

TRANSLATION No. 854/19.- DECREE. -----

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Decree No. 213/997. -----

The National Fisheries Institute /of Uruguay/, INAPE /for its acronym in Spanish/ is responsible for the sanitary and safety control of fish and fishery products.- -----

Ministry of Livestock, Agriculture and Fisheries, -----

Ministry of Economy and Finance, -----

Ministry of Industry, Energy and Mining, -----

Ministry of Public Health. -----

Montevideo, June 18, 1997. -----

**SEEN:** the Regulation bill for the sanitary and safety control of fishery products prepared by the National Fisheries Institute, to replace the Fishery Products Inspection Regulations passed by the Executive Power under Decree No. 663/987 of November 4, 1987; -----

**WHEREAS:** the said regulations update the regulatory provisions in force on sanitary and safety controls of fishery products, fishing vessels, plants, factories and retail outlets for fishing and fishery products; -----

**WHEREAS:** I) it is the competence of the National Fisheries Institute, inter alia, to control and supervise the hygiene, safety and quality of fishery products, including the control of fishing vessels, plants, retail outlets and factories of fish and fishery products; -----

II) that it is also the responsibility of said Institute to propose amendments to the provisions it deems convenient and

appropriate in order to update the regulations to be issued regarding the safety and quality of fish products, fishery products and by-products, as well as those referring to the extraction, transport, storage, handling, industrialization and their domestic and external commercialization; -----

III) Chapter 14 of the National Bromatological Regulation (Decree No. 315/94 of July 5, 1994) "Fish and Fishery Products", which defines and covers the provisions of the Fisheries Legislation, is insufficient from the point of view of sanctions, penalties and procedures. Therefore, the technical aspects that this National Bromatological Regulations do not include need to be completed and adapted; -----

IN VIEW OF: the provisions of articles 20 and 21 of Law No. 13,833 dated December 29, 1969, articles 2, 3, 5 and agreeing of Decree-Law No. 14,484 of December 9, 1975 and the proposal made by the National Fisheries Institute in this regard, -----

**THE PRESIDENT OF THE REPUBLIC DECREES:** -----

**CHAPTER I. GENERAL PROVISIONS** -----

**SECTION I - Scope of Application** -----

**ARTICLE 1** - The National Fisheries Institute (INAPE) is the official authority responsible for the sanitary and safety control of fish and fishery products in accordance with the provisions of the current legal and regulatory rules. -----

**ARTICLE 2** - The provisions of these regulations and the rules that INAPE sets in this regard shall be applicable to fish and fishery products for human or animal consumption, of national or foreign origin, as well as for their production, storage,

transport and placing on the market. Likewise, it is provided that fishing vessels, plants, retail outlets and factories of fishery products shall be subject to the aforementioned regulations. -----

**SECTION II - General Definitions -----**

**ARTICLE 3 - Definitions:** For the purposes of these Regulations, the following definitions shall apply: -----

1. Fish and fishery products: all aquatic animals or plants or parts thereof. -----

2. Refrigeration: procedure consisting of lowering the temperature of fishery products until it is close to that of melting ice. -----

3. Fresh products: whole or prepared fishery products, including vacuum packaged products or in modified atmosphere packaging, which have not undergone any treatment intended to guarantee their conservation other than refrigeration. -----

4. Prepared or processed products: fishery products that have undergone a modification of their anatomical integrity, such as gutting, deheading, slicing, filleting, chopping, etc. -----

5. Transformed products: fishery products that have undergone chemical or physical treatment, for example, heating, cooking, smoking, salting, dehydration, marinating, etc. applied to refrigerated or frozen products, associated or not to other food products, or a combination of these procedures. -----

6. Frozen products: fishery products that have been subjected to freezing until they reach the inside temperature of at least - 18°C after their thermal stabilization. -----

7. Packaging: material intended, among other things, to protect fishery products by means of a wrapper, a container or any other suitable material. -----

8. Batch: amount of fishery products produced in virtually identical circumstances and in a given time. -----

9. Means of transport: a place reserved for the loading of fish or fishery products in a means of transport, whether by land, sea or air. -----

10. Plant: any premises where fish or fishery products are processed, transformed or stored for export or the domestic market. -----

11. Bivalve Mollusc: lamelibranch molluscs that are fed by filtration. -----

12. Marine biotoxins: toxic substances accumulated in bivalve molluscs and gastropods by ingestion of plankton containing these toxins. -----

13. Production area: the parts of the maritime, river or lake territory where there are natural banks of live bivalve molluscs, or places where live bivalve molluscs and other products derived from aquaculture are cultivated or collected. -

14. Sanitary self-controls: a set of activities that guarantee and demonstrate that a fishery product meets the requirements set forth in these Regulations or in the Technical Standards issued by INAPE in this regard. It shall be part of the internal procedures of the plant or factory vessel and must be developed and carried out by those responsible for each plant

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and have the technical support of a veterinary professional accredited by INAPE. -----

15. Hazard: presence of a biological, chemical or physical agent that is harmful to human health and whose elimination or reduction to acceptable levels is essential for the production of healthy fish food. -----

16. Risk: probability of occurrence of a hazard. -----

17. Economic fraud: when the recipient or consumer of fishery products is deceived through the use of irregular labeling, in terms of declaration of species, products, ingredients, net weight, etc. -----

18. Critical point: any stage or procedure in the process in which any danger to food safety or economic fraud can be avoided, eliminated or reduced to an acceptable level through proper control. -----

