in place to differentiate the productions based on the category of the raw material and avoid cross-contamination between lots of different categories.

To export fish meal and oil to the EU the raw material must correspond to category 3, and therefore the by-products/waste received must not correspond to waste that has been in contact with the floor in the establishment of the supplier or have been exposed to another type of contamination source.

In adittion, it must be noted that by-products/waste used to produce fishmeal and/or fish oil intended for export to the EU, must come from raw material or products which comply with the health requirements of this market (e.g. MRLs for pharmaceutical residues in salmon). Consequently, in the event of an unfavorable result in the supplier plant, it must communicate the situation to the destination reduction facility, so that it can take the corresponding measures, blocking the affected product to the EU.

3.2.4 SPECIFIC REQUIREMENTS FOR THE APPLICATION AND AUTHORIZATION OF HEAT PROCESSES (M.09.03.18)

All fishery establishments manufacturing cooked and/or canned fishery products intended for export, that are part of the List of Companies under SERNAPESCA's Sanitary Control Programs, must comply with the requirements set forth in this Manual.

Pasteurized products are excluded since these are considered as raw products due to the heat processed applied.

The Temperature Distribution Studies must indicated the features of equipment (cooker and retort) and the measure instruments used form the control of thermal process.

A. PROCEDURES FOR THE APPROVAL OF HEAT PROCESSES

Fishery plants that require to export certified cooked and/or canned fishery products must request the approval of the Heat Penetration Studies for all their heat processes to SERNAPESCA. The company must present the Heat Processes Report Evaluation Request form (Part III, Annexes, Chapter II) including all the information required.

For each one of the products described in the request, the Heat Penetration Study must be presented.

In addition to the above, the Temperature Distribution Studies corresponding to the equipment used to apply the heat process must be presented.

An original and a copy of the Heat Processes Report Evaluation Request with all the required information must be presented at the SERNAPESCA Office under whose jurisdiction the processing plant is located; the original will be filed at the corresponding SERNAPESCA office, and the other copy will remain with the interested party. An additional copy must be presented when the plant is under a jurisdiction different from that of the corresponding Regional Directorate.

The Heat Penetration and Temperature Distribution Studies must be presented in a digital format (.pdf file), providing a separate file for each report presented.

These studies must include at least two experiences per product and the corresponding cooking equipment or autoclave. In the case of Heat Penetration Studies, at least 2 environmental monitoring and 3 product monitoring thermocouples for each experience must be used.

The reports must contain at least the following information:

- Title
- Name, location and address of the entity responsible by the studies.
- Place where the study took place.
- Report number (correlative and unique).
- Date of the study and issuance of the report.
- The number of each page with the total number of pages included in the report.
- Name, position and signature of the technical person responsible for the study.
- Proper and clear identification of the company requesting the study, including its full address.
- A full description of the product: Indicating the common and scientific name of the raw material, presentation (raw, pre-cooked, whole, eviscerated, cut, shredded, etc.) canning liquid (canned products), type of container, etc.
- The identification of the materials and equipment used in the study (for instance the identification of the cooker, the serial number or in its absence the internal identification, type and number of thermocouples, temperature logging equipment, etc.).
- An indication of the selected pattern microorganism to determine the heat process, as appropriate.
- Description of the conditions under which the study was conducted.
- Description of the systematic error of the pressure gauge or thermometer at the moment of the study.
- Calculation method used to conduct the heat penetration study.

- Results, including lethality calculations (must include graphs and tables with the temperature logs for the entire process) and the critical factors.
- Identification of the environment and product monitoring thermocouples.
- Identification of the thermocouples used for calculating the process.
- Conclusions of the study, which must be clarifying for critical factors (maximum weight or load, the arrangement of the containers, initial temperature, etc.) that must be applied by the companies in their corresponding processes.
- Equivalent or alternative processes (only if the process is determined based on a pattern microorganism).
- A statement indicating that the report cannot be reproduced neither totally or partially.
- Identification of the temperature distribution study.
- Thermocouples location chart.
- In the case of cooked mollusks that are exported to the EU, and as appropriate, the study must expressly indicate that the recommended process complies with the requirements set forth for the type of area. For B or C type areas.
- Time and temperature data sets for each one of the experiences.
- Signature of the technical person responsible.

Once the SERNAPESCA official verifies that all the requested information is included, he/she must stamp and date the copy of the plant and return it to the interested party indicating that its request has started the evaluation process.

All the information provided by the interested party will be confidential.

Once the information is received at the Central Office of SERNAPESCA it will be evaluated to verify its compliance with the program, as described in Item 3.2.4, Letter B. Once the evaluation has concluded, a report will be issued and will be sent directly to the company with a copy to the Office under whose jurisdiction the plant is located.

If the result of the evaluation proves that the heat processes applied in the plant comply with the requirements described in Item 3.2.4, Letter B, the reports for the heat penetration studies of every heat process will be approved. If there are any deficiencies or observations, the company must request the correction of the studies or for them to be conducted again, as necessary. A new document must be presented within 60 days from the date of notification of the results of the first evaluation. The approved reports of the heat penetration studies will be included in the Registered Heat Processes Records that will be kept by SERNAPESCA.

If there are any changes in the processes recorded in the Service, which imply reducing the initial temperature or the process temperature, reducing the processing time or changes in the formulation of the product and container, or in any other basic condition for the efficiency of the established process, this must be notified and reviewed by SERNAPESCA, prior to its implementation at the plant. The changes must have been previously checked, which the company must support through the report issued by the corresponding entity.

Apart from the requirements inherent to the heat process (sterilization), the requirements described in Item 3.2.4, Letters C and D, related to the containers, production and process controls must be met.

Once the heat processes reports are approved, random visits from SERNAPESCA officials may take place at the establishments with the purpose of evaluating the correct application of these processes.

If deficiencies or inconsistencies in the recorded heat processes that may lead to the production of a product harmful to health are detected, they must be immediately corrected. Otherwise, the plant will not be authorized to export the involved products.

All plants authorized by SERNAPESCA to export canned and/or cooked fishery products must immediately notify the Office corresponding to their jurisdiction if there are any products that may be harmful to public health, as a consequence of an incorrect application of the heat processes, regardless of the place where the product is located, either at a processing plant or in full distribution at destination. If it is an establishment with a Quality Assurance Program approved by SERNAPESCA, the measures described in its own Products Recall Program must be applied.

B. REQUIREMENTS FOR THE CREATION OF HEAT PROCESSES

a) Canned Products

The Temperature Distribution Study for the autoclaves of the plant must clearly identify the equipment in which the test was conducted. If there is more than one autoclave and all are of the same characteristics (brand, capacity, type of heating, etc.), it will be sufficient to carry out the study in the equipment that is farthest from the steam supply. The entity responsible for the study must indicate in the report, that it is valid for the rest of the autoclaves, also stating if all the autoclaves can or cannot operate simultaneously.

When conducting the Temperature Distribution Study, the proper functioning of the equipment must verify, including in the report a phrase that proves this verification.

The heat processes must be designed to ensure the destruction of the *Clostridium botulinum* spores, with a Fo factor of at least 3 minutes.
All canned products manufactured by the company must have their corresponding heat penetration study, understanding the following set of factors as the product:

- Species.
- Size of the container.
- Presentation (whole, shredded, cut).
- Type and composition of the canning liquid.

If a process can be applied to more than one product, this must be indicated in the report.

b) Cooked Products

All cooked products manufactured by the company must have their corresponding heat penetration study, understanding the following set of factors as the product:

- Species.
- Size of the container (as appropriate).
- Presentation (whole, flesh, ½ valve, etc.).

If a process can be applied to more than one product, this must be supported in the report..

- Fish, Cephalopods, Crustaceans, and Gastropods

Fish, cephalopods, crustaceans, and gastropods that are exported cooked to any market, with the exception of crustaceans destined to Brazil or Mexico, must be subjected to a cooking heat process that allows for the cold point of the product to reach a temperature of at least 70 C°. Cooked crustacean meat destined to Brazil and cooked crustaceans in general exported to Mexico, must comply with the instructions provided in items "Crustacean meat without shell (extractive fishing) destined to Brazil" and "Crustaceans destined to Mexico," described as follows.

If there is not a pattern microorganism defined for these cooking processes, the time and temperature data sets described in the heat studies must prove the compliance with the above requirements. For this, alternative or equivalent processes may not be applied.

- Bivalve Mollusks, Tunicates and Echinoderms destined to Markets different from the European Union

If the establishment produces cooked bivalve mollusks, tunicates or echinoderms and exports them to a market different from the European Union, it must have a heat process similar to that described in the item "Fish, cephalopods, crustaceans, and gastropods" above.

- Bivalve Mollusks, Tunicates and Echinoderms destined to the European Union

If the establishment produces cooked bivalve mollusks, tunicates or echinoderms from Type B or C extraction areas that are part of the Bivalve Mollusks Sanitation Program and exports them to the community market it must have a heat process for one of the following treatments:

- Sterilization heat treatment or
- Immersion in boiling water until reaching an internal temperature of at least 90 C° at the coldest point of the resources, maintaining this condition for a time equal to or above 90 seconds or
- Cooking for 3 to 5 minutes in a closed container at a temperature between 120 C° and 160 C° and a pressure between 2 and 5 kg/cm^2 and their further shucking and freezing at -20 C° in the center of the product or
- Steam cooking under pressure in a closed container where at least the internal time and temperature requirements for mollusk meat described in item b) are followed, and the homogeneity in the distribution of heat is guaranteed in the closed area by a methodology validated in the control program chart.

If there is not a pattern microorganism defined for these cooking processes, the time and temperature data sets described in the heat studies must prove the compliance with the above requirements. For this, alternative or equivalent processes may not be applied.

If the resources come from Type A or Approved extraction areas, it will not be necessary to comply with this item, applying what is set forth in the item "Fish, cephalopods, crustaceans, and gastropods" above.

- Crustacean Meat without Shell (Extractive Fishing) destined to Brazil

Cooked crustacean meat without shell from extractive fishing destined to the Brazilian market must accredit a heat process that guarantees a temperature of 70 C° at the coldest point of the product for at least 15 minutes.

In addition, what is described in Section III, Chapter IV, Item 2 must be followed.

If there is not a pattern microorganism defined for this cooking process, the time and temperature data sets described in the heat studies must prove the compliance with the above requirements. For this, alternative or equivalent processes may not be applied.

- Crustaceans destined to Mexico

Cooked crustaceans exported to the Mexican market must accredit the application of a heat process that ensures a temperature of 70 C° at the coldest point of the product for at least 5 minutes.

If there is not a pattern microorganism defined for this cooking process, the time and temperature data sets described in the heat studies must prove the compliance with the above requirements. For this, alternative or equivalent processes may not be applied.

c) Additional Requirements for Canned Products

All plants processing fishery canned products intended for export, and that are part of the SERNAPESCA Sanitary Control Program must have procedures that comply with what is described in this section.

C. REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF THE PROCESS

a) Preparation of the Product

Before using raw materials and ingredients susceptible to microbiological contamination, the processor must ensure that these raw materials and ingredients are suitable to be used in the production of canned products. This may be achieved through a guarantee or certification from the supplier, by the analysis of the microbiological condition of these materials/ingredients or by other acceptable methods and inspections of raw materials and ingredients made by the company's quality control staff.

When scalding or cooking raw materials for preparing canned food, it is recommended to conduct this process heating the food at the required temperature, maintaining this temperature for the necessary time and then quickly cooling the food or moving it promptly to the next stage. The above with the purpose of reducing the risk of contamination with thermophile bacteria in the scalding or cooking stages, where it is recommended to apply proper scalding processes (time/temperature) and keep a good hygiene and sanitation. If the product to be scalded or cooked is washed beforehand, this must be done with potable water.

The can filling stage must be controlled to comply with the parameters set in the planned or established process.
The *exhausting* process applied to remove the air from the containers must be controlled to achieve the conditions for which it was designed. These conditions may be met through the

extraction of air by heat, mechanical vacuum, use of hot covering liquid or steam injection (spray) before sealing.

When maintaining the pH (above 4.6) in low-acidity food is the basis for the establishment of a formulated process, the process must be supervised to ensure that the balance pH of the end product is met as established.

When the formulated process uses critical factors to prevent the development of microorganisms that are not destroyed by the heat process, these factors must be carefully controlled to ensure that the established limits are not exceeded in the formulated process. When low-acidity food requires enough solute to allow a safe process at a low temperature, such as boiling water, the process must be supervised closely to ensure that the water activity (aw) of the end product in the balance complies with what is set forth in the formulated process. In the case of foodstuffs that have an aw greater than 0.85 and/or lower than an aw that can allow the development of spores of microorganisms of significance to public health, the formulated process must be enough so as to produce food free of microorganisms which are capable of reproducing in the food under regular storage and distribution conditions (without refrigeration).

b) Formulated Process

The process formulated for low acidity food must be established by expert and qualified people with the knowledge on the requirements for the heat process for low-acidity food in air-tight containers. To establish a formulated process, the type, range, and combination of the variability found in the commercial production must be considered. Critical factors such as the minimum headspace, consistency, maximum filling weight, aw, etc. that may affect the effectiveness of a process must be specified in the formulated process.

On the other hand, acceptable scientific methods to establish the sterilization heat process must be used, as necessary, such as (but not limited to) heat destruction time data, process calculations based on heat penetration data or the use of inoculated containers. Calculations must be made in accordance with the procedures recognized by the competent process authorities. If incubation tests are necessary to confirm the formulated processes, it is recommended for these tests to include containers used in the essays and a number of containers originated by four or more of the commercial productions. It is recommended to determine the number of containers of a commercial production based on recognized scientific methods and for it to be enough so as to ensure a proper process.

Full records must be kept at every establishment, covering all aspects related to the determination of the formulated process, and when necessary, the analyses of the associated incubation tests. All these records must be permanently kept by the person or the organization that conducted these determinations.

c) Operations in the Heat Processing Room

The formulated processes for each product and container size and the venting and raising procedures in the autoclave (as appropriate) must be posted (visible) in an area near the processing equipment (autoclave) or must be made readily available for the autoclave operator. The formulated processes must also be readily available for the supervisor.

A system to control the circulation of the product in the autoclave room must be established, with the purpose of avoiding that the product that is not heat processed is not subjected to the sterilization process. Each basket, cart or tray used to keep the containers inside the autoclave, or one or more containers of these baskets, carts or trays must be clearly marked with a heat-sensitive indicator or any other effective method that may visually indicate the staff in the room that those units that were or were not heat processed. A visual verification must be conducted to determine if there have been any changes in the heat-sensitive indicator as a result of the heat process in all baskets, carts or trays of the autoclave, ensuring that each unit of the product was subjected to heat processing. A written record must be kept for this verification.

The initial temperature of the content of the containers to be processed must be determined and recorded with enough frequency to ensure that the temperature of the product is not lower than the initial temperature specified in the formulated process. The first sealed container must be identified and separated to record its temperature before putting it in the autoclave. For those operations that use water during the filling of the autoclave or during the process, it must be studied if it is necessary to apply any precautions to ensure that the water is not below the initial temperature of the product specified in the corresponding formulated process, before starting each formulated process.

The clocks used to record the information concerning the time of the heat process must be accurate to the extent that they ensure that the process time and venting/raising time is reached, as specified in the formulated process, and must be located in a visible area near the autoclave. Pocket watches, cell phones or wristwatches may not be used for controlling process times. Digital clocks may be used if the operative and venting/raising processes have a minute or a safety factor above the formulated process.

The time indicated in the temperature log chart must match the hour of the day of the process's written record so as to have a correlation between these records; with a time lag no greater than 15 minutes.

The steam supply in the processes room must be proper so as to ensure that there is sufficient pressure during the heat process, regardless of other steam supplies in the plant.

If silencers are used in the purging holes or venting lines, evidence must be kept in the files indicating that the purges or vents are operated in a way that does not significantly impede the removal of air. This evidence may be provided as temperature distribution data or other satisfactory evidence, such as a letter from the manufacturer, designer or entity responsible by the studies.

The autoclave and heat processing systems operators and the inspectors in charge of the closure of containers must work under the supervision of a person trained and accredited in these issues.

d) Process Deviations, Venting or Critical Factors Control

Any process applied in the plant that is lower than the formulated process will be considered as a process deviation. In this case, as well as when after the processor reviews the production records it is evidenced that the critical factors are outside of those established in the formulated process, all the product must be reprocessed, this is, all the product involved in the production with the deviation must be sterilized again, keeping full records of the reprocessing conditions applied or

alternatively, the affected lots must be segregated so as to be evaluated for their potential risk to public health.

Unless this evaluation proves that the product has undergone a heat process that ensures that it is free from microorganisms potentially relevant to public health, the segregated product must be completely reprocessed to make it commercially sterile or it must be destroyed. The evaluation procedures used and their results must be recorded.

After fully completing re-processing (and reaching commercial sterility) or after determining that there is not a significant potential risk to public health, that part of the affected product may be distributed as usual.

All process deviations that involve a failure in the compliance of the minimum requirements for the formulated process must be recorded and kept in a separate file providing details of the deviation, the actions taken, its evaluation and the final destination of the product. There must be a special area for storing products under evaluation, and the product must be labeled with the phrase "Product under observation".

e) Records and Reports for the Process

The establishments that produce canned products in air-tight containers must maintain, review and keep all the process records, process deviations, inspections when closing the container and other records for at least four years. In the case of cooked fishery products, there must be records of the cooking processes applied, which must be kept for the time equivalent to the duration of the product.

The autoclave or processing system operator or any other person appointed must record the observed processing and production information in the corresponding record forms. These forms must include the name of the company, identification of the product, batch number, date and number of the autoclave or processing system, size of the container, approximate number of containers involved, initial temperature of the product, processing time applied, mercury thermometer's readings, temperature logging equipment's readings and any other relevant processing data.

All the critical factors defined for a specific product, process or container must also be recorded. In addition, the following records for each type of autoclave must be kept:

- Autoclave statistics: Start time of the process (opening the steam valve), venting time and temperature, time in which the sterilization temperature is reached (CUT), sterilization time (until closing the steam valve).
- Water immersion autoclaves: Start time of the process (opening the steam valve), raising time (CUT), sterilization time and any other requirement specified in the temperature distribution studies.
- Continuous agitation autoclaves - steam: Operation of the condensate purge, autoclave rotation speed, sterilization time and any other requirement specified in the temperature distribution studies. In addition, in the case of specifying the headspace, consistency, maximum dry weight, minimum net weight and solids percentage in the formulated process.
- Discontinuous autoclaves with agitation - water: Raising time (CUT), autoclave rotation speed, sterilization time and any other requirements specified in the temperature distribution studies.

In addition, in the case of specifying the headspace, consistency, maximum dry weight, minimum net weight and solids percentage in the formulated process.

- Methods to preserve foodstuffs where critical factors such as water activity are used together with heat processes: The formulation of the product and the formulated processes used, including the heat process and its associated critical factors, as well as other critical factors and the results of the determination of water activity (aw).

The charts for continuous temperature logs must be identified with the date, autoclave number and any other necessary information so that they can be correlated with the written records of the operator for each heat process.

Each entry on the heat process and production logs must be made by the autoclave or processing system operator, at the specific moment in which the condition or operation of that autoclave or processing system takes places. The autoclave operator or another appointed person must sign or put his/her initials in every record form.

Before 1 day of work, after the operative process has been applied, and before loading or releasing a product for its distribution, a trained representative from the plant's management must review all the process and production records to determine their integrity and ensure that the product was subjected to the formulated process. Afterward, all records, including the temperature charts must be signed and dated by the person that reviewed the documents.

The records entered for all the analyses of container seals must specify the product's code, date and time of the seal inspection, the measurements obtained, the identification of the sealer, the format of the container and all the corrective actions taken. The records must be signed with the initials of the seal's inspector and must also be reviewed by management within 24 hours from the process.

Records of the distribution of each product must be kept for the purpose of facilitating, as necessary, the tracking and segregation of the specific lots of foodstuffs that may be contaminated or produced in an improper way for their end use.

Copies of all the records mentioned in this section, except for those corresponding to the formulated process, must be filed and stored in the process plant for at least a year from the production date. Additionally, these records must be kept for 3 more years, either in the same plant or in another area of easy access.

If during the first year when the records are filed, the plant is closed for a long period (for instance, between production or packaging periods), the records may be transferred to another place of easy access at the end of the production or packaging period.

D. REQUIREMENTS APPLICABLE TO CONTAINERS

a) Closures

During the production process, periodical observations must take place to detect the most noticeable defects in closures. Any defects, as well as the correctives actions applied, must be recorded.

The operator, seals supervisor or any other qualified person in seals inspections must thoroughly examine the seal of a can selected at random, for each one of the closure headings or the closure of any type of container used. This inspection must take place at frequent intervals, as defined in the following paragraphs with the purpose of ensuring a proper sealing. All observations must be recorded.

- Visual examination of the seals: For the double seal of a metallic container, each can must be visually examined for defects such as bumps, sharp seals, false seals, missing seals on the overlap, and the condition of the internal wall of the seal, to detect visible breaks caused by the head. Such measures and records must take place at reasonable time intervals. Additional visual inspections must take place in the closure immediately after the capping machine is stuck, after the machine is tuned and after the machine is started when it has been off for a long time. All observations must be recorded. When irregularities are found, the corrective actions to be applied must be recorded.
- Seal destruction tests: A qualified person must carry out destruction tests for taking apart the double closure in the metallic containers, and he/she must record the results at frequent intervals, selecting enough containers in each sealing station, to ensure that its integrity is preserved. Such tests and records must take place at intervals of no more than 4 hours. Additional destructive inspections must take place in the closure immediately after the closure machine is stuck, after the machine is tuned and before the machine is started when it has been off for a long time. The results of the destructive test must be recorded, and corrective actions must be taken, as appropriate, and recorded.

For other seals that are not of tin cans (double closure) or glass, proper and detailed inspections must be carried out at frequent intervals to ensure the correct operation of the sealing machine and the consistent production of the air-tight seal. The records of these inspections must be filed. Such destructive tests and records must take place at intervals of no more than 4 hours.

b) Cooling Water

The water used to cool the containers must be chlorinated or disinfected (using an agent different from chlorine) both for the use in autoclaves, cooling channels or for the use of recirculated water. There must be a measurable chlorine concentration (or of the disinfecting agent used) at the point of discharge or exit of water from the autoclave or channel that does not exceed 5 ppm.

Those autoclaves that are cooled with the same water used in the sterilizing process, which is heated and cooled indirectly, are exempted from this process.

c) Containers Coding

Each canned container must be marked with an identification code that is always visible (at first sight), which must be stamped in the container before the sterilization process. If a package cannot be embossed or printed, a permanently embossed tag firmly attached to the container may be used. The minimum required information in the code, which complements the description of Item 2.2 includes:

- Number of the plant where it was packed.
- The product contained.
- The year and date of sterilization.
- Process batch.
- Chile.

d) Handling Containers after the Process

When already processed tin containers are handled in a conveyor belt, it is recommended for them to be designed and built to reduce the contact between the double closures and between the belt and the double closure. Containers rolling over their double closure is considered as a bad practice. It is recommended to keep the equipment used for transporting containers after the sterilization process in good conditions (free of bumps, sharp edges, etc.) so as not to damage the container.

3.2.5 GUIDELINES FOR CONDUCTING STUDIES ON THE FACTORS OF CONCENTRATION OR DILUTION OF CONTAMINANTS

The studies to obtain the concentration or dilution factors of contaminants, such as Cadmium or other heavy metals in fishery products, must be conducted by the producers in order to justify any changes in the concentration of the contaminant caused by industrial processes such as drying, dilution or the transformation process itself. These studies must be properly supported with experimental data for the proposed factor.

The following guidelines are based on Commission Regulation (EC) No 1881/2006. According to this, the studies and reports must consider at least the following:

A. STUDY

a. Must be conducted specifically for each type of product and based on the production process established by the manufacturer.
b. The critical points in which the samples will be collected must be identified so that they are representative of the process stage under consideration.
c. The number of samples to be extracted in each production stage must be of at least 10 units. The sampling process must be in charge of a sampler authorized by SERNAPESCA and based on the Service's regulations in force.
d. The parameters to be determined in the samples collected at each stage of the process will be the concentration of the contaminant in the units described in the SERNAPESCA standards and the percentage of moisture, considering the reception of raw material as the initial stage.
e. The analysis must be conducted in a laboratory authorized by SERNAPESCA using the technique authorized for these purposes.
f. The concentration factor may be obtained based on the concentration variation of the contaminant during the production process, between the first and final stage. The factor will be the result of the contaminant's concentration at the initial stage (raw material) and its concentration at the final stage (finished product):
   Correction factor = Initial [contaminant]/ Final [contaminant]
   Where:
   Initial [contaminant] = Concentration of the contaminant in the raw material (ppm)
   Final [contaminant] = Concentration of the contaminant in the finished product (ppm)
g. The following will be taken into account in order to interpret the factor obtained:
   If the concentration factor is lower than 1, then the concentration of the contaminant increases (concentrates) during the production process.
   If the concentration factor is greater than 1, then the concentration of the contaminant decreases (is diluted) during the production process.
h. To apply this factor, the unfavorable result will be multiplied directly.

B. REPORT

a. Purpose of the study.
b. Clearly identify all the production stages, as well as the stages considered in the study and the reason why they were chosen.
c. Supplies and methods used for sampling and analysis.
d. Results summary clearly identifying each one of the production stages for the results, providing information on the average, standard deviation, and variation coefficient percentage.
e. Reference to the Trial Report with the partial results.
f. Determination of the factor, clearly indicating the calculations that allow obtaining this value, considering that it is based on the average results obtained at the initial (raw material) and final (finished product) stages.
g. Conclusion based on the description of item A. f
h. Name and signature of the person responsible for the report.

4. STORAGE ESTABLISHMENTS

This section applies to establishments that store fishery and aquaculture products intended for human consumption, such as cold stores, cold container facilities and establishments that carry out operations to extend shelf life and fish meal storage warehouses, all intended for export. Container yards or premises where only cold connection services are provided and where there are not any product handling or loading/unloading operations are excluded.

4.1 APPROVAL PROCEDURES

A sanitary approval for storage establishments responds to the need to ensure that the establishments that are part of the sanitary control of SERNAPESCA can store their products intended for export in other locations different from the establishment without losing their sanitary quality and controlling their entire production chain.

Those establishments interested in obtaining the approval must present the Cold Store Approval Program Application or the Meal Storage Approval Application (Part III, Annexes, Chapter II), accordingly, to the Regional Directorate under whose jurisdiction the establishment is located. Once the application is received, the Registry number for the establishment will be processed, and the inspection visit will be coordinated.

Those establishments that store products intended for human consumption will be inspected using the Inspection Checklist for Cold Stores, while for those that store fish meal the Infrastructure and Health Management Inspection Checklist for Warehouses Intended to Store Fish Meal will be used. Both checklists are available in Part III, Annexes, Chapter II.

For each one of the items included in these checklists, one classification for the observed deficiencies has been included (minor, major, serious and critical), with the purpose of conducting an objective evaluation of the establishments. The description for this classification can be found in Part I, Glossary of this Manual.

It must be mentioned that the classification of the deficiencies associated to the different items of the checklist is not final and that it may vary on the field, depending on the nature of the analyzed deficiency. Similarly, if at the moment of inspection other aspects that were not considered in the checklist are observed, these must be included in the remarks/notes section and will be classified according to the previously described definitions.

It must be noted that if the deficiency is repeated over time, its severity may increase in the next inspection.

If any deficiencies in the infrastructure are detected, and their solution requires a mid to long-term period and investment, the company may present an activities schedule to solve those deficiencies at SERNAPESCA for its review and approval.

While the schedule is in place and considering the application of mitigation measures, the deficiencies may be indicated in the inspection checklist, but their severity may be reduced. The SERNAPESCA Inspector must verify the strict compliance with the terms set in the schedule, and if not met it may imply revoking the establishment's authorization.

It must be mentioned that the application of work schedule charts for deficiencies related to sanitary management, as well as any aspects that have a direct incidence on the safety of the product, will not be accepted and must be solved immediately.

After the inspection, the Regional SERNAPESCA official will rate the establishment based on the description provided in items 4.1.1 and 4.1.2 as follows, informing this result to the interested party and to the Central Office of SERNAPESCA.

Those cold stores that are inspected for the first time and are approved may store fishery and aquaculture products from the date in which their approval is notified and once they are included in the "List of cold stores authorized to store export fishery and aquaculture products." Nevertheless, these products may not be destined to the EU or the EEU while the establishments are not duly registered in such markets.

The main aspects to be considered in the inspection visit, as well as the basic information to be included in the results report, are the following:

1. Background information.
   a) Name of the Inspector that conducted the inspection.
   b) Name of the inspectors that were part of the inspection.
   c) Name of the person responsible for the establishment with whom the inspection visit took place.
   d) Date of the inspection.
   e) Name of the establishment.
   f) Code of the establishment.
   g) Cold rooms - containers involved in the inspection (as appropriate).

