Part II: Section I

Control at Origin

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CHAPTER I. BIVALVE MOLLUSKS SANITARY CONTROL

This Chapter describes the standards and procedures that allow guaranteeing the sanitary quality of export bivalve mollusks through the classification and monitoring of extraction areas; and is extensive to echinoderms and marine tunicates.

To export bivalve mollusks, tunicates, and echinoderms in any presentation, to markets that require a control of these resources in their location of origin, the instructions described in this Chapter must be met, with the exception of gastropods and pectinidae coming from natural banks.

Fishery plants that export resources extracted from natural banks must be part of the List of Authorized Plants for the Bivalve Mollusks Sanitation Program, for which they must classify and monitor the natural banks from which the resources that they process come from.

When the extraction area corresponds to aquaculture concessions, those interested may request the creation of Mollusks Concession Groups (MCG) to the Service. In these MCGs a common monitoring program may be applied, previous evaluation. The elements to consider for the creation of these groups are described in Item 1.2 herein.

Moreover, the Fishermen's Trade Unions that manage these areas may request the classification of their management areas and further monitoring.

The resources extracted from management areas (MEABR) or farms may be processed in any plant authorized to export to the community market, without being necessary for these plants to be part of the monitoring process of an extraction area.

If the product to be exported is in the live state, in addition to the above, the establishment must be authorized to operate as a Distribution or Dispatch Center as described in Chapter I, Section II, Processes Control.

1. CLASSIFICATION OF EXTRACTION AREAS

1.1 ADMINISTRATIVE PROCEDURES

Those interested in classifying an extraction area must request so in writing to the SERNAPESCA Office under whose jurisdiction the area is located, for which they must present their Application for the European Union Bivalve Mollusks Sanitation Program (Chapter II, Part III, Annex 30). This request must be accompanied by all the information and supporting documentation required, which are detailed in the application.

If the area to be classified corresponds to a natural bank, the plan of the area, the geographic coordinates that set the limits of the extraction area (at least three pairs of coordinates), and a biomass study of the resources to be extracted must be presented.

The full name and email address of the natural or legal person (owner of a concession, company in charge of a natural bank, MEABR) that will assume the representation of the area to classify must be included for communication purposes.

Once the Application with its respective attachments is received, the office must check the validity or expiry of the farm or farms to be incorporated, via the RNA and/or Subpesca systems, in addition, the existence of resources from the concession(s) must also be checked by means of the Reporter system of the institutional Intranet.

In the case of a new area, once the Application to become part of the BMSP is evaluated, the official of the Municipal, Provincial or Regional Office under whose jurisdiction the extraction area is located, will require the interested party to hire the services of an authorized entity, with the purpose of conducting a Coast Line inspection visit to the area to be classified. This visit must be coordinated with the corresponding Office of SERNAPESCA, so as to conduct it jointly, and must consider the aspects described in letters a) to e) of Item 1.2. as follows.

The Municipal, Provincial or Regional Office will send the Application to become part of the BMSP with its respective attachments and reviewed Coast Line Report validated by the official that conducted the visit to the Central Office of the National Fisheries and Aquaculture Service. The National Directorate will develop the Classification Program for the extraction area, which will contain information on the sampling stations that must be set up, the type of analyses to conduct and the frequency with which each sampling will take place. Once the stations have been set up, the sampler will have five business days to send their coordinates.

The main purpose of the classification of the extraction area is to determine the sanitary condition of the area and the technological use that will be given to the resources extracted from it. It consists of the evaluation during 16 weeks of microbiological, toxicological, marine phytoplankton and chemical (pesticides and heavy metals) parameters.

The samples for the classification program must be collected from the sampling stations described in the classification program. For the above, the owners of the centers must ensure the permanent existence of resources in these points.

If there is more than one type of resource in an extraction area, the classification, as well as its further monitoring must take place using the species that can be considered to be indicative due to its characteristics. The priority order for the samplings is as follows:

a) Bivalves (cholga mussel, Chilean mussel, clams, etc.)
b) Tunicates
c) Sea urchins (only when it is the only resource in the zone)

The samplings will be conducted by authorized BMSP samplers, in accordance what is set forth in the Sampling Collection and Delivery Procedure described in Section IV, Chapter II. The companies must verify that the professional that they will hire to execute the sampling programs (classification and further monitoring) is authorized and registered in the List of Samplers of the BMSP, published on the institutional website (www.sernapesca.cl).

Each sample must be accompanied by the original BMSP Sampling and Analysis Form. In the case of samplings conducted in farms, the person responsible for the farm must stamp its approval in the form, at the moment of sampling.

The analyses must be conducted in laboratories authorized for the BMSP using the analysis techniques described in Chapter III, Section IV.

Once the classification program has concluded, the Central Office will inform the interested party the result of the classification of the area and its technological scope. The monitoring program will

also be sent to the classified area with a copy to the SERNAPESCA office under whose jurisdiction the extraction area is located.

SERNAPESCA will add the new delimited area to Annex I of the List of Extraction Areas of the BMSP, with the following information:

a) Region
b) Area (name of the area) and Registration number
c) Control number, number or resolution of the monitoring program
d) Responsible for the extraction area
e) Name of the farms or geographical coordinates, as appropriate
f) Delimitation of the area
g) Resources
h) Condition (compliance with the requirements for its classification)

This list will be published on a periodical basis at the Service's website (www.sernapesca.cl).

In parallel, the Central Office of SERNAPESCA must request before the Competent Authorities of the markets that require so, the incorporation of the new area in the list of bivalve mollusks production areas authorized to third countries. While this registration is being processed, SERNAPESCA may authorize the extraction of resources from the new area; however, the products processed may only be exported to the EU, once the corresponding Competent Authority includes this area in its records.

In the occurrence that once the sampling programs have started, the company requires to change the sampling entity, it must previously notify its intent in writing indicating the name of the new entity and attaching a letter of the entity that will cease to perform its functions, indicating the that the monitoring tasks conducted in the area are up to date and also any other relevant information for conducting samplings (maps of the stations, pending analyses, etc.).

1.2 ELEMENTS TO ESTABLISH MOLLUSKS CONCESSIONS GROUPS

To establish a Mollusks Concession Group, the Service will require certain basic elements that will allow determining that the oceanographic and safety conditions that affect a group of farms are of equal characteristics, which allows applying a common monitoring program in the area. These elements are the following:

a) Tides: The direction and frequency of the tides is an important factor to be considered since it allows to know the flows of the currents and the time in which the bodies of water stay in a certain area.
b) Currentometry: The coasts of the area to be grouped must be influenced by the same flood tide streams and ebb tide streams, which must describe a homogeneous water flow in one direction and not be affected by other currents that allow the entrance of toxic phytoplankton, without it being detected by the monitoring plan. The direction of the currents is a determinant factor in the distribution that Harmful Algal Blooms (HAB) may have on the coastline. Currently, its influence added to the organization of the concessions in the areas to be delimited, determines the location of the monitoring stations for phytoplankton and marine toxins.
c) Salinity and sea surface temperature (SST): International information, indicates that the salinity and surface temperature of water are determinant in the growth of phytoplankton, and therefore in the characterization of extraction geographic areas.
   In general terms, the SST can remain stable over a vast ocean surface; however, the influence of effluents of freshwater and the time of the year can determine changes in temperature. These factors are indicators for the growth of phytoplankton, thus impacting the influence of

algae in certain areas, which is of furthermost importance in the definition of the MCG (Mollusks Concessions Groups).
According to geospatial information, it is possible to determine sectors that maintain similar temperature and salinity characteristics, and that allow maintaining, reducing or increasing the probabilities of algae growth, and finally, it allows to define the geographic location of the monitoring stations.

d) Sources of contamination: After defining the areas that present similar parameters for the above characteristics and that are influenced by the same conditions, there must be detailed information on the direct and indirect sources of contamination that can potentially influence the safety condition of the MCG. It is in this analysis where all biological (population, domestic and wild animals, other farms, etc.) and chemical (vessels, docks, etc.), contaminants must be determined, through a visit to the coast of the MCG, conducting a geographic identification of each one of the contaminating points and carrying out microbiological analyses of the effluents that discharge in the area.

e) Historical information of the BMSP areas: The Service has a broad database with information on the results of the microbiological parameters and analyses, marine toxins and phytoplankton of several areas of the country. This information allows to objectively define affected areas during an algal bloom, a toxic event, and at the same time obtain a microbiological characterization of the area.
The information may be obtained from databases available in the Undersecretariat of Fisheries and Aquaculture, the Department of Environmental Management of SERNAPESCA, the Chilean Navy Hydrographic and Oceanographic Service (SHOA), and from the sources of the Foreign Trade Sub-Directorate, as well as the coastline evaluation studies and the existing results of the analyses for the BMSP areas.

This information can provide important facts for making decisions on the creation of Groups of Mollusks Concessions. Notwithstanding the aforementioned, additional information to that described above may also be requested.

Once the information is collected, working groups must be established between the industry, SERNAPESCA, sampling entities and analysis laboratories, so as to evaluate the information, and define and establish the monitoring stations set for the MCG.

From the administrative point of view, the MCGs need to use the same information used to establish the current BMSP areas, this is, the application, the layout for the concession, the coastline evaluation or its extension, if applicable.

In some cases, sub-areas may be established based on the geographic and hydrodynamic characteristics, the microbiological condition of certain areas and the extension of the group.

All Mollusks Concessions Groups may have Internal Regulations, where the person responsible for the groups is appointed before SERNAPESCA, also describing the way in which they will coordinate for the correct application of the monitoring program established by the Service. Notwithstanding the foregoing, all MCGs must appoint a representative that acts as the coordinator for the Service (it must be the owner of a center that is part of the MCG).

1.3 SANITARY REQUIREMENTS FOR CLASSIFICATION

To begin the classification stage of an extraction area, SERNAPESCA will request a Coast Line Inspection to the interested company, which must take place prior to the beginning of the sampling process. This must be conducted by an authorized BMSP sampler, who must comply with the

requirements set forth in Chapter I, Section IV and must be coordinated with the SERNAPESCA office under whose jurisdiction the growth area is located, in order to conduct it together.
In its implementation, consideration must be given to the following aspects:

a) Evaluation of the coastline: The evaluation of the coastline is an on-site inspection that consists of a visit and a walk around the coastal line, in front of the growing area, in order to directly establish the sources of contamination that affect the extraction area. This procedure must always be conducted during low tide. During the inspection of the coastline, every existing and potential source of contamination that may affect the growth area must be identified and assessed; the distance between the source of contamination and the growth area, and the impact of each source on the area must be determined; the safety and effectiveness of the wastewater treatment systems must be evaluated; the impact on the development of poisonous and deleterious substances must be determined; the presence of domestic animals, wild or resident animals and populations of migratory birds and their possible adverse effects on the growth area must also be evaluated.
b) Effects of meteorological, hydrodynamic and geographic characteristics: Following the inspection of the coastal line, the hydrographic and meteorological characteristics that may affect the distribution of contaminants, such as the extension and type of tides, water circulation patterns, depth, salinity, stratification, rain and intensity patterns, and predominant winds, among others, must be determined.
c) Evaluation of the sources of contamination: Where effluents near the extraction area are identified, samples must be collected in order to estimate their impact on the bacteriological quality of the water in the growth area. The microbiological parameters to be assessed must be in line with the ones used for the classification of the area.
Similarly, in the case of determining that other type of contaminants that are not considered in the classification, but that may have an effect on the health of potential consumers (such as chemical contaminants) may exist, they must also be evaluated in this inspection.
d) Determining the biomass in natural banks: Where the extraction area is a natural bank, along with the evaluation of the coastal line, an estimation of the biomass of each existing resource, within the limits established in the area, will be required.
e) Data analysis: A sanitary inspection report for the area must be written, integrating all the information from the different sources and factors described in the above paragraphs. This report must also include a layout of the extraction area with all the information collected in the sanitary inspection (sources of contamination, distances between the sources and the area, current directions, etc.)
f) The resulting report of the Coast Line Inspection will be validated by the SERNAPESCA inspector that went on the inspection, and will then be sent to the National Directorate to develop the classification program. The sampling entity has 1 month to deliver the report at the office assigned to the extraction area.

1.3.1 CLASSIFICATION OF EXTRACTION AREAS

The classification stage comprises a period of 16 weeks, during which consecutive microbiological, toxicity and chemical analyses must be conducted for the resource; and phytoplankton and oceanographic analyses for water.

The classification program will include the following analyses:

- Microbiological: *Escherichia coli*, Salmonella, *Vibrio parahemolyticus* and Norovirus (only oysters)
- Toxicological: Paralytic Shellfish Poison (PSP), Lipophilic Toxins Group, and Amnesic Shellfish Poison (ASP)
- Phytoplankton: Count and identification

- Heavy metals: Mercury, Cadmium, and Lead
- Pesticides: Halogenated organic compounds
- Oceanographic: Temperature, pH, Salinity and dissolved oxygen

Upon completion of the program, the production zone may be classified in one of the following 3 categories:

Type A For direct human consumption: The resources extracted from these areas may be exported alive, refrigerated or processed, and must comply with the following conditions:

1) Have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion, and normal amounts of intervalvular liquid.
2) Must have a maximum of 230 MPN of *E. coli* for every 100 grams of mollusk flesh and intervalvular liquid, considering 5 tubes and 3 dilutions.
3) Must not contain Salmonella in 25 grams of mollusk flesh.
4) Must not contain *Vibrio parahaemolyticus* in 25 grams of mollusk flesh.
5) In the case of oysters, they must not contain Norovirus in 15 grams of hepatopancreas.
6) They must not contain toxic or objectionable compounds occurring naturally or added to the environment in such quantities that the calculated dietary absorption exceeds the admissible daily intake (ADI) for humans or that can alter the flavor of the product.
7) The total content of paralytic shellfish poison, PSP, in the edible parts (the entire body or any edible parts separately) may not exceed 80 μg/100 g, according to the biological method, to which a saxitoxin detection chemical method or any other recognized by SERNAPESCA may be associated.
8) The maximum total level of okadaic acid, dinophysistoxins and pectenotoxins in bivalve mollusks, echinoderms, and tunicates (the entire body or any edible parts separately) will be of 160 μg of okadaic acid equivalent/kg, in accordance with the biological method or alternative detection methods.
9) The maximum level of yessotoxins in bivalve mollusks, tunicates and echinoderms (the entire body or any edible parts separately) must be 3.75 mg of yessotoxin equivalent/kg, in accordance with the biological method or alternative detection methods.
10) The maximum level of azaspiracids in bivalve mollusks, tunicates, and echinoderms (the entire body or any edible parts separately) will be of 160 μg of azaspiracid equivalent/kg, in accordance with the biological method or alternative detection methods.
11) The percentage of amnesic shellfish poison, ASP, in the edible parts (the entire body or any edible parts separately) must not exceed 20 μg of domoic acid per gram, in accordance with the HPLC analysis.
12) In the absence of the usual virus detection methods and virological standards, the sanitary control must be based on the count of fecal bacteria.