19. Risk analysis and critical control points (HACCP): a system that identifies specific risks and preventive measures for their control. -----

20. Deterioration: the alteration of fish or fishery products evidenced by sensory, physical, chemical or microbiological methods. -----

21. Harmful: fish or fishery products potentially dangerous to public health because they contains pathogenic microorganisms or their toxins, transmissible parasites or toxic substances. --

22. Processing: includes cleaning, filleting, refrigerating, packaging, canning, freezing, smoking, drying, salting,

marinating or preparing fish or fishery products or by means of any other method. -----

23. Clearance registration certificate: document issued by INAPE granting sanitary clearance, under the terms of Section VI of this Chapter. -----

24. Accredited Service: one that meets the requirements established by the Official Veterinary Inspection, to act as such, and is approved by INAPE under conditions determined by INAPE. -----

25. Preserves: any product contained in a sealed airtight container and subjected to an authorized thermal conservation process, and which under normal conditions of non-refrigerated storage, does not alter or represent any danger to human health. -----

**SECTION III - Regulations** -----

**ARTICLE 4** - INAPE may, with the objective of regulating the export, import, collection, domestic distribution and packaging of fish and fishery products, establish standards: -----

a) that prescribe grading, quality and standards for fish and fishery products, as well as standards in general for batch control (of any type of product) and sampling levels thereof; --

b) that refer to the processing, transformation, storage, classification, packaging, labeling, transportation and inspection of fishery products; -----

c) that regulate the records and authorization of Section VI of this chapter; -----

d) that prescribe the requirements for the health equipment and operation of plants, vessels, vehicles and other equipment used in relation to fishing and processing; -----

e) that prohibit the commercialization or storage of fishery and aquaculture products under any grading, denomination or standard prescribed by the provisions pursuant to these Regulations, unless all the said requirements and the subordinated rules thereto have been fulfilled. -----

f) that establish the information that must be included in the Export Certificate, whether it is a fishing or factory vessel, an approved industrial plant or artisanal fishing. Exports from artisanal fisheries or aquaculture production must come from fishing vessels less than 10 GRT or from plants or warehouses, as appropriate, that are authorized by the Executive Power and approved by INAPE; -----

g) that establish the legends that the labels must bear. -----

**SECTION IV - Inspections** -----

**ARTICLE 5** - The duties of the Official Veterinary Inspection of the fishing activity shall be performed within the scope of INAPE by veterinary professionals and suitable assistants of the Department of Industrial Development sufficiently accredited by the Institute. -----

**ARTICLE 6** - An inspector may at any time: a) request any information of a technical nature that he/she deems necessary and must also receive from the inspected subject the broadest collaboration for the proper fulfillment of his/her duty; b) enter any fishing vessel, place or facility, where fishery

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products are processed or stored, review any means of transporting fishery products and open any container containing the same; c) take samples free of charge for inspection purposes. -----

**ARTICLE 7** - Without prejudice to the current legislation, when an inspector believes, based on reasonable grounds, that there has been a breach of the present Regulations or subordinate rules, the same may detain any fishery product or container subject to such breach. Detained items may be confiscated or resampled and shall not be commercialized until INAPE rules on this. Items of products that have been inspected and declared as unwholesome for human consumption must be sent to authorized fishmeal plants or other authorized process, according to the procedures set by INAPE. When products are sentenced to reduction, the process shall be inspected by a representative of INAPE, who shall prepare a record of the procedure followed.

**ARTICLE 8** - In order to preserve the identity of any fishery product, an inspector may detain the product and attach a numbered label on which it is clearly written; -----

- 1) the word "detained"; -----
- 2) an identification number; -----
- 3) a brief description of the batch; -----
- 4) the date; -----

5) the inspector's signature. The company responsible shall be notified of the detained fishery product, the procedure performed and the characteristics thereof. No label of any fishery product nor its container shall be altered, mutilated

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or removed, nor said product be moved, sold or disposed of, unless a notice of release by INAPE has been issued. -----

**ARTICLE 9** - Any physical or legal person that proves an interest regarding the decision of an inspector upon an inspection carried out, may request a new inspection before INAPE, within twenty-four hours, by means of a well-founded document, endorsed by a veterinary professional registered by the company before INAPE. If the corresponding technical division considers that there are sufficient grounds, it shall order a re-inspection and the decision reached shall be deemed final. -----

**ARTICLE 10** - No re-inspection shall be ordered if the applicant of the same has not sufficiently accredited before the Institute that the identity of the fishery product subject to the inspection has been preserved. -----

**ARTICLE 11** - When an inspector has sufficient grounds to believe that the fishery product has deteriorated after the date on which it was inspected or that it does not comply with the requirements of these provisions, in any other way, he/she may inspect it again. -----

**SECTION V - Violations** -----

**ARTICLE 12-** The following shall be considered violations for the purposes of these Regulations: a) to falsify, alter or destroy any declaration, inspection certificate or other document issued under these Regulations or subordinate rules; b) prevent or hinder the action of INAPE inspectors in the performance of their specific duties; c) provide the Official

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Veterinary Inspection of the fishing activity with inaccurate information or deny information regarding sanitary and safety conditions, quantity or origin of the raw materials and ingredients used in the production of fish or by-products; d) develop or handle fishery products in violation of the provisions of these Regulations; e) allow people who do not have a health certificate to work in the plants; f) use, for the purpose of human consumption, fishery products that were found unwholesome for this purpose by the Official Veterinary Inspection of the fishing activity; g) permit adulterated or counterfeit fishery products to be destined for human consumption; h) breach regulations pertaining to the tagging, labeling or coding of fishery products. -----