2. Information related to the previous categorization.
   a) Survey of the deficiencies detected in the previous categorization process.
   b) If there is a work schedule, the inspector must verify the compliance of the commitments undertaken by the company.

3. Aspects related to the inspection checklist.
   a) The inspection report must include the items considered in the corresponding checklist, indicating in each case the observation detected (as appropriate) or that deficiencies were not detected:
   b) If there is a deficiency that is repeated over time, this condition must be clearly expressed in the report, assigning the corresponding severity level.
   c) Any observations not included in the checklist but that the inspector considers to be relevant must be included in the report indicating the assigned severity level.
   d) The observations that were solved during the inspection must be included in the report clearly indicating this condition and the assigned severity level, as appropriate.
   e) In those cases in which the Inspector determines to apply a severity level different from those provided in the field checklist, he or she must justify this decision and clearly inform it in the report.

4. Results of the categorization:
   a) The report must include the summary chart of the detected deficiencies and the category assigned to the establishment.

It must be mentioned that only those establishments that are approved or approved with observations may continue storing fishery products intended for export.

To address the observations, a work schedule may be presented within 30 days from the visit.

If an approved establishment does not store export fishery products for more than one year, it will be removed from the list. To become part of this list again, the approval procedure described in this item must be followed.

When an establishment is approved to store export fishery and aquaculture products, and it is lowered to the "rejected" category, the inspectors in charge must proceed as follows:

- Immediately report the change in the category via fax or email to the Central Office.
- Inform the interested party of the result of the inspection and suspend the authorization to store export fishery products.

It will be the responsibility of the establishment to inform its clients of the change in category. The products stored in the establishment will lose their sanitary quality, and they must be subjected to analyses if they require a sanitary certification to be exported.

4.1.1 COLD STORES, CONTAINER PREMISES, AND ESTABLISHMENTS THAT CONDUCT OPERATIONS TO EXTEND SHELF LIFE

The approval of a cold store, container premises, and establishments that conduct operations that extend the shelf life of products may only be partially granted considering only some of their rooms, which must comply with the infrastructure and sanitary management requirements described in item 4.2.1.

It must be mentioned that if a room for finished product in a fishery plant with a valid QAP Certification complies with the requirements set forth in Item 4.2.1., it may be authorized to store fishery products with QAP Certification from third party establishments.

The establishments located in the premises of A.M.B Airport in which physical organoleptic inspections are carried out on chilled-refrigerated fishery products intended for export, as well as in other cold stores in which products are sampled or re-packed, must comply with what is described in Item 4.2.1.1, in regards to areas assigned for fishery products samplings.

A Traceability exercise must be carried out in every inspection visit.

The approval or rejection of an establishment that stores frozen products intended for human consumption will be determined based on the following table.

Table: *Classification of deficiencies in cold stores*

CATEGORY	DEFICIENCY		
	MAJOR	SERIOUS	CRITICAL
Approved	≤13	≤5	0
Rejected		≥ 6	≥1

4.1.2 FISH MEAL STORAGE WAREHOUSES

The approval of a fish meal storage warehouse will be based on the infrastructure and sanitary management requirements described in item 4.2.2.

The approval or rejection of an establishment that stores fish meal will be determined based on following Table.

The storage warehouses must be sanitary inspected once a year, regardless of the association with reduction facilities with a QAP.

Table: *Fish meal storage warehouses deficiencies classification*

CATEGORY	CONDITION
Approved	Only with minor deficiencies
Approved with comments	Only with major deficiencies that do not alter the sanitary quality of the product.
Rejected	With major deficiencies, that alter the sanitary quality of the product, serious or critical deficiencies.

4.2 APPROVAL REQUIREMENTS

Those establishments that store export fishery or aquaculture products must comply with the following requirements, based on the type of activity that they conduct.

4.2.1 COLD STORES, CONTAINER PREMISES, AND ESTABLISHMENTS THAT CONDUCT OPERATIONS TO EXTEND SHELF LIFE

A. SURROUNDINGS, WATER SUPPLY, AND SEWAGE REQUIREMENTS

The facilities must be designed so that there is a proper drainage to the sewer or water treatment system of rainwater and loading/unloading platforms and road's wash water.

The roads inside the premises and towards the areas where product is handled, as well as pedestrian accesses and product's loading and unloading platforms, must be paved.

Roads, crosswalks and the surrounding areas of the establishment must always be kept clean and clear.

The establishment will have lidded containers for garbage collection, which must be installed on a paved or concrete surface. The area where the garbage containers are located may not be within 25 meters from the accesses to the cold store, loading and unloading platforms or any other area that represents a risk of contamination for the product.

Garbage containers must only be transported in vehicles intended for that purpose. In no case may these vehicles transport fishery products.

The garbage containers must be delivered cleaned and disinfected at the premises. This will be in charge of the transportation company or the cold storage itself who will be responsible for the sanitary treatment of the garbage containers. The establishment must have procedures and records in place for cleaning and disinfecting these containers.

The establishment must have a continuous water supply sufficient for all its operations. This supply will be of potable water from the public water system or of potable quality approved by the Competent Sanitary Authority, as per NCh 409/1 Of.2005.

If the cold store handles recirculated water, it may only be used for the compressor, irrigation system and for washing the exterior of vehicles. The potable and non-potable water pipes must be separated and painted with different colors and in no case may they be connected to each other. The water distribution points must clearly indicate "Potable" or "Non-potable." Alternatively, the establishment may have a pipes layout indicating those that are potable or non-potable.

The wastewater and general use collection systems will be separated and connected to the sewage system or the wastewater treatment system.

The cold store must have a proper and efficient pest control program (rodents, insects) in place around the entire perimeter of the premises. There must also be proper guards to avoid the entrance of unwanted animals such as insects, rodents, birds, etc. to the premises.

Rat and insect poison, disinfectants and other potentially toxic substances must be stored in locked rooms or closets and with restricted access.

The cold store must have records of the pest controls conducted.

B. DESIGN AND CONSTRUCTION OF THE COLD STORE OR CONTAINER

Cold rooms must be equipped with an easy-to-read temperature logging system, whose sensor must be located in the highest temperature area inside the room.

The company must ensure that the temperature logs of the rooms are available either in hard copies or in digital format.

The charts of the temperatures recorded must be available for SERNAPESCA's supervision for at least two years.

The walls, roofs, and doors of the cold stores must be smooth and easy to clean and disinfect. The floors of the rooms must be of an impermeable material, smooth and easy to clean and disinfect. The doors must have PVC or air curtains.

The cold store must have good lighting in all areas.

If shelves are used, these must be metallic or of impermeable material, easy to wash and must always be in good conditions.

The ventilation and air renewal process of the cold rooms must be conducted so as to avoid the alteration of the stored product. The air inside the cold rooms must not present any strange odors.

The cold room must have a maintenance program in place, including preventive and corrective maintenance with their corresponding records to ensure the proper operation of the rooms.

If repairs must be made in the cold rooms, ante-rooms, platforms and other adjacent premises, the company must guarantee that the products are not handled simultaneously.

C. REQUIREMENTS FOR STORAGE AND MEANS OF TRANSPORTATION

When entering the product in the cold room its temperature must be recorded and controlled, and it must match that described in the standard. This temperature will be informed to the manufacturer or owner of the product.

Once the stabilization period has concluded, the frozen products will be kept at a stable temperature of -18 C° or lower for the entire product. The chilled-refrigerated products will be kept at a temperature below 4 C°.

The stored product must be piled on pallets or shelves avoiding direct contact with the floor.

In exceptional circumstances, and only with the authorization of SERNAPESCA, may fishery products and meat by-products and derivatives of different animal species be stored in the same store room.

Those products stored in the cold rooms must be protected with proper packaging.

The stored products must have their original identification with which they were dispatched from the production establishment to the cold room.

If there are any market restrictions before the product enters the cold room, this information must be provided in a physical and visible way on the label or packaging. If the restriction is applied once the product is stored in the cold room, an identification through the computer system will be enough. The cold store must have records of this information.

The cold store will not conduct any changes in labels that contain the original identification of the establishment that manufactures the products, except for re-packings carried out under the following conditions:

- Only when there are broken or deteriorated boxes. This change of boxes must be realized by personal that have approved a course of Good Manufacturing Practice, of at least 8 hours. (M.08.02.18)
- Primary packages will not be changed.
- The re-packing operation will be conducted in a room equipped for this task (sampling room).
- There must be records of the changes in the packages by material damage.
- The compliance of the established procedure must be supervised.

In no other case may the products be packed or repacked in the cold room.

It is forbidden to open boxes to add any presentation of ice to the boxes (gelpack, dry or others). (M.05.01.18)

The products must be stowed in a way in which the label identifying the product is visible and remains in its place until the product is dispatched.

Those products that are subjected to samplings or checks inside the cold room must be properly identified as such until they are dispatched.

The cold room must have a system, procedure and records to identify those products that are expired or soon to be expired.

If the cold room receives the product in unclean conditions, with signs of deterioration, affected by mold or with strange odors, it must place it in an authorized, identified and delimited area to store defective loads, while a decision is made on its disposal. The cold room must have a procedure in place for these situations.

The segregated product must be visibly marked as such.

D. GENERAL HYGIENE CONDITIONS

The cold room must ensure that the garbage and the waste inside the facilities are transported, stored and disposed accordingly.

To conduct cleaning and disinfection tasks, the cold room must have trained and properly equipped (gloves, overall, safety shoes, boots, etc., as appropriate) staff. If external companies are used, they must comply with the same conditions.

The cleaning operations of the rooms must include the removal of ice and snow, as well as cleaning the walls, roofs, and other structures. If evaporators are used, cleaning tasks will be conducted so as to avoid the contamination of the stored product. The cold store must have procedures in place and records for these activities.

The disinfection of cold rooms will be conducted based on the procedures and records established, and it must take place:

- After emptying or leaving the rooms;
- When the growth of mold in the walls, roofs, materials, and equipment in the rooms becomes visible;
- When the stored product is affected by mold;
- When the microbiological analyses in the walls and air of the chambers are unsatisfactory.

If there is an excessive accumulation of ice, a deep-cleaning process will take place in the cold room. For this, there will be procedures and records that ensure a proper hygiene condition of the cold rooms.

E. SANITARY FACILITIES

The cold room must have a proper place for the personnel to change their clothes. Work clothes will be kept separately from off-duty wear.

Restrooms must be clean and in good conditions. They must have signs that indicate that it is mandatory for the personnel to wash their hands after using the restrooms.

They must have proper areas for cleaning, disinfection, and storage of work equipment and tools. These facilities will be built with corrosion-resistant and easy to clean materials and must have sufficient water flow for these operations.

F. PERSONNEL

The cold room must ensure that the personnel wears the proper attire for the tasks that they conduct.
The personnel in charge of handling and preparing products must wash their hands at least every time they resume their tasks, after using the restrooms, handling contaminated material and whenever necessary.

The company must adopt the necessary measures to avoid that personnel susceptible to diseases may contaminate the product.

Smoking, spitting, drinking, and eating are not allowed in the work areas and in the storage areas for fishery products.

All newly-hired operators must participate in an induction process, and their participation must be properly recorded. The training process will comprise at least the following:

- Personal hygiene standards.
- Handling tools, parts and maintenance materials.
- Regulations in force.
- Product handling (hand washing and disinfection, etc.).

G. TRACEABILITY

The cold room must have a control system to identify the products, at the reception, storage, re-packing and dispatch stages, that complies with the requirements set by SERNAPESCA and that allows guaranteeing the traceability of the products.

The establishment will have records of all the controls carried out.

H. SPECIAL REQUIREMENTS FOR DISPATCHING PRODUCTION BALANCES TO REDUCTION FACILITIES

If a cold storage requires to dispatch production balances that will not be exported, to reduction facilities, there must be a procedure to ensure that the product has not been in direct contact with the floor and/or has not been exposed to another type of contamination source.

It should be noted that by-products used to produce fishmeal and/or fish oil intended for export to the EU, must come from raw material or products which comply with the health requirements of this market (e.g. MRLs for pharmaceutical residues in salmon). Consequently, in the event of production balances blocked for the UE due to the presence of residues of pharmaceutical products, the cold storage must communicate this situation to the destination reduction facility, so that it can take the corresponding measures.

4.2.1.1 SPECIFIC REQUIREMENTS FOR FISHERY PRODUCTS SAMPLING AREAS

The surfaces of the walls, roof, windows, and doors must be smooth and easy to clean. The floor will be smooth, non-absorbent and with a slope to avoid the accumulation of water.

The temperature of the sampling room must not exceed 10 C°.
There must be enough tables for the sampling process, which must be of proper height so as not to hinder the handling of the product.

The surface of the sampling countertops will be smooth, washable and hygienizable. It must also be suitable for cutting the samples as necessary.

The room must be of the proper size to allow a proper maneuverability for the samplers of the authorized entities.

The room must have a non-touch hand-washing station with cold and hot water, a soap dispenser and disinfectant and a hand drying system (hot air or disposable towels).

There must be a non-touch garbage can available so as to avoid its contact with hands.

The room must have lockers for the samplers to store their work clothes.

It must have suitable lighting to carry out sampling activities.

4.2.1.2 SPECIFIC REQUIREMENTS FOR CONTROLLED ATMOSPHERE MAINTENANCE ROOMS (CAM)

The surfaces of the walls, roof, windows, and doors in the establishment must be smooth and easy to clean. The floor will be non-absorbent and with a slope to avoid the accumulation of water.

It must have suitable lighting for the activities that are carried out in the room.

Gloves must be impermeable and must be kept in perfect condition, clean and in proper sanitary conditions.

The product that is waiting for atmosphere medication will be kept under conditions that avoid an increase in its temperatures at readings over 3.3 C°.

The received boxes will be stored and subjected to controlled atmosphere under conditions that ensure their integrity.

The temperature measurement procedure must be conducted with clean instruments and in good condition so as to avoid the risk of introducing any foreign matters.

The records associated with temperature monitoring in the controlled atmosphere medication procedure must comply with the critical limit set (≤ 3.3 C°).

The bag containing the product (palletized or not) and preserving the atmosphere must be properly sealed and must not have any leaks.

The insufflation hoses must be clean and without any leaks. Their maintenance records must be kept.

If water is produced due to atmosphere modification and/or control operations, it must not reach the product, and it must not accumulate.
The company must have all the necessary supporting information on the product's microbiological and organoleptic analyses, as well as the supporting information on the microbiological control of the surfaces.

4.2.1.3 ADDITIONAL REQUIREMENTS FOR COLD ROOMS THAT STORE PRODUCTS DESTINED TO THE EEU

All the rooms must have humidity measurement devices. The establishment must have records in hard copies or in digital format. Relative humidity should be maintained between 90 and 95%.

A microbiological control (mold) must be conducted in the environment and the room's surfaces for chilled and frozen products at least once every three months. This control must be carried out while the cold storage is authorized, even in periods when it is not storing fishery or aquaculture products for export. In case of failure to comply with the above requirement, the establishment will be suspended for this market

The company must have records of the results from these controls and will make them available for the review of SERNAPESCA for at least two years.

The results of these analyses will be classified based on the criteria described in the following tables:

Table: *Evaluation criteria for the presence of mold in walls*

STORAGE TEMPERATURE	TOTAL AMOUNT OF MOLD PER 1 CM^2 OF SURFACE (3 PLATES ON AVERAGE)	EVALUATION
Rooms with temperatures of -12 C° or below	0 - 20	Good
	21 - 100	Satisfactory
	More than 100	Bad
Rooms with temperatures of -11,9 C° or above	0 - 30	Good
	31 – 150	Satisfactory
	More than 150	Bad

Table: *Evaluation criteria for the presence of mold in the environment*

STORAGE TEMPERATURE	TOTAL AMOUNT OF MOLD PRECIPITATED IN A PLATE FOR 5 MINUTES (5 PLATES ON AVERAGE)	EVALUATION
Rooms with temperatures of -12 C° or below	0 - 10	Good
	11 - 50	Satisfactory
	More than 50	Bad
Rooms with temperatures of -11,9 C° or above	0 - 10	Good
	11 – 100	Satisfactory
	More than 100	Bad

If a Bad result is obtained for the samplings, the company must inform SERNAPESCA local office within 24 hours after obtaining the result and will be suspended for storing product for the EEU while it carries out a thorough disinfection of the affected rooms. The suspension will be lifted once it is verified that analyses results at least Satisfactory.

If the results are Satisfactory, hygiene measures must be intensified at the premises, so as to reduce the microbiological load in the chambers.

The company must have a record of all the corrective actions implemented for Bad and Satisfactory results. The above will be evaluated by SERNAPESCA in the periodical inspections conducted at the facilities.

4.2.2 FISH MEAL STORAGE WAREHOUSES

A. SURROUNDINGS

1) The establishments must be located in areas far from sources of insalubrity and other contaminants and not exposed to floods.
2) The establishments intended to store fish meal must not be in the same place as the slaughterhouses or in the facilities that process by-products of non-marine origin unless they are located in a completely separated building (absence of land animal proteins).
3) Entrance areas and traffic areas within the production plant or in its surroundings must be of hard surface, paved and treated so as to control the presence of environmental dust. Unauthorized people or animals must not have access to the premises.
4) Garbage and waste must be properly removed, and the grass and the lawn surrounding the establishments must be properly cut so as to avoid any situations that could attract pests looking for a place to breed or shelter.

B. DESIGN AND CONSTRUCTION OF THE WAREHOUSE

1) Work areas must be large enough to carry out work activities in a proper manner and under proper hygiene conditions. The establishment must have a clean and a dirty area, properly separated and with sanitary barriers for disinfecting the shoes and hands of the operators.
2) Warehouses must have proper protective equipment and devices against pests such as insects, rodents, and birds.
3) The entrances to the clean area must be properly designed and must be clearly marked so as to assure the correct use of the corresponding sanitary filters.
4) The dirty area must have a covered area to receive the fish meal and must be built in such a way that is easy to clean and disinfect.
5) The lamps that are suspended over the stored product must be easy to clean and must be protected so as to avoid the contamination of food if they break.
6) The storage warehouses must have proper facilities to clean and disinfect the containers of vehicles that transport fish meal.
7) There must be areas available for disinfecting the wheels of vehicles every time they enter the clean areas. This area must be located or designed to avoid the risk of contamination of the processed products.
8) They must have a device to test the presence of metallic objects in the fish meal. The presence of foreign matter must be checked before starting the processing operations, and if detected it must be immediately removed.

C. GENERAL HYGIENE CONDITIONS

1) People that work in the dirty area must not enter the clean area without having undergone a shoe disinfection process. Equipment and tools must not be moved from the dirty to the clean area unless they are disinfected first. There must be a procedure in place to control the traffic of staff between the different areas and to determine the correct use of sanitary filters.

2) Any rodents, insects or any type of parasites must be exterminated systematically and preventively from all premises or materials. For this, a documented pest control program must be used. Rat and insect poison, disinfectants and other potentially toxic substances must be stored in rooms or areas locked with a key and must be used in a way that does not represent a risk for contaminating products.
3) Guard or guide dogs may be allowed only in some areas of the establishment to the extent that their presence does not contaminate the processed products, the surface in contact with them or their packing materials.
4) Trash or any other type of waste must be transported, stored and handled in a way that minimizes odors, that does not allow it to attract pests, that avoids the contamination of processed products, contact surfaces, water supplies and the land's surface.
5) Cleaning procedures must be established and documented for all areas within the plant. Cleaning devices and supplies must be provided for these purposes.
6) The stored fish meal must be handled and stored in the establishment so as to avoid its recontamination. Preventive measures to guarantee that it is not mixed with land animal proteins must be in place.

D. SANITARY FACILITIES

1) There must be enough changing facilities and restrooms, with walls and floors with smooth surfaces, impermeable and washable (see Table "Number of sanitary fixtures required based on the number of operators").
2) The sinks in the restrooms must have products for washing and disinfecting hands and disposable towels or hot air hand dryers.
3) Changing facilities, restrooms, entrance halls and yards located in the surroundings of the plant and those that are part of it must always be clean and properly maintained.
4) Restrooms and changing facilities must be adequately lit, ventilated and protected against insects.
5) Work clothes must not be mixed with everyday garments in the changing facilities, neither must other items (such as food or kitchenware or silverware) be stored in those areas.
6) Restrooms must have signs that remind employees that they must wash their hands after using them.

E. PERSONNEL

1) The personnel must wear suitable and clean work clothes.
2) Smoking, spitting, drinking, and eating are not allowed in the fish meal storage areas.

F. PACKAGING, STORAGE, AND TRANSPORTATION

1) Packaging must take place under proper sanitary conditions, avoiding the contamination of products.
2) There will be proper measures adopted to minimize condensation inside storage warehouses.
3) The processed product must be kept dry. Leaks and condensation must be avoided in the packing and storage areas.
4) Any unused packaging material must be stored in a separate area from the production area and must be protected from dust and contamination.
5) The necessary measures to identify products, to keep them separated, and to continue identifying them must be adopted during the packing and transportation of products. The

production date, the registry number of the production establishment and the word "Chile" should appear on the label as a minimum.

6) The production date used in the label must correspond to the date in which the processing method was applied or the date in which the mix takes place, as appropriate. It must be noted that a new batch is generated when a mixture is conducted, which acquires the new production date but maintains the expiration date of the oldest fishmeal used for the mixture. (M.10.07.17)
7) In the case of heat re-processing, the date of the last heat treatment applied must be provided. In the case of chemical treatments, the production date must not be modified.
8) When a lot is comprised of products with different production dates without mixes, the sub-units comprising the lots must be labeled so as to keep the traceability of each one, always associated to the production date of these sub-units.
9) In all previous cases, there must be a proper traceability system in place, associated with the production date and that allows identifying all the sources and processes applied to the product.
10) The fish meal must be collected and transported in air-tight and anti-corrosion vehicles or containers intended exclusively for the transportation of fish and marine animals, so as to avoid the contamination of a product with others different from fishery origin.
11) Vehicles and reusable containers, as well as all the reusable elements of the equipment or instruments that come into contact with the processed product, must be:
    - Cleaned and disinfected after each use,
    - Kept in clean conditions, and
    - Cleaned and dried before their use.

5. PREREQUISITES

5.1 MANUFACTURING BEST PRACTICES

Manufacturing Best Practices (MBP) describe the basic conditions and practices that must be followed to avoid the contamination of foodstuffs.

The Manufacturing Best Practices are described in different regulations. To create an MBP manual, at least Items 3.2 and 6 of this Chapter must and the instructions provided in this Item must be considered.

Additional information may also be found in the Sanitary Food Regulation; in the document "General Principles of Food Hygiene" of the *Codex Alimentarius* (CAC/RCP 1-1969); in Regulation (EC) 852/2004, on the hygiene of foodstuffs, and in the *Code of Federal Regulations*, Title 21, part 110, of the United States. In the case of establishments that produce fish meal and oil not intended for human consumption, information can be found in Regulation (EC) 1069/2009 and Regulation (EC) 183/2005

The establishment must have a manufacturing best practices manual related to the processes involved in the company. This manual must be known by the entire staff. It is suggested for it to be included in the company's internal regulations.

5.2 PRODUCT RECALL PROGRAM

The Product Recall Program consists of the efficient, coordinated and timely action of recovering a defective product (mainly focused on food safety issues) that is not with the producer anymore.

The purpose of this Item is to advise companies that produce fishery products on the aspects that they must take into consideration to set up a Product Recall Program.

A Product Recall Program must be subjected to active and periodical reviews and be susceptible to modifications as needed.

Recalling a product will be the measure to manage a risk detected from reports and/or unfavorable results obtained from national and/or international consumers, national and/or international competent authorities, from other processing establishments, farms, exporters or intermediaries.

It is important to consider that if the company is informed of any notifications, alerts and/or rejections from any destination market, and such information has not been directly provided to SERNAPESCA through the formal means recognized by competent bodies, the company must inform SERNAPESCA about the notification, alert and/or rejection within 48 hours, so as to evaluate the necessary measures to be applied to each case or situation. For the cases in which the companies fail to inform about this situation, the QAP of the plant will be affected, and it will be considered as a critical breach.

The production establishment will always be responsible for the correct removal of the product even if there are third parties involved or other links in the distribution chain. Nevertheless, in the case of manufacturing establishments with a limited scope of action due to the ownership of the product, their responsibility may be evaluated based on the information provided.

The purposes of recalling foodstuffs from the market are:

- Blocking affected products that remain in the country, with the purpose of avoiding their export and distribution in the national market. If the establishment must transport the product within the country, it must promptly inform the regional source and destination offices of SERNAPESCA in the country.
- Effectively and efficiently withdraw all the affected products from the market, even those that have already reached customers, intermediaries or distributors, as appropriate.
- Notify all the interested parties on the potential risks for health or any noncompliances with the requirements of the market that affect a certain product.

The entire product recall process must be conducted in the least time possible with the purpose of minimizing the exposure of consumers to products that may represent a risk to their health and to those that do not comply with the requirements of the destination markets. This requires well organized pre-established and tested mechanisms as described in the Product Recall Program, which must be put in place every time a problem is detected with a product.

The Product Recall Program must consider the following aspects:

1) Product recall team: The manufacturing establishment must appoint a team for removing the products and assign them responsibilities. It must also appoint a person in the team to act as the point of contact with SERNAPESCA given a recall event. Similarly, it must identify a surrogate in case the main person appointed is absent.

It is recommended to include a member from the company's commercial area, with the ability to contact the importer and/or the competent authority, as appropriate, to arrange the product's removal.
The team must develop a product recall plan and be prepared to remove any defective products in a quick and efficient manner. For this, it must be familiar with the regulations on product recalls and have the authority to implement recall procedures with the least amount of obstacles as possible.
The team must meet at least twice a year to review the company's recall procedures and the actions to be taken if failures in their application are evidenced. All the team's meetings must be properly recorded.

2) Traceability identification: The manufacturing establishment must have clear information on the traceability of the product involved in the recall, which must be available at all times as required by SERNAPESCA.
3) Customer's contact information: The establishment must have its customer's updated information.
4) Product recall simulation: The establishment must carry out a recall simulation at least twice a year, and this simulation must be documented. These records must be available as required by SERNAPESCA. A report on that activity must also be written, establishing the scope of the company in the distribution of its products and with different customers.
   The procedure must include at least:
   - Determination of the problem, alternating the type of recall in each simulation (Class I, II or III).
   - Conduct the traceability exercise for the involved lot, which must not exceed 48 hours.
   - Establish and support the means of communication with the customers (information and answers).
   - Design the different recall options.
5) Training: The product recall team must be trained so as to provide it with the necessary tools to properly comply with its duties. This training must be documented within the scope of the Training Program.

If there is an event that calls for a product recall, SERNAPESCA's Central Level will determine, based on the information provided by the company, the level in the distribution chain up to which the recall will become extensive.
For this, the impact that the detected hazard has on food safety and the health of people must be considered. Based on this, and with the purpose of channeling the strategy to be followed, the product's recall will be classified as follows:

- Class I Recall: The product poses a serious risk to the health of consumers. Ex: The presence of marine toxins, the presence of pharmaceutical products exceeding the established limits, the presence of pathogens, among others.
- Class II Recall: It is applied to those products where there is a reasonable probability of them posing a risk to the health of consumers. E.g.: the presence of *Escherichia coli*, the presence of prohibited or undeclared additives, among others.
- Class III Recall: The product does not pose a considerable risk to the health of consumers, but does not comply with the requirements of the destination market.

5.2.1 RECALL MANAGEMENT PROCEDURE

This Item must clearly describe the steps and activities that the company will carry out to remove a product, including the corresponding responsibilities.

Recalling a product from the market involves the following stages:

1) Start of the recall process: The process starts with the recall request issued by SERNAPESCA, this decision will be based on the information provided by the national or international Competent Authority and the results from the laboratory and company.
2) Recall classification and strategy: SERNAPESCA will classify the recall and will establish deadlines for any arrangements that allow its actual execution to take place.
3) Notification and alert: Based on the recall classification, the location of the product involved and the reaction capacity of the company, the Central Office of SERNAPESCA will evaluate the possibility to notify the National Competent Authority and the country of destination.
4) Monitoring and follow-up: The establishment must always inform the regional office of SERNAPESCA on the procedures applied and progress made in relation to the product's recall. The establishment must issue the following information to the regional office of SERNAPESCA as soon as possible:
    - The identification of the product (commercial name and species, packaging, presentation, production keys, traceability code, etc.).
    - Notification of shipment number.
    - Sanitary certificate number and certificate of origin number, as appropriate, and the export invoice number.
    - The reason for the recall, date, and circumstances under which the deficiency was discovered (for instance, report laboratories).
    - The hazard evaluation associated with the deficiency.
    - The total amount of the manufactured product and the product involved.
    - The total amount of product estimated per distribution channel by type of packaging and presentation.
    - Location and quantity of the product to be recalled, per distribution channel.
    - Distribution information including the identity of all the customers; name, address, email address, fax and telephone numbers.
    - A copy of the communication on the company's products recall sent to the customer.
    - The strategy proposed to conduct the product recall, including any measures to correct the problem and the disposal of the recalled product.
    - The name and telephone number of the person appointed in the company to be contacted for recalling the products. Also, the name and address of the manufacturer if it is different from the company that has started the products recall.