The tests aimed at assessing the compliance of the conditions set in this item must be conducted in accordance with scientific methods of proven efficiency, determined by the National Fisheries and Aquaculture Service.

Likewise, where the need to introduce other sanitary controls is scientifically demonstrated or to modify the parameters established to protect public health, such measures must be adopted by the Service.

Type B For depuration, relaying or application of approved heat treatments: The live resources, extracted from these areas, must:

1) Show, in 90% of the results, an index no greater than 4,600 MPN of *Escherichia coli* for every 100 grams of flesh and intervalvular liquid, using 5 tubes and 3 dilutions. The remaining 10%

may not exceed 46,000 MPN of *Escherichia coli* for every 100 grams of flesh and intervalvular liquid.
2) Comply with the requirements for the presence of marine toxins described for Type A areas.
3) Prior to consumption, bivalve mollusks must undergo a treatment in a relaying or depuration center in an authorized area. Following the relaying or depuration treatment they must comply with all the requirements established for Type A areas, or
4) Before their consumption, undergo some of the heat treatments described in Chapter I, Section II.

Type C For relaying for long periods of time or application of approved heat treatments: The live resources, coming from these areas, must:
1) Show an index no greater than 46,000 MPN of *Escherichia coli* for every 100 grams of flesh and intervalvular liquid, using 5 tubes and 3 dilutions.
2) Comply with the requirements for the presence of marine toxins described for Type A areas.
3) Made for human consumption, only after undergoing a treatment in a relaying area for a long period of time of no less than two months, or
4) Before their consumption, undergo some of the heat treatments described in Chapter I, Section II.

Table 1
Criteria for the classification of bivalve mollusks extraction areas

Category	Microbiological standard	Post-harvest treatment required
A	Samples of live bivalve mollusks from these areas must not exceed, in 80% of samples collected during the classification period, 230 MPN of *E. coli* per 100 gr of flesh and intervalvular liquid. The remaining 20% of samples must not exceed 700 MPN of *E. coli* per 100 gr of flesh and intervalvular liquid.	None
B	Live bivalve mollusks form these areas must not exceed, in 90% of the samples, 4,600 MPN of *E. coli* per 100 gr of flesh and intervalvular liquid. In the remaining 10% of samples, live bivalve mollusks must not exceed 46,000 MPN of *E. coli* per 100 gr of flesh and intervalvular liquid.	Depuration, relaying or cooking by an approved heat treatment.
C	Live bivalve mollusks form these areas must not exceed 46,000 MPN of *E. coli* per 100 gr of flesh and intervalvular liquid.	Relaying or cooking by an approved heat treatment.
Prohibited	>46,000 MPN of *E. coli* for every 100 gr of flesh and intervalvular liquid.	Harvesting is not allowed.

1.3.2 RECLASSIFICATION OF PRODUCTION AREAS

On a periodical basis the Service, during the first semester of the year in course, will review the previous year monitoring results for the authorized production areas, so as to determine if they must be reclassified. For this, the last 12 months results of microbiological analyses will be considered.

Nevertheless, if during the monitoring process some level of microbiological contamination exceeding the limits established for the area (A, B, or C) is detected, the contingency plan described in item 3.3 b) will be applied.

1.3.3 EXTENDING CLASSIFIED AREAS

If one or more farms need to be incorporated to an already classified extraction area, and when a natural bank area needs to be extended, the following documentation must be presented at the SERNAPESCA office under whose jurisdiction the extraction zone is:

- Application to become part of the BMSP, indicating that the request has to do with an extension.
- A letter signed by all the members of the area, in which they manifest their agreement with the incorporation of the new farm, or the extension of the natural bank.
- In case of natural banks, a new biomass study of the sector to be incorporated will be requested.

SERNAPESCA will evaluate the request and may require the extension of the coastline and the classification of the farms to be incorporated for its resolution, with the purpose of providing evidence that shows that their bacteriological condition is the same as the one established for the area requesting to be incorporated (A, B, or C).

This classification will consist of a monitoring process of microbiological parameters, according to the previous classification of the area, on a weekly basis for a period of 16 weeks. It must be mentioned that the incorporation of the new centers, or the extension of the natural bank will only become effective once this sampling period has concluded, and the results allow to evidence that the classification of the extraction area is maintained.

2. MONITORING CLASSIFIED AREAS

The monitoring program sent by SERNAPESCA must be applied on a permanent and indefinite basis in the extraction area, and may only be modified by the Service.

2.1 ADMINISTRATIVE PROCEDURES

The samplings for monitoring the extraction areas must be conducted by an authorized BMSP Sampler, in accordance with the same procedures described in Item 1.1 above.

2.1.1 REDUCED MONITORING

Reduced monitoring consists of the application of only one resource sampling for microbiological analysis, which must be conducted in accordance with the classification of the area (A, B, or C), in the stations and with the frequencies defined for this parameter; this monitoring may be applied when the extraction areas corresponding to farms are not conducting activities (without harvesting), during this period, these areas must maintain resources in the assigned stations. If for operational reasons of structures or facilities renovation, resources will not be maintained in the area during the fallowing period, samplings may be replaced by microbiological samplings in water.

To apply to this low-frequency monitoring, the interested party (representative of the area) must request it in writing to the office of SERNAPESCA under whose jurisdiction the extraction area is located, with a copy to the National Directorate's Foreign Trade Sub-Directorate.

Notwithstanding the aforementioned, during this period, A Type areas must apply all the parameters for their classification only once a month.

The request will be considered to be approved only when SERNAPESCA adds this information to the List of Extraction Areas of the BMSP, within five business days, and sends an email to the interested party authorizing the start of the reduced monitoring process also indicating the program to be applied. The regular monitoring of the area may not be suspended, until the publication in our List of Areas at (www.sernapesca.cl).

Any impediments found for the optimal compliance of the monitoring program must be immediately informed to SERNAPESCA.

If the extraction area corresponds to a natural bank, reduced monitoring may be applied under the following conditions:

a) The resources extracted in the area are subjected to long periods of bans, which must be notified by the Regional Directorate of the Service to the National Directorate, so as to include the information on the List of Extraction Areas of the BMSP. In this case, the sample of resources for microbiological analysis will be replaced by a water sample for microbiological analysis (*E. coli*), only in the case that there are no other resources in the area.
b) The company will not extract resources from the area for an extended period of time, which must be notified in writing to the National Directorate, so as to be included in the List of Extraction Areas of the BMSP. If it is a single natural bank monitored by the company, it may not export resources coming from natural banks to the EU, during the entire reduced monitoring period.

All the areas that adopt the reduced monitoring program must return to the regular monitoring program assigned to the area, at least 2 weeks before restarting the harvest or extraction process.

2.1.2 UNFAVORABLE RESULTS

Every time a monitoring process verifies the existence of adverse results that constitute a risk to public health, the contingency plans described on letter C Monitoring Follow-up in Classified Extraction areas, of this Chapter will be applied, and it will require the collection of consecutive samples for analysis.

2.1.3 NON-COMPLIANCE WITH THE MONITORING PROGRAM

If a non-compliance is detected in the application of the monitoring programs, the extraction area will be immediately suspended and incorporated to Annex II, List of Extraction Areas Temporarily Suspended or Removed from the PSMB.

An extraction area or a farm will be suspended or removed under the following causes:

- Non-compliance of the frequency and parameters defined in the monitoring program
- Falsifying information on the origin of the resources
- Not counting with resources in the sampling station defined in the area program.

The non-compliance with the monitoring program will be justified only by adverse weather conditions (supported by the report from the Chilean Army), considering that under the same cause harvesting will also be suspended until the monitoring process can be resumed.

In case the Chilean Army authorizes harvesting activities under these unfavorable conditions, the owner of the area must provide all the facilities to allow the sampling entity in charge, to attend to perform its task.

If the samplings were not performed according to the calendar, harvesting will be prohibited until the sampling processes are resumed.

It should be noted that samplings must be carried out in the stations established in the corresponding monitoring program. Nevertheless, according to Part II, Section IV, Chapter II, Item 1.1.5, if there is any inconvenience in extracting the sample in the specified station, sampling in a different site will be allowed, previous communication with the corresponding office, or by pointing it in the sampling report.

Before the reincorporation of the area, the interested party must request it in writing or via email to the office of SERNAPESCA under whose jurisdiction the extraction area is located, with a copy to the National Directorate.

If the area is removed for less than 3 weeks, the reincorporation will be granted once the results of analyses for one week of samplings are received, under the same conditions that it had before the suspension (open, closed, with or without harvest).

When an extraction area is suspended for more than 1 month, and the company responsible for its monitoring does not express its intent to be reincorporated to the List, the Service will proceed to request the Competent Authority of the market for which the area is registered, the indefinite removal from its records.

When an area has been removed from the List of Extraction Areas of the BMSP for 1 month and requests to become part of it again, it must conduct the analyses for a full month of sampling, before being readmitted.

After this term, the area must be subjected to a new classification.

If the analysis laboratories reject the samples, the owners of the areas will have 48 hours to rectify the situation. Otherwise, the area will be immediately suspended.

2.1.4 COAST LINE STUDY UPDATE

The extraction areas that are part of the BMSP, must carry out a coastline study every 3 years, which must include any new sources of contamination present in the area, as well as the reevaluation of the existing ones, and it must be conducted in a way that considers possible season variations in the area. Likewise, an annual review of each area must be carried out, verifying the current coastline information. This review must be conducted by the Service officials, based on the contamination sources identified in the current coastline inspection report. If during the review or the validity of the last coastline study, a source of contamination that may affect the condition of the area is detected, the Service's Regional and National Directorates must be notified, in order to determine the need for directly evaluating the new source of contamination or conduct the coastline study in advance. For natural banks areas, this report must also include a biomass estimation of the existing resources in the zone. According to the information obtained from the microbiological results and the annual review reports or checklists, a decrease in the frequency of the new coastline study from three to five years may be analyzed.

The sampling entity has 1 month to deliver the report at the office assigned to the extraction area.

2.2 SANITARY REQUIREMENTS FOR MONITORING EXTRACTION AREAS

The monitoring program of an area considers analyses that depend on the sanitary status of the region in which the resources are extracted.

- Microbiological analysis of 12 samples of flesh per station or sampling site (1 sample every 30 days) ;
- *Vibrio parahemolyticus* analysis of 24 samples of flesh per station or sampling site (1 sample every 15 days); applicable only to Type A areas);
- Norovirus analysis of 52 samples of flesh per station or sampling site (1 sample every 7 days, applicable only for Type A areas that grow oysters);
- Toxicological analysis of 52 samples of flesh per station or sampling site (1 sample every 7 days per toxin).
- Analysis of 2 samples of heavy metals (Cd, Hg, and Pb) per station or sampling site (1 sample every 6 months).
- Analysis of 2 samples of Halogenated organic compounds per station or sampling site (1 sample every 6 months).
- Phytoplankton analysis of 52 samples per station or sampling site (1 sample every 7 days). With the exception of the regions of Coquimbo, Los Ríos and Los Lagos Continental that must collect 24 samples, 1 sample every 15 days.
- Temperature measurement in 52 water samples per station or sampling site (1 sample every 7 days).
- Dissolved oxygen, pH and salinity measurement in 52 water samples per station or sampling site (1 sample every 7 days).

For the case of oceanographic information, the data provided by weather buoys or other devices or techniques that provide such information on a regular basis (once a week), and that are representative of the sector will also be valid. The owners of the area must describe the method to be used and the way in which the information will be sent to the Service.

3. MONITORING FOLLOW-UP OF THE CLASSIFIED EXTRACTION AREAS

This section establishes the criteria and contingency measures that must be applied when detecting an event of contamination or when obtaining an unfavorable result, in the framework of the controls applied in the classified extraction areas. Nevertheless, SERNAPESCA reserves the right to take any additional measures to face a situation of contamination or incidence in public health.

Every time that the laboratories authorized by SERNAPESCA detect the presence of marine toxins, abnormal levels of *Escherichia coli*, the presence of *V. parahaemolitycus*, Salmonella or Norovirus, high levels of heavy metals, pesticides or other contaminants, that may be harmful to public health; as well as any person related to fishing or aquaculture activities and that has a background record related to the contamination of an extraction area or of the resources extracted from it, they must immediately inform via phone or email the National Directorate of the National Fisheries and Aquaculture Service and the SERNAPESCA office under whose jurisdiction the extraction area is located.

With this information and further evaluation, the person in charge of the National BMSP will inform to:

- The Regional Directorate and the corresponding Provincial or Municipal Office.
- The Sampling Entity in charge of monitoring the affected area.
- Analysis laboratories.

Similarly, and depending on the parameters evaluated and the results obtained, the following persons or entities must be informed:

- National Fisheries and Aquaculture Director.
- Undersecretariat of Health
- Ministerial Regional Secretariat (SEREMI) of Health of the corresponding jurisdiction.
- Undersecretariat of Fisheries and Aquaculture
- SERNAPESCA Aquaculture Sub-Directorate.

It will be the responsibility of the corresponding Regional, Provincial or Municipal SERNAPESCA office, to apply the measures described in this section every time a contamination event or an unfavorable result is detected, as stated in items 3.1 and 3.2 as follows.

The Regional, Provincial or Municipal SERNAPESCA office will activate the contingency plan informing immediately the:

- Owner or Representative of the BMSP.
- Sampling Entity.
- Analysis laboratories.
- The establishments that have produced resources in the affected areas.
- Fishery companies participating on the BMSP.
- Ministerial Regional Secretariat (SEREMI) of Health of the corresponding jurisdiction.
- Corresponding regional authorities.

The people from the National Directorate in charge of the BMSP must be copied in all communications so that they can coordinate with the rest of the involved regions, notify the closures, openings or changes in the delimitations and conduct any modifications to the List of Extraction Areas of the BMSP. Similarly, this information must be provided to the Ministerial Regional Secretariat (SEREMI) of Health, for the purposes it deems appropriate.

In the case of detecting a contamination event not described in this section, the National Directorate will be in charge of coordinating, together with the Regional, Provincial or Municipal SERNAPESCA office, the necessary measurements to evaluate and/or overcome the contamination event.

If the extraction area where the contamination event is detected corresponds to a Mollusks Concessions Group (MCG), initially, the corresponding precautionary measure will be applied to the entire MCG and the monitoring in the contingency stations established in the subareas of the MCG will be activated, so as to override the restriction measures in those subareas that are not affected by the contamination event.

The contingency stations will be established by the Service in the MCG monitoring program.