**ARTICLE 13 - Adulterated.** For the purposes of the provisions of paragraph g) of Article 12, an adulterated product refers to: --

- a) products prepared with altered, non-hygienic or unhealthy raw materials, or otherwise, unwholesome for human consumption;
- b) products containing toxic substances harmful to health, such as poisons, antiseptics, pesticides or chemicals or any other non-approved product; -----
- c) products containing food additives whose use was not approved by the competent authority or in amounts exceeding the authorized limits; -----
- d) products industrialized, packaged or maintained in non-hygienic conditions and that have become contaminated; -----
- e) products packaged in a non-hygienic container or constituted by toxic substances that can make it harmful to health; -----

f) any substance that has been added to increases the weight or volume of the product or reduce its quality and nutritional value. -----

**ARTICLE 14** - Any other act, action or omission, which violates the provisions contained in these Regulations or the subordinate rules issued by INAPE shall also be deemed a violation. -----

**SECTION VI - Registration of Sanitary Clearance** -----

**ARTICLE 15** - Only fish and fishery products whose processing, transformation or storage have been verified in a plant authorized by INAPE may be marketed in accordance with the provisions of chapters III, IV, V, VII, and VIII of these Regulations. -----

**ARTICLE 16** - Fishing vessels greater than 10 GRT must have sanitary clearance in accordance with the provisions of chapter II of the present regulations. -----

**ARTICLE 17** - The transport of fishing and fishery products as well as their by-products must be carried out in vehicles authorized for said purposes by INAPE in accordance with the provisions of chapter VI of these Regulations. -----

**ARTICLE 18** - Any plant that produces ice to be used in the fishing activity must be authorized by INAPE. -----

**ARTICLE 19** - Sanitary clearance of vessels, deposits of fishery products, whether cold stores or not, plants or transport, shall have the following validity: vessels: semiannual; deposits: semiannual; plants: annual; transport: semiannual.

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When a plant is not operating for more than three months, a new clearance certificate shall be requested. -----

**SECTION VII - Labeling** -----

**ARTICLE 20** - Labeling means any legend or provision that is printed, adhered or engraved on a product or its container, wrapping or packaging. Any labelling, as well as the text of the indications or instructions that accompany the product must be previously approved by INAPE. -----

**ARTICLE 21** - Any packaging or label of national or imported products must be correctly and legibly marked to indicate at least: -----

- a) the name of the product bearing the common and scientific name of the intervening species (which form part of it); -----
- b) the name and address of the authorized processing plant; -----
- c) the net weight of the product unless the container or label indicates that the content must be weighed at the time of sale to the public; -----
- d) the ingredients of each container when there is more than one ingredient in it, numbering their proportions in decreasing order; -----
- e) the importer's Registration No. and the label "Approved by INAPE" in all imported products. -----

**ARTICLE 22** - Information that appears on the tags or labels shall not mislead nor deceive the consumer. -----

**ARTICLE 23** - Labels for fishery products and by-products destined for domestic consumption must be written in Spanish.

**ARTICLE 24** - Products of foreign origin must comply with the

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provisions of Art. 21 and also contain the name and address of the importer, faction operator or distributor, as well as the expiration date. -----

**ARTICLE 25** - It is prohibited to use labels that have amendments, added legends with characters other than the typographical ones that correspond to the same, as well as the overlapping of labels on the containers, except in cases expressly authorized by INAPE. -----

**ARTICLE 26** - The approvals of labels shall not be extended beyond the authorization of the processing plant, that is why the suspension or loss of sanitary clearance of a plant in a definitive manner shall imply the expiration of the approval of the label. -----

**SECTION VIII - Codification** -----

**ARTICLE 27** - The packaging of industrialized fishery products in Uruguay must be marked with a code as follows: -----

- a) the container must be marked with the word INAPE followed by the last digit of the current year and three digits to indicate the day of the year when the fish was processed; -----
- b) the code must be correctly and legibly marked on the visible part of the outside of the package; -----
- c) containers of fishery products that have been repackaged must be marked with the initial code to which the letter R. shall be added. -----

**ARTICLE 28** - In preserves, each container must be identified by a permanent code, easy to read and that does not adversely affect the integrity of the package. The code must indicate the

processing plant, production date as established in Art. 26 and thermal processing number of the day. This code must be noted on the corresponding graph of the thermograph. -----

**SECTION IX - Imports** -----

**ARTICLE 29** - The importation of fishery products, by-products and derivatives destined for human and animal food must comply with the requirements established in this section, as well as with the rest of the regulations where appropriate, without prejudice to the provisions of other bodies in this regard. ----

**ARTICLE 30** - Importers must submit the importation request in writing to INAPE, providing the information required. -----

**ARTICLE 31** - The BROU /Banco de la República Oriental del Uruguay - Bank of the Eastern Republic of Uruguay/ shall not process any importation complaint of fishery products, by-products and derivatives destined for human or animal consumption, until having the corresponding authorization by the Institute. -----

**ARTICLE 32** - In order to obtain the authorization referred to in the preceding articles, the applicant shall present an official sanitary certificate issued or validated by the competent authority of the country of origin, also indicating the means of transport and place of entry of the merchandise into the national territory. -----