The quantity produced must correspond to the quantity stored and/or distributed, this includes the responsibility of the establishment on its storage on an external cold store.

If there is not any clarity in this respect, the team must determine the causes for any discrepancies. A full count of the affected product must take place.

The date, quantity, and location of the dispatches must be determined as soon as possible.

If there is a serious health hazard, the product must be destroyed. If the customer destroys the product, it must be done under the supervision of one of the company's representatives that started the recall or other responsible person and of the competent authority.

A record of destruction must be written and signed by the person responsible for the affected company and the corresponding sanitary authority. The record must be issued in original and copy, and it must include at least the following information:

- Date of the procedure.
- Location.
- Identification of the product (commercial and scientific name, manufacturing, presentation, production code, among others).
- Quantity destroyed.
- Reason for the destruction.
- Person responsible for the procedure.
- Name of the customer, address, and country of destination.

If the product is returned to the establishment, the company must be prepared not only to receive the products of the date of manufacture that presented problems, but also any others that may be returned.

5) End: Based on the evidence provided by the establishment, the Central Office of SERNAPESCA will determine, as appropriate, the end of the product's recall process.
The entrance of the product to Chile must follow the procedures and requirements described in Section V of this Manual.

Final Recommendations

Regardless of the degree of sophistication of the Product Recall Program of the company, it is important for the recall team to be able to trace the raw materials involved from the line of production to storage, and to be able to determine the locations where these finished products were sent, so that the program is in fact effective.

5.3 PRODUCT TRACEABILITY

Traceability is a tool used to trace the origin of the product and its supplies within the food supply chain since it allows to identify and record each product from its origin to the end of the commercialization chain. The purpose of this procedure is to set up a strategy that allows reconstructing the production process, from capture to harvest, with the aim of being able to identify and separate a lot with problems. The products are traced, usually, for investigation purposes, due to customer complaints and to be recalled from the market whenever there is a suspicion or certainty of a sanitary risk for the population.

All fishery establishments must have a documented Traceability system in place, as follows.

5.3.1 GENERAL REQUIREMENTS

Fishery and aquaculture products production, storage and distribution establishments must have a Traceability Program in place to quickly and efficiently relate the end product with the raw material and manufacturing processes, associating the corresponding control records.

Information on the Traceability Program must be provided to raw material suppliers and distribution companies; this information must be updated and made available for the review of SERNAPESCA:

- Name and/or registered name.
- RUT.
- Country.
- City.
- Address.
- Contact name.
- Contact phone number.
- Email address.
- RPA (as appropriate).
- Commercializing agent code (registered at GIA).

In turn, the minimum information required in Item 5.3.2 must be made available.

The Traceability Program must consider at least the following:

- Procedure: Each production establishment must define a coding system for the manufactured products (involving information from the origin of the raw material to the end product), which must be properly recorded and included in the label or tag of the end product's primary and secondary packaging in a clear and permanent way so as to ensure its correct identification in the following manufacturing stages, as per the requirements described in Item 3.2 of this Chapter.
- Person responsible for the traceability program: The production establishment must appoint a person responsible for the traceability program, indicating the following information: full name, position, RUT, email address and telephone number.
- Scope of the traceability program: The production establishment must identify the coding system and define the scope of the Traceability program which will depend on the hazards associated with the resource and the production process to which they will be subjected.

5.3.2 SPECIFIC REQUIREMENTS

Notwithstanding the general information required for all fishery establishments, the traceability system specifically requires the following information based on the manufactured products and the processing procedures applied, with emphasis on high-risk products.

A. RAW MATERIAL

Bivalve Mollusks

For the purpose of this technical standard, the requirements for bivalve mollusks will also be applicable to gastropods, tunicates, and echinoderms.

The origin of the resources and the establishments involved in each one of the production processes must be identified, indicating the registered name and code of the companies.

In the case of origin, the extraction area must be clearly identified with its extraction area name for the case of areas registered in the Bivalve Mollusks Sanitation Program (BMSP) or with the name of the area or region for areas that are not part of this program. In the case of farms, the code assigned at the National Aquaculture Registry (RNA) must also be provided.

In addition, the establishment must have supporting documentation that avails its traceability system and the origin of the raw material, for example:

- RET, as appropriate.
- Transportation tax documentation from the extraction process or from other fishery establishments.
- Sworn Declaration of Origin.

In turn, for resources coming from extraction areas that are part of the BMSP, the procedures described in Section I, Chapter I, Item 6 must be applied.

If mollusks are sent to desanding plants, the production establishment will be responsible for requesting any supporting documentation to provide evidence of the correct traceability of the lots entered to the desanding plant, which must at least identify each desanding pool with the code and name of the extraction area and the RNA code of the farm, as appropriate.

Farmed Fish

The origin of the fish and the establishments involved in each one of the production processes must be identified, indicating the registered name and code of the companies.

In addition, the establishment must have supporting documentation for its traceability system and the origin of the raw material, for example:

- Name of the farm and/or harvesting center, as appropriate.
- RNA code of the center.
- Identification of the cage.
- Identification of the species.
- Tax documentation that proves the transfer or entry to processing.
- Date of entry of the raw material to the production establishment.

Other Species

Fish (except for farmed fish), crustaceans and cephalopods will be included in this group for the purposes of this Manual. The origin of the raw material capture vessel and the establishments involved in each one of the production processes must be identified, indicating the registered name and code of the companies.

In addition, the establishment must have supporting documentation for its traceability system and the capture vessel, including:

- Name of the vessel.
- RPA/RPI code, as appropriate.
- DA/DI document, as appropriate.
- Identification of the species.
- Tax documentation that proves the transfer or entry to processing.
- Date of entry of the raw material to the production establishment.

If the species are captured without a vessel, the registry of the collector or shellfish diver that carried out the task must be provided.

B. NON-FISHERY INGREDIENTS OR SUPPLIES

Non-fishery ingredients or supplies are those raw materials of animal, vegetable or another origin that are added to foodstuffs, including food additives. Packing material is not included in this definition.

For these supplies the production establishment must have at least the following information:
- Name of the product (commercial and scientific, as appropriate).
- Producer.
- Production date.
- Expiration date (as appropriate).
- Sanitary authorization issued by the Ministry of Health for its use in foodstuffs.
- Percentage or quantity used in each production process.
- Tax documentation that supports the purchase.

C. IMPORTED RAW MATERIAL

Any establishments that use imported raw materials for products that will be exported must have a traceability system in place to track the use of imported raw materials in the end product and the associated Entry Request for Fishery Products (Part III, Annexes, Chapter II).

Similarly, the company must use a template to control the stock of imported products that have not been re-processed and those that have ("imported products stock template.")

Whenever necessary and as a minimum during periodic inspections, the inspector of the establishment must verify: The record system, the raw material imported, expiration dates and that the product has been processed according to the description of SIPP, that is to say, it must track the imported raw materials following the procedures described in this Manual.

5.3.3 PROCESS IN FISHERY ESTABLISHMENTS

The product's primary and secondary packaging must include the information described in Letter H "Packaging and labeling" of Item 3.2.2.

The labeling in the following production lines must include this additional information:
- Canned products: Identification of the sterilization batch in the primary packaging.
- Smoked/salted products: Identification of the salting and smoking process in the primary packaging.

In addition, the establishment must have supporting documentation for its traceability system, including:
- For the reception of raw materials, the production establishment must have the documentation described in Item 5.1. In addition, when processed raw material is received from other establishments, the identification of the received lots must be considered, indicating the registered name and code of the establishment. The establishment must also have the EI-A Supply Declaration available.
- In terms of production, the product must be clearly identified in each stage of the process.
- In the storage of the end product, the information of the stores and warehouses and product quantity must be recorded.

- Product movements (entry and exit) either for export, sale or storage in other facilities; the establishment must have information on the warehouse or cold store (registered name and code if these are external), customer information (name, address, country, etc.) date of exit and means of transportation, as well as the quantity dispatched, waybill and balance. The establishment must also have the EI-A Production Declaration and the Destination Declaration available.

The following must be considered for mixes and production balances:

- Finished product balances must be identified both in the primary and the secondary packages, and must be able to be traced up to the raw materials.
- If the establishment mixes products of different origins, it must provide the necessary guarantees that ensure their traceability (Item 5.3.1 "Scope of the Traceability Program.") In this case, the company must assume the responsibility to take action on all the products that comprise the mix in case of any problems.
- If the production establishment mixes origins of different establishments, it must prove that they are aware of such procedure and that they will assume the responsibility for any problems, and they will commit to provide the necessary information.
- If the production establishment mixes origins of different cages or farms, it must prove that the farm is aware of such procedure and that they will assume the responsibility for any problems, and they will commit to provide the necessary information.

5.3.4 EXPORT FISHERY PRODUCTS STORAGE SERVICE

Cold stores and premises suitable for storing cold products that will be exported and will be subjected to sanitary certification, either produced in establishments with or without QAP certification, must have at least the following information:

- The product entry record must include the customer's information (name, address, and country), date of entry, means of transportation, condition of the product (temperature, packaging, label, etc.).
- The identification of the warehouse, room or storage container, product quantity, and movements (entry and exit) must be recorded.
- The product exit record must include the customer's information (name, address, and country), date of entry, means of transportation, condition of the product (temperature, packaging, label, etc.).
- Supporting documentation of all entries and exits (waybills, packing lists, AOSC, SMAE, etc.).
- Records on the existence of counter samples, with the sampling dates and information of the customer.

5.3.5 PROCEDURE TO AUDIT THE TRACEABILITY SYSTEM ON SITE

The following procedure must be applied to oversee the compliance of this Program, so as to verify all the necessary information on the site that allows guaranteeing the traceability of the product.

To correctly supervise a Traceability Program, the SERNAPESCA inspector must use the Traceability Checklist, included in Part III, Annexes, Chapter III.

The frequency for overseeing the Traceability Program will be associated with the inspection frequency of each establishment and to the application of the "Infrastructure and Health Management Inspection Checklist for Export Fishery Products Plants for Human Consumption" and

the "Inspection Checklist for Establishments with Quality Assurance Programs" (Part III, Annexes, Chapter III).

Nevertheless, whenever the situation may so require, and given any deficiencies associated with the Traceability Program (sanitary alerts, unfavorable verifications, product recalls, among others), the SERNAPESCA Inspector may conduct an extraordinary supervision. In this case, the observations detected must also be recorded in the SERNAPESCA Register or be informed to the company via fax or written notice.

To conduct the supervision, the Inspector must take one or several of the following documents issued by SERNAPESCA as a basis: AOSC, SMAE, NEPPEX, Sanitary Certificate, SIPP, RET, Declaration of Guarantee, DJO, Traceability Chart, Supply, Production and Destination Declarations, etc.

Based on this document, the Inspector will request the person responsible for the Traceability Program of the establishment all the information mentioned in the Traceability Checklist.

The documentation will be reviewed by the Inspector, and all the nonconformities will be informed to the responsible person of the company. If the traceability test takes place during a QAP or HPB supervision, the deficiencies detected will be considered in the final classification. If the supervision of the Traceability Program takes place on an extraordinary basis, and the detected nonconformities are Serious or Critical, the corresponding checklist must be applied immediately.

In the case of high-risk resources (products affected by marine toxins and farmed fish), if the origin and destination of a product cannot be traced, SERNAPESCA may apply the measures related to the sanitary certification of the product, such as market restrictions, additional analysis requests, change in the QAP or HPB category, as appropriate, among others.

5.4 CUSTOMER COMPLAINTS FILE

A customer complaints file must be kept and analyzed periodically to detect any trends and eliminate any possible causes for these complaints. The processes to be followed for customers' complaints must be identified.

The following alternatives may be established:

1. Responsibilities: The people involved in the complaints process will be responsible for the following:
   - Receiving and classifying complaints.
   - Carrying out an internal investigation that allows establishing the validity of the complaint.
   - Establishing and executing corrective actions.
   - Answering any questions from the customers.

2. The procedure for handling complaints considers the following:
   - Where the complaint is recorded and any necessary information, for instance: Customer's name, the person responsible for the complaint, product involved, identity, quantity, date, time, reason and the person responsible for receiving the complaint.
   - How the traceability of the complaint is handled in order to determine its validity.
   - Any corrective actions to be applied, as appropriate.
   - Write an answer for the customer.

- Keep a record of all the information collected in the complaint.

5.5 CALIBRATION AND CONTRAST OF MEASUREMENT INSTRUMENTS

The general objective is to keep the risk of a measurement instrument providing results with unacceptable errors within acceptable limits.

5.5.1 CALIBRATION PROGRAM

A fishery establishment that is part of the QAP certification program must have measurement instruments calibration procedures in place for those events associated with safety hazards and to the critical control points of its quality system.

The following must be considered in the creation of instrument calibration procedures:

- Calibration frequency: It must take place once a year for those instruments considered as internal patterns for the company.
  - In the case of autoclave thermometers, these must be calibrated annually or every 6 months.
  - Thermometers and pressure gauges for cookers or pots must be calibrated every year or semester.
  - New instruments that have calibration certificates provided by the manufacturer may validate them only if they include the traceability (to an internationally known instrument) of the instrument used as a pattern. This certificate will be valid for one year.
- The instruments that need to be calibrated are all those related to critical control points monitoring.
- Entity in charge of executing the calibration procedure: It must be executed by a calibration laboratory accredited by the National Institute of Standardization (INN). This laboratory must be accredited for the instrument to be calibrated, and this must be supported with the scope of the accreditation of the laboratory. The list of entities authorized by the INN is available at www.inn.cl, under accreditations.
- Calibration procedure: The instrument must be sent to the chosen laboratory, requesting its calibration and a quote, this is, an establishment that works with frozen products must request a temperature calibration for its cold stores where the finished product is kept, and also of the freezing temperature of the product and any other temperature related to the control of CCPs. The calibration must be traceable to any international measurement pattern, for instance, the NIST, ASTM or the PTB of Germany. The calibration laboratory must issue a calibration certificate that must include at least the following information:
  - Calibration certificate (as a title).
  - Logo of its accreditation system and its corresponding accreditation number.
  - Name, head office and address of the issuing laboratory, identifying the division, department, section or unit that issues the calibration certificate.
  - Place where the calibrations were carried out if it is different from the address of the laboratory described in the previous paragraph.
  - Correlative serial and unique number for the calibration certificate.
  - Calibration date and date of issuance of the certificate.
  - Number of each page with the total number of pages included in the calibration certificate.
  - Name, position and signature of the technical person at the laboratory responsible for authorizing the calibration certificate.

- Clear and correct identification of the company.
- The single, unequivocal and permanent identification of the calibrated item (for instance the brand and name of the equipment, serial number, and its internal identification if the latter is not available).
- The conditions under which the calibration took place.
- Identification of the specification, procedure, and standard employed.
- A declaration of any deviations from the specification, procedure or standard.
- The results of the calibration with accepted measurement units and associated uncertainties, specifying if the correction of the corresponding calibration must be applied for its use.
- A statement indicating that the report cannot be reproduced neither totally or partially.
- Objective evidence on the traceability of the calibration service provided.

- Use of the information included in the calibration certificate: When the company has the certificate, the quality assurance manager or the person responsible for the instruments calibration procedure must review it, sign it and date it. This information will be vital for the calculation of the systematic error of the instruments of internal use in the establishment.
- Use of the pattern instrument: It must only be used to compare its measurements against instruments or equipment of daily use in the establishment (contrast).
- Storage of internal patterns: It must be made so as to protect the instrument from changes due to improper storage conditions. For instance, standard weights must be stored in a fresh and dry place. There should also be a person responsible for their storage.

5.5.2 CONTRASTING PROCEDURES

This activity consists of comparing the measurement of the pattern instrument with the one used by the establishment for the purpose of verifying the measurement accuracy of the latter.

- Frequency: When the company is starting with the execution of this procedure, before starting the production process it must compare the measurements provided by the pattern instrument with those used on a daily basis in the establishment. This procedure must be conducted at least every fifteen calendar days; in the case of pot or cooker thermometers, it must take place each semester if they have not been calibrated on a yearly basis and in the case of autoclave thermometers as instructed in Item 3.2.4, Letter B.
  All instruments associated with safety hazards and the critical control points of their quality system must be considered in this procedure.
  The thermometers used in the process control of factory ships may be contrasted at the beginning of each tide, and it is not necessary for the pattern thermometer to be taken during the tide. The error calculated must be informed to the persons responsible for the Quality Assurance Program during the tide.
- Documentation: The company must have instrument contrasting procedures in place, describing the conditions to conduct this activity (schedule, location, work temperature, etc.).
- This operation may be carried out by any qualified person appointed by the company as defined in the work team chapter of the HACCP program. It is advisable to have more than one person with knowledge of this procedure in order to assume the responsibility in the absence of the person holding the original responsibility.
- Contrasting procedure development:
  - Conduct at least five temperature readings or other measurement related to the QAP's CCPs, with the internal pattern instrument and the one used on a daily basis in the establishment, the five readings must be taken in the same conditions.

- Calculate the average of each one of the five readings.
- Obtain from the instrument calibration certificate the systematic error given for the closest temperature to that of the readings.
- With the systematic error value provided in the certificate, the systematic error of the thermometer in use must be calculated using the following expression:
  Systematic error = [average readings of the instrument being calibrated] – [actual corrected value of the pattern instrument]
  Where:
  - Average readings of the instrument being calibrated: Corresponds to the average reading of the instrument being used on a daily basis in the establishment.
  - Actual corrected value: Average of readings from the pattern instrument minus the systematic error of this instrument provided in the certificate.

Example 1 for values above 0 C°:

Table: *Example of generic results from a thermometer contrasting procedure*

Pattern thermometer reading in C°	Reading of the thermometer used on a daily basis in the establishment in C°
4.9	5.0
4.8	4.9
4.9	4.9
4.8	4.9
4.9	4.8
Average = 4.86	Average = 4.9

- Calculate the average of each one of the five readings:
  4.86 C° for the pattern thermometer and 4.9 C° for the daily-use thermometer.
- Obtain from the instrument calibration certificate the systematic error given for the closest temperature to that of the readings: 5 C°.
- For this case, it will be assumed that the error at 5 C° provided in the certificate is of 0.1 C°.
- Calculate the systematic error of the thermometer being used, using the following expression:
  Systematic error: Average readings of the instrument being calibrated – Actual corrected value of the pattern instrument. Where:
  - Average readings of the instrument being calibrated: 4.9 C°.
  - Actual corrected value: 4.86 C° – 0.1 C° = 4.76 C°.
  - Systematic error: (4.9 - 4.76)= 0.14 C°

This value means that the daily use thermometer has a 0.14 C° error, this means that the readings taken with this thermometer are over-dimensioned in 0.14 C°.

Example 2 for values below 0 C°:

- Calculate the average of each one of the five readings:
  -21.02 C° for the pattern thermometer and -20.92 C° for the daily-use thermometer.
- Obtain from the instrument calibration certificate the systematic error given for the closest temperature to that of the readings: -21 C°.
  For this case, it will be assumed that the error at -21 C° provided in the certificate is of -0.2 C°.

Table : *Example of generic results from a thermometer contrasting procedure*

Pattern thermometer reading in C°	Reading of the thermometer used on a daily basis in the establishment in C°
-21.2	-21.0
-20.9	-20.9
-21.3	-21.0
-20.8	-20.9
-20.9	-20.8
Average = -21.02	Average = -20.92

- Calculate the systematic error of the thermometer being used, using the following expression: Systematic error: Average readings of the instrument being calibrated – Actual corrected value of the pattern instrument. Where:
    - Average readings of the instrument being calibrated: -20.92 C°:
    - Actual corrected value: (-21.02 C°) – (-0.2 C°) = -20.82
    - Systematic error: (-20.92-(-20.82))= -0.10 C°

This value means that the daily use thermometer has a 0.10 C° error, this means that the readings taken with this thermometer are under-dimensioned in 0.10 C°.

The company must decide if the value of the systematic error, calculated based on the previously described procedure:

- Will be considered in the process controls, adding or subtracting it, as the case may be, to the readings given by the instrument. For this situation the value of the calculated error must be available for the monitors, for instance labeling it in the instrument, or
- It will be informed in the control records so as to be able to see if the temperatures read comply or do not comply with the critical limits.

Measurement instruments contrasting must take place in the work conditions of the instrument and in a homogeneous environment. For instance, contrasting a thermometer used for controlling the freezing CCP must take place at temperatures close to -18 C°, in ice with salt at a 3:1 ratio.

- Recording information: All the data collected in the contrasting procedure must be recorded.

- Maximum permissible limits: Each company must define a maximum permissible error limit based on the instructions provided by the catalogs of the equipment or instruments or based on the tolerances of the process. In the case of thermometers, these must not exceed ±1 C°.

In instrument contrasts whose comparisons are done indirectly with certified pattern elements (standard weights or thickness patterns), it is not mandatory to calculate the systematic error, but the deviation of the instrument must be calculated, which is the difference resulting from the comparison. This deviation must be treated in the same way as the systematic error unless the instrument can be adjusted to zero to eliminate such deviation.

5.6 TRAINING

This item presents the types of training that must be provided by the company under the framework of the Quality Assurance Program, also indicating the people that must be part of them.

It is important to consider that the training provided must be adjusted to the different technical levels and responsibilities assigned in the company.

The company's training program must consider the requirements of SERNAPESCA, as described in Chapter II, Item 2 of this Section, and all other training programs focused on leveling the staff in basic HACCP and health basic topics. Newly-hired staff must have a training before starting their duties.

If the company resumes its production activities after a shut-down period or if it has seasonal workers, it must provide them with training before resuming its activities. This activity must be recorded.
There are two types of training programs that the company must implement, keeping the corresponding records for the review of SERNAPESCA:

HACCP and SOP procedures

- HACCP training: It must consist of at least 16 hours and be directed, among others, to:
  - The person in charge of the QAP.
  - Supervisors, monitors.
  - Heads of Quality Assurance.
  - Heads of Production.
  - Heads of Quality Control.
  - Factory ships captains.
  - Officers and petty officers of factory ships.
- SOP training: It must consist of at least 8 hours and be directed, among others, to:
  - The person in charge of the SOP.
  - Supervisors, monitors.
  - Heads of Quality Assurance.
  - Heads of Production.
  - Heads of Quality Control.

The above two trainings are mandatory requirements for the person responsible for the QAP and the SOP and their surrogates, respectively.

Training Program for the Food Handlers of the Establishment

The purpose of this training is to provide the staff the procedures and basic instructions on the HACCP, hygiene and food handling, as well as knowledge of Manufacturing Best Practices. The company must prove that all the food handlers have been trained in all these subject matters with the corresponding documentation.

For the proper operation of the Quality Assurance Program, the work team must guarantee the compliance of hygiene standards and manufacturing best practices by training its staff.

The skills of the operators will be tested in the different visits of the inspectors to the establishment. Not complying with this aspect will prove that the company's training program is not effective, and the company must reinforce training in those areas, which must be proven with the corresponding documentation.

This activity may be conducted by qualified staff from the establishment or through external consultants.

When the Regional Office of SERNAPESCA deems appropriate, it may supervise the training courses scheduled by the company.

The minimum training that the food handlers must have is the following:

a) HACCP
   - The importance of applying the HACCP in the fishery industry.
   - Guiding principles of the HACCP.
   - Practical know-how for the correct implementation of the HACCP in the company. Practical explanation of the company's CCPs, the importance of monitoring and corrective actions.
   - The meaning of the periodic verifications carried out in the Program, for instance, verifications on the food handlers, surfaces, product and water.

b) Manufacturing Best Practices
   - Personnel (disease control, cleaning, hygiene, education).
   - Building and facilities (land, construction, and design).
   - Cleaning operations (general maintenance, compounds used, pest control, storage or handling of equipment and tools).
   - Sanitary facilities and their control (water supply, plumbing, waste removal, sanitary services, etc.).
   - Equipment and tools (design, construction material).
   - Processes (manufacturing operations, product handling).
   - Product storage and distribution.

c) Sanitary Standards Applicable to Production
   - Cleaning and disinfecting procedures in the facilities and the equipment of the establishment.
   - Correct use of detergents and sanitizers.

d) Hygiene and Handling of Fishery Products
   - Basic notions of food microbiology.
   - Main contamination mechanisms of food.
   - Use of proper clothing for handling food products.
   - Hand cleaning and disinfection procedures.
   - Hygiene habits.

e) Traceability
   - Relevance of foodstuffs traceability in the food chain.
   - Purpose of the implementation of traceability operations in the production system.
   - Practical application of a traceability system.

All training activities must be backed up, the record will have as a minimum the content of the topics, duration, the name of the speaker, date of the course and an attendance list signed by the participants.

Finally, if the establishment is authorized for the Eurasian Economic Union, the training program must consider the subjects related to the health regulations for this market.

5.7 MAINTENANCE OF EQUIPMENT AND CONDITION OF THE BUILDING

This Item establishes the procedure to be considered for the operational maintenance of the equipment used during the production process and the facilities of the establishment (condition of the building) to comply with the requirements set forth in Item 3.2.

A. EQUIPMENT MAINTENANCE

The following aspects must be considered:

- Inventory with the list of equipment used by the establishment. The information must include:
  - Name of the equipment.
  - Identification of the equipment.
  - Name of the manufacturer.
  - Date of reception and start-up.
  - Condition in which the equipment was received (new, used, refurbished).
  - A copy of the manufacturer's instructions.

- Catalog of the equipment. This information must be kept organized, updated and available for the staff.
- Maintenance records for each piece of equipment, considering the following:
  - Type (electrical, mechanical, etc.) and the frequency of maintenance (associated with the age and use of the equipment).
  - Technical service responsible for carrying out maintenance tasks.
  - Maintenance frequency (indicating the date of the next maintenance scheduled).
  - Procedure to be carried out.
  - Person responsible.
  - Records with the results of the maintenance process.

Preventive Maintenance

- Preventive maintenance frequency.
- Type of maintenance (for instance: electrical, mechanical, etc.).
- Technical service responsible for carrying out maintenance tasks or person responsible at the establishment.
- Procedures to be carried out.
- Location of the maintenance procedure.
- Records with the results from the maintenance process (may correspond to the log kept by the Maintenance Department).

Corrective Maintenance

- Date and type of failure that called for corrective maintenance.
- Technical service responsible for carrying out maintenance tasks or person responsible at the establishment.
- Procedures to be carried out.
- Location of the repair procedure.
- Records with the results from the maintenance process (may correspond to the log kept by the Maintenance Department).

B. CONDITION OF THE BUILDING

This chapter considers the proper conditions for processing related to buildings, facilities, work surfaces and surrounding areas, as well as factory ship infrastructure aspects, with the purpose of complying with the requirements described in Item 3.2.

At least the following must be considered:
- Inspection frequency for the maintenance of the conditions of the building.
- Person responsible for monitoring.
- Monitoring results (associated records).
- Corrective or preventive actions.
- Procedures to be applied for corrective or preventive actions.
- People responsible for the execution.
- People responsible and any records associated with the verification of the solution or maintenance process applied.

5.8 SUPPLIERS CONTROL

This Item establishes the aspects to be considered in the identification and control of raw material suppliers used in the process in fishery establishments.

The fishery establishment must ensure that the raw materials and supplies that enter the process are safe, suitable to be used in contact with food and that they do not add unwanted characteristics to the end product.

All suppliers must be fully identified, including among other aspects, their name or registered name, address, telephone number, type of supply, technical specifications, etc.
In addition, every time supplies are received, the name and registered name of the supplier, type of supply received, type of packaging in which it was received, labeling, technical specifications, level of compliance with such specifications, destination of the supply (warehouse, cold room, immediate process, etc.) must be provided.

In the case of raw materials, the establishment of origin, as well as the company, must have the corresponding sanitary supporting documentation. The means of transportation must be identified describing the transportation conditions (temperature, labeling, and origin, among others).

All the above must be documented in a written procedure. The company must have an updated List of suppliers.

5.9 OTHER ASPECTS TO BE CONSIDERED IN A PREREQUISITES PROGRAM

Each establishment may develop all the procedures or instructions that it considers important for a better execution of the different operations in the process, for example: operation of a piece of equipment, procedure and handling of capture on board a factory ship, reception procedure for raw material, in fishery plants, instructions for dispatching products, etc.