3.1 CONTAMINATION BY THE PRESENCE OF MARINE TOXINS OF TOXIC PHYTOPLANKTON

3.1.1 PARALYTIC SHELLFISH POISON (PSP)

When the results of the monitoring programs detect the presence of *Alexandrium catenella* in qualitative water samples at a relative abundance level of 2 or higher, and there is no evidence of the presence of toxins in the flesh samples, an intensive sampling process must be applied as described in item 3.3 as follows.

If the presence of *Alexandrium catenella* is detected in quantitative water samples (integrated sampling with a hose), and there is no evidence of the presence of toxins in the flesh samples, an intensive sampling process must also be applied as described in item 3.3 as follows.

In the case of detecting paralyzing poison in flesh samples, regardless of the results of the water samples (qualitative and quantitative), the following steps must be undertaken:

- Apply intensive sampling if the levels of toxins are equal to or higher than 30 μg / 100 gr and equal to and lower than 80 μg / 100g of flesh.
- Close the area if the levels of paralyzing toxins exceed 80 μg /100g of flesh and start an intensive sampling procedure according to item 3, requiring all the results for phytoplankton so as to determine the presence of the causal agent.

The areas next to the affected areas must be evaluated for the purpose of determining if the application of contingency plans are required in them. The evaluation will be conducted expediting the following monitoring for the area; if the results indicate the presence of toxic agents or marine toxins at any level, the contingency sampling procedure described herein will be applied, otherwise, the area will continue being monitored as usual.

A follow-up for all the harvested or extracted products must be carried out before the finding, and its analysis must be required at the plant of the manufactured product. The processed products must comply with what is described in item 3.4 as follows.

3.1.2 AMNESIC SHELLFISH POISON (ASP)

If the results of the monitoring programs show evidence of *Pseudonitzchia australis* levels with an abundance over 65% of all the species present in the phytoplankton sample, an intensive sampling will be applied for phytoplankton and ASP analysis in flesh samples, in accordance with item 3.3.

If levels over 20 μg / g of ASP are detected in flesh samples, the area will be closed, and an intensive sampling procedure will be applied for the purpose of evaluating the evolution of the event.

If the level detected is greater than 0.5 μg /g, but lower or equal to 20 μg /g, only an intensive monitoring must be applied.

The areas next to the affected areas must be evaluated for the purpose of determining if the application of contingency plans are required in them. The evaluation will be conducted expediting the following monitoring for the area; if the results indicate the presence of toxic agents or marine toxins at any level, the contingency sampling procedure described herein will be applied, otherwise, the area will continue being monitored as usual.

A follow-up for all the harvested or extracted products must be carried out before the finding, and its analysis must be required at the plant of the manufactured product. The processed products must comply with what is described in item 3.4.

3.1.3 LIPOPHILIC TOXINS GROUPS

If *Dinophisis acuta* is detected in the results of the monitoring program, without detecting toxins in flesh samples collected on the same date, an intensive sampling procedure will be applied, as described in item 3.3.

If some toxins that are part of the lipophilic toxins group are detected in a sample analyzed with the LC-MS/MS technique, the following steps must be undertaken:

a) Apply the intensive sampling procedure if the levels of toxins in the okadaic acid, dinophysistoxins, and pectenotoxins groups are lower than the limits established for each one of the toxins.
b) Close the area if the levels of at least of one of the toxins of the lipophilic group exceeds the regulatory limit and start an intensive sampling procedure according to item 3.3 a), requiring all the results for phytoplankton so as to determine the presence of the causal agent.
c) Apply the intensive sampling procedure as described in item 3.3. a) if the levels of toxins of the yessotoxins group are higher than 1.9 mg eq of YTX/kilogram.
d) Apply the intensive sampling procedure as set forth in item 3.3. A), if the levels of toxins of the yessotoxins group are equal to or lower than 1.9 mg eq of YTX/kilogram and there is a presence of the causal agent in the water samples (*Protocertium reticulatum*.)

In this group of toxins, levels may not be exceeded the following values in bivalve mollusks, echinoderms, and tunicates (the entire body or any edible part separately):

a) In the case of okadaic acid, dinophysistoxins and pectenotoxins, 160 μg of okadaic acid equivalent/kg.
b) In the case of yessotoxins, 3.75 mg of YTX eq/kg.
c) In the case of azaspiracids, 160 μg of azaspiracids equivalent/kg.

The areas next to the affected areas must be evaluated for the purpose of determining if the application of contingency plans are required in them. The evaluation will be conducted expediting the following monitoring for the area; if the results indicate the presence of toxic agents or marine toxins at any level, the contingency sampling procedure described herein will be applied, otherwise, the area will continue being monitored as usual.

A follow-up for all the harvested or extracted products must be carried out before the finding, and its analysis must be required at the plant of the manufactured product. The processed products must comply with what is described in item 3.4.

3.1.4 MARINE TOXINS IN SAMPLES THAT DO NOT CORRESPOND TO MONITORING PROGRAMS

Every time the presence of marine toxins is detected in samples that do not correspond to the BMSP monitoring programs, for instance in manufactured product and QAP verifications, the people from the National Directorate in charge of the BMSP will verify the monitoring processes from the date and extraction area, with the purpose of stating the final end product control to the product processed from resources extracted after the last date monitored.

Any detection of marine toxins or toxic phytoplankton in samples that are not part of the BMSP monitoring process, namely, raw materials sampled at the moment of unloading, sampling of raw materials at the reception at the plant and samplings additional to those from the BMSP, the contingency measures described in item 3.1, will be applied on the declared extraction area.

3.2 MICROBIOLOGICAL OR CHEMICAL CONTAMINATION

When levels above the limits established for an extraction area classified as A, B or C are detected, the people from the National Directorate in charge of the BMSP will notify that the corresponding intensive sampling process must be applied. At the same time, the date from which the resources extracted must be subjected to a heat process corresponding to the category of the contingency applied, will be informed in the List of Extraction Areas.

To prevent any incidences in public health related to *V. parahaemolyticus*, the companies that harvest or extract resources from Type A areas must apply the procedure described in item 4.1, during the period of greater risk, this is between December and March.

When in a Type A extraction area, levels of the following are detected:

- *Escherichia coli* over 230 MPN/100 g in flesh and in intervalvular liquid,
- Presence of *V. parahaemolyticus*,
- Presence of Salmonella or
- Presence of Norivirus,

The extraction with category A for export will be immediately and temporarily prohibited while evaluating if the area is still contaminated. This evaluation must include a report from the sampler of the area, indicating if during the monitoring process any abnormal situations that may justify the contamination event were detected, which must be submitted within 48 hours after obtaining the results, and will be requested by the area inspector.

If levels of *Escherichia coli* above the standards established for B or C areas are detected, the intensive sampling procedure described in item 3.3. b) must be applied.

If the problems detected are of a chemical type and they imply a harm to public health, the area will be closed for the extraction of the resources.

In these cases, special reports will be required from the samplers that conduct the monitoring programs in the affected areas, so as to interpret the results of the analyses with any notes and observations on site.

In the case of detecting levels of Cd, Hg and Pb that exceed the levels established by the EU, the intensive sampling procedure described in item 3.3 b) will be applied.

3.3 INTENSIVE SAMPLING PROCEDURE APPLICATION

Every time an intensive sampling procedure is required for confirming results or to conduct a follow-up of a contamination event, it must be applied in accordance with the following monitoring procedure:

a) Marine toxins or toxic phytoplankton

A water sample must be collected for phytoplankton analyses, and a sample of the resource for toxins analyses, in all the stations assigned to the affected area, every other day. Afterward, and based on the results obtained, the following steps must be applied:

- If the analyses demonstrate that the causal agent is still present in the concentrations that call for the intensive sampling, but there is no evidence of toxins in the resources, this sampling process must continue until the presence of toxic phytoplankton is not detected in the water samples (as described in item 3.1) in two consecutive samplings.

- If the results indicate the presence of PSP at levels equal to or lower than 80 μg /100 g, ASP equal to or lower than 20 μg/g, and/or some of the toxins of the lipophilic group below the limits indicated in item 3.1 a) and b), the intensive sampling will continue until obtaining two consecutive results where the presence of the toxin is not detected in the resources and of the causal agents in the water samples.
- If the analyses demonstrate an increase in the concentration of the toxin above the levels indicated in item 3.1, the extraction areas will be closed.
- If the toxicity levels presented in an event have reached very high values, the frequency of the collection of samples may be biweekly or monthly, and the area will remain closed. When the analyses show a decrease in the toxicity levels, the sampling frequency will return to once a week and then every two days.
- In the specific case of the detection of yessotoxins, the frequency of the intensive sampling process will be every two days only if the presence of the agent is detected in the water and yessotoxins levels are over 1.9 mg/kg. In the other cases of detection described in item 3.1 c) above, the intensive sampling process may take place every three days.

If this intensive sampling process is not applied, the extraction area will be closed.

The MCGs have contingency stations, which are activated with toxic events or with the presence of harmful phytoplankton.

If the MCG is divided into subareas, the contingency stations of the adjacent subsector must be activated. If the initial detection implies a precautionary closure, the condition of the adjacent subarea will be evaluated based on its own results.

b) Microbiological or chemical contamination

If the microbiological contamination event is detected in a Type A area, the extraction for export with this category will be temporarily suspended, and an intensive sampling process will be applied, consisting of two samples collected every 2 days. If the results are favorable, the extraction in the area with category A may be resumed. Otherwise, it will be reclassified based on the instructions of item 1.3.2 above.

When a microbiological contamination problem exceeding the established limit for B type areas is detected, two new consecutive samples will be collected immediately, in those stations assigned for microbiological sampling, with a 2-day frequency, so as to detect the problem and establish if the event has been overcome. If the microbiological problem persists, the area will be reclassified or closed, accordingly, based on the microbiological results obtained.

When the microbiological result exceeds the limit for a C type area, the extraction of resources form the zone will be immediately prohibited and a new monitoring process for classification will be conducted.

When the contamination detected is chemical (Cd >1 ppm, Hg >0.5 ppm, Pb >1.5 ppm, and the presence of pesticides), and the findings correspond to a sample of the BMSP, the company in charge of monitoring the area may apply a special sampling process in the area of growth, with the purpose of determining those points in the area that are affected by the contamination. This sampling process will consist of the following:

- Identifying the farms with their respective harvesting lines, selecting the representative lines of the farm to be sampled.
- Three samples of flesh will be collected from each line of farming for the analysis at the same depth (start, center, and end of the line, in parallel to the surface of the sea). (M.03.05.17)

If the finding corresponds to a sample of processed product whose raw material comes from an extraction area that is part of the BMSP, the information on this detection will be included in the List of Extraction Areas of the BMSP. The need to apply an intensive sampling process, like the one described in the previous paragraph, will be evaluated based on the information on the date of extraction of the resources.

The companies that supply from these extraction areas of the List of Areas with the presence of Cadmium, with raw materials must take the necessary measures to ensure the compliance of their products with the requirements established for the markets to which they will be destined.

If chemical contamination different from that described above is detected, the National Directorate will evaluate the situation and may keep the area open, controlling all the processed products, with the purpose of verifying their compliance with the requirements for their consumption.

3.4 SAMPLING AND STOPPING OF THE AFFECTED PRODUCT

All possibly affected products will be identified and may not be exported until confirming their fitness for human consumption. For this, all the lots of finished products processed from the date of the last sampling with normal levels to the date in which the application of this contingency plan was established will be sampled, as established in the List of Extraction Areas.

The sampling plan will be described in Chapter II, Section III, in accordance with the type of contamination that caused the closure of the affected area and the destination market of the product.

3.5 APPLICATION OF ADDITIONAL MEASURES

If the products affected by marine toxins, pathogenic microorganisms or chemical contaminants were shipped, the Competent Authorities will be immediately informed of the following: The keys of the exported product that may be affected, the shipment date, the final recipient, the motor ship, and the date of arrival at the destination market, among others. The fishery production company must act in accordance to what is established in its Quality Assurance Program for recalling these products.

3.6 OVERRIDING THE PROHIBITION

3.6.1 CONTAMINATION BY RED TIDE

Toxins of the Lipophilic Group: When the results of toxins demonstrate the absence of BMP when the analysis was conducted through bioassay, or levels lower to those indicated in item 3.1.3, when the analysis has been conducted by LC-MS/MS, the restriction on the extraction will be overridden. After its opening, an intensive sampling process must be maintained in the area, until obtaining the results, according to the following:

- The presence of *Dinophisis acuta* is not detected in the water samples,
- Toxin levels are not detected on the resources, and
- The presence of *Protocertium reticulatum* is not detected, and the levels of yessotoxins are lower than 1.9 mg/kg.

PSP: When the results for toxins demonstrate that the PSP levels have been reduced from 80 µg/100 g of flesh in two consecutive samples, the restriction to the extraction will be overridden.

After its opening, an intensive sampling process must be maintained in the area, until obtaining the results, according to the following:

- The presence of *Alexandrium catenella* is not detected in the samples of quantitative water (integrated sample in a hose),
- The result of the qualitative water samples (sampling in net) is lower than a level 2 of relative abundance, and
- Toxin levels are not detected on the resources.

ASP: When the results demonstrate that levels lower than or equal to 20 μg/ g of domoic acid have been obtained, in two consecutive samplings, the National Fisheries and Aquaculture Service will override the restriction on the extraction for export. After opening it, an intensive sampling process must be maintained in the area, until the results demonstrate that the concentration of *P. australis* has been reduced from 65 % and that toxins are not detected in the samples of flesh. If this intensive sampling process is not applied, the extraction area will be closed again until obtaining the previously mentioned results.

Once the extraction area recovers its normal condition, the office of SERNAPESCA under whose jurisdiction the extraction area is located will inform the interested party that the contingency is over, and it may return to the regular monitoring process.

When a precautionary closure is applied due to the presence of marine toxins in an extraction area of an MCG and the sampling is started in the contingency stations established in the subareas, the precautionary measure may be overridden, if the first contingency sampling provides results within the ranges allowed for the extraction (item 3.1 above), to the extent that none of the regular monitoring stations that triggered the contingency in the MCG are within the subarea.

All this information will be sent to all the involved parties and to the Ministerial Regional Secretariat (SEREMI) of Health and will be incorporated in the List of Extraction Areas of the BMSP, available online at (www.sernapesca.cl).

3.6.2 MICROBIOLOGICAL AND CHEMICAL CONTAMINATION

Once the contamination event has been overcome, the area will be opened for extraction and will go into a normal monitoring regime. This will be communicated to all the involved parties and the corresponding Ministerial Regional Secretariat (SEREMI) of Health.

3.7 MOVING SEEDS DURING CONTAMINATION EVENTS

Every time a contamination by PSP and Lipophilic Toxins takes place in areas intended for the production of bivalve mollusks seeds, these may not be relocated in non-affected areas open to extraction.

The seeds may be taken to open areas that have been affected by the phenomenon before, following the procedure of seed collection and rope washing with fresh water.