**ARTICLE 33** - The National Customs Directorate shall allow the entry of merchandise to the country upon delivery of INAPE's final authorization. Fishery products and by-products shall not be mobilized from warehouses for the storage of fishery

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products authorized by INAPE, without prior authorization from the Institute. The products referred to in this article introduced to the country which are not in compliance with its provisions shall be detained by INAPE without further proceedings, and importing firms shall not be entitled to any compensation nor claim without prejudice to the corresponding legal sanctions. -----

**ARTICLE 34** - Fishery products that have no national origin under any title upon entering the national territory and that acquire Uruguayan origin for commercial purposes, shall have the mandatory sanitary intervention of INAPE. -----

**CHAPTER II. SANITARY and SAFETY PROVISIONS OF FISHING AND UNLOADING OPERATIONS** -----

**SECTION I - FISHING** -----

**ARTICLE 35** - Fishing vessels that do not have cold isothermal chambers or that cannot carry ice for the conservation of the fishing obtained, shall not remain out of port carrying out said operations for more than 24 hours. -----

**ARTICLE 36** - All storage rooms where fish and ice are stored must be provided with sufficient insulation to protect the fish and ice from atmospheric conditions. -----

**ARTICLE 37** - The ice used to cool fish in a vessel must be manufactured with clean water, in an establishment authorized by INAPE and must be stored in the storage room of the fishing vessels in such a way that the risks of contamination are minimal. Said ice must be finely divided. -----

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ARTICLE 38 - Whenever feasible after fishing and as soon as possible, fish should be washed and neatly placed in a box with enough ice to keep temperatures properly low until it is delivered for processing. -----

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ARTICLE 39 - Boxes must contain the adequate amount of fish allowing enough space for the ice, so that the fish does not suffer the pressure of the upper boxes. -----

ARTICLE 40 - Species that are too large to be stored in boxes should be stored in storage areas that are part of the structure of the storage room, with enough ice to keep temperatures adequately low. -----

ARTICLE 41 - Ice that has been previously used for some other purpose may not be used to cool fish. -----

ARTICLE 42 - Fish should be stored and cooled as quickly as possible after the catch. -----

ARTICLE 43 - Any treatment to be applied to the raw material on board, different from that described in these Regulations, must be approved by INAPE prior to its implementation. -----

ARTICLE 44 - Fishery products shall not be transported on deck, except in exceptional cases duly founded and authorized by INAPE. -----

ARTICLE 45 - Boxes used to transport fish must be made of smooth, non-absorbent and corrosion resistant material, with no cracks or crevices and must be constructed in such a way that they allow drainage and protect the fish from crushing when boxes are stacked. They shall have the approval of INAPE. -----

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**ARTICLE 46** - Boxes that are used to transport fish in a vessel must be in good sanitary and food safety conditions. -----

**ARTICLE 47** - Storage rooms where fish and ice are stored must: -

a) be provided with a drainage system to remove meltwater and ensure that fish and ice do not come in contact with bilge water or other contaminants; -----

b) be separated from the machine compartments and other areas of the vessel by watertight bulkheads. Also their walls shall be of a non-porous and easily washable smooth material. -----

**ARTICLE 48** - Sanitary facilities must be provided for the hygiene of the personnel in the vessels, and they must be kept in good conditions of cleanliness and hygiene. -----

**SECTION II - Unloading** -----

**ARTICLE 49** - The unloading of fish shall begin as soon as possible after the arrival of the fishing vessel at the port and it must be authorized by the Official Veterinary Inspection of the fishing activity. Said unloading should take as little time as possible to protect the catch, and it may be postponed if the INAPE inspector understands that the weather conditions are not adequate. -----

**ARTICLE 50** - Maximum precautions must be taken during the unloading of fish to prevent contamination by fuel, glass and other undesirable materials. -----

**ARTICLE 51** - Precautions must be taken to protect fish from shocks and other damage during handling, boxing, storage and unloading. -----

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ARTICLE 52 - Storage rooms where the raw material and the equipment used for the unloading are stored should be cleaned and disinfected as soon as possible after the unloading by using drinking water or clean sea water and chemical agents approved by INAPE. -----

ARTICLE 53 - Whenever the Official Veterinary Inspection of the fishing activity deems necessary, a general disinfection, disinsectization and rat extermination of the entire fishing vessel shall be carried out. Cleaning products, disinfectants, insecticides and any substance that may present toxicity, shall be stored in premises or cabinets equipped with locks and shall be used without risk of contamination of the fishery products. The vessel company must have an operational program for the cleaning and general sanitation of the fishing vessel, approved and monitored by INAPE. -----

ARTICLE 54 - Fish boxes that are disembarked must be loaded directly to vehicles that are authorized by INAPE for this purpose. -----

ARTICLE 55 - The Inspector of INAPE may order the removal of fishery products that do not meet the sanitary and safety requirements established. -----

ARTICLE 56 - Persons employed in the unloading of vessels must:  
a) wear clean and hygienic clothing; b) comply with sanitary practices during the operation; c) have a health certificate; d) avoid all types of contamination of the unloaded product. ---

ARTICLE 57 - Factory ships shall be covered, when appropriate, by the scope detailed in Chapters III, IV and V. -----

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CHAPTER III. REQUIREMENTS FOR THE CONSTRUCTION AND EQUIPMENT OF  
FISH PROCESSING PLANTS -----

ARTICLE 58 - The areas that are used to store, classify, wash, box or ice raw material shall be separated from the processing area. -----