6. SANITATION OPERATIONAL PROCEDURE

To correctly produce, implement and keep a Quality Assurance Program there must be a solid base that allows ensuring the safety of food, this is comprised of prerequisite programs for fishery plants and factory ships to implement Quality Assurance Programs and Sanitation Operational Procedures (SOP).

Each plant or factory ship must have a written or implemented Sanitation Operational Procedures Manual (SOP) which consists of a detailed description of the hygiene and sanitation procedures and practices of the establishment.

It is important to consider that many of the risks identified in the QAP may be controlled through the Sanitation Operational Procedures, and therefore they are of great importance. These hazards include those associated with the processing environment, the staff or supplies.

The following is a description of the differences between the QAP controls and the SOP procedures:

Table: *QAP and SOP control measures*

Hazard	Control measure	Control program
Product with high levels of histamine due to excessive time and temperature.	Time and temperature control for susceptible species.	QAP
Product contaminated by the survival of pathogenic agents due to under cooking.	Cooking time and temperature control.	QAP
Product contaminated with pathogenic agents due to handling.	Control of the habits of food handlers.	SOP
Product contaminated with pathogenic agents due to the insufficient renewal of cooling water.	Frequency control of water renewal.	SOP
Product contaminated with pathogenic agents due to the uncleanliness of surfaces.	Cleaning procedures control for contact surfaces.	SOP

The following describes in detail the aspects to be considered in the Sanitation Operational Procedures of a fishery establishment.

6.1 WATER AND ICE CONTROL AND SAFETY

This item must include a description of the type of water used in the fishery establishment, mainly in terms of the water that comes into contact with foodstuffs and the surfaces that come into contact with them. It must be mentioned that for this purpose, the water used to keep resources alive inside the establishment is also considered.

The description of the type of water used must clearly specify:

- its supply (public grid, wells, seawater, surface or deep origin, etc.),
- potable water treatment (as appropriate),
- storage (if any) and
- distribution inside the fishery establishment.

In the case of ice, it must be mentioned that at least:

- origin,
- storage conditions,
- handling, and

- distribution.

The following considerations must be taken for any type of water supply:

- A schematic map of the plant with the location of the numbered water terminals to be considered in the free-chlorine concentration monitoring process and monthly verifications must be provided.
- All the water outlets in the establishment that come into contact with the product must be considered in the free-chlorine concentration monitoring process.
- If the plant has main water outlets that feed into several terminals (for instance on filleting tables), a *pool* of 5 water outlets coming from the main lines may be grouped for the monthly verifications.
- The water samples collection process must take place as described in Section IV, Chapter II, Item 3.
- The name of the laboratory authorized by SERNAPESCA responsible for that analysis must be included in all determinations.
- It is recommended to use the Production Days Template - SOP to record the day of the month in which the water and ice sampling takes place.

Modelo de registro de días productivos - POS
Folio: N° 000000

PROGRAMA DE ASEGURAMIENTO DE CALIDAD
Planilla de Días Productivos - POS

Planta Pesquera: Mes:

DIA	ESPECIE	LÍNEA DE ELABORACIÓN	SUPERFICIES – MANIPULADOR (c/15 días productivos)		AGUA – HIELO (1 vez al mes)
			N° día productivo	Fecha de muestreo	Fecha de muestreo
01					
02					
03					
04					
05					
06					
07					
08					
09					
10					
11					
12					
13					
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22					
23					
24					
25					
26					
27					
28					
29					
30					
31					

Figure: Production days log model – SOP.

6.1.1 MONITORING

A. ESTABLISHMENT INTENDED FOR HUMAN CONSUMPTION

At least the following monitoring steps must be taken into account to ensure that the proper conditions and storage for water distribution are maintained

Table *Aspects to consider in wáter and ice monitoring.*

Aspects	Frequency
Concentration of free chlorine in different points of the plant, which must be alternated on a periodical basis. This monitoring process must include a control of residual chlorine concentration in the water that feeds the machines used to make ice. The limit established for water coming into contact with the product is from 0.2 to 2 ppm. In the case of using chlorine dioxide, the permissible limit is between 1 and 3 ppm	Daily
Hose handling in the establishment	Daily
Checking the absence of cross-connections inside the establishment. The establishment must prove the absence of cross-connections, for instance with a distribution layout of the different types of waste waters.	Monthly or or whenever changes occur
Structural and management conditions for water storage tanks (if any).	Daily
Discharge point of waste water and sea water supply in factory ships	Every tide
Structural and management conditions for ice silos (if any).	Daily

The following must be monitored when ice is not produced by the plant:

- Microbiological quality, supported by analysis reports provided by the supplier, which must consider at least the water requirements set forth in this Manual and must be carried out by a laboratory authorized by SERNAPESCA.
- Hygienic conditions during transportation, handling, and storage.

The following must be indicated for all monitoring processes:

- The frequency of the process.
- How it is conducted.
- The personnel responsible for its execution.
- Corrective actions.
- Records.

B. ESTABLISHMENT NOT INTENDED FOR HUMAN CONSUMPTION

In the case of this establishments, at least the following must be considered:

- A study of the water used in the process and when cleaning the equipment must be included in the QAP document. Both the required standards and the monitoring frequencies must be determined by the establishment.
- An ongoing and updated record on the quality of water must be kept.

- Whenever additives are used (such as softening, anti-scale, anti-corrosion agents, etc.) these additives must:
  - be considered in the QAP document,
  - the dosing systems must be controlled to ensure a correct addition level, and
  - records must be kept.

6.1.2 VERIFICATION

The verifications for water and ice must be realize according the following:

A. ESTABLISHMENT INTENDED FOR HUMAN CONSUMPTION

Annual Analysis for water and ice

Establishments that produce, products intended for human consumption which are supplied directly from the drinking water network, or obtain it from wells, tops, seawater or other sources, and store them or not in a pond, must be carried out in the water once a year, at the entrance of the plant and by origin, the analysis of indicator parameters will be those indicated in NCh 409/1 of 2005. The determinations of the radioactive elements incorporated in the Chilean norm quoted, should only be made at the moment in that there is a presumption of radioactive contamination.

In case of seawater, it is not necessary realize the following analysis, due the specific characteristics of this water:

- Flavor
- Color
- Odor
- pH
- Turbidity

When the plant is fed directly from the potable water grid, without prior storage, it may request the service provider a copy of the chemical analyses conducted by the company over the last year. If these analyses are incomplete according to the parameters required by the regulation, the establishment may request an authorized laboratory to complete the determinations not included in the report provided by the service provider.

Monthly analysis for water and ice

The plants should perform the following routine microbiological tests, once a month (while there is a process) for each water source, in the different keys of the plant, alternating them so that they are all sampled at least once a year. The analyzes to be carried out will be those contemplated in NCh 409/1 of 2005.

The exception above mentioned for seawater, are also applicable for this verification.

Those companies that make and supply ice to establishments under the sanitary control of SERNAPESCA, beside from the microbiological analyses, must conduct chemical analyses in the water used to make ice, as described in Item 2.2 of this Chapter. In these cases, the production establishment must request the service provider a copy of the microbiological analyses and the annual water analyses for the water used to make ice over the last year.

Procedures for unfavorable verification results

The procedures to be followed by the company if the results of the verifications are unfavorable must be clearly stated. In addition to this, the verification of the same faucet with an unfavorable result must always be considered for the following sampling, taking into account that at the end of one year all the main water supplies must be analyzed.

The company must conduct a follow-up of the product possibly affected by this unfavorable result and must keep the Service informed. Among the activities to be carried out, the review and analyses of the records related to the problem, the review of preventive control measures and monitoring activities must be considered.

B. ESTABLISHMENT NOT INTENDED FOR HUMAN CONSUMPTION

In the case establishments that produce fish meal and oil not intended for human consumption, verifications of the parameters indicating the quality of water used in the establishment must be conducted by a laboratory authorized by SERNAPESCA.

Both the parameters to be measured as well as the frequency must be determined by the study to monitor these type of establishments, as described in Item 6.1.1 above.

If there is any supporting information on the quality of the water used in the process, this may be presented in the location where the study takes place, thus replacing the periodical verification. The supporting documentation will be valid to the extent that it consists of analyses that are conducted at least once a year and that the analyzed substances and the standards attained are considered to be sufficient for that purpose.

6.1.3 CONTROL OF STAGNANT WATER

Stagnant waters are those used in the process, in direct contact with the product (packed or not) that are kept in containers (cooling waters, glazing, flavoring, etc.).

This definition must consider continuous renewal water (water always coming in and out), where the refill procedure does not provide guarantees for total renewal, allowing the existence of areas where water is not renewed (dead areas) inside the container, for instance, overflow.

The refill frequency for these type of waters must be supported by microbiological studies, with the purpose of ensuring that these will not become a source of contamination for the end product. The studies must contain at least:

- Microbiological results, considering at least fecal coliforms; in addition, the company may include another type of microorganism associated with the type of product or resource that it produces. The critical limits considered by the company must also be included.
- Sample collection procedure, indicating the extraction times of the samples, container volume and type of water, the quantity of product manufactured and the time span.
- Conclusions
- The person responsible for the study.

This study and the microbiological analyses may be conducted by the company's staff of the staff

of external entities.

The study will be valid to the extent that the conditions in which it took place are preserved.

The water refill study is not a requirement for the fishery plants that manufacture canned products. In the case of plants that manufacture cooked-frozen products, it is not necessary to conduct a stagnant water study in operational steps that precede the cooking process. However, it is mandatory when this situation takes place after the cooking process.

The water refill process record for stagnant waters is optional since it is associated with the company's best practices.

6.2 CONDITION AND CLEANING OF SURFACES THAT COME INTO CONTACT WITH FOODSTUFFS

This Item must consider the design, construction, maintenance and cleaning and sanitation procedures applied to all the surfaces that come into contact with foodstuffs and those that drain over foodstuffs or over the surfaces in contact with foodstuffs, that may lead to, either directly or indirectly, their contamination during their processing. These surfaces must consider kitchenware, knives, counters, cutting boards, processing equipment, trays, conveyor belts, gloves, aprons, etc.

A full description of the cleaning and sanitation processes must be provided including at least:
- The frequency of the procedure and the person responsible for it.
- Stages or type of cleaning and sanitation.
- Detergents to be used (active principle, concentration and time of action).
- Sanitizers to be used (active principle, concentration and time of action).

Monitoring

At least the following monitoring steps must be taken into account to ensure the control of the maintenance, cleaning and sanitation conditions in the contact surfaces:
- Visual inspection of the condition of the surfaces.
- Visual inspection of the cleanliness of the surfaces.
- Sanitizers' concentration chemical tests.
- Verifying that the gloves and clothes that may come into contact with the food are clean and in good condition.

The following must be indicated for all monitoring processes:
- The frequency of the process.
- How it is conducted.
- The personnel responsible for its execution.
- Corrective actions.
- Records.

In the case of sanitizers used by the establishments, it is important for them to have the necessary elements to properly measure the concentration of the product used. When purchasing sanitizers, its corresponding kit must be considered so as to allow to measure its effective concentration.

It should be noted that after sanitization, the corresponding rinsing process must be performed in order to avoid contact of the product with the sanitizing compound. This rinse may be ignored in the event that the destination market has no restrictions on this matter, and the product must be

blocked for all other markets that prohibit product sanitization.

Additionally, in case the sanitizing compound's technical data indicates that at a certain concentration it is possible not to rinse, guaranteeing adequate draining and an established withdrawal period, in which case no market restrictions will be established. The company must keep records of the correct application of the procedures established in the corresponding data sheet.

Verifications
Microbiological verifications must be considered for work surfaces, indicating:

- Determinations to carry out.
- Maximum levels accepted by the company, indicating its expression unit.
- Areas to be sampled.
- Techniques employed for the determinations.
- Statistically reliable sampling plans.

The name of the laboratory authorized by SERNAPESCA responsible for those analyses must be included in the microbiological determinations that must take place every 15 days of production.

It is recommended to use the Production Days Template-SOP to record the production days of each line (as appropriate) and the days of the month in which the sampling of the surfaces takes place.

Those plants that manufacture products destined to the European Union and that produce food ready for consumption and raw products where there is no certainty that they will be consumed cooked, must always take samples of the production areas and equipment as part of their sampling plan, with the purpose of detecting the possible presence of *Listeria monocytogenes*.

In the case of factory ships, the surface verifications must be made at all tides, in its landfall, and to the extent possible, before conducting any maintenance tasks that usually take place at the port.

The verifications are conducted to prove the efficiency of the cleaning procedures, and therefore must take place on clean surfaces.
The procedures to be followed by the company if the results of the verifications are unfavorable must be clearly stated in the program. In addition to this, the verification of the surface with unfavorable results must always be considered for fifteen days later or in the next landfall.

The company must conduct a follow-up of the product possibly affected by this unfavorable result and must keep the Service informed. Among the activities to be carried out, the review and analysis of the records related to the problem, the review of preventive control measures and monitoring activities must be considered.

6.3 PREVENTION OF CROSS-CONTAMINATION

This item addresses the practices that operators must apply in order to prevent the contamination of product (hand-washing, moving from one place to another, product handling, waste management, etc.); how the physical separation of the raw and cooked product takes place (as appropriate); and also the way in which the design of the establishment prevents cross-contamination.

Monitoring

To supervise the prevention of cross-contamination in the establishment, the following monitoring processes must be taken into account:

- Control handling and storage of products that are at different stages of the process.
- Control the separation and handling of raw products and their possible relationship with cooked products (at the beginning of the work day or shifts and during the process).
- The behavior of the operators that move between the different areas of the establishment, that go to the restrooms and grab tools (cleaning and disinfection of hands).
- Handling equipment and tools between areas for raw and cooked products or clean and dirty areas.
- Storage of cooked products.
- Solid and liquid waste management.
- Storage of ingredients and packing material.

The following must be indicated for all monitoring processes:

- The frequency of the process.
- How it is conducted.
- The personnel responsible for its execution.
- Corrective actions.
- Records.

Verifications

Microbiological verifications should be considered for handlers every 15 days of processing or at the end of the tide for factory ship crew members, indicating:

- Determinations to carry out.
- Maximum levels accepted by the company, indicating its expression unit.
- Statistically reliable sampling plan.
- Techniques employed for the determinations.

As mentioned in the item above, and for the purpose of the verification, this must take place while the operator has cleaned his/her hands, for instance when entering the plant or after using the restrooms. The verification for clean hands in crew members of factory ships must be conducted during their stay at the port, once they have passed the sanitary filter, as they normally do during the tide.

The procedures to be followed by the company if the results of the verifications are unfavorable must be clearly stated in the program. In order to verify the solution to the problem, any operators with results exceeding the maximum permissible limits must be controlled fifteen days after. For factory ship crew members this must take place on the next landfall. The person onboard responsible for the QAP must be informed as soon as possible if there are any unfavorable results and the ship has already left the port, with the purpose of taking the corresponding measures with the affected crew member.

The company must conduct a follow-up of the product possibly affected by this unfavorable result and must keep the Service informed. Among the activities to be carried out, the review and analysis of the records related to the problem, the review of preventive control measures and monitoring activities must be considered.

The name of the laboratory authorized by SERNAPESCA responsible for that analysis must be included in all verifications.

It is recommended to use the Production days template (PDT/SOP) to record the production days of each line (as appropriate) and the days of the month in which the sampling of the surfaces takes place.

6.4 MAINTENANCE OF HAND-WASHING AND DISINFECTION STATIONS AND OF RESTROOMS

This Item addresses the condition and maintenance of the hand-washing and disinfecting stations and restrooms. This topic is closely related to the proper hand-washing and disinfection techniques to avoid cross-contamination.

Monitoring

To oversee that the hand-washing and disinfecting stations and restrooms are properly maintained, the following monitoring steps must be taken into consideration:

- Conditions of hand-washing stations in restrooms and hand-washing stations in food processing and handling areas. In accordance with Item 2.2, it must be verified that there is a proper number of sinks, that the faucets are not hand operated and that they are kept properly cleaned. In addition, clear instructions promoting a correct hand-washing process must be posted.
- Conditions of the hand disinfection stations, availability of water and soap, disinfectant, disposable towels or hot-air dryers and waste containers (not hand-operated).
- Conditions of the restrooms, making sure that they work properly, their hygiene and availability of toilet paper.
- The concentration of disinfectants in the cleaning stations located in the restrooms and in the processing areas.

The following must be indicated for all monitoring processes:

- The frequency of the process.
- How it is conducted.
- The personnel responsible for its execution.
- Corrective actions.
- Records.

6.5 PROTECTION OF FOODSTUFFS

The purpose of this Item is to ensure that foodstuffs, contact surfaces, and packing materials are protected from different microbiological, chemical and physical contaminants, such as:

- Lubricants.
- Fuel.
- Pesticides.
- Cleaning compounds.
- Disinfecting agents.
- Condensate and splashes from the floor.

Monitoring

The presence of any contaminants in foodstuffs, contact surfaces and packing material must be avoided, including:

- Condensates that contaminate surfaces in contact with food.
- The presence of an accumulation of liquids in the floor.

- Potential toxic compounds.

The following must be indicated for all monitoring processes:
- The frequency of the process.
- How it is conducted.
- The personnel responsible for its execution.
- Corrective actions.
- Records.

6.6 CHEMICALS LABELING, STORAGE, AND HANDLING

Considers the labeling, storage and use of chemical compounds so as to avoid a contamination hazard for fishery products.

Chemical products used in most processing plants include cleaning compounds, disinfectants, sanitizers, pesticides, machines lubricants and food additives.

Monitoring

The following aspects must be taken into account when handling chemicals:

a) Labeling

The original containers must indicate:
- Name of the compound.
- Name of the manufacturer.
- Clear use instructions.
- Approval from the relevant health authority (for sanitizers and disinfectants).
- Safety measures in case of an accident and prevention.

The containers must describe:
- Name of the compound.
- Instructions for their proper use (application area, concentration).

b) Storage
- Check that their storage is proper, with restricted access and away from processing areas as described in Item 3.2.
- Different storage areas for cleaning products and pesticides.
- Segregated areas for food-grade chemical products.
- Check that the containers used for dosing chemical products in bulk are easy to clean and hygienic and that they are properly labeled.
- Labeling.
- Dosing containers of exclusive use.

c) Use
- In accordance with the instructions of the manufacturer.
- Proper use, avoiding cross-contamination, adulteration, and diseases.

The following must be indicated for all monitoring processes:
- The frequency of the process.
- How it is conducted.
- The personnel responsible for its execution.

- Corrective actions.
- Records.

It must be mentioned that monitoring the use and proper handling of chemical products in the plant must be done on a daily basis.

6.7 CONTROLLING THE HEALTH CONDITIONS OF FOOD HANDLERS

This Item addresses the procedure to be followed by the company with food handlers when they are diagnosed with diseases or when they present any symptoms associated with diseases, wounds or other conditions that may become a source of bacterial contamination.

The company must consider the application of any necessary controls to ensure that food handlers do not transmit any diseases or contaminate the food through the handling process (vaccinations, medical checks, hand-hygiene control, training, etc.).

This control is only applicable to establishments that process products intended for human consumption.

Monitoring

To oversee that the health condition of the employees at the plant is controlled, the following monitoring steps must be taken into consideration:

- Observing any symptoms of diseases and wounds in food handlers.
- General conditions of the food handlers when entering the plant and during the process.
- Checking the hands of the food handlers when entering the plant.
- Controlling the operators that come back to the production process after being affected by a medical condition or disease that kept them away from handling food.

The following must be indicated for all monitoring processes:

- The frequency of the process.
- How it is conducted.
- The personnel responsible for its execution.
- Statistically reliable sampling plan.
- Corrective actions.
- Records.

6.8 PEST CONTROL SYSTEM AND PERIODICITY

This Item considers the exclusion of pests, such as rodents, insects, pets, and birds from fishery establishments.

Monitoring

To supervise the control to avoid the presence of pests in the establishment, the following monitoring processes must be taken into account:

- The presence of pests (insects, rodents, birds, and pets).
- Recent evidence of the presence of pests such as excrement, rodent marks and evidence of nesting.
- Surveillance of other related conditions, which if not properly controlled, may lead to problems such as pests, for instance, the proper maintenance of the plant and the correct

implementation of programs to avoid the presence of unwanted animals, as described in Item 3.2.
- Control of storage and waste disposal conditions, ensuring that they do not constitute a source of contamination for the plant or that they do not cause any disturbances to the environment, as described in Item 3.2.
- Supervise the proper disposal of waste from the inside of the processing room.
- Conditions of the containers where the waste is sent (easy to clean and disinfect and with a lid).
- Proper cleaning and sanitation for waste disposal and storage.
- The existence of a waste water disposal device with the proper hygienic conditions.
- Control of the characteristics of the floor in the processing areas, so as to facilitate water drainage or for it to have a device that allows draining waste water.

The following must be indicated for all monitoring processes:
- The frequency of the process.
- How it is conducted.
- The personnel responsible for its execution.
- Corrective actions.
- Records.

It must be mentioned that monitoring the direct presence of pests in the plant is to be done on a daily basis. In the case of factory ships, this must be done before they take off.

Verifications
Pests must be eliminated in a systematic and preventive manner, based on the instructions provided in Item 3.2.

Records for rat control and disinfection tasks must be kept. Such certificate must consider all the pesticides used, the date of application and expiration, as well as the degree of infestation and the number of baits at the moment of the visit.
A sketch map of the baits used must be provided by the pest control company, which must be verified by the sanitation staff of the plant, at least every fifteen days. In the case of factory ships, this verification must take place in the port, at the end of each tide.

6.9 CONTROL OF BY-PRODUCTS/WASTE DESTINED TO PROCESSING ESTABLISHMENTS

This item addresses the controls applied to management or handling procedures of by-products or waste destined to processing establishments. By-products or waste will be understood as the heads, viscera, pin bones, skin or other parts of the raw material that may be used to produce fish meal and oil.

The establishment must have procedures in place to ensure that the by-products and/or waste are collected directly from the processing line, are handled separately from those that enter in contact with the floor or other stages of the process. These by-products and/or waste must be handled and transported so as to ensure the compliance with the requirements set forth in letters G and K of item 3.2.3, Chapter I of this Section.

Monitoring
To supervise the control to properly handle these by-products and/or waste, the following monitoring processes must be taken into account:

- Supervise the proper disposal of by-products and/or waste inside the processing rooms so as to ensure that they do not come into contact with the floor or other types of waste.
- Conditions of the containers where the by-products are placed (easy to clean, of a distinctive color and impossible to confuse with another type of waste).

The following must be indicated for all monitoring processes:

- The frequency of the process.
- How it is conducted.
- The personnel responsible for its execution.
- Corrective actions.
- Records.

6.10 RECORDS

All records of the SOP must consider at least the following:

- The title of the form.
- Name and address of the plant.
- Time and date of the monitoring process.
- Name of the procedure being monitored.
- Actual measurements and observations.
- Monitoring frequency.
- Signature or initials of the person in charge of the monitoring process.
- Signature or initials of the person verifying the documentation.
- Start and end time of the process.
- Verification date.

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CHAPTER II. QUALITY ASSURANCE PROGRAM

The Quality Assurance Program (QAP), based on the concept of Hazards Analysis and Critical Control Points (HACCP) is a voluntary certification program to which all the fishery plants and factory ships in the country may apply. Its implementation is mandatory for all plants and factory ships whose products are destined for markets that require the production under the HACCP system, in accordance with the specifications provided in Section III, Chapter IV, Item 2.

1. PRESENTATION OF THE QUALITY ASSURANCE PROGRAM

Those fishery companies interested in participating in this program must present at the SERNAPESCA the QAP Processing Request in digital format (Part III, Annexes, Chapter II). The interested companies should select "Evaluation" option, and send it by e-mail to the SERNAËSCA inspector in charge of supervising the establishment. (M.05.01.18)

Together with the request, its Quality Assurance Program must be presented in .pdf format via email complying with the minimum format requirements, as follows:

a) Separate files for QAP, SOP, and Prerequisites.
b) Version
c) Date of issuance of the document.
d) Code (as appropriate).
e) Pages (X of XX).

Prior to sending the information via email, the SERNAPESCA official must ensure that the request contains all the required information and that the establishment is classified under category A or B, based on the infrastructure and sanitary management requirements established by the Service in Chapter I of this Section. It must also verify that in the QAP, have been developed all the points indicated in Point 2 of this Chapter, as well as the special requirements contemplated in Part II, Section III, Chapter V, Item 2, if applicable. If not, the application with its attached documentation will be returned to the interested party.

The Regional officer will send the request with all its documents, to the Foreign Trade Under-Secretariat, who will later refer it to an organization designated by this Service as an evaluator that will analyze the program presented by the company, according to the SERNAPESCA Work Guide,

If an establishment has several production lines, it must develop a QAP for each one of them based on the following classification: (M.05.01.18)

1. Chilled refrigerated-frozen fish and cephalopods.
2. Chilled refrigerated-frozen salmonids.
3. Chilled refrigerated-frozen crustaceans.
4. Chilled refrigerated-frozen bivalve mollusks
5. Chilled refrigerated-frozen echinoderms and tunicades.(M.09.03.18)
6. Chilled refrigerated-frozen gastropods.
7. Canning
8. Smoked fishery products.
9. Salted fishery products.

10. Marinated fishery products.
11. Breaded fishery products.
12. Dried fishery products.
13. Algae derivatives
14. Surimi.
15. Ready cooked meals.
16. Sausages.
17. Fish oil intended for human consumption.
18. Fish meal, oil or peptones not intended for human consumption.
19. Live fish, molluscans or crustaceans

The quality assurance program presented by the company must only contain the products that it actually process. Similarly, it must include the destination markets of the products to which it is authorized to export (as necessary) and to those that it actually exports (Part II, Section III, Chapter V, Item 2). (M.05.01.18)

The costs of the evaluation for each QAP will be in charge of the interested party.

1.1 APPROVAL OF THE QUALITY ASSURANCE PROGRAM

The approval process will take place in two stages:

1.1.1 EVALUATION OF THE THEORETICAL PROGRAM OF THE ESTABLISHMENT

Foreign Trade Under-Secretariat will contact to the establishment to inform the procedures for begin the evaluation of the QAP.

After the analysis of the establishment's program has concluded, the evaluator will issue an evaluation report that must be sent to the Foreign Trade Under-Secretariat. This report must be delivered within 5 business days from the payment of the evaluation. (M.05.01.18)

Once the information received in the Foreign Trade Under-Secretariat has been analyzed, a final report will be prepared on the basis of which it will be possible to:

- Approve the QAP document for certification audit.
- Approve the QAP document with observations, for certification audit.
- Reject the QAP document.

A. APPROVAL OF THE THEORETICAL PROGRAM

- Approved for QAP Certification Auditing:

If the program has been properly developed and no relevant observations are detected in its evaluation, it will be approved for auditing. The Office under the jurisdiction of the production establishment will communicate its decision to the interested party by official action with a copy to the Regional Directorate of SERNAPESCA, as appropriate, and the Foreign Trade Under-Secretariat, attaching the respective report.

From this moment the establishment must implement the program for its further QAP certification auditing, which must be requested within 2 months. This term may be extended if the establishment is not processing on a periodical basis.

- Approved for QAP Certification Auditing with Observations:

If the establishment's program is correctly structured, it is coherent, and if the observations detected allow its implementation, it will be approved with observations for auditing. The Office under the jurisdiction of the production establishment will communicate their decision to the interested party by official action with a copy to the action with a copy to the Regional Directorate of SERNAPESCA, as appropriate, and the Foreign Trade Under-Secretariat, attaching the respective report.

From this moment, the establishment must implement the program for its further auditing. When requesting the program's audit, the establishment must send the corrected document again according to the observations included in the evaluation report at least 5 business days before the audit, in order that the document be reviewed previously. (M.05.01.18)

Before the auditing visit, the SERNAPESCA Inspector must conduct an inspection to the implementation of the QAP so as to approve this procedure, which must be informed to the Central Office of SERNAPESCA.

The audit must be requested by the interested party within 2 months. This term may be extended only if the establishment is not processing on a periodical basis.

B. REJECTION OF THE THEORETICAL PROGRAM

The program will be rejected by SERNAPESCA when the extent and the number of observations detected indicate that the entire program must be restructured. The process to inform the interested party will be the same described for the previous case.

The term to present the new version of the program will be within 30 business days from the issuance of the report. In case of exceed this term, the establishment should initiated a new evaluation process, accordance the above describe. (M.05.01.18)

1.1.2 QAP CERTIFICATION AUDIT

Once the QAP Certification and the theoretical program of the establishment are approved for auditing, the interested party may request its audit presenting the QAP Processing Request (Part III, Annexes, Chapter II), marking the "QAP certification audit" section. This document must be presented via e mail (pdf format) at the SERNAPESCA Local Office, with copy to Regional Office if corresponding, and to the Central SERWNAPESCA Office, attaching the corrected theoretical program, within 5 business days before the auditing visit.