Nevertheless, the transportation of entire collectors between open areas that have been affected by the same type of phenomenon may be authorized, with a prior request in writing to this Service. This request must be presented at the SERNAPESCA office under whose jurisdiction the area where the transportation will take place is located. To grant the authorization, SERNAPESCA may request conducting phytoplankton and microalgae cysts analyses in the collectors, in those cases in which they have been exposed to a previous phenomenon. Both the sampling and analyses must be conducted by authorized entities. This transportation may be done by sea, to the extent that the

vessel does not navigate over an area that has not been affected by the red tide; for this, the navigation track must be presented for its approval.

The interested party must also present a document detailing the way in which the seeds will be transported.

Finally, the seeds may be transported by land from one closed area to another, affected by the same phenomenon.

3.8 INFORMATION FROM THE QUALITY ASSURANCE PROGRAMS

All the product analyses results from plants with Quality Assurance Programs, either from verification, raw materials control, internal controls, etc., that indicate the presence of marine toxins or other contaminants hazardous to public health, must be communicated by the processing plants and analysis laboratories immediately, via telephone or email, to the National Directorate and the Regional Directorate of SERNAPESCA.

The possibly affected product, according to its origin, date of extraction, vendor, production date, etc., must be subjected to the sampling procedure described in Item 1.9, Chapter II, Section II of this Manual, so as to determine if it represents a risk to public health.

4. EXTRACTION AND TRANSPORTATION

This item describes the standards for the extraction and transportation of bivalve mollusks to processing establishments, distribution centers, relaying areas or depuration centers.

Harvest and transportation must be conducted under proper sanitary conditions, avoiding the contamination of live resources.

Each lot of raw material must be supported by a Record of Extraction and Transportation of Live Bivalve Mollusks of the BMSP in original, except for 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. The procedures to issue the Record of Extraction and Transportation of Live Bivalve Mollusks are described in Item 7 as follows.

For the identification and follow-up of live bivalve mollusks, the raw material harvested must be arranged in sacks or another type of proper containers, which must be perfectly identified with a label (weather-resistant and with permanent ink) containing at least the following information:

- Origin (name, area number and center code, if applicable.)
- Resource.
- Time and date of the extraction.
- Approximate weight.

Bulk raw material transportation may be used, to the extent that it comes from an aquaculture area, and that all the resources come from the same farm. The raw material must always be unloaded directly at the processing establishment and will not require the use of the aforementioned label.

Similarly, products transported in sacks may abstain from using the label, using a security seal instead in the vehicle. The number of this seal must be registered in the Waybill and in the Record of Extraction and Transportation of Live Bivalve Mollusks. All the raw material transported in this way must have the same origin; and in the case of aquaculture areas, it must come from only one farm. The administration and use of the security seals will be the responsibility of the person in charge of the farm where these resources were harvested.

4.1 SANITARY CONDITIONS FOR EXTRACTION

The collection and handling techniques must not cause contamination or serious damage to shells or tissues of bivalve mollusks, nor significant alterations that may affect their suitability to be depurated, processed or relayed.

Live bivalve mollusks must be properly protected to prevent crushing, brushing and vibrations after harvesting and may not be exposed to extremely cold or hot temperatures.

From the start of the harvesting, the temperature of the resources must be controlled to prevent it from rising above the normal water temperature at the time of extraction, and to maintain the cold chain. Ice or another cooling medium must be used where necessary.

Between harvesting and unloading on shore, live bivalve mollusks may not be re-immersed in water to prevent additional contamination.

If carrying out conditioning processes in natural sites, only areas classified as Type A by SERNAPESCA may be used.

Apart from these conditions, the following must be applied during the summer season (spring-summer) to avoid the development of *V. parahaemolyticus*:

a) Harvesting must not take place at extreme times in order to avoid the hours of maximum heat in harvesting areas.
b) Harvesting times must be as short as possible to avoid the over exposure of the resource.
c) From the beginning of the harvesting, the temperature of the resources must be controlled to prevent it from rising above the normal water temperature at the time of extraction. Ice or another cooling medium must be used where necessary.
d) The resource must be processed immediately in order to maintain the cold chain.

4.2 CONDITIONS FOR HARVESTING CENTERS AND MEANS OF TRANSPORTATION (SEA AND LAND)

The establishments that are part of the harvest, whether on land or at sea, of bivalve mollusks coming from farms that are part of an extraction area of the BMSP must comply with the requirements set forth in Section II, Chapter I, Item 1.

The means of land transportation must have the Resolution of the local Health Authority that allows them to transport food, with the exception of those transporting resources in bulk.

Bulk transportation is considered to be that where the resources are transported in bins, maxi sacks or even without any type of packaging or container (dump truck.) This type of transportation may only be used for intermediate distances, with a transportation time no longer than 3 hours.

The means used to transport live mollusks must be used in conditions that prevent any additional contamination and crushing of the shells.

They must also be easy to wash and rinse. In the case of carrying live bivalve mollusks in bulk to a dispatch center, depuration center, relaying area or processing establishment, during a long trip, the means of transportation must be equipped in such a way to provide the best conditions for their survival and, in particular, they must comply with the following requirements:

- The inside surface or any other part which may come into contact with live bivalve mollusks must be of corrosion-resistant material, and the walls must be smooth and easy to clean.
- They must be conveniently equipped to protect mollusks from extreme cold or hot temperatures, soiling, dirt and damage caused to shells by vibrations and scrapping.
- Live bivalve mollusks may not be transported together with other products that may contaminate them.
- Shipments of live bivalve mollusks must be conveyed and distributed with the use of vehicles or containers that maintain the products at a temperature that will not have a negative effect on their quality and viability.
- Packages that contain live bivalve mollusks may not be transported in direct contact with the floor of the vehicle or container and must be placed over a device to avoid such contact.
- If ice is used to transport shipments of live bivalve mollusks, it must be obtained from tap water or clean sea water.

4.3 TRANSPORTATION TO PROCESSING ESTABLISHMENTS OR DISTRIBUTION CENTERS

When receiving the raw materials, the processing establishment or distribution center must enter the date in the record document. The original document must be filed in the establishment, and the first copy will be for the Gatherer and the second one for the SERNAPESCA office assigned to the growth area, or otherwise for the one assigned to supervise the establishment that received the raw materials. The originals and copies of the Record of Extraction and Transportation of Live Bivalve Mollusks of the BMSP must be filed for the time equivalent to the life of the product, which must not be less than 12 months.

The processing establishments or distribution centers that have a Quality Assurance Program in place must incorporate the following procedures to their programs:

All processing establishments or distribution centers authorized to export to the EU that process resources from extraction areas of the BMSP, must require as a preventive measure at the entry of the raw materials, the Record of Extraction and Transportation of Live Bivalve Mollusks, aimed at accrediting the origin of the resource, regardless of the final destination of the product. If the raw materials received were transported in a sealed truck, the number of the seal must be recorded in the CCP Reception Template, and file it with the other records. The seal must correspond to the one described in the Waybill and RET. Otherwise, the resources will lose their BMSP status and may not be exported to markets that require it.

When the product is destined to the European Union, the processing establishment, apart from the above, must accredit that the technological process applied corresponds to the use that should be given according to the delimitation of the extraction area.

The record must be required, maintained and filed by the processing establishment or distribution center and made readily available for the professionals of SERNAPESCA supervising the operation of the QAP. Also, every time an inspection to fishery plants takes place, the presence of the RET file for all the lots of bivalve mollusks entered to the establishment, coming from areas of the BMSP will be verified.

The SERNAPESCA inspector must verify at random, the veracity of the records through any other tool available in the region, such as the Registry of Artisanal Fishermen, Artisanal Unloading Report, Cast off Authorization, National Registry of Aquaculture, Aquaculture Monthly Activity Report, Free Flow Waybills, and other tools available.

If there is not a record that supports the entry of raw materials into the processing establishment or distribution center, the company, as a corrective action, must keep the batch under observation and conduct the end product analysis. This product will not be able to obtain the QAP Certification, neither may it be exported to the EU. Its final certification to other markets will be subject to the results of the analyses, as per the document described in Section III, Chapter IV.

Those establishments that also process products that do not come from areas that are part of the BMSP, with a destination market different from the Community market, must set up a follow-up process for the product that allows to relate the origin of the raw materials with the end product and differentiate it from the one destined to the Community market.

If the raw material is rejected and it does not enter the processing establishment or distribution center, the company must send, within 24 hours, for 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.
- The reason for the rejection.

The SERNAPESCA office receiving the information must issue it to the corresponding Sanitary Authority.

4.4 TRANSPORTATION TO RELAYING AREAS OR DEPURATION CENTERS

Before transporting live bivalve mollusks from an area authorized for the UE to a relaying area or depuration center, the interested party must request the Record of Extraction and Transportation of Live Bivalve Mollusks at the SERNAPESCA office under whose jurisdiction the area is located.

The record must contain all the required information, and also the following phrase must be stamped "The product is destined to an authorized relaying area or depuration center," providing details on the relaying area or depuration center. The record with all its copies must be filed until the product is destined to a processing establishment or distribution center.
When the product enters a processing establishment or distribution center, the same Record proving the information on the transportation of the product from an authorized extraction area to a relaying area or a depuration center must be presented with all its copies, filling in the item "Exclusive Use of Fishery Plant."

The original Record must be filed by the processing establishment or distribution center, the first copy must be filed by the person responsible for the relaying or depuration, and the second copy must be filed at the SERNAPESCA office assigned to the growth area, for the entire life of the product, which may not be lower than 12 months.

The processing establishment or distribution center must follow the same procedure described in item 6.3 above.

5. EXTRACTION CONTROL

For every lot of live bivalve mollusks extracted from extraction areas that are part of the BMSP, the Gatherer must complete the Record of Extraction and Transportation of Live Bivalve Mollusks (RET), as per the instructions of Part III, Annexes, Chapter II, in accordance with the origin of the resources. The Gatherer must also date and sign the record.

The RET must be requested by the gatherer, intermediary or supplier of the resources, at the SERNAPESCA office, and must be provided for all resource batches that come from an area that is part of the List of Extraction Areas of the BMSP, even when they are not destined to one of the markets regulated by this program, nor to a processing establishment authorized to export them, with the sole exception of those resources coming from farms destined to an establishment (distribution, processing or depuration) that belongs to the same company or holding.

It is the responsibility of the requestor to provide all the information required in the items Information of the Requestor, Destination, and Origin, in the RET form, before SERNAPESCA stamps and signs this document. In the case of areas comprised of farms, the information on the line where the resources were harvested may be omitted, to the extent that the center does not have the physical identification of the lines of harvesting.

When the information on the establishment where the raw material will be dispatched and the means of transportation to use (trucks license plate number) is known, it must be included in the document. The information on the date and time of entry of the raw materials to the processing establishment may only be completed at the moment of reception in the plant.

All establishments receiving live raw materials with their corresponding RET, and that then destine their products or part of them to other establishment to be subjected to a process different from production for their further export, must issue the Sworn Declaration of Origin for products affected by Marine Toxins, in accordance with the format available in Part III, Chapter II, Item 2. This declaration must accompany the product until the final establishment. The RET document will remain filed in the primary production establishment. If the raw material is received without a RET, as established in Item 6 above, the RET column of the Sworn Declaration of Origin must indicate "Own Center."

On a weekly basis, these primary production establishments must provide the SERNAPESCA office assigned to its jurisdiction, a summary of the manufactured products with raw materials received with RET and that were destined to another establishment, as follows:

- RET number.
- Resource.
- Quantity of raw materials received.
- Reception waybill.
- Manufactured product.
- Quantity.
- Destination plant.
- Dispatched quantity.
- Balance.
- Delivery Date.
- Delivery waybill.

In addition to the above, the primary production establishments must accredit before the SERNAPESCA office assigned to its jurisdiction that the product that they have manufactured will be then sent to a fishery establishment that will destine it to export.

5.1 RESOURCES FROM FARMS THAT ARE PART OF THE BMSP

When the resources come from a farm, the gatherer must request the delivery of the RET at the SERNAPESCA office under whose jurisdiction the farm is located, for which it must present the waybill previously marked as approved by the Service's Control Department. The official must verify in the List of Extraction Areas of the BMSP, that both the area as well as the center are authorized, and that the area, is also opened for extraction. If due to contingency measures a kind of special control must be conducted on the manufactured products, this must be indicated in the RET.
The RET may be issued once all the information is reviewed, for which the SERNAPESCA official will stamp and sign the document under his name, including also the date and office in which it is issued, entering the following information in the "Bivalve Mollusks Origin Control" system.

- RET number.
- Date of issuance.
- Office.
- Name of the official.
- Area number.
- Name of the area.
- Code of the center.
- Delimitation.
- Resource.
- Extraction date.
- Waybill number for the raw material.
- Quantity (kilograms, bundles, dozens, units, meshes, etc.).
- Primary plant (when known).
- Transportation waybill from the primary plant (as appropriate).
- Destination plant (when known).
- Name of the person receiving the document.
- Notes.

It must be mentioned that as part of the normal procedure, the delivery of the RET must always take place with the presentation of the approved waybill (as appropriate) and individually for each harvest. Nevertheless, in those cases in which the owner of the farm has the SIVAX system in place, a certain amount of blank forms may be provided, before the harvests. These blank forms must be signed and stamped at the moment of delivery to the interested party. The number of forms provided in advance must be equivalent to the number of SIVAX labels provided to the farm.

The above may only be applied under regular harvesting conditions, that is to say, in periods when the area is not affected by any contamination events that call for the application of the contingency plan, and for harvesting periods that do not exceed one month. The farm must return to SERNAPESCA the copies of the RETs used within one week, with all the information required in the document, only with the exception of the date and time of entry to the plant, so that it can be entered in the "Bivalve Mollusks Origin Control" system. In addition, the company must provide the detail of the RETs used with their corresponding SIVAX, in accordance with the format set forth in Part III, Annexes.

If not all the RETs were used, these will remain pending for the next period. It must be mentioned that the application of this special delivery process will be subject to the compliance of the farm on the terms set to return the copies to SERNAPESCA.

All farms that need to use this RET advanced provision procedure and comply with the aforementioned requirements must request it expressly at the SERNAPESCA office under whose jurisdiction the extraction area is located.

In addition to what has been mentioned in this document, to provide the RET for resources coming from farms, the harvesting facilities must comply with the requirements set forth in Section II, Chapter I, Item 1.

5.2 RESOURCES COMING FROM BMSP NATURAL BANKS

The gatherer, intermediary or supplier will present the following documents at the SERNAPESCA office assigned to the extraction area or port of unloading:

- Authorization of cast-off and landfall issued by the Maritime Authority of the port of cast-off and landfall. It must be mentioned that the information contained in this document must correspond with the information entered for the areas of the BMSP.
- Waybill of the product from the port of unloading to the processing plant or approved invoice of the purchase, as appropriate.
- Artisanal Unloading Form.
- Toxicological analysis of the raw materials, as appropriate.