ARTICLE 59 - The areas that are used for the storage of packing material must be separated from the working areas and designed in such a way that they protect the packing material from contamination and moisture. -----

ARTICLE 60 - Wet working areas must: a) have floors, where fish is received, stored or processed, built in waterproof, washable, non-slip, non-toxic and easily cleaned and disinfected materials, joined to the walls without forming an angle with the proper slope for adequate drainage; b) have the internal surfaces of the walls built in smooth, waterproof and light colored material, of a height not less than two meters and that can be thoroughly washed. -----

ARTICLE 61 - The drainage system must be of a type and size sufficient to evacuate the effluents from the process and water from the cleaning operations and must be equipped with traps or other devices that prevent the entry of gases, insects or rodents into the building. -----

ARTICLE 62 - Ceilings must be constructed and finished in order to avoid the accumulation of dust and condensation, and they must be easy to clean. -----

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ARTICLE 63 - All openings shall have anti-insect mesh or other appropriate system that prevents insects from entering into the process rooms. -----

ARTICLE 64 - Natural or mechanical ventilation systems must be used to provide fresh air, evacuate undesirable odors, steam and smoke and prevent condensation in the working rooms. -----

ARTICLE 65 - Sanitary facilities for personnel handling fishery products must be of the type and number approved by INAPE and they must have at least: a) staff restrooms that cannot communicate directly with the processing areas; b) sanitary sinks, with running water and non-manual taps, liquid or powder soap and air dryers or disposable towels; c) adequate amount of drinking water with a minimum pressure of 1.4 Kg/cm<sup>2</sup>; d) boot washers at the entrance of the processing area. -----

ARTICLE 66 - Non-drinking water used for steam production, refrigeration, fire control and other similar purposes must be transported by completely separate pipes, perfectly identifiable (preferably with color) so as to avoid any connection with the drinking water system. -----

ARTICLE 67 - Equipment for processing fishery products must have: -----

a) all framework built of non-corrodable surfaces or other appropriate material; -----

b) tables constructed in such a way that the tables themselves and the areas below them can be easily cleaned; -----

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c) material other than wood shall not be used for the construction of any part of a conveyor or other equipment such as shovels and pallets in wet areas. -----

**ARTICLE 68** - If receptacles are used for the deposit of waste, they must be waterproof, made of material approved by INAPE and when necessary, in order to avoid contamination of the plant or of any fish that is processed there, they must have perfect-fit-lids. -----

**ARTICLE 69** - Conveyors used for the transport of raw material and products must be constructed in such a way that the raw material is never transported on the processed product or on surfaces through which it can come into contact with the processed fish. -----

**ARTICLE 70** - A minimum lighting intensity of 220 lux must be provided on all working surfaces in the processing areas. Lamps must be protected to prevent contamination of the food in case of breakage. -----

**ARTICLE 71** - Conveniently located facilities must be provided for the disinfection of protective gloves used in the processing areas. -----

**ARTICLE 72** - Cutting, filleting and skinning boards must be made of a material other than wood, which must be smooth and without crevices. -----

**ARTICLE 73** - Surfaces other than cutting, filleting or skinning tables or boards, in which fish is processed, must be made of a non-absorbent and corrosion-resistant material, other

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than wood, and all the joints in said surfaces must be smooth and waterproof. -----

**ARTICLE 74** - Labels used for identifying the product during processing must be made of materials approved by INAPE, other than paper or cardboard. -----

**ARTICLE 75** - Trays used for fish processing must be made of corrosion-resistant material, other than wood, and they must have smooth surfaces with no cracks or crevices. -----

**ARTICLE 76** - Equipment and utensils used in the preparation and handling of fishery products must be in good conditions of use, free of all corrosion, and the material and its construction must ensure the best sanitary condition. -----

**ARTICLE 77** - Enameled utensils or wire meshes not approved by INAPE shall not be used in the processing. -----

**ARTICLE 78** - The packing area must be kept dry and at a temperature between 8°C and 12°C in processing plants of refrigerated and frozen products. -----

**ARTICLE 79** - Factories must be adequately equipped to ensure that processing operations can be carried out without stopping the product at any stage of the work due to the lack of processing or storage capacity. -----

**ARTICLE 80** - Canning factories must be designed and equipped in such a way that all handling and processing operations can be carried out efficiently, and all materials and products can go from one phase to another of the manufacturing process in an orderly manner and with a minimum of delay without agglomeration of equipment and personnel. -----

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ARTICLE 81 - The design, size, equipment and total capacity of the autoclaves must have been approved by INAPE and all operations must be carried out under competent supervision. ----

CHAPTER IV. OPERATIONAL REQUIREMENTS FOR PLANTS PROCESSING FRESH, FROZEN, PRESERVED AND CANNED FISH -----

ARTICLE 82 - Any person engaged in the handling or processing of fish must have a health certificate. -----

ARTICLE 83 - The following persons shall not be eligible for any working areas which imply direct contact with fishery products: a) people who are known to suffer from a contagious disease; or b) people who are known to be "carriers" of some disease; or c) people who have an infected lesion or wound somewhere in their bodies. -----

ARTICLE 84 - Any person engaged in the handling or processing of fish must wash their hands with water and liquid or powder soap before starting their work or upon re-entering their working station after any absence therefrom. Before entering the process area they must carefully wash their boots. Indicating signs shall be placed in convenient places, and there should be adequate supervision in this regard. -----