To request the audit, the establishment must be processing (the line to be audited) with the QAP in place for at least 15 days, and in the case of factory ships, they must have the corresponding QAP records for the last tide. Additionally, and in order to complement the on-site review of the implementation of the QAP, the establishment must have at least one product QAP verification sample. In the case of establishments that produce farmed fish, they must also have a sample of verification of residues of pharmaceutical products, prohibited substances, unauthorized substances and contaminants. (M.05.01.18)

When auditing lines of cooked or sterilized products intended for human consumption, heat penetration studies must be approved and available at the visit (as per the description provided in Chapter I, Item 3.2).

The company must send the QAP to the Local SERNAPESCA office and to the Central Level, within 5 working days before the visit. If the company has not completed the corresponding administrative proceedings, the audit will not be conducted.

Once the program for the audit is received at the Local Office, this office will contact the Foreign Trade Under-Secretariat to coordinate the audit visit in a timely manner. The Central Office will send the information to the evaluating entity who will contact the interested company, in order to generate the corresponding administrative aspects

The audit will be conducted by a professional from the evaluating entity together with a SERNAPESCA official (who must be part of the entire process), who will verify in the field the practical implementation of the theoretical program in the establishment. For this, it will be necessary for the establishment to have enough raw material for normal production, according to its production capacity. (M.08.02.18)

In the case of factory ships, the procedure will take place during the ship's landfall.

Once the audit visit has taken place, the professional from the evaluating entity will issue a report to the Central Office of the Service within 5 business days from the audit visit. This audit will consider those products that the company in fact processes. SERNAPESCA will issue the report, based on which the audit may be approved, approved with observations or be rejected.

- QAP Certification Audit Approval:

If the audit report does not include any observations related to the implementation of the program in the establishment, the local SERNAPESCA Office, will proceed to approve the QAP. The interested party will be informed by official action, with a copy to the Regional Directorate of SERNAPESCA, as appropriate, and the Central Office of SERNAPESCA of its incorporation to the QAP Certification (see Item 1.2 of this Chapter).

- Approved QAP Certification Auditing with Observations:

Whenever there are observations related to the implementation of the program, the Local SERNAPESCA will issue a report to the interested party, by official action, with a copy to the Regional Directorate of SERNAPESCA, as appropriate, and to the Central Office of SERNAPESCA. This report must contained the detailed observations that must be completely solved, so as to incorporate the company to the QAP certification for the products and markets to which the company in fact exports.

The establishment will have a month to correct such observations. Otherwise, the audit will be rejected. This term may only be extended if the establishment is not processing.

The Local SERNAPESCA Office must verify the compliance with the observations provided in the audit, which will be communicated to the Central Office.

Once the theoretical document has been corrected, the establishment must present it (digital file) at the Local SERNAPESCA Office, who will send it to the Central Office to be sent to the evaluating entity, in order to carry out the QAP Certification post-audit review.

Once the program's audit is approved, the establishment will be included in the Certification in accordance with the Quality Assurance Program of the Service.

Once the QAP Certification has been granted, the establishment will be able to export all the product elaborated since the first date of the preparatory period for the certification audit, which will be indicated in the corresponding report (M.08.02.18). For this, the establishment must have carried out the corresponding periodic verifications (first 15 days and during the observation period) and have favorable results. Samples will be sent to a Laboratory authorized by SERNAPESCA, accompanied by an FEM-PAC. If any of these verifications is unfavorable, the establishment must apply the procedure described in the Procedure for the Control and Follow-Up of Unfavourable results detected in Verification Export Products (Chapter III, item 1 of this Section). The above does not apply to live and chilled products, due to the short useful life of these products. (M.05.01.18)

- QAP Certification Audit Rejection:

If the audit report indicates that inconsistencies were found between the theoretical program and its implementation in the establishment, that its execution is not correct or that what is reported in the theoretical document does not match the reality of the establishment, the audit will be rejected. The Local SERNAPESCA Office This will be communicated to the interested party, by official action, with copy to the Regional Directorate of SERNAPESCA, and to the Central Office, attaching the respective report.

Once the program has been adjusted according to the observations included in the report, the company must, within 2 months, present a new QAP Certification audit request and follow the procedure described in Item 1.1.2 of this Chapter.

The establishment must send the corrected theoretical document, in digital format, to Local Office of SERNAPESCA, who will send it to the Central Office for its delivery to the evaluating entity, who will proceed to carry out the review.

The SERNAPESCA inspector must verify on site that the non-compliances have been solved before scheduling a new audit visit.

For this new visit, the establishment must have at least 15 days of records from the date of SERNAPESCA verified the total compliance of the observations. Additionally, and in order to complement the on-site review of the implementation of the QAP, the establishment must have at least one product QAP verification sample. In the case of establishments that produce farmed fish, they must also have a sample of verification of residues of pharmaceutical products, prohibited substances, unauthorized substances and contaminants. (M.05.01.18)

This process implies new auditing costs that will be charged to the interested party.

1.2 CERTIFICATION IN ACCORDANCE WITH THE QAP

The establishments that are part of the Quality Assurance Program may apply for the official certification in accordance with this Program must request an Authorization at Origin for Sanitary Certification - AOSC (Part III, Annexes, Chapter II) for the products and markets to which the company actually exports. The Authorization at Origin for Sanitary Certification corresponds to the document that proves that the items described in it have been produced in an establishment whose Quality Assurance Program is properly operated.

The procedure related with issuing and expiration of this document are described in Part II, Section III Export and Certification Control (Chapter II).

1.3 QAP SUPERVISION

Supervision corresponds to a periodical review of the establishment conducted by SERNAPESCA officials, which must comply with certain standardized procedures at a national level.

Before the supervision visit, the SERNAPESCA official must be familiar with the establishment's program, on all issues related to Critical Control Points (critical limits, monitoring, records, and verifications) and on any previous issues, if any.

To carry out the supervision, the official will use the information provided in the inspection checklist corresponding to the type of establishment to inspect (Part III, Annexes, Chapter III), based on which it will be Approved or Rejected. (M.05.01.18)

At the moment of the inspection, is essential that the establishment is processing or there is evidence of the process has been. It is necessary that the person responsible for the QAP of the establishment must accompany the SERNAPESCA official. This person will be informed about the purpose of the inspection (QAP, incorporation of a new product, etc.) and of any deficiencies observed during the visit. (M.05.01.18)

When the establishment does not have production process, either for maintenance, ban or un-availability of resources as the case may be, it must present a formal letter indicating the time it will be without productive process. This document supports the fact that the supervisions have not been carried out during that period. If necessary, according to the sanitary condition and infrastructure of the establishment, a new authorization of the establishment can be made at the moment of resuming the process. (M.05.01.18)

In the case of factory ships, all the records for the last tide must be reviewed, as well as those that are being completed for the day of the inspection, for instance, for unloading, transportation, classification in land, etc.

Similarly, the SERNAPESCA official must verify the plant's sanitation procedures and the prerequisites programs.

If during the inspection the establishment is not in production, the supervision will be based on reviewing the records, infrastructure, etc.

The category in which the establishment is classified will depend on the number and type of deficiencies detected during the supervision. The official must provide a clear description of any

observations for the deficiencies detected. These deficiencies may be Critical, Serious, Major or Minor (see Part I, Glossary).

It must be mentioned that the classification of the deficiencies associated with the different items of the checklist is not final and that it may vary on the field, depending on the nature of the deficiency detected. If the deficiency being rated is below the checklist recommendations, it must be clearly justified.

When applying the inspection checklist, the risk associated with the detected deficiency must be taken into consideration, especially in terms of the sanitary quality of the product.

If during the inspection visit the production establishment solves any of the deficiencies detected, the Inspector may not assign a severity level taking into account the risk associated with the product.

When adding up the deficiencies detected in the establishment, this may be classified as Aprroved or Rejected, based on the description provided in the following chart:

For fishery plants that manufacture products intended for human consumption:

Table: *Classification of establishments by category* (M.05.01.18)

	DEFECTS			
CATEGORY	MINOR	MAJOR	SERIOUS	CRITICAL
Approved	-	13	3	0
Rejected	-	≥14	≥4	≥1

Although he check list contains Minor non-conformities, which must be registered as inspection evidence, they do not influence the final classification result of Approved or Rejected. However, these Minor non-conformities must be addressed by the company given that in case of repetition they will be considered with greater severity. (M.05.01.18)

Establishments that obtain a category Rejected may not obtain, from that date, the Authorization at Origin for Sanitary Certification, where the sanitary certification will be subject to the analysis of the final product (only for markets that do not require a QAP), until the all deficiencies have been solved. This must take place not longer than 45 days after de inspection, otherwise the program must undergo a new process of review and certification audit. (M.05.01.18)

Those establishments that are classified Rejected in two consecutive supervisions will be automatically removed from this Program. To become part of it again, their programs must be audited, as described in Item 1.1.2 of this Chapter. (M.05.01.18)

If an establishment changes its category to one different from "A" or "B," SERNAPESCA will be automatically suspended its QAP Certification. In case of recovering its category "A" or" "B, within a period not exceeding two months, they may retake this certification after the verification by the SERNAPESCA official of the correct implementation of the QAP.

If this period is longer than two month, the program must be audited, as described in Item 1.1.2 of this Chapter, to enter to the QAP Certification again.

The result of the supervision, as well as the any deficiencies detected, their severity, and the action made by the establishment for solve de observation of the previous visit, must be registered on the SERNAPESCA inspection book, or sending to the establishment by other way, at least the next working day. In any the above cases, the result of the visit must be indicated in the inspection book before finishing the visit. (M.05.01.18)

It must be noted that if any of the deficiencies described in the sections of the checklist is repeated in the next SERNAPESCA inspection, its severity level may increase. If an observation is repeated, the establishment must present a schedule of activities, in order to commit to the resolution date for each observation. This schedule, its monitoring and compliance will support that the severity has not increased. The above based on the risks associated with the sanitary quality of the product. (M.05.01.18)

Once a year (or after a production year in the case of establishments that do not process on an ongoing basis), the SERNAPESCA official in charge of the establishment will conduct a more thorough inspection. This procedure should ideally match the QAP's comprehensive verification for the establishment. (M.05.01.18)

As a supervisory process, it has also been established that part of the verifications usually included in the QAP for each establishment will be sent to the SERNAPESCA Verification Laboratory..

The frequency will vary based on the type of product manufactured by the establishment:

- 1 out of 6 plant verifications for the QAPs for live, chilled refrigerated-frozen fish, live, chilled refrigerated-frozen salmon, canned, salted, dried and dried-salted fishery products, frozen and preserved raw mollusks and fish oil intended for human consumption, algae derivatives.
- 1 out of 4 plant verifications for the QAPs for frozen crustaceans, frozen-cooked mollusks, smoked fishery products, and ready-made meals.
- 1 out of 2 verifications for factory ships.
- 1 out of 6 plant verifications for the QAPs for fish meal and oil not intended for human consumptions or peptones.

Sending these samples to the SERNAPESCA Verification Laboratory does not imply conducting an additional verification from those considered in the company's QAP, it only implies a change in the laboratory in charge of conducting such analyses. To deliver these samples the analyses of all the requirements of the different destination markets included by the company in its QAP for the product to be analyzed must be required.

If due to low production it is not possible to comply with the necessary verification frequency to send samples to the official SERNAPESCA Verification Laboratory, the establishment may conduct this procedure once a year.

The following procedure must be applied when sending QAP samples to the Verification Laboratory:

- The company will notify the Local SERNAPESCA Office of the date in which the samples must be sent to the Verification Laboratory, in accordance with the production days (which will be verified in the QAP inspections).

- Samples must be selected by SERNAPESCA Officer, and collected by an authorized sampler. The samples must be packed and sealed with SERNAPESCA's tape in presence of the inspector and then dispatched to the SERNAPESCA Verification Laboratory, this with the purpose of guaranteeing its reception under optimum conditions.
- The samples must be delivered to the laboratory with the form especially designed for this purpose (QAP verification samples delivery form, Part III, Annexes, Chapter II) which must clearly indicate the analyses to be carried out. The original form must be attached to the sample to be sent to the Verification Laboratory, leaving the corresponding copies for SERNAPESCA and the production establishment.
- The delivery of samples must be alternated depending on the type of product manufactured by the establishment, for instance, different species or presentation.

The results of the analyses conducted by the SERNAPESCA Verification Laboratory will be sent directly to the establishment, with a copy to the Central Office of the Service.

1.4 QAP RECERTIFICATION AUDIT

The QAP will be valid for two years, from the date of the certification visit in accordance with the QAP, after this period a new audit for re-certifying the program must take place. The monitoring of the deadlines associated to the QAP Recertification, will be in charge of the Local Sernapesca inspector, who must inform of this situation with anticipation to the each establishment in charged.

Those establishments that due to a lack of raw materials have processed for less than 6 months over the last year, may request a one-year extension of the validity of the program, after which it must be subjected to re-certification.

Before the term for presenting the recertification, the updated document must be presented at the Local SERNAPESCA Office, in accordance with the procedures describe at the Pont 1.1.2 above.

The presented document must contain all the modifications that have taken place during the period between the two audits. This document must contain a change control system, that allow identify every change realized.

The recertification will be conducted by a professional from the evaluating entity together with a SERNAPESCA official, who must simultaneously supervise the QAP of the establishment.

Once the recertification visit has taken place, the professional from the evaluating entity will issue a report to the Central Office within 5 business days from the visit.

Once the information has been analyzed, the Central Office will write a final report, based on which the audit may be approved, approved with observations or be rejected.

In the event of the Recertification audit be Approved with Observation, the establishment must resolved all the observations in a period no longer than 1 month, in order to continue with QAP Certification. Otherwise, The QAP Certification of the establishment will be suspended until all the observation are solved.

If a result of the recertification audit is Rejected, the establishment will not be able to continue certifying under QAO. This will also be reflected in the result of the inspection realized by SERNAPESCA inspector during the audit.

1.5 QAP MODIFICATIONS

Any modifications to the document that are in the following situations must be reviewed by the evaluating entity, and the costs will be in charge of the interested party, which will be determined by the Central Office and informed via email to the interested company:

- Modifications that affect the production process and that are related to any Critical Control Points, such as changes in the definitions of hazards, lay-out, operational steps, monitoring, sampling plans, and corrective actions, among others. (M.05.01.18)
- Changes that affect the implementation of the QAP, such as changes in the format of CCP records. (M.05.01.18)
- When new products of the same line of production are included in the QAP in place, and these are considered to be specific market requirements.
- When new markets with specific requirements are included in the QAP in force.
- When the previous official action indicates so. (M.05.01.18)

For this purpose, the theoretical document must be sent via email to the Local SERNAPESCA Office with copy to the Central Office, together with the QAP Processing Request where the "Review" process must be selected.

The modifications must include a track changes system so as to clearly see them in the document.

SERNAPESCA at the Central Office will send the document to the evaluating entity who will proceed to conduct the review.

Once the review is paid, the evaluator will issue an evaluation report that must be sent to the Central Office of SERNAPESCA. This report must be delivered within 5 business days from the payment of the review. (M.05.01.18)

Once SERNAPESCA receives the report from the evaluator, the Central Office and the inspector in charge of the establishment, will proceed to its analysis, who once the modification been approved, must be verify its implementation. The deadline for doing that will depend of the importance of the modification (the incorporation of a new product must be verify before the process begun. A minor modification could be verify at the next QAP supervision). (M.05.01.18)

Any minor changes that do not comply with the instructions described above will not be reviewed. In such case, the company must inform the changes to the Inspector in charge of supervising the establishment, compiling them and presenting this compiled in the document with which the next recertification audit will take place. (M.05.01.18)

1.6 GENERAL CONSIDERATIONS

The establishments with QAP certification that have suspended their activities for more than a year must go through a recertification process to be included in this system again.

The establishment must have all the information sent by SERNAPESCA, related with their QAP, available.

If an establishment loses the QAP Certification, the Local Office must notify all SERNAPESCA offices, with a copy to the National Directorate's Foreign Trade Sub-Directorate. In Addition, if its process considers the sale of semi-processed raw material or final product for re-processing, the establishment must inform this to all of its clients, keeping the traceability documents available for SERNAPESCA to verify them.

1.7 SPECIFIC REQUIREMENTS TO CONSIDER PER RESOURCE AND PROCESS WHEN CREATING A QUALITY ASSURANCE PROGRAM

1.7.1 BIVALVE MOLLUSKS, GASTROPODS, ECHINODERMS AND TUNICATES

A. MARINE TOXINS

Marine toxins shall be understood as Paralytic Shellfish Poison (PSP), Toxins of the lipophilic group (LC-MS/MS instrumental analysis) and Amnesic Shellfish Poison (ASP).

The establishments that process susceptible resources must consider the following in their Quality Assurance Program:

- Hazards Analyses and Determination of Critical Control Points:

The "Presence of marine toxins" hazard in the "Reception of raw material" operational step must always be considered as a significant hazard.

It is mandatory for this hazard to be part of the CCPs for the "Reception of raw material."

- Monitoring raw material:

  - For those plants that receive resources susceptible of being affected by marine toxins, from natural banks of areas classified by the BMSP of SERNAPESCA, the "Records of Extraction and Transportation of Live Bivalve Mollusks" are required; and as appropriate, and depending on the origin, the supplier and the susceptibility of the resource, a marine toxins analysis must be made to the raw material.
  - Those plants that receive resources susceptible of being affected by marine toxins, from farms that are part of the BMSP of SERNAPESCA, must be subjected to a document control of origin that requires the form "Records of Extraction and Transportation of Live Bivalve Mollusks."
  - Those plants that receive resources susceptible of being affected by marine toxins, from areas that are not part of the BMSP of SERNAPESCA, must conduct a monitoring process for each origin or extraction area, on a weekly basis and with n=1. If one of the weekly monitoring processes detects the presence of marine toxins, all the products manufactured from the origin in question must be blocked from the last favorable raw material monitoring process. This possibly affected product will be subjected to an End Product toxins analysis, as described in Item 1.1.21 of Chapter IV, Section III of this Manual.

The RET is not required to be presented in those cases in which the resources come from a farm and are destined to an establishment (distribution, processing or depuration) belonging to the same

company or group of companies, which must be accredited with the corresponding notarized documents and/or the incorporation of the company(s). In all other cases, the document will be provided by SERNAPESCA under the request of the interested parties, regardless of the destination of the resources, even if the processing establishments receive shucked raw material. The above is based on what is stated in Section I, Chapter I, Item 6.

If the company receives raw material from extraction areas with Cadmium contingency, it must evaluate the situation and take action, as appropriate, so as to guarantee that the resources comply with the regulations in force, which may be verified by the Inspector in the periodical inspections.

All the entries in the Reception CCP, regardless of the origin of the raw material, must be supported with the original or a copy of the waybill that accredits its origin, the extraction, and transportation record for the batch entered (according to the areas classified by SERNAPESCA's BMSP).

All establishments receiving live raw materials with their corresponding RET, and that then destine their products or part of them to another establishment to be subjected to a process different from production for their further export must issue a sworn declaration, in accordance with the format available in Part III, Annexes, Chapter II. This declaration must accompany the product to the end establishment, and the RET document will remain filed in the primary production establishment.

If the raw material is rejected and it does not enter the processing establishment or distribution center, the company must send, within 24 hours, a fax or email to the SERNAPESCA office under whose jurisdiction the establishment is located, with the following information:

- Time and date of the rejection.
- Origin of the raw material (name and area code).
- Waybill number.
- RET number.
- Reason for the rejection.

The SERNAPESCA office receiving the information must issue it to the corresponding Sanitary Authority.

- Periodical verifications:

Verifications for marine toxins in finished products must take place every 15 days for all those plants in which the origin of the resources corresponds to one of the following:

a) Natural bank located along the country, whether it is part of the SERNAPESCA BMSP or not.
b) Farm located in the country, whether it is part of the SERNAPESCA BMSP or not.
c) Farm located in the region of Los Lagos (included) and the south that is part of the SERNAPESCA BMSP.

The establishments that process resources from areas that are part of the BMSP or that are not part of it must carry out a control of marine toxins in their periodical verifications, for both types of origins.

In the case of resources that come from farms from the Region of Arica and Parinacota to the Region of Los Ríos that are part of the SERNAPESCA BSMP, the marine toxins analyses must take place in 1 of every 4 periodical verifications.

In all cases, there must be a rigorous follow-up system in place to relate the raw material lots received with the end product lots.

The verification must be conducted as per the instructions provided in Item 1.1.21, Chapter IV, Section III of this Manual. This verification must be conducted for all the products manufactured with resources that are more susceptible.

If the company manufactures products with raw material from extraction areas with Cadmium contingency, it must evaluate the situation and take action, as appropriate, so as to guarantee that the resources comply with the regulations in force, which may be verified by the Inspector in the periodical inspections. In addition, the analyses must be conducted in external laboratories authorized by SERNAPESCA.

The analyses for marine toxins (both for raw material and end products) must be carried out with individual samples, in accordance with the "n" established for the sampling plan. For this, a sufficient amount of product must be collected for each one of the samples. That is to say, the analysis of the composite will not be accepted.

The frequency of the verifications may be reduced to the extent that the historical results of the plant prove that the hazard is being fully controlled.

Those plants that have their own laboratories authorized by SERNAPESCA to determine the presence of marine toxins in the raw material or that conduct periodical verifications for these toxins (according to the requirements described in Section IV, Chapter I, Item 1), must indicate it in the document, also describing their work methodology. These procedures will be inspected in the monthly visits of SERNAPESCA.

All the previously mentioned programs and plans to control the hazard of marine toxins may be modified in case of a contingency, and this situation will be informed to the interested parties by SERNAPESCA so that they can make any necessary adjustments to the QAPs.

Also, those establishments that consider the community market in the Quality Assurance Program must take the following into account:

- Chilled-refrigerated raw bivalve mollusks must come from type A areas for the European Union, or they must be approved for the United States.
- For the identification and follow-up of live bivalve mollusks, each lot must be supported with a "Record of Extraction and Transportation of Live Bivalve Mollusks" from the BMSP. The document will be provided by SERNAPESCA as requested by the interested parties.
- For each lot, the Collector must clearly indicate in the form everything described in Section I, Chapter I, Item 7.
- When receiving a lot of bivalve mollusks, the production establishment must include the time and date in the record document. In addition, it must follow the indications provided in Section I, Chapter I, Item 7.
- This procedure must be included in the Quality Assurance Program of the fishery plant, considering the following aspects:
    - As a preventive measure, all fishery plants that are part of the BMSP must require at the entry of the raw materials, the "Record of Extraction and Transportation of Live Bivalve

Mollusks," aimed at accrediting the origin of the resources, regardless of the final destination of the product.

- When the resources are destined to the European Union, the plant must accredit that the technological process applied corresponds to the use that should be given according to the delimitation of the extraction area.
- The resources destined to other markets must have their corresponding records, describing the origin of the raw materials and the market to which they are destined in the form. Similarly, it must establish a follow-up procedure for the product that allows to relate the origin of the raw materials with the end product and to differentiate it from those destined to markets with other requirements.
- The record must be required, maintained and filed by the establishment and made readily available for the professionals of SERNAPESCA supervising the operation of the QAP. The Service will control the existence and content of the records on a periodical basis.
- If there is not a record that supports the entry of raw materials into the plant, the company, as a corrective action, must keep the batch under observation and conduct the analysis of the end product. This product may not apply to the QAP certification, and its certification will be subject to the results of the analysis, as described in Section III, Chapter IV, Item 1 "Sanitary Requirements and Sampling Plans for the Sanitary Certification of Export Fishery Products."

B. VIBRIO

Vibrio parahaemolyticus:

All production establishments processing chilled-refrigerated or raw bivalve mollusks, gastropods, echinoderms, and tunicates, must include the *Vibrio parahaemolyticus* hazard in their corresponding QAPs. Raw bivalve mollusks, gastropods, tunicates, and echinoderms extracted and processed in the Region of Magallanes are excluded from this requirement.

C. RAW OYSTERS (LIVE, FRESH OR FROZEN)

The establishments that process raw oysters (live, fresh or frozen) must obtain raw materials from an area that is part of the Bivalve Mollusks Sanitation Program, under category A, and must consider the Norovirus analysis in the verifications of their Quality Assurance Program.

The standard is "absence."
Frequency: Every 15 days of production.
n = 3 for each origin received in the 2-week period.

D. SCALLOPS WITH VISCERA OR PART OF THEM

The establishments that process scallops with viscera or part of them and that export to markets that require Cadmium control must conduct the analyses in accordance with the sampling plans established in Section III, Chapter IV, Item 2, for each production date to be exported. Periodical verifications do not apply for these products.

E. PECTINIDAE FROM NATURAL BANKS AND GASTROPODS EXTRACTED FROM AREAS THAT ARE NOT PART OF THE BMSP

The establishments that process pectinidae from natural banks and gastropods extracted from extracting areas that are not part of the BMSP, and that include the European Union as the destination market, must comply with and incorporate the following requirements in their Quality Assurance Program:

- These resources must come from areas that are part of the "List of extraction areas of pectinidae from natural banks and gastropods that are not part of the BMSP."
- When receiving the raw material, the tax documentation (waybill or invoice) that accompanies the product will be required to have the following information:
  - Identification of the extraction area in accordance with the "List of extraction areas of pectinidae from natural banks and gastropods that are not part of the BMSP."
  - Extraction date.
  - Identification of the resources and
  - Quantity of the resources.

  A copy of this document will be kept as a record for the CCP Reception of raw material.
- A monitoring process will be applied to raw material considering the sampling and analysis of resources to determine the presence of marine toxins (PSP, Lipophilic Toxins Group, and ASP), with a sample size of n=1 for each origin and reception date.
- If the company manufactures raw products, the analysis of *Escherichia coli* must be included in the monitoring process of the raw material, with a sampling size of n=1 for each origin and reception date.
- Periodical verifications will consider all the analyses required by the European Union for these type of resources.

These requirements are additional to those described in the Item Hazards Analyses and Determination of Critical Control Points described in Letter A above.

1.7.2 FISH FROM FARMS

The instructions provided in Section I, Chapter II, must be followed.

1.7.3 CANNED PRODUCTS

When manufacturing canned products, the establishment must have implemented, as part of its CCPs controls or internal controls, a visual control and a double seam destructive test.

The parameters to be considered will be those recommended by the manufacturer, which must be duly supported in the documentation of the establishment.

1.7.4 MEAL AND OIL FROM BY-PRODUCTS OR FISH WASTE

The processing establishments that obtain raw material from establishments that manufacture products intended for human consumption (by-products or waste) or cold storages, must provide their suppliers' specifications on the raw material used so as to ensure that it complies with the standards set for the markets that are part of their QAP.

The processing plants that receive raw material from salmonids must request a declaration from the supplying plant at the moment of entry. This declaration must guarantees that the raw material complies with the standards set by the European Union and their corresponding LMRs for fish flesh and skin, described in Part II, Section I, Chapter II of the Food Safety and Certification Manual,

regarding the control of pharmaceutical products residues, prohibited substances, unauthorized substances and contaminants. The supplying establishment must have all the supporting documentation that proves the veracity of the declaration provided.

The establishments that export to the European Union must have a procedure in place that guarantees that in case of receiving material other than that of Category 3 (for instance mortalities, products with pharmaceutical residues that exceed the LRMs of the UE, waste or by-products that have been in contact with the floor or chemical substances, etc.), this will be processed in independent or separate lines or at different times so as to avoid confusion or cross-contamination between the lots. Similarly, they must ensure that these products are stored separately from those destined to the market of the EU.

1.7.5 MORTALITIES REDUCTION PROCESS AND/OR ANTICIPATED SALMONIDS HARVESTING DUE TO CONTINGENCIES

The process of mortalities reduction and/or anticipated salmonids harvesting in the plants with Quality Assurance Programs is an "extraordinary measure" which must be previously authorized by SERNAPESCA. It must be mentioned that in accordance with article 24, paragraph 2, letter b) of the community Regulation No 1069/2009/EEC, these authorizations will be temporary and will be applicable only under extraordinary and unexpected circumstances.

The company must inform SERNAPESCA in writing the start and end date for this exceptional process. All the products manufactured during the contingency period will have the same category as the product obtained from the mortalities process. The company must have the corresponding records and supporting information as a guarantee.

The production from this extraordinary period may only apply for the QAP certification if the risks associated with the mortalities processing (material from category 1 or 2) are included in such program and have been validated by SERNAPESCA.

The manufactured product may be destined to markets that do not have any restrictions on the processing of mortalities or anticipated harvesting, as described in the Food Safety and Certification Manual (Part II, Section III, Chapter IV and Part II, Section II, Chapter I, Item 3.2.3) or in the sanitary certificate forms.