The SERNAPESCA official must verify the documents presented, and that the extraction area is opened for extraction.

The RET may be issued once all the information is reviewed, for which the SERNAPESCA official will stamp and sign the document under his name, including also the date and office in which it is issued, entering the following information in the "Bivalve Mollusks Origin Control" system.

- RET number.
- Date of issuance.
- Office.
- Name of the official.
- Area number.
- Name of the area.
- Code of the center.
- Delimitation.
- Resource.
- Extraction date.
- Waybill number for the raw material.
- Purchase invoices.
- Quantity (kilograms, bundles, dozens, units, meshes, etc.).
- Artisanal Unloading Form number.
- Primary plant (when known).
- Transportation waybill from the primary plant (as appropriate).
- Destination plant (when known).
- Name of the person receiving the document.
- Notes.

In those cases in which the fishery plant is part of more than one shipment, or the resources arrive at a port in a hauling vessel, requesting the RET for all the raw materials extracted, also the copy of the Artisanal Unloading (AU), Fresh Trading Agents (FTA) or Declaration of Activity and Unloading of Transporting Vessel (LTC-01) must be presented, in which all the vessels that were part of the process may be identified. The document must accompany the RET to its destination, and an

additional copy will be filed together with the rest of the supporting documentation at the corresponding SERNAPESCA office.

5.3 RESOURCES COMING FROM AREAS THAT ARE NOT PART OF THE BMSP

When the products to be exported have been processed with resources coming from these extraction areas, either from farms or natural banks, that are not part of the BMSP, the Notification of Extraction from the interested party or the RET from SERNAPESCA must not be presented, and the following document control must be applied:

At the moment of authorizing the export, the official of SERNAPESCA must verify that the extraction area was opened by the Ministry of Health, on the date in which the resources were extracted.

If the origin is a farm, the waybill approved by the Control Department must be requested, as appropriate.

If the resource comes from a natural bank, the following information must be required:

- Authorization of cast-off and landfall issued by the Maritime Authority of the port of cast-off and landfall.
- Waybill of the product from the port of unloading to the processing plant or approved invoice of the purchase, as appropriate.
- Artisanal Unloading Form.
- Toxicological analysis of the raw materials, as appropriate.

All this documentation is additional to the sworn declarations that must be presented prior to the export.

5.4 OFFICIAL EXTRACTION CONTROL

SERNAPESCA will file all the BMSP Records of Extraction and Transportation of Live Bivalve Mollusks issued by the office, with the purpose of keeping a control of this procedure.

Also, every time an inspection to fishery plants takes place, the presence of the RET file for all the lots of bivalve mollusks entered to the establishment, coming from areas of the BMSP will be verified.

The SERNAPESCA inspector must verify at random, the veracity of the records through any other tool available in the region, such as:

- Registry of Artisanal Fishermen.
- Artisanal Unloading Report.
- Authorization of cast-off.
- National Registry of Aquaculture.
- Aquaculture Monthly Activity Report.
- Free Flow Waybills.
- Other tools available.

5.5 DETECTION OF IRREGULARITIES IN THE DECLARATION OF ORIGIN

If the Service determines that there is a reasonable doubt, regarding the actual origin of the resources under the risk of marine toxins, as bivalve mollusks, tunicates, and echinoderms, in their obligation to guarantee the sanitary quality of the export fishery products, the following

procedures may be applied, on the suppliers of raw material and the fishery plants involved in the irregularity.

Farms

If an irregularity or possible forgery of the documents that accredit the origin of the resources, with the purpose to appear as if they were harvested in a center that is part of the BMSP is detected, when they actually come from a farm that is not part of this Program, the following process will apply:

a) The center that provided this waybill to commit this offense will be excluded from the List of Areas of the BMSP, a condition that will remain while the Service does not have any clear guarantees that this will not be repeated.
b) SERNAPESCA will carry out an investigation to determine the exact quantity of the product involved. While this investigation takes place, the product manufactured with the raw material being questioned may not be exported or transported from its storage location. The involved farm and the plant that manufactured the product must provide all the required information, which will be analyzed with the tools available for Sernapesca. This information must be delivered within 4 days from the request.
c) This evaluation will be done together with other departments of the Service (GIA, FIP, Legal, etc.,) so as to analyze all the legal implications involved. SERNAPESCA must solve this situation within 30 days from receiving all the required information.
d) If deemed appropriate, any other public bodies that may be affected by the irregularity detected (SII, Ministry of Health, Public Prosecutor's Office, etc.) will be informed.
e) Once all the involved parties are informed of the situation, in order to adopt the corresponding resolutions, SERNAPESCA will evaluate the possibility of exporting the product. Nevertheless, given the lack of certainty caused by the detected irregularity, in no case may it be exported to a market that requires a BMSP. To authorize the export, the product will be subjected to a thorough toxicological control. Only in case that, as a result of the investigation, it is determined that the product, in fact, comes from a BMSP area, the export to a regulated market may be authorized.
f) If eventually, the product or a part of it was already exported to a market that requires a BMSP, without having issued the sanitary certification, it will not be issued, and therefore, the production or exporting company must arrange the return of the product to the country or if possible, its destination to another market.
g) If the product were re-entered to the country, it will remain available to the Ministry of Health, until determining its fitness for human consumption. If there are not any sanitary issues, the product may be re-exported to a market that does not require a BMSP.
h) All raw materials delivered to any fishery plants from the farm that committed the offense (the one that provided the waybill), will be subject to rigorous document controls. This implies the full verification of all the necessary documents before authorizing any exports.
i) If the farm commits this offense for the second time, it will be permanently removed from the BMSP.

If none of the centers involved in the irregularity of the declaration of origin are part of the BMSP, actions will be taken according to what is described in letters b) to g) above.

Natural Banks

When it is detected that the product received at a fishery plant does not come from a natural bank of the BMSP, though it was initially declared as such, the following actions will be taken:

a) SERNAPESCA will carry out an investigation to determine the exact quantity of product involved in the irregularity, and the manufactured product with the questioned raw material

may not be exported nor be transported from its place of storage while this investigation is in place. The involved supplier of raw material and the plant that manufactured the product must provide all the required information, which will be analyzed with the tools available for the Service (artisanal unloading declarations, authorization of cast-off, etc.) This information must be delivered within 4 days from the request.

b) This evaluation will be done together with other departments of the Service (GIA, FIP, Legal, etc.,) so as to analyze all the legal implications involved. SERNAPESCA must solve this situation within 30 days from receiving all the required information.
c) If deemed appropriate, any other public bodies that may be affected by the irregularity detected (SII, Ministry of Health, Public Prosecutor's Office, etc.) will be informed.
d) Once all the involved parties are informed of the situation, in order to adopt the corresponding resolutions, SERNAPESCA will evaluate the possibility of exporting the product. Nevertheless, given the lack of certainty caused by the detected irregularity, in no case may it be exported to a market that requires a BMSP. To authorize the export, the product will be subjected to a thorough toxicological control. Only in case that, as a result of the investigation, it is determined that the product, in fact, comes from a BMSP area, the export to a regulated market may be authorized.
e) If eventually, the product or a part of it was already exported to a market that requires a BMSP, without having issued the sanitary certification, this will not be issued, and therefore, the production or exporting company must arrange the return of the product to the country or if possible, its destination to another market.
f) If the product were re-entered to the country, it will remain available to the Ministry of Health, until determining its fitness for human consumption. If there are not any sanitary issues, the product may be re-exported to a market that does not require a BMSP.
g) All further supplies of raw materials at any fishery plants, acquired from the supplier that committed the irregularity when declaring the origin, will be subject to rigorous document controls; this implies the full verification of all the necessary documents before authorizing any exports.

Fishery Plants

All fishery plants that produce bivalve mollusks, tunicates or echinoderms, must have evaluation procedures for their suppliers in place, so as to avoid the reception of products potentially harmful to health.

If the processing establishment has a Quality Assurance Program, it must consider this procedure in its Program. If the processing establishment is repeatedly involved in the reception of raw materials from false origins, SERNAPESCA will conduct an audit inspection with the purpose of thoroughly evaluating the raw material supply records and the traceability procedures in the plant.

If as the result of the audit it is concluded that the records of entry of raw material do not provide information on the origin of these resources, this Service may suspend the plant's QAP Certification until a proper control of origin is guaranteed when receiving the raw material.

As stated in the letters of Item 7, SERNAPESCA will carefully review all the documentation provided prior to authorizing an export, analyzing it against the available tools, not authorizing the shipment until being sure about the veracity of what is declared in the documents.

If apart from the fact that the declaration includes false information on the origin, there are doubts about their legality, SERNAPESCA may deny the authorization to export and/or the sanitary certification when it is requested, confiscate the product and file a complaint before the courts, as established by law.

6. RELAYING CONDITIONS FOR LIVE BIVALVE MOLLUSKS

Relaying of live bivalve mollusks must only take place in areas authorized by SERNAPESCA to this end and for the purposes of cleaning or depuration, or their sale for direct human consumption. The introduction of seeds into a delimited area is not considered as relaying. Thus the requirements of this paragraph will not apply. A seed is understood as a specimen of a size no greater than 1.5 cm.

The following conditions will apply for relaying live bivalve mollusks:

a) Live bivalve mollusks must have been gathered and transported in accordance with Item 6 above.
b) The handling techniques must allow for the resumption of the filter feeding following the immersion in natural waters.
c) Live bivalve mollusks must be relayed with a density that allows for depuration.
d) Live bivalve mollusks must be immersed in sea water in the relaying area, during an appropriate period of time, set based on the temperature of water, for at least 2 months, unless SERNAPESCA authorizes a shorter period.
e) The relaying areas for live bivalve mollusks must be clearly delimited with the use of buoys, poles or other stationed material. There must be a proper distance between them and between the different relaying zones and the production areas, in order to reduce any risks of spreading contamination to a minimum.
f) The various parts of each relaying area must be well separated so as to avoid mixing different lots. The "filling and emptying" system must be used so as to avoid introducing a new lot before removing the preceding lot.
g) The people in charge of the relaying area must keep a permanent record of the origin of live bivalve mollusks, relaying periods, relaying site and further destination of the lot, and such record must be kept at the disposal of the Competent Authority.

7. CONDITIONS FOR THE AUTHORIZATION AND OPERATION OF HARVESTING AND DEPURATION CENTERS

The representative of a harvesting or depuration center must request the authorization of the facility in writing to the Regional Directorate of SERNAPESCA under whose jurisdiction the facilities are located.

The inspection will be carried out by the SERNAPESCA Inspector under whose jurisdiction the establishment is located, at the date agreed with the interested parties.

At the moment of the visit, the establishment and/or installations must comply with all the requirements described in this section, which will be verified applying the inspection checklist described in Section III, Chapter III, Item 21.

The authorization will be granted only if, at the moment of the visit, the establishment and/or facility complies with the following criteria, according to the classification of deficiencies established in the Glossary:

Table 2
Classification of deficiencies

Critical	Serious	Minor
0	2	3

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 of a harvesting or depuration center, SERNAPESCA will notify the European Union 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 and writing.

If the establishment does not comply with the requirements of the Program, the Center must take the necessary measures to solve the non-compliances and request a new visit, following the same procedure.

In the case of harvesting facilities, the provision of the Record of Extraction and Transportation of Live Bivalve Mollusks for the resources harvested in the inspected facility will be subject to the compliance of the sanitary requirements stated in Section II, Chapter I, Item 1. If the document has been provided before the inspection and the requirements are not met, it may be annulled immediately.

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

The inspection to the centers will be carried out by the Inspector in charge of the Regional Office of SERNAPESCA, applying the inspection checklist described in Section III, Chapter III, Item 21.

If during the inspection any critical deficiency is detected, it must be immediately corrected. Otherwise, the establishment will be suspended until its proper correction. Similarly, if 4 or more 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.

7.1 CONDITIONS AND REQUIREMENTS FOR THE AUTHORIZATION OF HARVESTING CENTERS

Bivalve mollusks must be protected from all sources of contamination, taking into account any type of processing to which they will be subjected later.

They must be kept clean, and when necessary, the containers, boxes, vehicles, and vessels must be properly disinfected after the cleaning process.

Potable water or clean water will be used when necessary to avoid contamination.

It will be guaranteed that the staff handling food products is in good health condition and that it is trained on health risks.

Animals and pests that cause contamination must be avoided.

Waste and hazardous materials must be stored and handled so as to avoid any type of contamination.

The introduction and spreading of contagious, communicable diseases to humans through food will be avoided.

The results of the relevant analyses conducted on the samples collected from animals or other samples that are of importance to human health will be taken into account.

The additive for feed and medication for animals will be employed correctly, according to the current legislation.

The above provisions apply to the transportation, storage, and handling of bivalve mollusks in the production area, to the extent that its nature is not substantially altered and to the transportation of live bivalve mollusks.

7.2 CONDITIONS AND REQUIREMENTS FOR THE AUTHORIZATION OF DEPURATION CENTERS

On-shore 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, water resistant 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 so as to avoid the contamination of the pumped water.

The pools must be proper for the volume and type of products subjected to depuration.

Before starting the depuration process, live bivalve mollusks must be washed with clean water so as to remove mud and other materials adhered.

The depuration system must allow for mollusks to quickly resume and maintain their filter-feeding and for them to be clean of contaminating residues, not to become contaminated again, and to stay alive in proper conditions for their packaging, storage, and transportation before placing them on the market.
The quantity of live bivalve mollusks to be depurated may not be higher than the capacity of the depuration center. The process must be uninterrupted and be extended over the necessary time to comply with the microbiological standards set forth.

The depuration center must take into account the information related to raw material (type of bivalve mollusks, the area of origin, microbial content, among others,) if it were necessary to extend the depuration period and guarantee that the bivalve mollusks comply with the bacteriological requirements set forth.

When the depuration pool contains several lots of live bivalve mollusks, they must be of the same species, and the duration of the treatment will be applicable to the lot that requires the most extended depuration period.

The containers that are used to keep bivalve mollusks in the depuration system must be made so that seawater circulates inside it. The thickness of the piled layers of mollusks must not obstruct the process of opening the shells during the depuration process.

During the depuration of bivalve mollusks, there may not be crustaceans, fish and other marine species in the same pool.

The depuration centers must keep a record where the following information must be entered on a regular basis:

- The results of the microbiological water tests for the depuration system at the entrance of the depuration pools.
- The results of the microbiological tests for live depurated bivalve mollusks.
- The date and quantity of the live bivalve mollusks entered to the depuration center with the corresponding copy of the Record of Extraction and Transportation of Live Bivalve Mollusks that supports their origin.
- The filling and emptying of the depuration systems (duration of the depuration.)
- The information provided on the dispatch of deliveries after depuration.