ARTICLE 85 - Employees who handle fish with bare hands must not use nail polish. -----

ARTICLE 86 - All waterproof garments must be properly cleaned after each shift change. -----

ARTICLE 87 - Smoking and spitting in the working area of a plant is prohibited. -----

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ARTICLE 88 - Protective gloves worn by employees in the filleting and packing areas must be disinfected at each break during shift change. -----

ARTICLE 89 - Employees engaged in processing operations must observe good cleaning habits and shall be provided with appropriate hygienic clothing and footwear, which they shall keep clean. -----

Workers employed in cold stores shall be excepted and shall wear clean outer clothing. -----

SECTION II - Working Areas -----

ARTICLE 90 - Sanitary facilities must be maintained satisfactorily and a sufficient quantity of disposable towels must be available in each hygienic cabinet and at the entrance of the processing areas. -----

ARTICLE 91 - Liquid waste must be disposed of in such a way that it is inaccessible to insects and that the plant's water supply is not contaminated. It must also comply with the provisions of the general regulations in force. -----

ARTICLE 92 - Waste and scrap must be continuously removed from the processing area and it must be disposed of in a manner satisfactory to INAPE. -----

ARTICLE 93 - If waste receptacles are used, they must be used only for said purpose. -----

ARTICLE 94 - No pets shall be allowed in establishments that handle fishery products. -----

ARTICLE 95 - Each plant must have a rodent and insect control program which must include at least: a) the name of the



operator responsible for the supervision; b) the list of pesticides authorized by INAPE. -----

**ARTICLE 96** - No unnecessary material or equipment shall be stored in the working area of an establishment. -----

**ARTICLE 97** - The area and the surrounding premises under the control of a plant must be kept clean and tidy. -----

**ARTICLE 98** - Brushes, swabs, hoses and all other equipment and cleaning materials must be available at all times at the plant.

**ARTICLE 99** - Rooms used for the storage of raw material for processing must be maintained at an approved temperature ranging between -0.5°C and 2°C. -----

**ARTICLE 100** - The identity of all fish stored for processing or under processing must be maintained at all times. -----

**ARTICLE 101** - In the sequence of raw material processing, the fish caught first should be processed first. -----

**ARTICLE 102** - Raw material waiting to be processed must be kept under conditions that prevent its deterioration, protected against all types of contamination or damage. -----

**ARTICLE 103** - Whole or skinned fish must be washed properly before processing. -----

**ARTICLE 104** - Boxes containing fillets or fish in other stages of processing must not be placed directly on the floor. -----

**ARTICLE 105** - Only clean ice, made with water from an approved source may be used in a plant processing fresh or frozen fish. Ice used must be finely divided. -----

**ARTICLE 106** - The flow of products must be continuous, avoiding delays or intermediate storage. Normally, not more than 3 hours

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shall elapse from the beginning of the processing of the raw material to the beginning of the freezing of the final product. The temperature of the products being processed must be controlled and kept as low as possible and should not exceed 10°C. -----

**ARTICLE 107** - Floors of all working areas must be kept clean and must be washed and disinfected after each shift. -----

**ARTICLE 108** - The equipment including conveyor belts and tables that come into contact with the fish that is processed, other than packaged fish, must be cleaned and disinfected at the end of each day. -----

**ARTICLE 109** - In the plants for fresh and frozen fish, all the equipment and utensils used in the operations of said plants must be kept in good status and sanitary conditions. -----

**ARTICLE 110** - The fish or fishery product shall not be removed from the freezing equipment until it has reached a temperature of -18°C or lower in its center. -----

**ARTICLE 111** - Product glazing must be carried out hygienically and efficiently. -----

**ARTICLE 112** - Fishing companies must have a self-control system based on the Hazard Analysis and Critical Control Points (HACCP), determined and signed by a veterinary professional responsible for the application of the sanitary criteria for fisheries before INAPE. However, the integration of HACCP teams at the company level that are part of the system should preferably be inter and multi-disciplinary. -----

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**CHAPTER V. REQUIREMENTS FOR FROZEN FISH STORAGE PLANTS** -----

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**ARTICLE 113** - Frozen fish storage plants or cold stores in which frozen fish is stored must be kept at a temperature that guarantees  $-18^{\circ}\text{C}$  in the center of the product. They should be equipped with easy-to-read temperature recording systems and the temperature sensor must be placed in the area where the temperature is highest. Temperatures in cold stores must be read, recorded and dated at least every 2 hours, and a record of said temperatures must be kept for a period of at least 12 months. -----

**ARTICLE 114** - Each cold store must be equipped with a precise thermometer or other instrument to measure and record the temperature, placed in such a way that it indicates the average temperature representative of the cold store air. -----

**ARTICLE 115** - Frozen fish must be protected to minimize temperature increase in the product when it is outside the cold store. -----

**ARTICLE 116** - Items that may have a detrimental effect on fishery products shall not be stored in the cold stores used for frozen fishery products. -----

**ARTICLE 117** - A record must be kept of the identity and date of freezing of all stored fish. -----

**ARTICLE 118** - Frozen fish must be stored in a way that allows access to all stored products. -----

**ARTICLE 119** - Frozen fish must be stored at a sufficient distance from the floor, walls and ceiling of the cold store to allow adequate air circulation. -----

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ARTICLE 120 - Defrosting of the cooling equipment in cold stores must be carried out in such a way to maintain the air temperature at  $-18^{\circ}\text{C}$  or lower. -----