During the entire value chain, the product must be properly identified and separated from the rest of the products manufactured with raw material from another origin. When storing the product, the productions coming from the contingency must be clearly identified, and all the necessary precautions must be taken to avoid them being mixed with different productions.

At the end of the measure and before resuming regular activities, the processing establishment must implement a deep cleaning and disinfection process in the entire line of process from the reception area of the raw material to the storage areas. This procedure must be documented, informing the end date to SERNAPESCA and attaching a report describing the sanitary conditions through photographic records and other objective information.

A verification of the surfaces will be required, in accordance with the establishment's Sanitary Operational Procedure, at the end of the cleaning and disinfection process. The results must be available at the processing establishment to be verified by SERNAPESCA.

A periodical verification of the finished product must take place at the end of the first day of the normal operation of the establishment's QAP.

In terms of the supply and production statistical declaration provided to the Service, if the contingency is related to mortalities, these must be declared with the code for salmon mortalities and not as waste.

The company, in any event, must comply with the usual procedures that regulate the activity, in statistical terms, for authorization, specific requirements, traceability, etc.

All the records and information supporting this extraordinary measure must be filed in the plant and must be made available for the review of SERNAPESCA.

2. WORK GUIDE FOR THE CREATION OF QUALITY ASSURANCE PROGRAMS

To create a QAP based on the HACCP system, each company must follow at least the instructions provided in this Guide, using as a basis the prerequisite programs for establishments with QAPs (Item 5, Chapter I of this Section) and the Sanitation Operational Procedures (item 6, Chapter I). Both must be developed in a manual and implemented together with the QAP since they allow to guarantee the safety of the food produced by the establishment.

In the design operations and application of HACCP systems, the effects of the raw material, the ingredients, the food production practices, the role of the production processes, the intended use of the product, the affected consumer categories and the epidemiological tests for food safety must be taken into account with the purpose of identifying, evaluating and controlling the hazards.

Whenever a modification to the product is introduced, during the process or at any stage, the application of the HACCP system must be examined, and the necessary changes must be applied.

The original QAP document must be signed and dated by the establishment's manager.

2.1. DEVELOPMENT STAGES OF A QUALITY ASSURANCE PROGRAM

The HACCP system has a structure that is described in this Item. It consists of seven (7) principles which are implemented through twelve (12) steps that must be developed in a sequence.

Before implementing the HACCP system, the prerequisites must be documented and executed, as well as the commitment made by management on the implementation, execution, and completion of the HACCP system.

2.1.1. SETTING UP A WORK TEAM

The first step for developing a quality assurance plan is to set up a work team, comprised of personnel of the establishment with or without the involvement of external consultancy services, whose purpose is to develop the program in question, thus creating the HACCP team.

This team must have all the necessary knowledge related to the production (manufacturing, storage, and distribution), consumption and potential hazards for each product.

The work team may be comprised of the following people:

a) A quality control specialist, qualified to determine the biological, chemical and physical hazards of a certain group of products;
b) A production specialist responsible for the technical manufacturing process for the product or highly involved in it;
c) A technician with practical knowledge in the operation and hygiene of the equipment and tools used to manufacture the product;
d) A person with specific knowledge in microbiology, hygiene, food technology and public health;
e) A person that has approved an HACCP methodology course. It must be the person responsible for the QAP and its surrogate;
f) A person that has approved a Sanitary Operational Procedures (SOP) course. It must be the person responsible for the SOP and its surrogate.

A person may be responsible for several roles to the extent that the team has all the necessary information and that it is used to guarantee the reliability of the system in place. It is recommended, only when possible, for the person in charge of the QAP to be different from the one in charge of the SOP, so that these two areas are independent of each other in the establishment.

The QAP developed by the company must include at least the following information for each one of the team members:

- Name, profession or level of experience, position, responsibility, work conducted in the QAP, and the corresponding surrogates in the corresponding QAP.
- HACCP and Sanitation training.

When describing the responsibilities, special emphasis must be made in the execution of the QAP, those who are and are not responsible for the monitoring processes, corrective actions, verifications, SOPs, etc.

The description of the work team must be provided separately from that of the personnel that participated in the creation of the theoretical document.

In addition, an organizational chart of the work group with the execution of the QAP must be included.

The HACCP team must constantly be trained so as to maintain its technical competence.

It is vital to have the commitment from management, as well as all the necessary knowledge to apply an effective HACCP system. Such effectiveness also depends on the knowledge of management and the employees, on their commitment and the proper skills that they have for the HACCP system and its application.

2.1.2. DEFINING THE PRODUCT

The establishment must identify and define every product that effectively will process, with the purpose conducting a systematic evaluation of all the hazards associated with these products and their ingredients. (M.05.01.18)
This description must consider at least:

- Name of the product as per the GIA tables*.
- Species (common and scientific name).
- Line of production as per the GIA tables*, for example, frozen, chilled-refrigerated, canned, etc.
- Type of product as per the GIA tables*, for example, smoked, raw, IQF, in sauce, etc.
- Presentation as per the GIA tables*, for example, fillet, ½ shell, whole with viscera, etc.
- Composition (ingredients, additives, etc.).
- Intrinsic characteristics (at least pH, moisture or aw).
- Type of packaging (primary and secondary).
- Shelf life of the product and storage conditions.
- Distribution system (direct dispatch from the production establishment, storage in an external cold store, description of the distribution logistics for the product before its final dispatch, etc.).
- Destination markets: it is necessary incorporate in this item only those markets which the establishment will actually exported, because the QAP control must consider all the requirement of these markets even when the company does not export regularly. (M.05.01.18)
- Sanitary requirements: must indicated the general requirements of SERNAPESCA and those specific by destination market, if is applicable, including the parameters and standards per each of them. The updated version of Items 1 and 2 of Chapter IV, Section III may be mentioned, in order to avoid transcribe the requirements. Nevertheless, the company will always be responsible for knowing the updated standards. (M.05.01.18)

In the case of including requirements that are not officially required by the destination market, such condition must be mentioned.

(*)GIA tables: Refers to the tables describing products used in the Statistics and Exports Systems. A summary of these tables is presented in item 2.1.4

2.1.3. DETERMINATION OF THE INTENDED USE OF THE PRODUCT

The normal or intended use of the product must be documented, and it must consider at least the users, recipients and final consumers, the vulnerable groups of the population, their shelf life, the preparation methods, and the storage and preservation conditions.

2.1.4. CREATING THE FLOW CHART

The following step is creating a process flow chart that represents all the operational steps involved in handling the product through the establishment. This schematic flow chart must present in a simple, clear and orderly manner the steps from the reception of the raw material to the dispatch of the end product.

To the extent possible it must comprise all the operations that are under the control of the producer (farming, transportation of the raw material, end product, etc.).

Linea	Presentacion	Presentacion (Cont)
EMBUTIDOS	ALAS	TENTACULOS O RAMALES
MARINADOS	ALETAS	TRONCO / H.G.T.
SECO (SOLO ALGAS)	ANILLOS	TUBO O VAINA
ENFRIADO REFRIGERADO	BELLY	VEJIGAS
CONGELADO	BROCHETAS	1 VALVA / 1/2 CONCHA
SURIMI	CABEZAS	ALBONDIGAS
CONSERVAS	CALDILLO	2 VALVAS / ENTERO
HARINA	CALLO CON GONADAS	FANCY
ACEITE	CALLO SIN GONADAS	CON CABEZA SIN COLA
DESHIDRATADO	CALUGAS	GRANULOS
PEPTONA	CARPACCIO	DESECHO
VIVOS	COCOCHAS / BARBILLAS	ENTERO CON VISCERAS
SALADO	COLAS ENTERAS	RECORTES
DERIVADOS DE ALGAS	COLAS PARTIDAS	CAPARAZONES
	COLLARES	CONCHA
TipoProducto	CON CONCHA	CABEZA/CUELLO/NUCA
CRUDO IQF	SIN CONCHA	
AHUMADO IQF	DESCABEZADO	Tipo Presentacion
PLATO PREPARADO	CARNE	CON PIEL / CON ESPINAS /CON ESCAMAS
COCIDO IQF	DESMENUZADO / MINCED	CON PIEL / CON ESPINAS / SIN ESCAMAS
CRUDO BLOQUE	DESPUNTE / CUT OFF	CON PIEL / SIN ESPINAS / CON ESCAMAS
AL NATURAL	ENTERO SIN VISCERAS/HON	CON PIEL / SIN ESPINAS / SIN ESCAMAS
AL ACEITE	ESCALOPAS	SIN PIEL / CON ESPINAS
EN SALSA	ESQUELON	SIN PIEL / SIN ESPINAS
EN SU JUGO	FILETE	CON VISCERAS
EN SU TINTA	FILETE MARIPOSA	SIN VISCERAS
AHUMADO AL ACEITE	FILETE MERCURIO	MEDIA CONCHA
AHUMADO EN SALSA	FILETE REBANADO / RODAJAS / STEAK	GLASEO
AHUMADO EN SU JUGO	EVISCERADO SIN CABEZA / HG	SIN AGALLAS
REFINADO	HAMBURGUESA	SIN CONCHA
SEMIREFINADO	HARAMI	CON CASCARA
ACIDULADO	HARASU	SIN CASCARA
WINTERIZADO	KIRIMI	CON AGALLAS
SECO	LENGUAS	Porciones
HUMEDO	LOMOS / LOINS	HIDRATADO
AGAR - AGAR	MANTO	Con Cabeza
ALGINATO	MEJILLAS / POMULOS	Sin Cabeza
CARRAGENINA	MOLIDA/PICADA	
COLAGAR	NUCAS	
CRUDO PAN	OVAS / HUEVOS / GONADAS	
AHUMADO BLOQUE	PASTA	
APANADO IQF	PATE	
CRUDO MADURADO	PELLET	
COCIDO	PICADILLO / GRATED	
CRUDO	PINZAS	
AHUMADO	POLVO	
COCIDO BLOQUE	PORCIONES O TROZOS	
ALCOHOL	PULPA	
ESCABECHE	RIBETES	
AHUMADO EN SALMUERA	ROLLITOS	
CRUDO CON SAL	SLICE	
AL LIMON	SOPAS	
CRUDO REMOJADO	SURTIDO	
COCIDO EN SALSA	SUSHINETA	

Figure: GIA tables summary

To complete this flow chart a brief description of each one of the steps included must be provided, considering, among other factors, the holding times between the different stages, the types of cuts (manual or mechanical), refill frequencies for stagnant waters, preparation, treatment, addition of ingredients and additives with their corresponding concentrations. And also the technical parameters of the operations, such as those referring to time and temperature, including holding times. In addition, must indicate the Processing capacity, either by operational step or by processing line. (M.08.02.18)

All the operational steps involving stagnant waters must indicate the refill frequency. In addition, in

the stages where there may be a strong source of contamination for the end product, the refill frequencies must be supported by a study, as specified in Item 6, Chapter I of this Section.

All the temperature procedures must be supported by heat penetration studies. The minimum content to be included in the studies is described in Item 3.2.4 of Chapter I of this Section. The report number supporting the heat process must be included in the products description.

If the QAP of the establishment states that it will produce cooked products intended to be used for manufacturing canned products in a Chilean establishment, it is not necessary to conduct a study that provides proof of the cooking process.

The following is an example of a process flow chart for chilled-refrigerated fish.

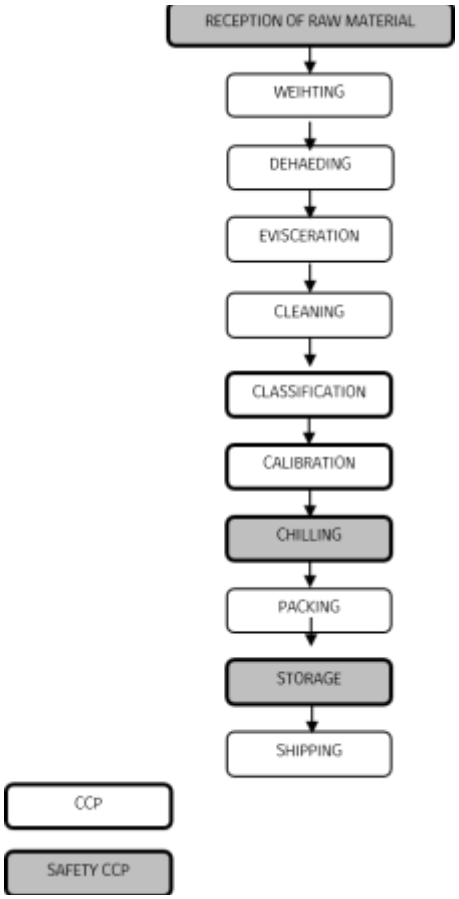


Figure : Example of a process flow chart for chilled-refrigerated fish.

All production lines, storage areas and restrooms for the staff must be represented in a layout of the establishment, to identify air currents, a possible source of crossed-contamination among raw products, in-process and finished products, additives, lubricants, refrigerating agents, personnel, and packing materials; staff areas must be sanitized and free of pests.

After determining the Critical Control Points (CCP) (see Item 2.1.9 of this Guide), these must be indicated in the flowchart, and those CCPs associated to safety hazards must be highlighted in a special manner.

The following is an example of a process flow chart for fish meal.

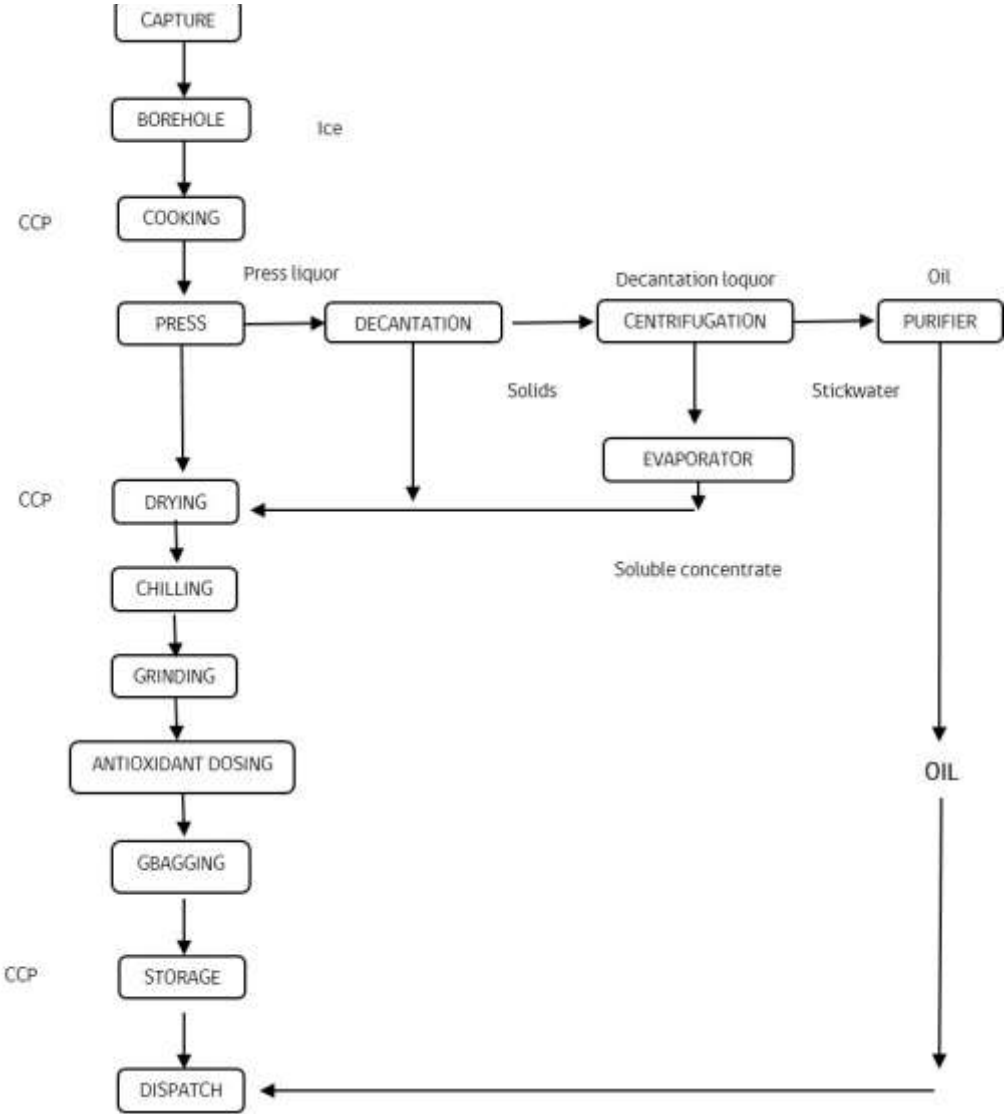


Figure : The following is an example of a process flow chart for fish meal.

2.1.5. CONFIRMING THE FLOW CHART ON SITE

The equivalence between the flow chart and all the stages and times of the manufacturing operation must be confirmed and changed as appropriate.

The flow chart must be signed by the person responsible for the HACCP team, as a means of confirmation.

2.1.6. CONDUCTING A HAZARD ANALYSIS (PRINCIPLE 1)

2.1.6.1. IDENTIFYING THE HAZARDS AND DETERMINING THE CONTROL POINTS

Once the product to be manufactured by the establishment has been determined, and the process flowchart has been designed, a list with all the possible safety hazards associated with the product in any of its manufacturing stages must be created, from the primary production to the point of consumption, as appropriate. All the hazards that may arise must be taken into account, considering the epidemiological information, historical information of the company and the level of severity of their effect.

To identify the hazards associated with the manufacturing process of the product, the work team must consider the following hazard areas:

- Food safety: Are the aspects of a product that may cause diseases or death. These may be biological, chemical or physical.
- Wholesomeness: Are unwanted characteristics or elements present in a product or process that do not cause diseases or death.
- Economic fraud: Are accidental or intentional actions where the consumer is deceived.

It must be noted that the main purpose of a Quality Assurance Process is to establish a control system that allows providing a safe product for consumers. From this standpoint, the identification and evaluation of the safety hazards for consumers are vital.

The hazards identification must focus on ensuring the safety and quality of the products to be processed, taking also into account those inherent to certain types of resources, such as the presence of drugs residues, raw material with marine toxins, among others.

In the case of fish, the identification of a hazard due to the presence of internal parasites is mandatory.

In the case of fish meal, the lots of finished product from different processing operations will be entirely affected by the same hazards of any of the origin processes that comprise them, this is an important factor to consider within the hazards associated with this practice.

On the other hand, in the case of doing mechanical cuts in the process line, a hazard related to the presence of metallic traces in the product must be identified.

In the operational steps where the labeling of the end product takes place (primary and secondary packaging, as appropriate), a hazard related to the loss of traceability due to defects in labeling must be identified. This hazard must be considered as a Safety hazard due to the following:

- Confusing lots of raw material with those that have intrinsically associated safety hazards (such as species coming from farms, susceptible to marine toxins or forming histamine).
- Error in the production date or process lot printed on the label (associated with shelf life

abuse).
- Products with market restrictions (each establishment must define in advance the way in which it will identify products subject to market restrictions, e.g. EEU).

Those hazards identified that are inherent to the product or that are associated with a processing stage must be controlled through the QAP. The hazards associated with the processing environment or to the personnel will be controlled through a proper sanitation program in accordance with the item 6, Chapter I of this Section, "Sanitary Operation Procedures (SOP)."

On the other hand, the storage hazards for supplies are controlled through Standard Sanitary Operational Procedures, but the hazards inherent to supplies must be controlled through the prerequisites programs (item 5, Chapter I of this Section).

To identify the hazards in an orderly manner, first the following process components must be listed in each operational step of the flowchart:
- Supplies: This includes raw material as well as each one of the components used in each operational step of the process, and that are part of the end product; that is to say, any ingredient including water, ice, salt for brine, among others; and packing materials such as plastic, boxes, and others (tools such as knives, spoons, bowls, weighing scales, etc. are not considered as supplies).
- Operations: These include all the actual actions involved in this operational step that are under the control of the producer.

The hazards associated with each supply and operation involved in each operational step must be identified with their corresponding hazard area.

The identification of the hazard must be as detailed as possible, mainly defined in accordance with the product, more than the cause of the problem. The following hazards are not very specific or address their causes:
- Contamination (Of which type?)
- Incorrect glazing (Over or underglazing?)
- Time-temperature abuse (it should be: Organoleptic deterioration or loss of freshness due to time-temperature abuse)

Hazards must be identified based on the end use of the product, especially taking into account its destination and further use. All the hazards must be considered during this identification process, even if they seem to be insignificant. It is not correct identify hazards based on market requierements.

In addition, when identifying the hazards, it is important to consider that these may appear in the production stages or after them.

Many of the hazards that appear during post-production stages refer to production factors that may affect the product once it leaves the establishment and is out of the control of the producer, for instance, the incorrect labeling of use instructions may lead to incorrect handling of the product from the consumer, if it is established that the product must be consumed cooked this must be indicated on the label.

When describing the identified hazard, this must be done with as many details as possible, clearly indicating the unacceptable characteristic of that product.

Once the operational steps of the process and the hazards associated with the supplies and operations have been identified, the process control points must be determined.

Control Point (CP): It is defined as any operational step in a process that involves a hazard.

Therefore, the operational steps that involve hazards must be identified.

2.1.6.2. ANALYZING THE HAZARDS

A hazards analysis must take place to identify any hazards related to the HACCP system and the hazards that must be eliminated or reduced to acceptable levels to produce safe foodstuffs.

Once the process control points have been established, and with the purpose of analyzing each one of the identified hazards, the following must be determined:

- Severity
- Probability of occurrence.

Severity: Severity will be understood as the extent of the consequences of the hazard in the consumer. This is, the effect that a hazard has to the consumer.

Probability of occurrence: Is the frequency of the possible occurrence of the identified hazards, which is determined in a qualitative manner, based on the following occurrence levels: Frequent, probable, occasional, remote.

For this, several sources of information may be used to help identify the frequency in which the hazard may take place, for instance, old company files, product samplings or follow-up tests, causes for rejection, etc.

Table: *Criteria applied to determine the effect of hazards*

Severity	Effect of the Hazard
Very serious	Permanent disability, fatality or dismemberment.
Serious	Injury or illness, without permanent disability.
Moderate	Minor injury or illness.
Minor	No injuries or illnesses.

Table: *Ratings by probability of occurrence of hazards*

Probability	Meaning
Frequent	More than twice a year.
Probable	No more than 1 to 2 times every 2 to 3 years.
Occasional	No more than 1 to 2 times every 5 years.
Remote	Highly improbable, but may happen sometime.

Note: The probability rating table may be adapted to the reality of the company. Those establishments that are starting to implement the QAP must support their decisions with this Table and with bibliographic information or statistics from the production sector.

2.1.6.3. EVALUATING THE HAZARDS

The stage after the analysis of hazards is determining which of the hazards presented in the flow chart are significant.

This evaluation carried out by the work team must be based on the information obtained from the hazards analyses, that is to say, weighing the extent and importance of the severity and probability of occurrence for each identified hazard.

Based on this analysis it must be evaluated if the hazard is significant or not. There are not any formulas to carry out this evaluation, and the decision must be made at the discretion of the work team since many of these hazards will be specific for the establishment and the product.

The following tables may be used as reference:

Table: *Criteria to determine a significant hazard*

Is it a significant hazard?		Probability			
		Frequent	Probable	Occasional	Remote
Severity	Very serious	YES	YES	YES	YES
	Serious	YES	YES	NO	NO
	Moderate	YES	NO	NO	NO
	Minor	NO	NO	NO	NO

2.1.6.4. DEFINING PREVENTIVE CONTROL MEASURES

Preventive control measures are actions and activities that may be used to prevent, eliminate or reduce a hazard to an acceptable level.

All significant hazards identified in the process must have at least one preventive control measure. It is important define the way to register each preventive measure, what could be by control point record (CP) or critical control point record (CCP)

2.1.7. DETERMINING CRITICAL CONTROL POINTS (PRINCIPLE 2)

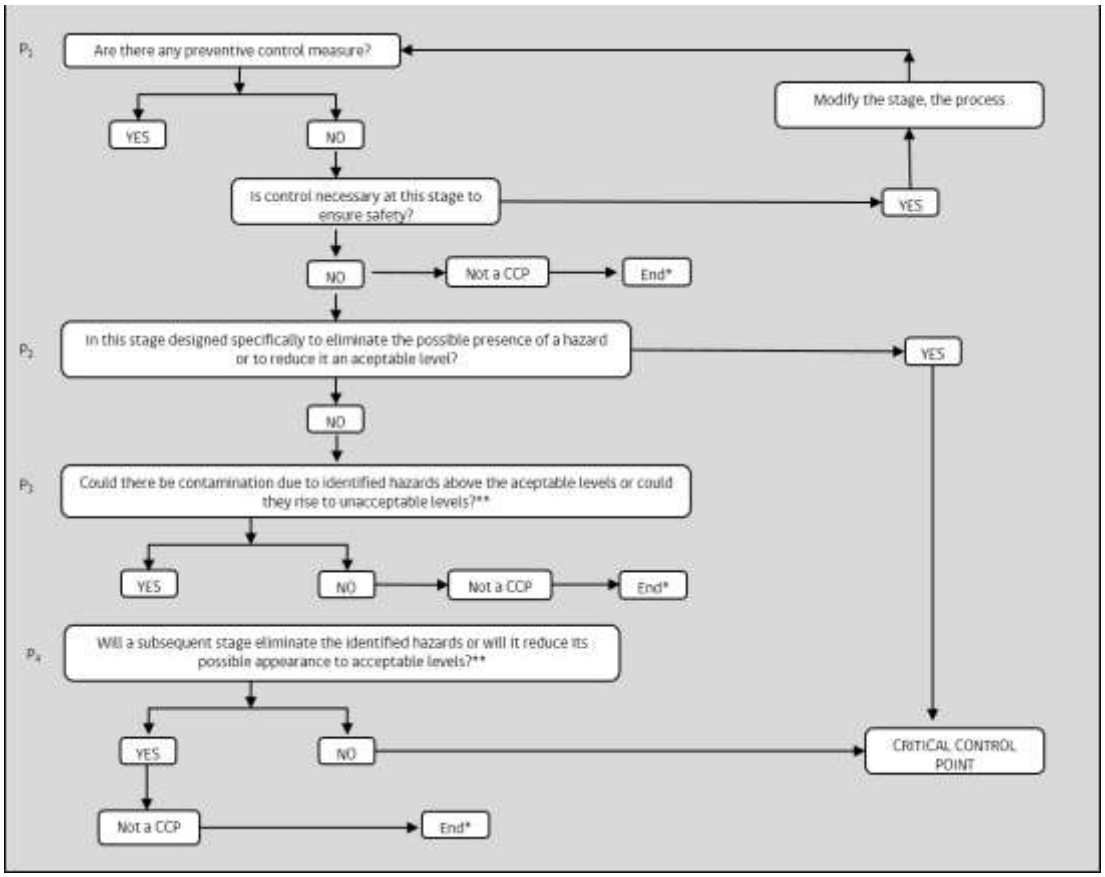
This stage identifies if the critical control points within the process, with associated significant hazards, are critical.

A critical control point (CCP) is any operational step in food processing, where the lack of control may immediately cause a product to represent a safety problem.

The determination of a CCP in the HACCP system may be facilitated through the application of a decision tree. The decision tree must be applied in a flexible manner, and it must be used as a guideline to determine the CCPs.

The following decision tree is recommended to determine where each significant hazard will be controlled. This example of a decision tree may not be applicable to all situations, and therefore other approaches may be used.

It is recommended to provide training on the application of the decision tree.



*) Move to the next identified hazard in the described process.
**) Acceptable and unacceptable levels must be determined in the scope of the general objectives when identifying the CCPs of the HACCP system.
Answer the questions in the provided sequence.

Figure : Example of a decision tree to identify CCPs.

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a) The points of a process where control is desirable but not essential are not CCPs. For instance, controlling the size of frozen salmon at reception is "desirable" but not critical, since this control will take place in a further stage of the process, for example, before the grillage.
b) A control point is not a CCP if the subsequent process eliminates the hazard. For example, the detection of parasites in the raw material during its reception will not be a CCP since there is a further internal parasite control process that will reduce the occurrence of this hazard.

When identifying this issue, it is important to stress on the fact that one of the objectives of Quality Assurance Program is to reduce and focus hazard controls to a minimum number of control points within the process.

An example of this is the sterilization process in low-acidity canned products. There are several steps in the process where there may be microbial contamination. However, there is one - sterilization - that controls this hazard, thus becoming the CCP for the microbiological contamination hazard.