The notes must be complete, accurate and legible, and a permanent record must be kept available for the inspection of SERNAPESCA.

Each packaging containing depurated live bivalve mollusks that is sent to a distribution center must have a tag certifying the effective depuration of its entire content.

8. SANITARY CONTROLS AND SUPERVISION OF PRODUCTION

The National Fisheries and Aquaculture Service must carry out a sanitary control to ensure the compliance with the conditions established in this Manual through:

Regular inspections of the relaying and production areas for live bivalve mollusks in order to:

- Avoid frauds related to the origin and destination of live bivalve mollusks.
- Verify the microbiological quality of live bivalve mollusks in production and relaying areas.
- Verify the eventual presence of toxic plankton in production and relaying waters and marine toxins in live bivalve mollusks.
- Verify the possible presence of chemical contaminants.

The verification sample collection will consider (see Item 3 of this Chapter):

- The possible variations of fecal contamination in every production and relaying area;
- Possible variations in production or relaying areas of the presence of plankton containing marine biotoxins.
- The possible contamination of mollusks in the production or relay area.

Laboratory tests used to verify the compliance with the requirements that apply to the product.

Controls on storage and transportation conditions in shipments of live bivalve mollusks.

The requirements for establishments that process live bivalve mollusks destined to the European Union must comply with what is set forth in Section II, Chapter I, Item 1.

9. EXPORT

9.1 MARKETS THAT REQUIRE THE CLASSIFICATION AND MONITORING OF EXTRACTION AREAS

The export process considers a control from the extraction of the resources to the shipment of the product, and the Regional Office must verify for granting the certification, that the products come

only from those areas of growth authorized by the program, that have been produced in plants authorized for such purposes, and that the means of transportation have been duly authorized.

9.2 MARKETS AND/OR RESOURCES THAT REQUIRE THE CLASSIFICATION AND MONITORING OF EXTRACTION AREAS

a) Refrigerated Live Bivalve Mollusks

If the resources come from an area other than a BMSP area, the company interested in their export must manifest its intent to SERNAPESCA in advance, so as to arrange a special sampling program in the extraction area, which must be conducted prior to the export. This monitoring will consist of 1 sample for the analysis of:

- *Escherichia coli.*
- Salmonella.
- *Vibrio parahaemolyticus.*
- Norovirus (only oysters).
- Marine toxins.

These analyses will have a duration equivalent to the monitoring frequencies, set forth for each parameter in the areas of the BMSP, as described in Item 2 above.

b) Gastropods and Pectinidae from natural banks, processed and extracted from areas that are not part of the BMSP destined to the EU.

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 EU as the destination market, must comply with what is established in Section III, Chapter IV, Item 13.

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."

c) Processed bivalve mollusks

Bivalve mollusks extracted from areas that are not part of the BMSP may only be exported to markets that do not require to classify and monitor the extraction area. The authorization for export and/or sanitary certification of the products manufactured with these resources will be granted based on the procedures and requirements set forth in Section III, Chapter IV, Item 13 and Section III, Chapter IV, Item 12, accordingly.

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CHAPTER II. CONTROL OF PHARMACEUTICAL PRODUCTS RESIDUES, PROHIBITED SUBSTANCES, UNAUTHORIZED SUBSTANCES AND CONTAMINANTS IN AQUACULTURE

This Chapter describes the standards and procedures for the control of residues of pharmaceutical products, prohibited substances, unauthorized substances and contaminants in farmed fish, with the purpose of guaranteeing the safety of the products manufactured with these resources.

The establishments that are subjected to the procedures and requirements established in this section will be all the farms and establishments that process these type of resources.

The failure to comply with any of the procedures described in this manual may determine the impossibility to harvest fish and/or export products manufactured with raw materials coming from the involved farms.

1. GENERAL PROCEDURES

1.1. **FARMS**

The farms must comply with what is established in the Regulation of Protection, Control and Eradication Measures for High-Risk Diseases for Hydrobiological Species, SD 319/01 and its amendments, as well as their General and Specific Sanitary Programs.

In addition to the aforementioned, they must also accredit that the concentrations of pharmaceutical product's residues in fish do not exceed the limits established by this Service, in every lot of raw material entering the process. For this, the person responsible for the center must issue a Declaration of Guarantee, based on the form available in Chapter II, Part III, Annexes of this Manual, through which it is testified that the resources destined to a process comply with the standards established by the Service.

Each Declaration of Guarantee supports only the fish that comprise a lot. This document must be presented at the entry of the raw material to the plant and per each lot received, attaching a copy of the corresponding analysis reports.

1.2. FISHERY PLANTS

All the processing plants that receive raw material coming from farms must require at the moment of entry, the Declaration of Guarantee, accompanied by copies of the analysis reports that support it; documents that must be filed and made available to SERNAPESCA.

If the processing plant receives raw material with restriction to destination markets indicated in its Declaration of Guarantee, the Quality Assurance Program (QAP) of the plant must include and approve the hazards associated with this practice, with the purpose of complying with the requirements of the destination market. If it supplies another processing plant, it must provide the corresponding documentation indicating the market restrictions to its client.

If receiving raw materials coming from stockpiling centers, hatcheries, slaughterhouses or primary plants, the plant must require a copy of the Declaration of Guarantee with all its supporting documentation. Also, a Simple Sworn Declaration must be required, available in Chapter II, Part III, Annexes of this Manual, issued by the person responsible for the stockpiling center, certifying that fish have not been fed with or that they have undergone treatments with pharmaceutical products. This declaration must provide information on the traceability of the harvested fish, indicating at least: the number of fish received, the number of fish harvested, the balance for each cage harvested and a request for sampling.

The establishments that only receive processed raw materials from plants with QAP (for instance, frozen products to be smoked, raw materials for canned products), must require a declaration of the processing establishment of origin, clearly identifying the Declaration of Origin that supported the entry of fish into such plant, as well as the lot entering. The establishment of origin must inform its client of the levels of residues with which the fish used to produce the raw material were harvested and must also attach, a copy of the Declaration of Guarantee that supports the lot entering into a new process. Alternatively, a summary chart may be presented, indicating at least: Number of declarations of guarantee, internal lots, production keys, the center of origin and their code, cage, Sampling Request No., Results Report No., and name of the laboratory. Also, the QAP unfavorable verification results must be attached.

If there are intermediaries between the farm of origin or between the establishment that carries out the first process and the establishment that manufactures the end product, the raw material must always be accompanied by the aforementioned documentation, in each one of the transfers.

1.3. CORRECTIVE ACTIONS

If the farm has not presented the original Declaration of Guarantee or such declaration is incomplete or erroneous, the processing plant, as a corrective measure, must take samples of the entered lot, according to the terms established in their Quality Assurance Program, using for this the sampling mechanism described in items 2.2 and 2.3 of this Chapter. In no case the samplings of these lots entered to the processing plants may be used to support other lots coming from the same farm, neither may they replace the samplings that have not been conducted on the farm.

For the cases in which the Declaration of Guarantee has not been presented, the analyses to conduct will correspond to all the determinations included in Item 3 of this Chapter. When the Declaration of Guarantee is incomplete, only those analyses that are not supported will be conducted.

This corrective action must also be applied by those plants that receive raw materials processed in plants with QAP and that do not enter with the corresponding documents.

The plant must inform this corrective action to the Regional Office of SERNAPESCA, the farm from which the fish comes and the processing plant, accordingly. The information issued to SERNAPESCA must specifically indicate the farm and the name and code of the center.

When sending these samples to the SERNAPESCA Verification Laboratory, it must be expressly indicated in the Samples Delivery Form, that it corresponds to a corrective action executed by the processing plant.

Once the sampling has been conducted, the plant may process the raw materials received, keeping the manufactured product under observation, waiting for the results of the SERNAPESCA Verification Laboratories.

If the corrective action is not applied, the SERNAPESCA official will proceed in accordance with what is established in Section II, Chapter II, Item 1.3 (Supervision of the Quality Assurance Program).

1.4. SAMPLING AND ANALYSIS OF FINISHED PRODUCT

Given some situations that will be evaluated on a case by case basis SERNAPESCA may require conducting the sampling and analysis of the finished product. For the above, a Sampling and Analysis Request for Export (SMAE) must be processed at the SERNAPESCA office of the location of storage of the product.

It must be mentioned that SERNAPESCA may require samplings and analyses additional to those established in this Manual if deemed appropriate.

The number of samples to analyze will depend on the size of the shipment, for which the following table will be applied, considering each container as an independent shipment:

Table *No. of samples for the analyses of finished products*

Size of the shipment (net tons)	n
< 1	5
1 – 10	10
>10 – 21(*)	15

(*) equivalent to the maximum capacity of 1 container

Each sample must be comprised of a minimum of 400 g of flesh and must be dispatched in proper conditions, according to its presentation, to the laboratories authorized by SERNAPESCA to conduct the analysis.

2. CONTROL PROCEDURES

Farms, as well as the establishments that process these resources, must implement control procedures so as to verify that the harvested and manufactured products comply with the standards established in Section III, Chapter IV.

2.1. PHARMACEUTICAL PRODUCTS RESIDUES CONTROL IN FARMS

Residue control of pharmaceutical products in farms will be conducted through pre-harvest samplings, carried out directly in the farms, to groups of fish treated over the last 6 months, with the exception of those destined to the Eurasian Economic Union that have received Oxytetracycline treatments; in this case a pre-harvest analysis of all the group of fish treated during the fattening stage, even when the treatment has taken place before the last 6 months.

For the case of fish treated with injectable pharmaceutical products, the pre-harvest sampling may take place even when the treatment has taken place before the last 6 months.

In the case of parasitic treatments by immersion, the sampling will only be conducted to the groups of fish treated with Cypermethrin during the last 2 months.

These samplings must be carried out according to the Aquaculture Control Procedures for Pharmaceutical Products, Prohibited Substances, Unauthorized Substances and Contaminants described in Items 1.1.4 and 2.1.3.5, Chapter II, Section IV of this Manual.

If a farm has not conducted any treatments, the Doctor of Veterinary Medicine must issue a Simple Sworn Declaration, certifying that pharmaceutical treatments have not been applied.

The Request will support the groups or cages treated, only to the extent that the conditions of the farm are maintained at the moment of the analysis, that is to say, that there have not been any treatments applied after the definition of the groups or cages.

For cages treated with injectable pharmaceutical products, the group sampling will not be considered, establishing only the release modality per each cage.

The cages or groups may be released for harvest only when all the analyses results comply with the requirements set forth in Item 3 of this Chapter.

If the concentrations described in Item 3 are not met, the withdrawal period must be extended and carry out a new sampling.

In the case of exceptional harvests authorized by the Service, in which the fish are destined to plants that have incorporated in their QAP a hazard related to the mix-up of lots, the farm will clearly inform in the Declaration of Guarantee the concentrations of waste with which the fish were harvested.

a) Other Aspects to be Considered

For those cases in which the farm requires applying procedures such as cleavages, mixes, selection, etc. of the already sampled cages, the person in charge of the sanitary aspects of the farm must issue a document describing the originally sampled cages to which this procedure was applied, and their date. The identification of the new cages must be stated in the Declaration of Guarantee.

The results of the analysis reports will support an entire cage or group, accordingly. In the case of applying treatments after the pre-harvest sampling date, the company must conduct a new sampling and analysis for the pharmaceutical products applied after the sampling.

Also, the reports must clearly identify each one of the constituent cages or tanks. This will be supported by the person responsible for the farm, through the issuance of the Declaration of Guarantee.

Each Declaration of Guarantee must be supported in the files of the farm by the corresponding harvest analysis reports and sampling requests, which must be available for SERNAPESCA.

2.2. PROHIBITED AND UNAUTHORIZED SUBSTANCES CONTROL IN FARMS

The control of prohibited and unauthorized substances will take place through official samplings, directly at fish farms, to be conducted together with the routine control that the Service carries out in any phase of the productive cycle. The sampling will be carried out once a year at farms with fish in the stage of reproduction, breeding and/or smoltification (fish rearing stations, river and lake farms and estuary smoltification,) and a sampling during the fattening stage for sea farms.

The sampling must be targeted to higher risk lots, for which some information such as the following may be considered: Use of currently unknown substances, diseases that suddenly arose in specific areas, an indication of fraudulent activities, information on previous positive results, etc.

These samplings must be carried out according to the Aquaculture Control Procedures for Pharmaceutical Products, Prohibited Substances, Unauthorized Substances and Contaminants described in Items 1.1.4 and 2.1.3.5, Chapter II, Section IV of this Manual.

The presence of prohibited substances in the flesh and skin of fish will be the responsibility of the farm from which the fish come.

For those cases in which the farm requires applying procedures such as cleavages, mixes, selection, etc. of the already sampled cages, the person in charge of the sanitary aspects of the farm must issue a document describing the originally sampled cages to which this procedure was applied, and their date. The identification of the new cages must be stated in the Declaration of Guarantee.

a) Procedure for Unfavorable Results

Unfavorable results will be directly communicated by the SERNAPESCA Verification Laboratory to the Foreign Trade Sub-Directorate at a central level.

Unfavorable results will be sent via email to the National Directorate assigned to the farm and the processing plant (as appropriate), requesting the information on the disposal and destination of the lots involved. Similarly, the Animal Health Department of the Sub-Directorate of Aquaculture will be informed via email, so that it can carry out the investigation to determine the possible causes of the unfavorable event, in accordance with the procedures set forth by the Department for this purpose.

b) Detection of Prohibited Substances

In the case of detecting prohibited substances, the fish may not be harvested or transported to other facilities without the prior authorization of SERNAPESCA.

If any harvesting took place before the date in which the results were communicated, the farm must inform the SERNAPESCA office assigned to the location of the center, the destination of the raw material within 48 hours.

This situation must also be informed to the processing plants that have received such raw material, with a copy to the SERNAPESCA office under the jurisdiction of each processing plant, so as to adopt the necessary corrective actions.

SERNAPESCA will supervise the final arrangements for these lots which may not be transported without its authorization.

All this information will be notified to the Ministerial Regional Secretariat (SEREMI) of Health, and all the corresponding legal actions will be taken against those that are responsible for the use of the product.

If the analysis of the information shows that all or part of the affected product was exported, SERNAPESCA will evaluate the situation and will notify the Competent Authority of the country of destination.

c) Detection of Unauthorized Substances

In the case of crystal violet (CV) and leuco crystal violet (LCV), to determine when a result is unfavorable, the presence of both analytes will be considered, that is to say, crystal violet (CV) + leuco crystal violet (LCV), or only the presence of leuco crystal violet (LCV). This applies in the same manner for malachite green (MG) and leuco malachite green (LMG).