ARTICLE 121 - Precautions must be taken to avoid any loss of cold and ingress of moisture through the doors of cold stores for frozen products. -----

ARTICLE 122 - Only frozen fish products with a temperature of  $-18^{\circ}\text{C}$  in the center of the product shall enter cold stores. ----

CHAPTER VI. REQUIREMENTS FOR VEHICLES TO BE USED FOR FISH TRANSPORTATION -----

ARTICLE 123 - When transporting fish destined for human consumption, no other material shall be permitted in the vehicle's body. -----

ARTICLE 124 - Immediately after the unloading of a vehicle, its body must be thoroughly washed and disinfected. -----

ARTICLE 125 - Fresh fish must be transported in plastic boxes or in any other way approved by INAPE. -----

ARTICLE 126 - Plastic boxes used to transport fresh fish must be clean and in adequate sanitary conditions. -----

ARTICLE 127 - During transportation, fresh fish must be kept at a temperature between  $-1^{\circ}\text{C}$  and  $3^{\circ}\text{C}$ . -----

ARTICLE 128 - Vehicles for the transportation of fishery products shall be categorized in the manner indicated below, and must also comply with the following conditions: -----

a) Vehicle Category "A" authorized to transport fresh and frozen fish for human consumption: -----



- 1) the walls of the refrigerated body of the vehicle must be insulated and the internal surface must be smooth and made of a material that has the approval of INAPE; in addition, it must be completely impermeable in all joints and with rounded tips;
  - 2) provisions should be taken to avoid direct drainage to the outside of the vehicle during the transport of fresh fish; ----
  - 3) the refrigeration equipment must be able to maintain a constant air temperature inside the vehicle's body and must be suitable for the transported product; -----
  - 4) equipment must be provided to accurately record the temperature of the air inside the vehicle's body and it must be clearly legible from the outside; -----
  - 5) necessary precautions must be taken so that during transportation the temperature of the frozen products does not exceed  $-18^{\circ}\text{C}$ . - -----
  - 6) storage of frozen fish for transport must be carried out in such a way as to facilitate the satisfactory circulation of refrigerated air. -----
- b) Category "B" vehicles authorized to transport fresh fish for human consumption: -----
- 1) the walls of the refrigerated vehicle body must be insulated and the internal surface must be smooth and made of a material that has the approval of INAPE; in addition, it must be completely impermeable in all joints and with rounded tips. ---
  - 2) provisions should be taken to avoid direct drainage to the outside of the vehicle during the transportation of fresh fish;

c) Category "C" vehicles authorized to transport waste, fish for animal consumption, for fertilizer manufacturing or for other purposes that do not include human consumption: -----

1) the interior surface of vehicles with a closed body must be smooth, made of a non-porous and corrosion-resistant material, other than wood, with rounded edges and joints that allow easy and efficient cleaning. -----

2) provisions must be taken to prevent the escape of drainage liquids to the outside; -----

3) vehicles with an open cargo bed must have a waterproof tarp, which must be kept clean and cover the entire cargo of the vehicle; -----

4) the cargo bed must be divided into compartments not more than 2 meters long. Compartment divisions must be made of smooth, non-porous and corrosion resistant material, other than wood, and must have the approval of INAPE. -----

CHAPTER VII. OPERATIONAL REQUIREMENTS FOR CANNING PLANTS OF MARINE PRODUCTS -----

ARTICLE 129 - The plants dedicated to the elaboration of canned and preserved products shall comply in turn, and when applicable, with the requirements of chapter III of the present Regulations. -----

ARTICLE 130 - Canned and preserved products must be prepared with good quality raw material, prepared in suitable and airtight containers and treated thermally in order to remain attractive and safe for human consumption for a long time under normal conditions. -----

**ARTICLE 131** - Processing plants must regulate the volume of raw material they receive so that their supplies do not become excessive for processing, while at the same time fish is kept in excellent quality conditions. -----

**ARTICLE 132** - For the storage of raw material, processing plants must have cooling rooms or cold stores, or both if applicable, according to their needs. -----

**ARTICLE 133** - When the fish is eviscerated, deheaded, skinned, deboned or portioned for canning or preserves, all these operations must be carried out in a clean and hygienic manner, and they must also be carried out with extreme care to avoid spoiling the quality of the product or denaturalizing it. -----

**ARTICLE 134** - Bivalve molluscs must be washed before being shucked. -----

**ARTICLE 135** - Special care must be taken so that the fragments of shells, sand, etc., are completely removed from the meat of shellfish. -----

**ARTICLE 136** - Methods used to precook or smoke fish or shellfish for canning and preserves must be chosen in such a way that they produce the desired effects with a minimum of delay and handling. -----

**ARTICLE 137** - The cooling down of fish and precooked and hot smoked seafood must be carried out as quickly as possible and under conditions that prevent contamination of the product. ---

**ARTICLE 138** - Solutions used to treat the products in brine, solutions of other kinds, or preservatives or flavoring agents as a pre-canning operation, must be renewed and the containers

and appliances used must be cleaned perfectly at frequent intervals. -----

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**ARTICLE 139** - Additives or chemical products used in solutions to submerge the products must be authorized by INAPE. -----

**ARTICLE 140** - Containers used for packaging fishery products must be of a suitable material and built in such a way that they can be easily closed and made airtight to prevent the entry of any contaminating substance. Containers for packaged fish must meet the following requirements: -----

a) they must protect the contents from contamination caused by microorganisms or any other substance; b) their inner surfaces must not react with the content in any way that could harm the product or the containers; c) their outer surfaces must be resistant to corrosion under any possible storage conditions; d) they must be sound enough to withstand all mechanical and thermal stress that may occur during the packaging process and also resist any physical damage they may suffer during distribution; e) they must be able to open and empty easily. ---

**ARTICLE 141** - Containers for preserved fish must be of a size and shape suitable for the quantity and type of product to be packaged, and when necessary, be coated with a suitable sanitary varnish. -----

**ARTICLE 142** - Containers and lids must be inspected immediately before going to the filling machines, or packing tables, to ensure that they are perfectly clean and without visible waste.