It may not always be possible to reduce the control of a hazard to a specific point in the process, sometimes this control is critical at more than one point, for instance, when producing frozen jack mackerel, the hazard of the production of histamine must be controlled at reception and in any other step of the process that involves "stopping" the product. If the product does not have histamine problems at its reception, this hazard may appear if it is not properly handled during the process, due to which such hazard must be part of other CCPs apart from the Reception.

Therefore, we must now identify which are the points of the process where its control is critical.

2.1.8. SETTING THE CRITICAL LIMITS IN EACH CCP (PRINCIPLE 3)

Once the critical control points have been determined in the flow chart, the critical limits for each significant hazard associated to the CCP must be established.

A critical limit is defined as the pre-established tolerance that must not be exceeded to keep a hazard under control.

The most frequently used parameters to define the critical limits are time, temperature, moisture, pH, salt concentration, and net weight, among others.

These critical limits may be quantitative (T°) or qualitative (organoleptic evaluation).

Critical limits can be direct, this is, that are controlled directly on the product or indirect, where the necessary conditions of the process are established to ensure that such specific hazard is under control. For the latter, scientific tests must be carried out to ensure that controlling these factors will always be equivalent to directly evaluating the hazard in the product.

Each hazard in each CCP must have at least one critical limit assigned. There may be more than one critical limit for a critical control point. In the CCP reception of the fish, a critical limit of internal temperature of the product of 5 °C, must be consider for hazard "microbial growth by increase in the temperature".

It is important to set reasonable limits and in line with the establishment's reality, that ensure the control of a hazard, avoiding the definition of values that far exceed what is usually recorded in the process. The establishment may set more strict criteria than the critical limits to be used by an operator in order to reduce the risk of deviation, these are known as operational risks. If the monitoring process shows a tendency to exceed the operational limits of a CCP, the operator must take action to control the CCP before it exceeds the critical limit. The point where the operator takes that action is known as an operational limit, and the action itself is known as a process adjustment.

The decision to use operational limits depends on each company. Only critical limits must be included in the QAP.

The critical limits may be obtained from different sources. If they are not included in the regulatory guidelines or in the production practices guidelines, the work team must support their validity in terms of the control for the identified risk.

The critical limits must be clear and specific, avoiding ambiguities such as: "based on the requirements of the client" or "based on production standards."

2.1.9. ESTABLISHING MONITORING PROCEDURES FOR EACH CCP (PRINCIPLE 4)

Once the critical limits have been established, the monitoring processes must be determined.

A monitoring process is defined as a process where scheduled tests or observations are carried out, which are recorded by the establishment to inform the results of the controls established in each CCP.

It is important to stress on the fact that all monitoring processes must be documented.

The purpose of a monitoring process is to basically obtain the necessary information to keep the process under control. It provides early evidence that control is being lost or that the process is out of control. Therefore actions can be taken to resume it and reduce any losses due to a defective product.

This process also helps to locate the cause of the problem when control is lost.

The monitoring procedure for a hazard of a CCP, must consider at least:

- Procedure
- Sampling plan
- Frequency
- Responsible
- Location
- Records

HOW TO DESIGN THE MONITORING PROCESS

Since monitoring is a data collection process, it is important to obtain this information correctly, for this, the following recommendations must be followed:

- Ask the right questions that must be related to the specific required information.
- Design simple templates or forms, however effective for collecting data. Verify that the templates are easy to understand, that allow recording all the necessary information and that they are designed to reduce the possibility of errors.
- The monitoring form must include the corresponding critical limits, with the purpose of comparing them with the data collected from the monitoring process, along with the process start and end times and interruptions, if any.
- Select an impartial person to collect the data.
- Prepare instructions.

- Test the forms and instructions and modify them as needed.
- Train the staff in charge of collecting data.
- Check the data collection process and validate the results.

When the monitoring processes are being designed for each CCP, it must be verified that these are specific and designed to monitor the control of each identified hazard.

TYPES OF MONITORING PROCESSES

The monitoring process can be done through observation or measurement. Usually an observation provides a qualitative control index, for instance, the physical-organoleptic test; however, a measurement provides a quantitative control index, for example, T° measurement. Therefore, when deciding if a monitoring process will take place through observation or measurement, or both, it will depend on the identified hazard, on the critical limit set and the available methods, as well as the time and costs involved.

The data collected in the observation monitoring process must be compared with the critical limits.

There are automatic systems for the measurement monitoring process. If the automatic systems are calibrated and well maintained, they may help to reduce the risk of human errors, for instance, through the use of a thermograph. These systems will only be useful if they are frequently monitored or if they have an alarm that triggers when the critical limits are reached.

Most of the monitoring procedures for critical control points must be conducted quickly, since one of the basic principles of a Quality Assurance Program is to prevent, control and correct any problems during the process.

This does not mean that these tests or other slower methods cannot be used to verify the effectiveness of the processes' controls.

HOW TO CONDUCT THE MONITORING PROCESS

The procedures or methods that the person in charge of the monitoring process will apply must be clearly defined. Among the information used for these purposes, the type of measurement, the measurement unit and the sampling plan to be applied must be considered. Statistical analyses must be used to determine the sampling plans, which will depend on the risk level that the establishment is willing to accept.

In addition, it is important to take into account that the person in charge of the process must sign and date the corresponding record, collect the information directly in the form designed for such purpose without transferring it from separated pieces of papers or notepads. Similarly, when the parameters to be measured are quantifiable, expressions such as "compliant or non-compliant" should not be used. Instead, the measurement must be directly recorded.

WHEN TO CONDUCT THE MONITORING PROCESS

It should be ideally conducted on a permanent basis. Nevertheless, in practice, many times it is necessary to set monitoring intervals that guarantee that the hazard is under control.

It is important to consider that, regardless of the frequency set for a monitoring process, if the person in charge notices a deviation in a CL outside of the times established for this process, such information must be communicated in a timely manner.

WHERE TO CONDUCT THE MONITORING PROCESS

The monitoring process must be conducted in the CCP that exactly reflects the condition of a critical limit, however, sometimes it is necessary to monitor other points to avoid any interruptions in the production flow.

WHO MUST CONDUCT THE MONITORING PROCESS

It is important for the person that will be in charge of the process to have easy access to the CCPs and the necessary skills and knowledge to understand not only the food production process but also the importance of the monitoring activity.

In cases such as the sensory analysis to determine decomposition or chemical analysis, the person must be highly qualified and experienced. The person must also be impartial and reliable.

Some examples of monitoring processes are:
- Inspection of raw material.
- Temperature control of the product.
- Product storage time control.
- Raw material pH control.
- Products visual inspections.
- Readings of equipment instruments.

2.1.10. ESTABLISHING CORRECTIVE ACTIONS (PRINCIPLE 5)

Once the monitoring procedures have been determined, corrective actions must be established.

Corrective actions are defined as the procedures to be followed when a critical limit is reached or exceeded, with the purpose of recovering the control of the process and avoiding the production of defective products.

All corrective actions must be documented and recorded.

Corrective actions to eliminate the identified hazard must be designed for all critical control points, to the extent that there is an unacceptable deviation in the set limits.

Due to the variations in the products and to the different associated deviations, specific corrective actions must be developed for each critical limit at each critical control point.

Every time that a corrective action is applied there must be supporting documentation available for future reference. This will be useful for modifying any recurrent problems in the program, as well as to determine the actions to be taken with the affected product.

To establish each one of the corrective actions, corresponding to the deviation of the critical limits of all the significant hazards for each CCP identified, at least the following items must be included in the program:

- Possible deviations of critical limits, their corresponding corrective actions and the procedures to handle the affected product.
- The person responsible for the corrective action.
- Tests to establish their acceptability.
- Disposal of the product.
- Documentation and signatures.

Corrective actions must include:

a) **Immediate corrective actions:** These are to be immediately applied and avoid the production of defective products. These actions must require intensive monitoring to adjust the process, at that moment, to the critical limits. For example: Continue cooking a product lot to reach the minimum required T°. The establishment must verify the effectiveness of the corrective action, and this must be recorded.

b) **Closure corrective actions:** Those that return the process to control and correspond to final solutions that address the cause of the problem, and must, therefore, be always considered. This type of action must be included for each critical limit deviation for each CCP, indicating that an investigation will take place to find the cause of the problem and avoid its recurrence. For instance: Investigate the cause of the temperature rise in the process line and correct the problem.

When a deviation from a critical limit is detected, the condition of the manufactured product since the last monitoring must be evaluated, with results within tolerable limits, until the correction of the problem, which must be duly recorded.

Afterward, the actions to be taken with the affected product must be determined, for which the following steps must be applied:

- Separate and identify the suspect product.
- Inform the corresponding staff.

Once the suspect product has been isolated, it must be subjected to analytical tests that verify the safety, wholesomeness and the possibility of an economic fraud, accordingly. Therefore, the establishment must have access to the proper tests and necessary information that allows destining the affected product to:

- Reprocessing to make it acceptable.
- Destruction.
- Re-destination.

The occurrence of a problem must always be recorded, the corrective actions to correct the problem and the actions to be taken with the affected product, with the purpose of setting up a file containing all this information in an organized manner.

The ongoing analysis of the corrective actions may lead to determine the cause of recurring problems and establish modifications that ensure a better control, for instance:

- Changing the process or flow of the product.

- Modifying the QAP.

The program must describe all the corrective actions that avoid the production of a defective product and those that may be established to return the process to control.

2.1.11. ESTABLISHING VERIFICATION PROCEDURES (PRINCIPLE 6)

The verification consists of the periodical review procedure executed by the establishment to prove the correct operation of the program.

This verification must be carried out by the personnel specifically appointed for this task.

Daily, periodical and complete verifications must be included when programming and executing verification procedures:

Daily verification

Corresponds to the daily review of the records and monitoring procedures for each CCP and any other related records. This means that the person in charge of carrying out these verifications must confirm the proper performance of the person in charge of the monitoring process and that the measurements have been correctly recorded, as programmed.

As a proof of this daily verification, the person in charge must sign the records when reviewing them, including the date in which it took place.

Periodical verification

These verifications may include random samplings, product analyses, and other necessary checks to ensure that the CCPs are under control. It must be mentioned that these verifications must include the control of the end product.

In this verification, the name of the laboratory accredited by the INN conducting the analyses must be informed, as well as the sampling plans and the sanitary requirements described in the chapter Definition of Products for the company's Quality Assurance Program.

The end product verification must take place in a no longer period than 15 days of processing (consecutive or accumulative, depending on the production), with a minimum sample size of 5 (except when the regulations require something different, for instance with contaminants for the European Union). (M.05.01.18)

After a year of periodical verifications to the QAP with ongoing production (at least 15 results for periodical verifications), the company may request SERNAPESCA to reduce the frequency of this procedure, to the extent that the results can justify this decision. If after this any of the following situations is detected, SERNAPESCA may request the company to return to the bi-weekly frequency:

- Unfavorable results in product verifications.
- Change of category to C, D or NC. (M.08.02.18)
- Not issuing the Authorization at Origin for Sanitary Certification (AOSC) because a category Rejected was assigned to the QAP.

Chilled-refrigerated products must also be considered in this verification, using the parameters and standards established for frozen products described in Section III, Chapter IV, Item 1 "Sanitary Requirements and Sampling Plans for the Sanitary Certification of Export Fishery Products" and Section III, Chapter IV, Item 2 "Sanitary Requirements for the Certification of Export Fishery Products in accordance with Destination Markets," when it is related to the destination market.

Fishery establishments with QAP Certification do not need to carry out the physical-organoleptic evaluation with a laboratory authorized by SERNAPESCA prior to shipment (at the airport). The verification procedure for temperature and organoleptic conditions will be under the full control of the establishment, as described in its QAP.

Taking into account that verifications are a system to prove the effectiveness of a Quality Assurance Program and that they do not provide support for an export batch, the sampling plans by establishment category described in Section III, Chapter IV, Part 1 have not been considered for this purpose, instead the sampling plan for a Category A establishment has been considered; for instance, for frozen raw fish, the standards for *E. coli* would be m=100, M=500 and the sampling plan n=5, c=3.

The procedures to be followed by the company if the results of the verifications of the end product are unfavorable must be clearly stated in the program. These procedures must include the investigation of the cause of the problem, which must also be recorded. The cause of the deviation in the parameters to be controlled must be reflected in the QAP records system.

In the case of manufacturing establishments, the level of the information collected may be limited to that provided by the company owning the products.

It must be noted that as part of a SERNAPESCA supervision process, it has been established that the verifications regularly considered in the QAP for each plant or factory ship will be sent to a Verification Laboratory of the Service (see Item 1.4 of this Chapter).

In the case of periodical verifications, all the analyses for heavy metals (lead, cadmium, mercury), histamine and melamine may be excluded, except for certain products in which the analyses must be made based on the following:

Table: *Analyses that must be applied per product*

Product	Analysis
Bivalve mollusks	Cadmium
Lobster, albacore, cod, cuttlefish, and hake (austral, gayi, etc.)	Mercury
Cupleidae, scombridae and jack mackerel by-products.	Histamine

For QAPs that consider the Eurasian Economic Union as the destination market for products manufactured in the establishment, the heavy metals analyses must be conducted on a monthly basis and the histamine analysis every two weeks.

Notwithstanding the aforementioned, the periodical verifications that take place in the Verification Laboratory of the Service must consider all the heavy metals, histamine and melamine analyses, accordingly.

Samplings and analyses for dioxins/PCBs control must be conducted on a yearly basis and will be mandatory for all the production lines of the establishments with QAPs. The sampling plan considers the collection of 10 samples and 1 analysis for all export fishery products, except for fish meal and oil, whose procedure and sampling n is described in Part II, Section IV, Chapter II of this Manual.

Complete Verification

Corresponds to a full review of the QAP that involves conducting hazard analyses in all operational steps, such as during the initial development phase of the program. This type of verification must take place at least once a year and whenever any of these situations arise, including:

- The existence of a product suspicious of transmitting a disease.
- Failure to comply with the established criteria.
- Use of new ingredients.
- Change in the shape of the ingredient.
- Change in the process (temperature, time).
- New potential hazards:
  - New pathogens.
  - New environmental contaminant.
  - New methods to control an existing hazard.
- Changes in the design of the process.
- Change in the type of consumers or in the way of consuming the product.
- Obtaining an unfavorable product verification result

This verification requires the arrangement of a meeting with the work team.

In addition, the complete verification must consider the analyses of the data collected throughout the year. Within the analysis, it is necessary to include the review of the information collected (CCP, SOP, or others) and the information on the results of the periodical verifications (product, water, surfaces, and handlers). With this information, conclusions must be made on the used monitoring procedures, to evidence the need to restructure the program or to continue with the current one. If the latter is the case, this decision must be supported and evaluated by SERNAPESCA.

All of the above must be presented as a report, indicating at least the results and conclusions. This report must be reviewed and approved by Management.

The personnel in charge of conducting the verifications must have the necessary knowledge and training for its optimal design. Management must guarantee that the staff has the necessary independence and authority to carry out their duties.

In the company's organizational chart, ideally, the staff in charge of the verification will report directly and exclusively to Management.

The work team must write a periodical report addressed to Management with the result of the daily and periodic verifications, and it must sign it as a proof of its review.

2.1.12. SETTING UP THE DOCUMENTATION AND RECORD SYSTEM (PRINCIPLE 7)

To apply an HACCP system, it is vital for it to have an efficient and accurate record system. The HACCP system's procedures must be documented, and the documentation and records systems must adjust to the nature and scope of the operation in question and must be sufficient to prove that the HACCP controls are carried out and maintained. Instructions on the HACCP system provided by experts (for instance, HACCP guidelines specific for a sector) may be used as part of the documentation, to the extent that such instructions refer specifically to the food production procedures of the interested company.

The following, among other information, must be documented:
- Hazard analyses;
- Determination of the CCPs;
- Determination of the critical limits:
- Procedures for non-compliant products; and
- Verification procedures.

For each critical control point records that prove the execution of the monitoring procedures, corrective actions and verifications must be designed so as to keep track of the product in all the stages of the program.

The objectives of the records system are the following:
- Document the results of monitoring activities.
- Document the corrective actions applied.
- Document the verification procedures.
- Trace the product with documentation.

The records may be of different type and must be as simple as possible; forms or records that are already used in the establishment may be adjusted, to the extent that they provided the required information. The records must be readily available and kept in an efficient and orderly manner, these may be combined in one form to avoid the excess of forms, to the extent that it is practical for the person in charge of the monitoring process.

A number must be assigned to the forms by the company prior to their use, and they must include the name and address of the establishment (this applies to all forms and not only to those associated to a CCP).

The program must include a systematic analysis of these records. The correct review of the records developed in the program will help management to determine if there are any unwanted trends, where and how to avoid their recurrence.

The types of records that can prove that the CCPs are being controlled are:

Critical Control Points Monitoring Records

These records must include all the specific information needed to inform the results of the controls established in each CCP. The critical limit must be included in the monitoring record as an ongoing warning for the examiner or observer. The information on the systematic error of the instrument

used for the measurement may also be included, calculated in the contrasting procedure, as a warning for any possible deviations on the monitored variables. The records must be designed so as to allow the collection of information under the same terms of the monitoring process, this is, complying with the frequency, the number of samples, variables to be recorded, etc.

The records of the CCPs must include at least the following information:

- Title.
- Name and address of the establishment.
- Identification of the traceability lot.
- Time and date of the monitoring process and other information (times and dates), as appropriate.
- Identification of the product being monitored.
- Quantity of the product involved in the control lot.
- Data collected.
- Critical limits for the controlled points.
- Sampling plans.
- Monitoring frequency.
- Signature, name or initials of the monitor.
- Signature, name or initials of the person reviewing the documentation.
- Start and end time of the process, as appropriate.
- Interruptions in the process.
- Review date.

Records on Corrective Actions and Unforeseen Situations

The records on corrective actions are only used when deviations to the critical limits are detected through the monitoring process. They indicate the actions that were taken to correct the detected problems. They can also provide complementary information for the other processing records used on a regular basis. They can also be used to record unforeseen, incorrect or unacceptable events, from the point of view of safety, wholesomeness or economic fraud.

The corrective actions taken given any deviations in the critical limits controlled in the critical control points may be recorded in the corresponding CCP records, and an additional record is not required.

The records for corrective actions or unforeseen situations must include at least the following information:

- Time and date of the event.
- CCP involved.
- Deviation of the critical limit.
- Corrective action taken.
- Maintenance conditions for the affected product.
- Disposal of the affected product.
- Personnel responsible.
- Review of the effectiveness of the corrective action.
- Other comments.

Verification Records

Are those records that prove that the verifications of the program are made and include their reports and results.

Production Days Logs

The record system of the establishment must clearly describe the shifts or production days, per production line, with the purpose of underpinning the absence of records for those days and shifts without production and count the days in the process for the end product verification. For this, the following model is suggested:

Folio: N° 000000

PROGRAMA DE ASEGURAMIENTO DE CALIDAD

Planilla de Días Productivos

Establecimiento: Mes:

Línea de elaboración:

DIA	Clave / lote	PCC1	PCC2	PCC3	PCC4	PCC5	PCC6	Empaque	Despacho	N° Día Productivo	Laboratorio	
											Privado	Verificac
01												
02												
03												
04												
05												
06												
07												
08												
09												
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Figure : Production days log model.

Production days or processing days are those where products are handled, regardless of the processing method.

In addition, the establishment must keep another type of record to control and evaluate the production process; these include, among others:

a) Records involved in the Prerequisites Programs
b) Control records for manufactured product stock.
c) Sanitation Program Records.
d) Time and temperature logs for the cold containers storing the end product.

The records must be filed for at least two years. This period will be of four years for canned products.

2.1.13. VALIDATION

Validation is an activity that is conducted separately from verification and prior to the start-up of the HACCP system, or that is applied whenever necessary (for instance, given changes in the process, changes in supplies, new products, etc.). The purpose of the validation is to ensure that the hazards that were originally identified by the HACCP team have been completed, corrected and are effectively controlled under the proposed plan. To comply with the objectives of the validation, it is necessary to review the effectiveness of the scientific evidence used for developing the HACCP plan, as well as the control measures, the monitoring system, and the corrective actions.

The validation will take place by proving that:

- The list of hazards associated with safety is complete and is based on reliable scientific evidence;
- The questions asked to evaluate the significance of the hazards were answered using reliable scientific evidence and consistent criteria;
- The preventive control measures are appropriate for controlling the hazards, for example, they are *ad hoc* to prevent, eliminate, reduce or maintain a hazard at an acceptable level.
- The fluctuations of the control parameters are kept within the critical limits defined;
- The parameters and methods used to monitor the preventive control measures are appropriate;
- The corrective actions are appropriate and must avoid the release of unsafe products, and also prove that the situation can be corrected immediately.

It is important to note the role that the industry and the Competent Authority plays in the validation of control measures. The industry is responsible for the validation of control measures, while the Competent Authority ensures that the industry has efficient systems for the validation and that the control measures are duly validated.

The validation focuses on the collection and evaluation of scientific, technical and observation information to determine if the control measures are or are not capable of achieving their specific objective based on the control of hazards. The validation takes place when designing a control measure or when the changes that occurred indicate the need of a revalidation. In consequence, the validation of the control measures must take place before they are fully applied.

The concepts of validation, monitoring and verification tend to be confused. The validation of control measures is different from verification and monitoring since the last two take place after the application of the validated control measures. Monitoring and verifications are tools used to check if the control measures are compliant and to prove that they operate as expected.

All the information used to conduct the validation must be available for inspection.

Tasks to be carried out prior to the validation of control measures

Before validating the control measures, it is important to carry out certain tasks so that the validation can take place in an effective and efficient manner. The following are some examples of these tasks:

- The identification of the hazards that must be controlled in the product and in the specific environment.
- The identification of the required result in terms of food safety.
- The identification of the control measures that must be validated.
- If the control measure has already been validated.
- The priority assigned to the validation, taking into account the harmful effect on health, the historical experience, constraints, among others.
- Capacity to monitor and confirm the control measure.
- Scientific, technical and resource-related viability.
- Resources

VALIDATION PROCESS

There are several methodologies that can be used for the validation process, which depend on the nature of the raw material and the product, the type of control measures selected to control the hazard and the strictness of the control.

a) Validation methodologies for control measures

- References from scientific or technical journals, previous validation studies, or historical knowledge on the operation of a control measure.
- Scientifically validated experimental data that prove the suitability of the control measure (laboratory tests, tests in pilot plants, among others).
- Collection of data during regular operation conditions of the food production process.
- Mathematical models.
- Surveys.
- Information from the Competent Authority and/or references from international organizations.

b) Stages of the validation process

- Define the methodology or a combination of methodologies to be applied.
- Define the criteria and decision parameters to prove that a control measure of a combination of control measures are capable of constantly controlling a hazard with an expected result.
- Gather the relevant information for the validation and conduct studies as needed.
- Analyze the results, and
- document, record and review the validation.

c) Validation results

If it is demonstrated that the control measure or a combination of control measures:

- Are capable of controlling the hazard with the expected result; they may be implemented if applied correctly.
- Are not capable of controlling the hazard with the expected result, they must not be implemented; which can lead to re-evaluating the formulation of the product or the parameters of the process.

- Leads to a greater reduction than necessary to control the hazard, it is feasible to adjust the frequency of the planned verification.

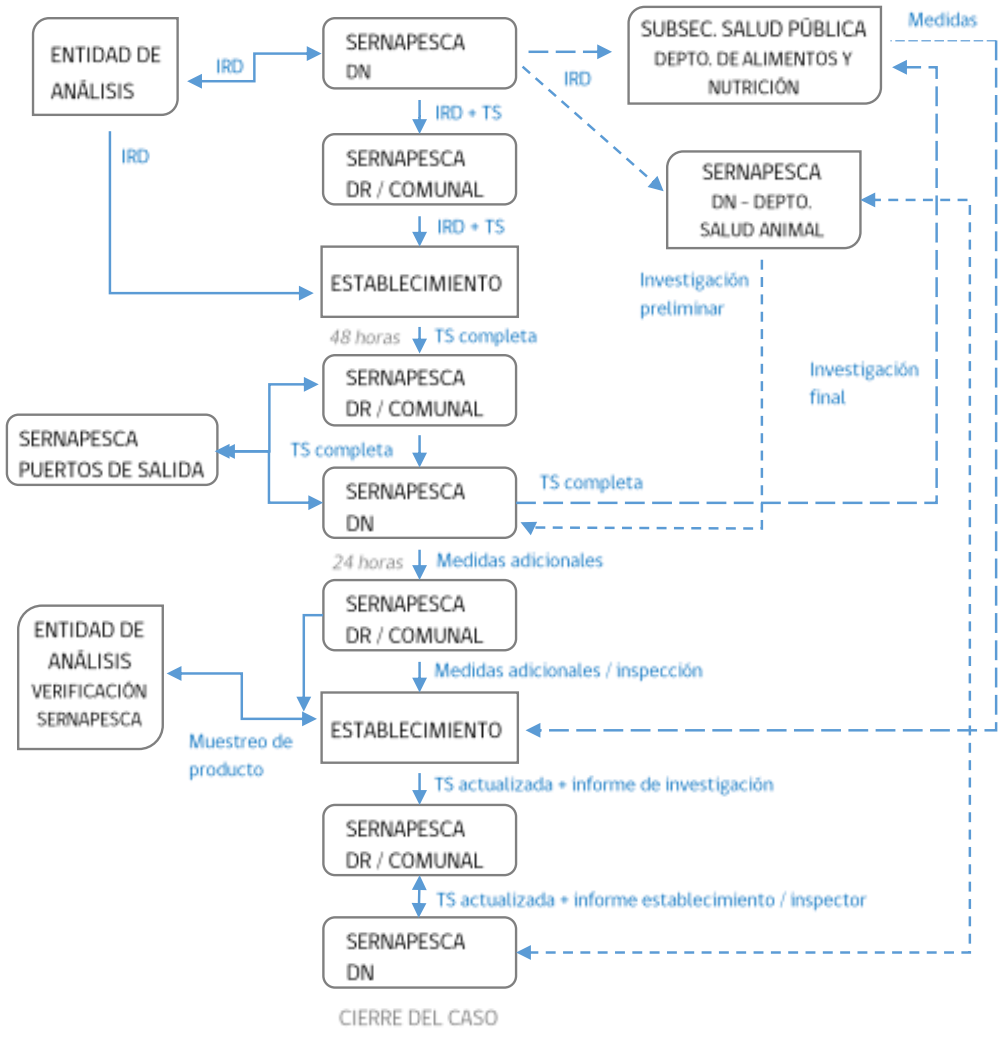
The theoretical document must include the list of supporting documentation, which will be verified on site. The following are examples of supporting documentation, in addition to what is indicated in the previous paragraphs:

- Bibliography that supports the most common hazards in the type of process/resource.
- Bibliography or studies that support the critical limits to be used.
- Shelf life studies, as appropriate.
- Water refilling studies.
- Calibration certificates.
- Heat processes reports.
- Studies on the concentration or dilution of contaminants.

BACK TO TOP

CHAPTER III. PROCEDURE FOR NONCONFORMITY OF FISHERY AND AQUACULTURE PRODUCTS FOR EXPORT.

1. PROCEDURE FOR THE CONTROL AND FOLLOW-UP OF UNFAVOURABLE RESULTS DETECTED IN VERIFICATION EXPORT PRODUCT



1.1 PROCEDURE AND INFORMATION FLOW

In case of unfavourable results in PAC verifications, or monthly verification under the Residue Control Program, the following procedure must be followed:

1) The notifying analysis entity shall submit the Unfavourable Result Report (IRD, its abbreviation in Spanish) (format available in Part III Annexes, Chapter II) via e-mail to an existing distribution list including the members of the PSMB team, Process Control, Residue Control and Laboratory Control, Head of Unfavourable Management in the Foreign Trade Subdirectorate at National Headquarters.

   In turn, the analysis entity must copy the e-mail to the processing facility, which must be received simultaneously by SERNAPESCA.

2) Upon receiving the IRD from the analysis entity, the administrator of the processing facility shall trigger the procedures established in these cases in their PAC document, which considers actions such as suspending the eventually affected product (production period of unfavourable product and raw material from farm of origin) for involved market(s), notifying clients (i.e. exporters, importers at destination, distributors in national markets, other manufacturing and/or processing facilities, etc.), follow-up of involved product (traceability), triggering the recall procedure. (M.08.2.18)

   At this point, the facility must indicate its intention regarding the affected product, releasing it by means of a laboratory analysis (except manufacturing dates or previously analyzed products) or applying and maintaining an export suspension to corresponding destination markets. If the first option is chosen, the facility must coordinate the inspection of this sampling procedure with the SERNAPESCA official. It should be noted, that the sampling option for release does not apply in case of unfavorable residues of pharmaceutical products, contaminants, prohibited and / or unauthorized substances. (M.08.02.18)

   In any case, a case investigation is mandatory to detect the cause and apply prevention or corrective actions or others that may apply.