If the result comes from samplings in freshwater centers (fish rearing stations, lakes), the following will apply:

- The fish may only be transported for stockings to other facilities, with the prior authorization of SERNAPESCA.
- All the fish from the center must be tracked up to their stage in seawater.
- In the case of land stocked trout (*pan size trout*), a pre-harvest sample must be conducted prior to the harvest, considering n=5 per tank.
- These fish must be subjected to new samplings after their development (fattening).
- If the detection is made on a group of spawners kept in fish rearing stations, these fish may only be destined to a plant for their processing after a pre-harvest sampling considering n=5 per tank.
- The fish of the involved tank may not be intended for human consumption.

If the result comes from samplings in seawater centers (fattening), the following will apply:

- The fish may not be harvested or transported to other facilities.
- SERNAPESCA will request the traceability information of the involved cages, which must be sent within 5 days.
- The farm must be subjected to a pre-harvest sampling per cage, for which n=10 per cage must be considered.
- If the fish are intended for spawning, they may be transferred to a fish rearing station without the need to conduct any samplings. However, their products may not be intended for human consumption. If the intention is to destine products to the plant, the fish must be subjected to new samplings in further stages of their development.

Both the restrictions on harvesting and movement will be revoked when it is demonstrated through new samplings and analyses that the specimens do not present residues of unauthorized substances or metabolites.

If any harvesting took place before the date in which the results were communicated, the farm must inform the SERNAPESCA office assigned to the location of the center the destination of the raw material within 48 hours.

This situation must also be informed to the processing plants that have received such raw material, with a copy to the SERNAPESCA office under the jurisdiction of each processing plant, so as to adopt the necessary corrective actions.

SERNAPESCA will supervise the final arrangements for these lots which may not be transported without its authorization.

If the analysis of the information shows that all or part of the affected product was exported, SERNAPESCA will evaluate the situation and will notify the Competent Authority of the country of destination.

The cages may be released for harvesting only once all the results are obtained. No residual levels are accepted.

2.3. CONTROL OF PHARMACEUTICAL PRODUCTS RESIDUES, PROHIBITED SUBSTANCES, UNAUTHORIZED SUBSTANCES AND CONTAMINANTS IN PROCESSING PLANTS

Processing plants must incorporate in their Quality Assurance Program verifications, the analysis of 10 samples per month to determine the presence of pharmaceutical products residues, prohibited substances, unauthorized substances, and contaminants, by a Verification laboratory recognized by SERNAPESCA for such purposes.

The determinations included in the verifications correspond to those informed in Item 3 of this Chapter.

Based on the requirements and the procedures of destination markets and the use of veterinary drugs at a national level, the residues analysis for other pharmaceutical products or contaminants may be incorporated.

These samplings must be carried out according to the Aquaculture Control Procedures for Pharmaceutical Products, Prohibited Substances, Unauthorized Substances and Contaminants described in Items 1.1.4 and 2.1.3.5, Chapter II, Section IV of this Manual.

The results will be directly issued by the SERNAPESCA Verification Laboratory to the Foreign Trade Sub-Directorate at a central level. Also, the laboratory will send a copy of these results to the company involved.

The establishments that only receive processed raw materials from plants with a QAP (frozen product to be smoked, the raw material for canned products,) must not carry out verification analyses for pharmaceutical products, prohibited substances, unauthorized substances, and contaminants.

The above does not apply to establishments that receive raw materials from slaughtering or primary plants, which must conduct monthly verifications.

For those establishments that conduct maquila operations or export sporadically (less than 20% of their annual production,) or that process sporadically (less than 6 processes per month,) must carry out the verification of pharmaceutical products, prohibited substances, unauthorized substances, at least on a quarterly basis, so as to conduct 4 samplings per year. To adopt the quarterly verifications system, the interested establishment must communicate its intent in writing to the Regional Directorate of the National Fisheries and Aquaculture Service under whose jurisdiction the processing plant is located.

The SERNAPESCA inspector in charge of the establishment will be responsible for confirming the information that supports this verification. Afterward, the National Directorate must inform the name of the establishments that are part of this system to the Foreign Trade Sub-Directorate at a central level.

Procedures for unfavorable results

Unfavorable results will be directly communicated by the SERNAPESCA Verification Laboratory to the Foreign Trade Sub-Directorate at a central level.

Unfavorable results are considered to be those that indicate residues concentrations above the maximum residual limits (MRL) established for the destination markets and/or the national MRL,

once it is verified that the residue levels detected in the analyzed samples are not supported by the market restrictions stated in the Declaration of Guarantee and that the plant's QAP has included and approved the hazard for receiving this raw material in these conditions.

Unfavorable results will be sent via email to the corresponding Regional Directorate of SERNAPESCA, requesting the information on the arrangements and destination of the lots involved. Similarly, the Animal Health Department of the Sub-Directorate of Aquaculture will be informed via email, so that it can carry out the investigation to determine the possible causes of the unfavorable event, in accordance with the procedures set forth by the Department for this purpose.

SERNAPESCA will supervise the final arrangements for these lots. The involved company must inform the corresponding SERNAPESCA office, the destination of the raw materials originating from the affected cages, the rest of the cages from the same treatment group or farm, accordingly, within 48 hours, in accordance to what is described in the Follow-up Instructions for Export Products with Unfavorable Analysis Results (see Section II, Chapter II, Item 1.3.2.).

If the analysis of the information shows that all or part of the affected product was exported, SERNAPESCA will evaluate the situation and will notify the Competent Authority of the country of destination, as deemed appropriate.

If there are affected products exceeding the national MRL, SERNAPESCA will inform these results to the Ministry of Health.

A new sampling lead by SERNAPESCA must be conducted, who when carrying out the next monthly verification in the processing plant must select the products from the affected farm, from the lots entered during the month of the verification.

If on the farm of origin there are still unharvested fish, corrective actions for that hazard must be applied, and also, the farm must carry out a review of their internal processes, so as to guarantee that a similar problem will not be repeated.

SERNAPESCA may incorporate in its inspections program, an inspection visit to the processing plant to verify the implementation of the corresponding corrective actions.

3. MAXIMUM RESIDUAL LIMITS IN FISH FLESH AND SKIN

Table *MRL IN PHARMACEUTICAL PRODUCTS*

Pharmaceutical product	Chile (µg/kg)	European Union (µg/kg)	Japan (µg/kg)	Eurasian Economic Union (µg/kg)	China (µg/kg)
Oxolinic acid	100	100	100	100	300
Amoxicillin	50	50	50	50	50
Ampicillin	50	50	50	50	50
Benzylpenicillin	50	50	-	50	50
Emamectin Benzoate	100	100	100	-	-
Cypermethrin	50	50	30	1.5	-
Chlortetracycline and its 4-epimer	-	100	-	-	-
Colistin	150	150	-	150	-
Danofloxacin	-	100	-	100	100
Deltamethrin	30	10	30	-	30
Diflubenzuron	1000	1000	1000	-	-
Doxicycline	-	100	-	-	-
Erythromycin	200	200	200	200	200
Spectinomycin	-	300	300	300	-
Spiramycin	-	-	200	-	-
Flavophospholipol	-	-	-	700	-
Florfenicol	1000	1000	200	1000	1000
Flumequine	500 (trout) 600 (other salmonids)	600	500	600	500
Fluoroquinolones (sum of Ciprofloxacin and Enrofloxacin)	-	100	-	-	100
Fluoroquinolones (sum of Ciprofloxacin, Enrofloxacin Pefloxacin, Ofloxacin, Norfloxacin)	-	-	-	100	-
Lincomycin	-	100	-	100	-
Neomycin	-	500	500	500	-
Oxytetracycline	200	-	200	-	-
Oxytetracycline and its 4-epimer	-	100	-	-	-
Sulfonamides	100	100	100	100	100
Teflubenzuron	500	500	-	-	-
Tetracycline and its 4-epimer	-	100	-	-	-
Tetracyclines (sum of Chlortetracycline, Oxytetracycline, Tetracycline and its 4-epimer)	-	-	-	10	100
Tilmicosin	-	50	-	50	-
Tylosin	-	100	-	100	-
Trimethoprim	-	50	80	50	50

Table 5 *MRL IN CONTAMINANTS*

Aldrin	0.1 ppm	Chlordane	0.05 ppm
DDE	5.0 ppm	DDT	3.0 ppm
Dichlorvos	Absence	Dieldrin	0.1 ppm
Diquat	0.1 ppm	Heptachloride	0.05 ppm
Epoxy Heptachloride	0.05 ppm	Mirex	0.1 ppm
TDE	5.0 ppm	2,4-D	1.0 ppm

Table *MRL IN PROHIBITED SUBSTANCES AND UNAUTHORIZED SUBSTANCES*

Chloramphenicol	Absence
Steroids (17β-estradiol)	Absence
Stilbenes	Absence
Nitrofurans	Absence
Nitroimidazoles	Absence
Crystal Violet and Leucocrystal Violet	Absence
Malachite Green and Leucomalachite green	Absence

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CHAPTER III. VESSELS CONTROL

This Chapter addresses the procedures and requirements that apply to artisanal and industrial vessels that are part of the capture and extraction of fishery and aquaculture resources that will be destined to a fishery plant for their further processing and export to the European Union.

To obtain an authorization for a vessel, the requestor (owner of the vessel, fishery plant, trade union, etc.) must accredit that the vessel has all the legal and regulatory authorizations for its operation, and comply with the procedures and requirements described in Items 1 and 2 as follows, according to the type of vessel.

1. ARTISANAL VESSELS

To request an authorization for an artisanal vessel, the interested party must manifest its intent, either verbally or in writing at the Office of SERNAPESCA assigned to the port of unloading of the vessel. For the above, the interested party will provide all the information described in items II and III of the Approval Checklist/Report for Artisanal Vessels SPA (Chapter III, Part III, Annexes.)

The SERNAPESCA official will verify the information, and will sign, stamp and assign a number to the Checklist/Report before the inspection. It must be mentioned that any omissions or erroneous information will cause the suspension of the vessel inspection.

The regional inspector of SERNAPESCA will coordinate the date of inspection of the vessel, so that it matches its landfall, for the purpose of inspecting aspects related to infrastructure, health management on board and unloading. For these aspects included in the Checklist/report, a classification of deficiencies has been defined (minor, major, serious and critical), with the purpose of conducting an objective evaluation of the artisanal vessels. This classification is associated with the risk that the detected deficiency may directly affect the sanitary quality of the product.

Critical deficiency (CR): A deficiency that does not comply with the requirements for the vessel's infrastructure, health management on board and/or the safety of the resources, thus producing foodstuff that is a threat to public health.

Serious deficiency (S): The vessel does not have the proper infrastructure, neither a correct health management system on board and/or product safety of the resources, which can lead to the alteration of food.

Major deficiency (MJ): Does not comply with the requirements for the vessel's infrastructure, health management on board and/or the safety of the resources, thus reducing their quality, without becoming critical.

Minor deficiency (MN): Does not match the infrastructure requirements for the vessel, sanitary management on board and/or safety of the resources. Its impact on the condition of the final product is that it slightly affects its general hygiene.

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 the vessel transports the catch for less than 24 hours, only the aspects included in the item "Vessels that transport the catch for less than 24 hours" of the Checklist/Report will be evaluated. If the vessel transports the catch for more than 26 to 36 hours, all the aspects included in the checklist will be evaluated.

The artisanal vessels used for the capture of fishery resources in their natural environment, or for handling or processing them after their capture must comply with the structure and equipment requirements set forth in Item 1.2 as follows.

The operations carried out on board vessels must take place in accordance with Items 1.1, 1.3 and 1.4, as follows.

1.1 GENERAL HYGIENE PROVISIONS APPLICABLE TO RAW MATERIAL AND ASSOCIATED OPERATIONS

Small and privately owned fisheries and vessel owners must implement all the following measures, as appropriate:

- The raw materials must be protected from any sources of contamination, considering their further processing.
- All the facilities used for raw materials and associated operations must be kept clean.
- The equipment, containers, boxes, trays, bins, and vessels must be kept clean, and when necessary, they will be properly disinfected after the cleaning process.
- Clean water will be used, as necessary, to avoid contamination.
- It must be guaranteed that the staff (crew members or fishermen) handling fishery products are in good health condition and that they are trained on health risks. The staff (crew members or fishermen) in charge of the handling operations of fishery products must follow the standards of personal hygiene (including their clothes).
- Residues and hazardous substances will be stored and handled (for instance, fuel and lubricants), so as to avoid the contamination of the fishery resources.

1.2 STRUCTURE AND EQUIPMENT REQUIREMENTS

The vessels must be designed and built so as to avoid the contamination of captured fishery resources due to bilge water, waste water, smoke, fuel, oil, grease and other harmful substances.

The surfaces that come into contact with captured fishery resources must be of a proper material, resistant to corrosion, smooth and easy to clean. The linings of the surfaces must be made to last and non-toxic.

The equipment and the instruments used for handling the captured fishery resources must be made with corrosion-resistant materials that are easy to clean and disinfect.

When the vessels manually take the water used with fishery products, they must do it in a way to avoid its contamination.

When the vessels have a water intake for the water used with captured fishery resources, it must be located in a way that avoids its contamination.

The containers used to store ice-packed captured fishery resources must avoid the thawing water from entering into contact with the products.

Requirements applicable to vessels that keep onboard fresh fishery products for more than 36 hours for those intended for the production of fish oil, and for more than 24 hours for manufacturing other products

The fishery vessels designed and equipped to preserve onboard fishery products for more than 24 hours, will be equipped with storage areas, cisterns or containers for storing fishery products under the following conditions:

- When appropriate, captured fishery resources will be kept at a temperature close to ice melting.
- Live captured fishery resources will be kept at a temperature and in a way that does not negatively impact the safety of the food or their viability.

The storage areas must be separated from the machines room and from the areas reserved for the crew with leak-proof bulkheads, to avoid any contamination of the stored fishery products. The storage areas and containers used for storing the fishery products must guarantee their preservation in satisfactory hygienic conditions and, when necessary, avoid for the ice-water slurry to come into contact with the products.

1.3 HYGIENE REQUIREMENTS

When using the areas of the vessel or the containers reserved for the storage of fishery products, these must be kept clean and in good condition and, in particular, may not be contaminated by fuel or the bilge water.

From the moment of their shipment, captured fishery resources must be protected from contamination and the effects of the sun or any other source of heat. Clean water must be used for washing them, clean sea water may be used.

Captured fishery resources must be handled and stored so as to avoid any bruising. Those who handle them may use sharp instruments to move fish of large sizes or for fish that may hurt them, to the extent that the skin and the flesh of such product are not deteriorated.

Captured fishery resources, except for those kept alive, must be subjected to a refrigeration process as soon as possible after their shipment. If it is not possible to refrigerate them, they must be unloaded as soon as possible.

The ice used to refrigerate captured fishery resources must be made with clean water. Before its use, it must be stored under conditions that avoid its contamination.

If fish are de-headed or eviscerated onboard, such operations must be carried out in a hygienic manner, and as soon as possible after their capture, and the captured fishery resources must be washed immediately and thoroughly with clean water. In this case, 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. Liver and gonads intended for human consumption will be preserved in ice, at a temperature close to ice melting, or frozen.

The equipment used for evisceration or de-heading, and the different containers, tools, and devices that come into contact with captured fishery resources will be made of or covered by weather-

proof, incorruptible, smooth, and easy to clean and disinfect material. They must be completely clean when using them.

Whole and eviscerated captured fishery resources may be transported or stored in refrigerated water on board the vessels.

When whole fish intended to be canned is frozen in salt brine, the temperature for that product must be equal to or lower than -9 C°. Salt brine must not constitute a source of contamination for the fish.

1.4 REQUIREMENTS FOR THE STAFF

The staff (crew members or fishermen) must wear suitable and clean work clothes.

The staff (crew members or fishermen) in charge of handling and related operations of the fishery products must wash their hands every time that they resume their tasks.

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

All the necessary measures must be put in place to avoid having staff that may contaminate captured fishery resources when working with and handling them until their fitness to do so without any risks is demonstrated.

If gloves are used when handling captured fishery resources, they must be in perfect condition and clean. Gloves must be made of impermeable material. The use of gloves will not exempt the operator (crew member or fisherman) from washing his hands properly.

The staff (crew members or fishermen) in charge of handling fishery products and any related operations must be trained by SERNAPESCA.

1.5 OTHER ASPECTS

As the result of the inspection, the vessel will be classified in one of the categories described as follows. Each one of these categories is determined by adding the deficiencies detected during the visit:

Table *Classification of vessels that transport the catch for less than 24 hours*

CLASSIFICATION	DEFICIENCY		
	MAJOR	SERIOUS	CRITICAL
Approved	≤ 6	1	0
Rejected	≥ 7	≥ 2	≥ 1

Table *Classification of vessels that transport the catch for more than 24 hours*

CLASSIFICATION	DEFICIENCY		
	MAJOR	SERIOUS	CRITICAL
Approved	≤ 15	≤ 3	0
Rejected	≥ 16	≥ 4	≥ 1

Although there are minor non-conformities in the Ship Inspection Guidelines, and they will remain as such registered in the record of the inspection visit, they do not influence the final classification result of Approved or Rejected. Notwithstanding the foregoing, these minor non-conformities must be addressed by the owner or owner of the vessel, given that if repeated, the severity will increase, considered as a major non-conformity.

The Regional SERNAPESCA official that carried out the inspection, will provide the copy of the Approval Checklist/Report for Artisanal Vessels SPA to the owner of the vessel in person, and if appropriate, will include the vessel in the National Sanitary List of Authorized Artisanal Vessels, which will be published on the web page of the Service and on the Intranet.

After each evaluation, the regional office of SERNAPESCA must enter the inspection into the database provided for these purposes.

In regards to the maintenance of the approval for an artisanal vessel, this will be based on the result of the supervisions carried out by the Regional SERNAPESCA official, according to the following procedure:

- The Sanitary Approvals will be valid for one year, where they will remain as part of the "National Sanitary List of Authorized Artisanal Vessels."
- Those vessels that after the inspection are rejected will be removed from the "National Sanitary List of Authorized Artisanal Vessels" until the interested party does not solve the deficiencies found and requests a new inspection through the approval procedure described in this Manual.
- If a Regional SERNAPESCA official detects deficiencies during the unloading operation in an already authorized artisanal vessel, it may conduct an inspection applying the corresponding field Checklist/Report. If the vessel is rejected due to the result of that inspection, the owner of the vessel must be immediately notified, and it will be removed from the National Sanitary List of Authorized Artisanal Vessels.
- Once the deficiencies detected during the last inspection are solved, the owner of the vessel may request a new approval visit. If the result of this inspection is favorable, the vessel may be included again in the above-mentioned List.
- If the vessel has its approval up to date, it will remain as part of the National Sanitary List of Authorized Artisanal Vessels and will be able to deliver raw material to plants that export to Europe.

It must be mentioned that if a deficiency is repeated over time, its severity may increase in the following inspection.

2. INDUSTRIAL AND HAULING VESSELS

To apply for the approval of the industrial or hauling vessel, the interested party must present at the SERNAPESCA office, the Vessels Approval Request (Chapter II, Part III, Annexes,) in original and copy, providing the following information:

- Identification of the requestor (name, address, city, region, phone, email.)
- Information on the vessel (type, identification, the name of the vessel, RPI/RPE No., registration number, port of unloading and species that it captures/transports.)
- Activities carried out on board (capture, evisceration, transportation, use of ice, among others).

The inspection will be based on the application of the Infrastructure and Health Management Inspection Checklist for Vessels that destine their capture to fishery plants intended for human consumption, which can be found in Chapter III, Part III, Annexes.

The Regional Inspector of SERNAPESCA will coordinate the date of inspection of the vessel, so that it matches its landfall, for the purpose of inspecting aspects related to infrastructure, health management on board and unloading. For each one of these aspects of the Infrastructure and Health Management Inspection Checklist for Vessels that destine their capture to fishery plants intended for human consumption, a deficiencies classification has been defined (minor, major, serious and critical,) with the purpose of conducting an objective evaluation of the vessels. This classification is associated with the risk that the detected deficiency may directly affect the sanitary quality of the product.

Critical deficiency (CR): A deficiency that does not comply with the requirements for the vessel's infrastructure, health management on board and/or the safety of the resources, thus producing foodstuff that is a threat to public health.

Serious deficiency (S): The vessel does not have the proper infrastructure, neither a correct health management system on board and/or product safety of the resources, which can lead to the alteration of food.

Major deficiency (MJ): Does not comply with the requirements for the vessel's infrastructure, health management on board and/or the safety of the resources, thus reducing their quality, without becoming critical.

Minor deficiency (MN): Does not match the infrastructure requirements for the vessel, sanitary management on board and/or safety of the resources. Its impact on the condition of the final product is that it slightly affects its general hygiene.

It must me 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.

The industrial and hauling vessels used for the capture of fishery resources in their natural environment, or for their handling or processing after their capture, must comply with the structure and equipment requirements set forth in Item 2.2 as follows.
The operations carried out on board the vessels must take place so as to meet the following items:

- The vessels used for the capture of fishery resources in their natural environment, or for their handling or processing after their capture, must comply with the structure and equipment requirements set forth in this Manual.
- The operations carried out onboard the vessels must comply with the instructions provided in this Manual.

2.1 GENERAL HYGIENE PROVISIONS APPLICABLE TO RAW MATERIAL AND ASSOCIATED OPERATIONS

Small and privately owned fisheries and vessel owners must implement all the following measures, as appropriate:

- The raw materials must be protected from any sources of contamination, considering their further processing.
- All the facilities used for raw materials and associated operations must be kept clean.
- The equipment, containers, boxes, and vessels will be kept clean and, when necessary, will be properly disinfected afterward.
- Clean water will be used when necessary to avoid contamination.
- It will be guaranteed that the staff handling fishery products is in good health condition and that it is trained on health risks. The staff in charge of the handling operations of fishery products must follow the standards of personal hygiene (including their clothes).
- Residues and hazardous substances will be stored so as to avoid contamination.

2.2 STRUCTURE AND EQUIPMENT REQUIREMENTS

The vessels must be designed and built so as to avoid the contamination of captured fishery resources due to bilge water, waste water, smoke, fuel, oil, grease and other harmful substances.

The surfaces that come into contact with captured fishery resources must be of a proper material, resistant to corrosion, smooth and easy to clean. The linings of the surfaces must be made to last and non-toxic.

The equipment and the instruments used for handling the captured fishery resources must be made with corrosion-resistant materials that are easy to clean and disinfect.

When the vessels have a water intake for the water used with captured fishery resources, it must be located in a way that avoids its contamination.

The containers used to store fresh and ice-packed captured fishery resources must avoid the ice-water slurry from entering into contact with them.

The industrial vessels authorized for processing fishery products, must have a valid authorization regarding the resources to be captured, given by the Undersecretariat of Fisheries and Aquaculture.

If vessels are intended for carrying out processes on board, they must have hand washing stations available.

There must be enough changing facilities and restrooms, with walls and floors with smooth surfaces, impermeable and washable (see the following Table). The sinks in the restrooms must have products for washing and disinfecting hands and disposable towels or hot air hand dryers.

Table *Number of sanitary fixtures required*

Number of workers	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

When there are more than one hundred workers per shift, one toilet, and one sink will be added for every fifteen people and one shower for every ten people. In the case of replacing individual sinks with 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.

Vessels designed and equipped to preserve on board fresh fishery products for more than 24 hours must:

- Be designed and equipped to preserve on board captured fishery resources for more than 36 hours, in the case of those destined to make fish oil; and for more than 24 hours, for manufacturing other products, will be equipped with warehouses, cisterns or containers for storing captured fishery resources under the following conditions:
  - When appropriate, fresh captured fishery resources will be kept at a temperature close to ice melting.
  - Live captured fishery resources will be kept at a temperature and in a way that does not negatively impact the safety of the food or their viability.
- The storage areas must be separated from the machines room and from the areas reserved for the crew with leak-proof bulkheads, to avoid any contamination of the stored captured fishery resources. The storage areas and containers used for storing the fishery products must guarantee their preservation in satisfactory hygienic conditions and, when necessary, avoid for any ice-water slurry to come into contact with the captured fishery resources.
- In vessels equipped to refrigerate captured fishery resources in clean-refrigerated seawater, the tanks must have devices to maintain a homogeneous temperature inside; such devices must reach a refrigeration index that guarantees that the mix of fish and clean seawater reaches a temperature no greater than 3 C°, 6 hours after the shipment or 0 C° 16 hours later and allow the supervision and, if appropriate, recording temperatures.

2.3 HYGIENE REQUIREMENTS

When using the areas of the vessel or the containers reserved for the storage of captured fishery resources, these must be kept clean and in good maintenance conditions and, in particular, may not be contaminated by fuel or bilge water.

From the moment of their shipment, captured fishery resources must be protected from contamination and the effects of the sun or any other source of heat. Clean and abundant water must be used for washing them.

Captured fishery resources must be handled and stored so as to avoid any bruising. Those who handle them may use sharp instruments to move fish of large sizes or those that can hurt them, to the extent that the flesh of such product is not deteriorated.

Fishery products, except those preserved live and those intended to produce fish oil that will be processed within 36 hours from their capture, must be subjected to a refrigeration process, as soon as possible after their shipment. If it is not possible to refrigerate them, they must be unloaded as soon as possible.

The ice used to refrigerate captured fishery resources must be made with clean water. Before its use, it must be stored under conditions that avoid its contamination.

If fish are de-headed or eviscerated onboard, such operations must be carried out in a hygienic manner, and as soon as possible after their capture, and the products must be washed immediately and thoroughly with clean water. In this case, 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 captured fishery resources intended for human consumption. Liver and gonads intended for human consumption will be preserved in ice, at a temperature close to ice melting, or frozen.

The equipment used for the evisceration or de-heading, and the different containers, tools, and devices that come into contact with captured fishery resources will be made of or covered by a weather-proof, incorruptible, smooth, and easy to clean and disinfect material. They must be completely clean when using them.

Whole and eviscerated captured fishery resources may be transported or stored in refrigerated water on board the vessels.

When whole fish intended to be canned is frozen in salt brine, the temperature for that product must be equal to or lower than -9 C°. Salt brine must not constitute a source of contamination for the fish.

2.4 REQUIREMENTS FOR THE STAFF

The staff (crew members or fishermen) must wear suitable and clean work clothes.

The staff (crew members or fishermen) in charge of handling fishery products and any related operations must wash their hands every time that they resume their tasks.

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

All the necessary measures must be put in place to avoid having staff that may contaminate captured fishery resources when working with and handling them until their fitness to do so without any risks is demonstrated.

If gloves are used when handling captured fishery resources, they must be in perfect condition and clean. Gloves must be made of impermeable material. The use of gloves will not exempt the operator (crew member or fisherman) from washing his hands properly.

The staff (crew members or fishermen) in charge of handling captured fishery resources and any related operations must be trained by SERNAPESCA.

2.5 OTHER ASPECTS

Once the inspection has concluded, the Regional Inspector of SERNAPESCA will issue a visit report to the interested party, which must include the deficiencies observed and the category in which the vessel was classified. That report must be sent within 3 business days from the inspection visit for the vessels whose change of category means a modification to its sanitary condition. If the result of the visit does not alter the sanitary condition, the report must be sent within 15 days

The vessel will be classified in any of the following criteria:

Table *Classification of vessels*

CLASSIFICATION	DEFICIENCY		
	MAJOR	SERIOUS	CRITCAL
Approved	≤ 10	≤ 2	0
Rejected	≥ 11	≥ 3	≥ 1

Although there are minor non-conformities in the Ship Inspection Guidelines, and they will remain as such registered in the record of the inspection visit, they do not influence the final classification result of Approved or Rejected. Notwithstanding the foregoing, these minor non-conformities must be addressed by the owner or owner of the vessel, given that if repeated, the severity will increase, considered as a major non-conformity.

On a periodical basis, the Central Office is also informed of the list of vessels subjected to this evaluation with their corresponding category, so that they are included, as appropriate, in the "National List of Industrial and Hauling Vessels."

When a vessel is "Approved with comments," it must request a new inspection so as to clear the comments made, within 30 days after the first visit. During this period, the resources captured may be used for processing fishery products for human consumption intended for export to the EU. If 30 days elapse and the visit has not taken place (without any prior justification), the vessel will be immediately removed from the List of Authorized Vessels.

If the result of the inspection of a vessel is under the "Rejected" category, a new visit from the Regional Inspector of SERNAPESCA must be requested. During this period, the resources captured may not be used for processing fishery products for human consumption intended for export to the EU.

If a Regional SERNAPESCA official detects deficiencies during the unloading operation of an industrial or hauling vessel, it may conduct an inspection applying the corresponding field checklist (Section III, Chapter III, Item 13). If the vessel is rejected as a result of that inspection, the owner of the vessel and the Central Office must be immediately notified, and the latter will remove it from the National Sanitary List of Authorized Artisanal Vessels.

Once the deficiencies detected during the last inspection are solved, the owner of the vessel may request a new approval visit from the Regional Inspector of SERNAPESCA. If the result of this inspection is favorable, the vessel may be included again in the above-mentioned List.

When a vessel is approved to deliver captured fishery resources to fishery plants authorized to export, and it is lowered to the "Rejected" category, the inspectors in charge must proceed as follows:

- Immediately report the change in the category via mail to the Central Office.
- Inform the interested party of the result of the inspection and revoke the authorization to deliver captured fishery resources to plants authorized for export.

When a vessel moves up in the category, the same process will apply also informing the corresponding authorization.

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

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