3) The Manager of Unfavourable Results or acting Manager, in parallel, must assess the information on the IRD against the standards set in Section II Part III of the Safety and Certification Manual, and if it actually applies to an unfavourable result, confirm the reception to the relevant laboratory, copied to the team in charge of Laboratory Control. On the contrary, the Manager shall notify this team regarding the non-conformity submitted by the analysis entity.

   The unfavourable results, will be valid for all those markets, that apply the same requirements, for which the unfavourable was trigger. (M.09.03.18)

4) The Manager in charge of Unfavourable Results shall:
   a. Enter the IRD information to the Master Spreadsheet[1], located in the Unfavourable Repository.

[1] This record applies to any unfavourable result, without prejudice of the subsequent assessment.

b. Create the unfavourable file, where the information related to the case shall be stored. Its name shall follow the following format:

IRD Date [dd-mm-aaaa]	-	Facility Code	-	Facility Name	-	Unfavourable Parameter

5) The Manager of Unfavourable REsults shall immediately submit the following files via e-mail to the Inspector in charge of the facility:
   a. Unfavourable Results Report (IRD).
   b. Table format for the Follow-up of Unfavourable Analysis (TS) (refer to Part III Annex, Chapter II).

   This e-mail notification shall be copied to:
   - Head of Foreign Trade Subdirection of the relevant regional/comunal office,
   - Process Control Team, National Headquarters, and
   - PSMB and/or Residue Control Program, National Headquarters, where appropriate.

   In case of an unfavourable results for residues, the Foreign Trade Department at Headquarters shall notify the Animal Health Departament under the Aquaculture Subdirection, in accordance with Section I, Chapter II, item 2.3. As per this Section, such Department shall perform an investigation to determine the eventual causes of the event, applying the procedures established to this end.

   If the result obtained in the analysis does not meet the requirements established by the Food Sanitary Regulations (RSA), the person in charge at National Headquarters must send a copy of said results to the Food and Nutrition Department of the Undersecretary of Public Health, in accordance with the agreement between both institutions.

6) The SERNAPESCA Inspector responsible for the supervision of the processing facility, or its designated replacement, in turn must forward by e-mail, attachments, the IRD and the TS format to the processing facility consigned in the report. This communication shall also indicate that the maximum deadline for delivery of said information to SERNAPESCA is 48 hours.

7) The manager of the processing establishment must send the requested information to the Local SERNAPESCA inspector, within the period above mentioned. In order to facilitate the collection of the information required in the Monitoring Table (TS), the company can generate information from their own systems or computer applications, which must be delivered in an Excel file and contain at least the information which is currently included in the TS format. This file must be reviewed and accepted by the inspector in charge of the establishment. (M0.9.03.18)

   The TS or Excel file created by the establishment (M0.9.03.18) must consider the information of the products in all the presentations included in the PAC involved and, therefore, considered in the affected production period. In the case of an unfavorable result involving waste, any raw material received and processed from the involved farm must be considered. The above also applies to the products, by-products and / or waste originating from the farm and provided to a processing plant.

In the case of PSMB (marine toxins and heavy metals) the harvesting area and dates must also be considered.

8) The inspector, after receiving the information, must verify that the submitted TS or Excel file created by the establishment, contains all the required information and that it has been completed in an appropriate manner. If this is not the case, the issuance of AOCS to the establishment shall be suspended as of that date; if the situation is maintained and there are finding that indicate that The Trazability Program does not work properly, the establishments will be qualifies with a critical deficiency, leaving the QAP in category Rejected. (M0.9.03.18)

   The information must be entered in the Unfavorable Repository, attaching the information contained in the TS or Excel file created by the establishment to the unfavorable file, and notified to the shipment ports. (M0.9.03.18)

9) SERNAPESCA officials in charge of certification at the ports of departure of the company's shipments, must verify the pertinent information in the Unfavorable Repository indicated via email by the facility inspector. In particular, the one related to the NEPPEX export document stating whether certification has been requested and, if so, specifying if it was issued, the type of certificate and if it was already delivered to the exporter, additional data that must be entered into the Repository in the relevant case file.

   The deadline to carry out these actions is 24 hours from the notification of the unfavorable result to the ports of exit. This information will be used as an input for the technical assessment of the case.

   When appropriate, the Manager of Unfavorable Results at National Headquaters shall send a copy of the TS or Excel file created by the establishment to the Department of Food and Nutrition of the Undersecretary of Public Health, in accordance with the agreement between both institutions, to indicate the location of the product. (M.09.03.18)

10) The inspector of the processing facility, or its appointed replacement, and the technical assessment team created at National Headquarters will jointly assess the risk of the unfavorable result with respect to the product.

    To this end, they will consider, among others, the information contained in the TS or Excel file created by the establishment, and in the facility's PAC. In the case of unfavorable results related to waste, it will also include preliminary information regarding the investigation carrried out by the Department of Animal Health. (M.09.03.18)

11) The Sub-Directorate of Foreign Trade at National Headquarters shall submit the result of the technical assessment carried out within a maximum of 24 hours from the receipt of the information provided by the processing facility. Notwithstanding the above, should new information arise, the term for the technical evaluation will be renewed for a new period of 24 hours, or more if necessary. Likewise, this term will not be applicable if SERNAPESCA considers that the information delivered by the processing facility is incomplete.

    As a result of the technical assessment, additional and/or complementary measures may be applied to such measures that have already been established by the facility, and determine whether they apply only to the manufacturing date involved, to the entire product across the

period covered by the unfavorable verification or only to certain products. In addition, the measures to be taken with respect to the processing facility shall also be indicated.

This decision must be communicated by the Subdirection of Foreign Trade at Headquarters via email to the Inspector responsible for the supervision of the facility. Such Subdirection shall submit the assessment result within a maximum of 24 hours from the reception of the information provided by the facility. Notwithstanding the above, should new information arise, the term for the technical evaluation will be renewed for a new period of 24 hours, or more if necessary. Likewise, this term will not be applicable if SERNAPESCA considers that the information delivered by the processing facility is incomplete

12) The SERNAPESCA Inspector, or his/her designated replacement, shall be responsable for informing the Company regarding such decision, follow-up and enter the information in the Unfavourable Results Repository.

13) The facility, in accordance to provisions established by SERNAPESCA, and once implemented, shall complete a new TS or create a Excel file with the suspended manufacturing date and keep track of the involved products. (M.09.03.18)

The Company shall keep records (copy of NEPPEX, certificates, etc.) ensuring that the total amount of affected products was traded in markets other than those to which they were restricted.

Updated information must be recorded by the SERNAPESCA Inspector in the Unfavourable Results Repository.

14) The responsable Inspector shall inform the Subdirection of Foreign Trade at National Headquarters regarding the follow-up performed in the field and shall provide an investigation report to close the case. The case shall be closed jointly between the Inspector, or a designated replacement, and the Manager of the Unfavourable Results at Headquarters. The Local SERNAESCA Inspector will inform the close of the case to the establishment. (M.09.03.18)

The research report shall be recorded in the Unfavourable Results Repository by the Inspector, together with the last TS version or the Excel file created by the establishment, , complemented by the decision of the Department of Food and Nutrition of the Public Health Under-Secretariat, if applicable. (M0.9.03.18)

1.2 REGARDING THE INVESTIGATION, ITS REPORT AND MEASURES TO BE APPLIED

1.2.1 REGARDING THE FACILITY

Measures and/or actions to be applied

a. In case of a product eventually affected during voyage or upon arrival at destination, the Company shall perform a recall, where appropriate.

b. The eventually affected product stored in the country or about to be shipped, shall not be intended to the unfavourable market not those with restriction, until demonstrating compliance with the requirements of the destination market.

Investigation Report

For the purpose of this investigation, the facility must issue a report in PDF format, at least containing the following information:

a. Details of products involved in unfavourable result. In case of shellfish, gasteropods, tunicates or equinoderms, the harvesting date and area must be included. In the case of harvested fish, the cage, farm, harvesting date, assurance declaration and related documents, with relevant background information, must also be included.
b. Assessment of information held by the facility to establish the origin of the unfavourable result.
c. Result of the PAC verification.
d. Corrective and preventive actions adopted by the facility to avoid a the repetition of the unfavourable result.
e. Measures adopted by the facility with regards to the eventually affected product.

1.2.2 REGARDING REGIONAL, PROVINCIAL OR COMMUNAL SERNAPESCA OFFICES

The SERNAPESCA Inspector responsible for the supervision of the processing establishment will be in charge of coordinating and making the follow-ups for the technical evaluation process and its subsequent application. As a summary of the measures developed and actions taken, the Inspector must update the report of the case in the Unfavorable Repository.

Measures and/or actions to follow

a. As of the start of the unfavorable event, and during the technical assessment period, the issuance of shipment notifications, certificates and documentation to qualify for the sanitary certification of the products involved in the production period linked to the unfavorable verification (M.08.02.18), shall be suspended. In the case of unfavorable pharmaceutical waste, such measure shall apply to all products originating from the same farm. The duration of this period will depend on the company's response times and the deadlines established in this procedure.

b. If the processing facility does not submit the information within the established deadlines or if such information is not satisfactory, the facility shall immediately qualify as having a critical deficiency, on account of a deficient Traceability Program. The Inspector in charge, or his appointed replacement shall notify the deficiency in writing to the facility as soon as possible and inform the PAC IV classification as of such date, as well as the consequences implied.

c. In case the decision of technical evaluation team involves a sample of the verified manufacturing dates involved in the production period (except for the manufacturing date of the affected products), the analysis must be carried out in a SENAPESCA Verification Laboratory, accompanied by the relevant FEM by manufacturing date, indicating in the Observations field that it consists of a complementary sample related to an unfavorable verification. (M.08.02.18)

   Therefore, the relevant FEM and TS shall be available for both samples, allowing for the release or suspension of product intended for export. The updated information must be entered by the SERNAPESCA Inspector in the Unfavorable Repository.

It should be noted that in the case of an unfavorable residue result, release sampling shall not be carried out for the same place of origin.

d. Once the results of laboratory analysis have been obtained, and following their assessment, the manufacturing dates involved in the unfavorable event may be released or maintained suspended. The manufacturing dates with favorable results may be released and may be deducted from the stock indicated in the TS. The above shall be complemented with the determination by the Food and Nutrition Department of the Undersecretary of Public Health.

This information must be consulted at all times by officials at the ports of exit, by checking the Repository of Unfavorable Events.

Research Report

The SERNAPESCA Inspector shall prepare a research report considering the various aspects involved during a follow-up of unfavourable events and lifting non-conformities.

1.2.3 REGARDING SERNAPESCA HEADQUARTERS

Measures and/or actions to be followed

a. SERNAPESCA may notify the Competent Authority of the destination market(s) involved, following 5 days since the Sernapesca Inspector, or his/her replacement, has informed the unfavourable result to the processing facility and the facility has not delivered satisfactory information and/or has not carried out actions to withdraw the product or return the original sanitary certificates involved.

1.3 SPECIFIC ACTIONS IN CASE OF UNFAVOURABLE RESULTS

In addition to the procedures and general actions in case of an unfavourable result set forth in ítems 1.1 and 1.2 above, additional actions must be considered in case of repetition and depending of the parameters involved.

1.3.1 ACTIONS TO BE TAKEN WITH THE FACILITY IN CASE OF UNFAVOURABLE RESULTS

The frequency of unfavourable results submitted by a facility shall be assessed considering a time frame of 8 consecutive verifications in order to determine complementary actions to be applied.

a. First unfavourable result
   - The following verification of the challenged manufacturing line must be sent to the SERNAPESCA verification laboratory.
   - A comprehensive PAC verification must be made.
   - If the facility is making monthly verifications, the frequency must change to every fornight.

b. Second unfavourable result in the assessed period
   - The first actions are repeated.
   - The deficiency is considered serious.

c. Third unfavourable result in the assessed period

- The first actions are repeated.
- The deficiency is considered critical.

d. In case of repeated events of non-compliance of specific market requirements, this condition shall be assessed until the facility provides assurance of solving the cause of such unfavourable results.

1.3.2 UNFAVOURABLE RESULT IN PRODUCT VERIFICATION FOR RISK OF MARINE TOXINS

The presence of marine toxins at sub-toxic and toxic levels in a product shall be understood as unfavourable.

a. Presence of marine toxins at sub-toxoc levels in products:

Table *Definition of marine toxins at sub-toxic levels in a product*

Parameter	Limit
Paralytic Shellfish Poison (PSP)	≤ 80 µg/100 g
Amnesic Shellfish Poison (ASP)	≤ 20 y > 0,5 µg /g
Toxins of lipophilic group (instrumental analysis LC-MS/MS)	
Summative okadaic acids (OA), dinophysis toxins (DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2)	≤ 160 µg equivalents of okadaic/kg acid in flesh (whole body or any eatible separate part).
Summative of yesstoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX)	> 1,9 y ≤ 3,75 mg equivalents of yesotoxins/kg in flesh (whole body or any eatible separate part).
Summatory of azaspiracids (AZA1, AZA2 and AZA3)	≤ 160 µg equivalents of azaspiracids/kg of flesh (whole body or any eatible separate part).

These cases trigger the following actions in accordance with section 1) above:

- The product must be immediately suspended for consumption, notifying the corresponding Health Service.
- Depending on the background provided by the company, samples from the entire products manufactured from the date of the last favorable result, until the date of appearance of the toxin may be requested. The disposal of the product will depend on the results. If the result is sub-toxic, the product shall be released, otherwise, if the detected value is toxic, notification will be given to the corresponding Health Service.
- Proceed as indicated in the contingency plan for these events (refer to Section I, Chapter I).

b. Presencia en producto de toxinas marinas en niveles tóxicos:

Table *Definition of toxic levels of marine toxins in products*

Parameter	Limit
Paralytic Shellfish Poison (PSP)	> 80 µg/100g
Amnesic Shellfish Poison (ASP)	> 20 µg/g
Toxins of lipophilic group (instrumental analysis LC-MS/MS)	
Summative okadaic acids (OA), dinophysis toxins	> 160 µg equivalents of okadaic acid/kg of flesh

(DTX1 and DTX2) and pectenotoxins (PTX1 and PTX2)	(whole body or any separate eatible part).
Summative of yesstoxins (YTX, homo YTX, 45 OH YTX and 45 OH homo YTX)	> 3,75 mg equivalents of yesotoxins/kg of flesh (whole body or any separate eatible part).
Summative of azaspiracids (AZA1, AZA2 and AZA3)	> 160 µg equivalents of azaspiracids/kg of flesh (whole body or any separate eatible part).

These cases trigger the following actions in accordance with section 1) above:

- The product must be immediately suspended for consumption, notifying the corresponding Health Service.
- Depending on the background provided by the company, samples from the entire products manufactured from the date of the last favorable result, until the date of appearance of the toxin may be requested. The disposal of the product will depend on the results. If the result is sub-toxic, the product shall be released, otherwise, if the detected value is toxic, notification will be given to the corresponding Health Service.
- Proceed as indicated in the contingency plan for these events (refer to Section I, Chapter I).

1.3.3 UNFAVOURABLE RESULT IN PRODUCT VERIFICATION FOR RISK OF RESIDUES IN PHARMACEUTICALS, CONTAMINATING, PROHIBITTED AND/OR UNAUTHORIZED SUBSTANCES

An unfavorable result shall be understood as the presence of residues of pharmaceutical products, contaminants, prohibited and / or unauthorized substances in limits that exceed the highest restrictive market standard described in the facility's PAC.

a. First unfavorable result in a product
- The SERNAPESCA Office under whose jurisdiction the establishment is located shall assess the quality of the corrective action of the establishment on the basis of the timeliness of investigation carried out, monitoring and disposal of the affected product, and the information provided to the client.
- Products from the same farm of origin shall be provided during the following verification.
- If the establishment does not perform the corrective actions, or if the assessment do not consider at least the actions indicated above, it may be considered as a Critical PAC deficiency.

b. Second unfavourable result in a product

- The SERNAPESCA Office under whose jurisdiction the establishment is located shall assess the quality of the corrective action of the establishment on the basis of the timeliness of investigation carried out, monitoring and disposal of the affected product, and the information provided to the client.
- Products from the same farm of origin shall be provided during the following verification.
- If the establishment does not perform the corrective actions, or if the assessment do not consider at least the actions indicated above, it may be considered as a Critical PAC deficiency.

1.3.4 UNFAVOURABLE RESULT IN DISPATCHED PRODUCT

When an affected product that has already been exported, and as a result of a product verification an unfavorable result is reported above the standard of the destination market, the processing company, owner and / or exporter of the product, as the case may be, shall be responsable for the recovery of the product.

The processing establishment is also responsible for providing SERNAPESCA with all the necessary information related to the recall or recovery of the product, as established in Section 5.2 of Chapter I.

In these cases, the actions indicated in this Chapter concerning unfavourable results in product verifications shall also be triggered.

2. PROCEDURE FOR HANDLING NON-COMPLIANT EXPORTED FISHERY PRODUCTS NOTIFICATIONS FROM DESTINATION MARKETS

The following procedure must be conducted every time an alert that affects export fishery and aquaculture products is issued. An alert will be understood as the occurrence of an unfavorable situation detected by a Competent Authority (CA) of a destination market, whatever its form and mode of communication.

If the company (processing establishment or exporter) involved is informed of the alert before it is informed by the CA at the destination, it must immediately report the situation to SERNAPESCA. The failure to inform the alert will lead to the suspension of the shipment authorizations and/or certifications until the situation has been clarified. Also, if the processing establishment has a Quality Assurance Program (QAP) in place, the situation will be considered to be a Serious or Critical deficiency in its evaluation, considering the identification of a serious risk related food or feedingstuffs.

2.1 Procedure and Flow of Information

When an alert is issued from a destination market the following procedure must take place:

1. The National Directorate of SERNAPESCA will request additional information, as needed.

2. Once the notification is received, the National Directorate of SERNAPESCA will send an email with all the information associated with the alert, to which eventually more information provided by the CA, the Service or the establishment may be added. The notifications will be issued via email from the National Directorate to the person in charge of foreign trade of the office corresponding to the involved establishment, who must appoint an Inspector for the investigation. This, with the purpose of ensuring that the procedure will take place in the agreed terms and to avoid its delay if the officials that normally inspect the facilities are not available.

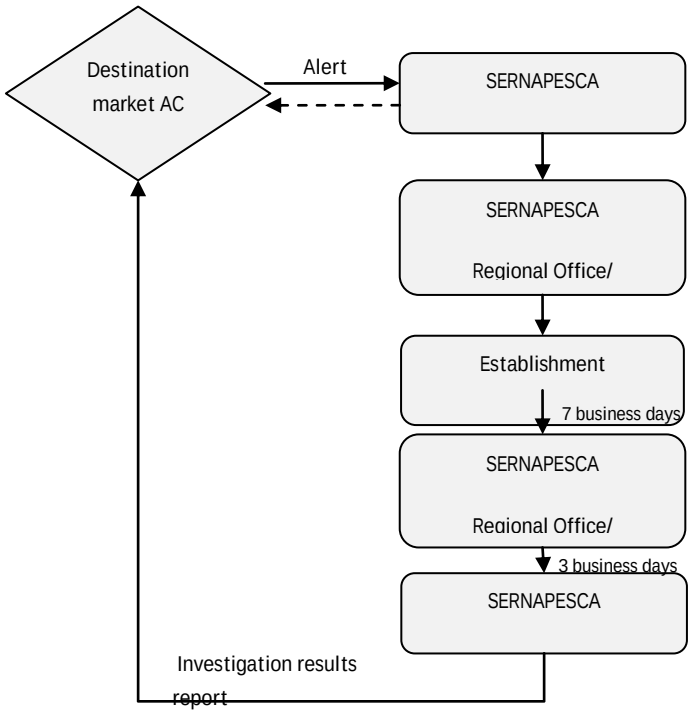


Figure 2: Flow of information related to alerts for export fishery and aquaculture products.

3. The Regional, Provincial or Municipal SERNAPESCA office must inform the involved establishment immediately about the alert received. Such communication may take place through the following available written means: email, fax or written notice.

4. The involved establishment must conduct an investigation within 7 business days from the date of issuance of the notification of the corresponding SERNAPESCA office, so as to determine the origin of the non-compliance in its products at the destination and establish any relevant mitigation actions and corrections.

5. The SERNAPESCA office under whose jurisdiction establishment is located must conduct an investigation including, among other aspects, an inspection of the involved establishment within 7 business days, to evaluate the measures being implemented.

6. The notified establishment must deliver, before the 7-day term, an investigation report, in its corporate format, and include at least the content described in the Manual for these purposes. The Inspector must review, analyze, and, if necessary, request the correction of the report to the establishment. The report must include information on the investigation carried out at the establishment, verifying the causes that triggered the event, the results of the analyses, etc.

7. The final version of the report, once approved by the corresponding official Inspector, must be signed and stamped by the company's management. If required by the markets, the company will be asked to provide a translated version of its report in the corresponding language.

8. The Inspector assigned to the case, of the SERNAPESCA office under whose jurisdiction the establishment is located, will write its report in the format "Investigation Report" available on the Service's website. It is necessary to verify that its content matches the information included in the report written by the establishment. This document must be issued to the National Directorate, signed and stamped by the official, scanned if possible in color, in PDF format, together with the report from the establishment, also scanned in color, in PDF format, and including any necessary annexes, within 3 business days from its delivery by the establishment.

9. The National Directorate of SERNAPESCA, if required by the CA of the destination market sending the notification, must send, within two business days from the date of approval of the information received from the involved SERNAPESCA office, the original report from the Inspector with the results of the investigation. Thus, it will include the corrective and preventive actions adopted by the establishment, and the measures adopted by SERNAPESCA to guarantee the compliance with the requirements established by the market. Similarly, SERNAPESCA may formally request to lift the restriction measures and for the establishment to be reincorporated as an authorized producer to export to the market in question, at the discretion of the CA at the destination.

10. If an alert notification for pharmaceutical products residues, prohibited substances, unauthorized substances or contaminants in products coming from farmed fish is issued, the Foreign Trade Sub-Directorate will inform the situation via email to the Animal Health Department of the Aquaculture Sub-Directorate, so that it can conduct the investigation for determining the possible causes of the event, applying the procedures set forth by this Department for these purposes.

2.2 ABOUT THE INVESTIGATION, ITS REPORTING, AND THE MEASURES TO BE APPLIED

2.2.1 ABOUT THE ESTABLISHMENT

Measures to be Applied

If products possibly affected during their transportation or at the arrival at destination have been found, the company must recall them, if the results of the evaluation prove so.

If the possibly affected products are stored in the country or are soon to be shipped, they must not be sent to the destination market issuing the alert neither to those that apply the same restrictions, until they have been proven to comply with the requirements of the destination market.

If the parameter in question corresponds to a direct risk to the health of the consumers, the product may not be sent to any markets.

Investigation Report

For the purposes of the investigation, the establishment must issue a report in PDF format, containing at least the following information:

- Detailed information on all the shipments sent to the destination market that issued the alert after the date of the shipment being questioned.
- If a sanitary certification has been issued, the establishment must provide the certificate number and attach its corresponding copy.
- Detailed information of the destinations of the products with the same production date, if only a part of them was part of the shipment that triggered the alert. In the case of bivalve mollusks, gastropods, tunicates or echinoderms, it must also include the extraction date and the place of origin. Similarly, for farmed fish, the cage, the farm of origin, the harvest date, and the declaration of guarantee with its supporting information must be provided.
- Review of the information that the establishment has and that allows defining the origin of the notified event. The establishments with a Quality Assurance Program (QAP), must review their associated risk analysis.
- Measures adopted by the establishment for the possibly affected product in the national territory.
- Corrective actions and preventive measures adopted by the establishment to avoid the reoccurrence of the unfavorable situation.
- Review of biweekly QAP verifications given possible unfavorable results associated with the product triggering the alert

2.2.2 ABOUT THE REGIONAL, PROVINCIAL, OR MUNICIPAL SERNAPESCA OFFICES

Guidelines for the Investigation

The SERNAPESCA Office under whose jurisdiction the establishment is located must conduct an investigation that includes the on-site verification of at least the following:

a. Last categorization and related observations.
b. Observations on QAP visits conducted during the production period of the product with problems at the destination.
c. Waiting conditions of the product during the process: type of product (filet, cuts, etc.), environmental temperatures and temperatures of the product, waiting times, waiting areas, stage of the process, etc.
d. Use of sanitizers in the elaboration of products.
e. Equipment maintenance program.
f. Implementation of research on water exchange (as appropriate).
g. Identification of cross-contact in products, clear definitions of clean areas and dirty areas.
h. Receptions from the slaughter plant: disposal of raw material, temperature, associated times (as appropriate).

Measures to be Applied

The following three shipments destined to the notifying market that include products from the establishment in question (already issued AOSC, but without being shipped, or AOSC to be issued, as appropriate) must be sampled through a SMAE (one per shipment), by production date (n=5), for the parameter that triggered the alert, and will only be authorized once the result is approved. When

the cause of the alert is the presence of injuries in farmed fish, pre-shipment inspections must be carried out instead of a laboratory analysis, with an authorized sampling entity, and will be authorized only if the sampling shows the absence of injuries all the evaluated pieces.

It should be noted that it is mandatory to complete the procedure for the three shipments indicated above, that is to say, sampling and export authorization against conformity of analysis, before requesting authorization to export to the notifying market for a fourth and subsequent shipment.

If a market calls the temporary restriction of export to an establishment, SERNAPESCA will suspend the shipment authorization to the notifying market from the date of communication. Based on the evaluation of each case it may be extended to other destinations.

In addition, the SERNAPESCA Inspector may request the execution, during this period, of a sampling of the affected and/or suspected to be affected product, located in the national territory, to be analyzed by a laboratory authorized by SERNAPESCA. The results will be informed directly by the laboratory to the involved establishment and to SERNAPESCA. The sampling must be conducted by an entity authorized by the Service, in the presence of the SERNAPESCA Inspector, and considering n=5 per production date.

Investigation Report

The content of the Inspector's report must reflect the work conducted by himself together with the company to arrive at the determination of the cause of noncompliance with the notified shipment, the visits, therefore, carried out, and the on-site verification together with the approval of the applied corrective measures.

The report written by the inspector will be sent to the Competent Authority of the notifying destination market, therefore, due to the differences in their languages and systems, the following guidelines must be considered:

- Avoid the use of acronyms, and whenever used indicate their meaning between parentheses.
- Write in a simple and clear manner.
- Provide, through the content of the report and the measures adopted, the sanitary guarantees required by our Service and the destination market.

It must be noted that it is necessary to conduct a follow-up and an evaluation of the preventive measures and corrective actions implemented by the establishment over time.

2.2.3 ABOUT THE NATIONAL DIRECTORATE OF SERNAPESCA

The National Directorate of SERNAPESCA, based on the information on the case, specifically regarding the direct risks to the health of the consumers, and the information contained in the investigation reports, may require taking the following actions, among others:

a) For establishments with a QAP
   - The establishments that conduct monthly verifications must go back to conducting them on a biweekly basis.
   - The establishment subject of the alert must conduct a complete verification of its QAP.

- The establishments that do not comply with the terms set forth will be assigned a category IV.
- SERNAPESCA may suspend the authorization to export to the processing establishment, if:
  - The parameter informed corresponds to pathogens, toxins or other situations of serious risk for consumers.
  - It is determined, as a consequence of the investigation conducted in the establishment, that there is a prior detection associated with the cause of the alert, whether it has been investigated or not.
  - The procedures and investigations conducted by the establishment do not provide any guarantees on the product produced by it.
  - The establishment, repeatedly and in different events, does not comply with the terms set forth.

b) Suspension of the Authorization of Export or the Sanitary Certification
- If the parameter informed corresponds to pathogens, toxins or other situations of serious risk for consumers.
- If as a consequence of the investigation conducted in the establishment, it is determined that there is a prior detection associated with the cause of the alert, whether it has been investigated or not.
- If the procedures and investigations conducted by the establishment do not provide any guarantees on the product produced by it.

c) Increase in the Controls applied to the Involved Establishment
- Depending on the evaluation of the alert, the shipment inspections, the inspections to the establishment, etc. will increase. In addition, the product manufactured by the establishment will be subjected to reinforced controls for the parameter that originated the alert, in at least three of the following shipments. If the parameter in question corresponds to a direct risk to the health of the consumers, the reinforced control will be applied to all destination markets. If the parameter in question corresponds to a specific requirement of the market, the reinforced control will be considered for those shipments destined to the market that originated the alert.
- Notification to the Ministry of Health or other local authorities.
- Notification to the Competent Authorities of other countries.
- Verify if the notified product was subject to the shipment inspection or the Customs valuation, prior to its dispatch.

The measures that apply to the establishment will be valid until it offers satisfactory guarantees regarding the resolution that triggered the alert.

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