**ARTICLE 143** - When the packing of fish or shellfish is done manually, there must be a continuous supply of raw material and

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empty containers within easy reach of all packers. Filled containers shall be inspected and engraded immediately. The accumulation of raw material or full containers on the packaging table shall be avoided. -----

**ARTICLE 144** - Canned or preserved fish must be produced with sufficient vacuum to prevent containers from deforming when they are subjected to high temperatures, or a low atmospheric pressure, which they may experience during transportation, storage or commercialization. -----

**ARTICLE 145** - Every canning or preserve factory shall establish procedures that prevent canned or preserved fish from being accidentally transported to the storage area without going through the autoclaves. -----

**ARTICLE 146** - The heat treatment shall start preferably within one hour after sealing the containers. -----

**ARTICLE 147** - Periodic inspections shall be carried out to ensure that the autoclaves are equipped and functioning in such a way that they provide a complete and efficient heat treatment. -----

**ARTICLE 148** - All steam autoclaves shall have a precision thermometer, a pressure gauge and a time and temperature recorder. A precision clock shall be set up in the autoclave room in a well visible place. Autoclave temperatures shall only be obtained from precision thermometers. -----

**ARTICLE 149** - A permanent record of the time, temperature and pressure and other pertinent details shall be kept for each load that enters the autoclave: date, autoclave number, type of

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product treated, code, package size and number of cans. These records shall be available to INAPE for two years. -----

**ARTICLE 150** - Products packaged in containers of different sizes and in different covers should not be treated together in the same autoclave. -----

**ARTICLE 151** - The heat treatment time shall not start until the minimum safe purge time has elapsed and the autoclave temperature has reached exactly the level set for the specified treatment. -----

**ARTICLE 152** - When treating products packed in glass containers, care shall be taken regarding the initial temperature of the water in the autoclave to make sure it is slightly lower than that of the product being used. Air pressure shall be applied before the water temperature rises. Nonetheless, care must be taken so that the water temperature does not decrease to such an extent that there is a danger that the glass may break due to an abrupt change of temperature. ---

**ARTICLE 153** - Packaged fish, after being subjected to heat treatment, must be cooled down in pressurized water, which shall be potable and chlorinated. -----

**ARTICLE 154** - Canned and preserved products treated thermally shall not be handled unnecessarily before they are cooled down and completely dry. In no case shall they be handled abruptly or in such a way that their surfaces are exposed to contamination. -----

**ARTICLE 155** - Thermal processes applied in commercial sterilization shall be approved by the Official Veterinary

Service of the fishing activity, in compliance with the established requirements. -----

**ARTICLE 156** - Samples of preserves from each lot shall be examined in order to ensure that there are no defective packages. -----

**ARTICLE 157** - Materials used for the labeling and packaging of canned and preserved fish shall not contribute to the corrosion of the container. Boxes used shall have the right dimensions and shall be strong enough to protect the product during distribution. -----

**ARTICLE 158** - Any individual container containing preserved fish or shellfish shall carry, in addition to the provisions of Art. 21, marks embossed or in indelible ink, stating the number of the processing plant, the product identification code, date and production shift as specified by INAPE. -----

**ARTICLE 159** - The code marks that appear on containers of preserved fish shall also be indicated on the boxes in which they were packed, as per INAPE codification. -----

**ARTICLE 160** - Preserved fish shall be stored in such a way that it remains dry and is not exposed to extreme temperatures. ----

**ARTICLE 161** - Fish preserves shall not be released for sale before 20 days of production have elapsed. -----

**ARTICLE 162** - Labels shall contain the following information:  
a) product; b) species (common and scientific name); c) type of product; d) additive ingredients; e) net weight; f) drained weight; g) name and address of the company. -----

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ARTICLE 163 - All the information that appears on the labels must be legible and its design and format shall not be confusing nor mislead the consumer. Only labels with INAPE approval shall be used. -----

CHAPTER VIII. OPERATIONAL REQUIREMENTS FOR SALTING, DRYING AND SMOKING PLANTS -----

ARTICLE 164 - The salt to be used in the salting process shall respond to an analysis that yields at least 97% purity expressed in sodium chloride; it shall be free of excessive dirt and moisture and shall not contain chemical impurities such as magnesium and calcium salts that exceed 1%. INAPE shall take samples whenever it deems necessary to verify the degree of purity and determine the contamination it may have. -----

ARTICLE 165 - The preparation, handling, drying or smoking of fish or preparations in plants that have not been authorized for such purposes shall be prohibited. -----

ARTICLE 166 - The preparation of fish shall be carried out in a hygienic way; the parts resulting from such handling must be washed before being subjected to salting. -----

ARTICLE 167 - The brine used in the curing and packaging of salted fish in brine shall be made with clean, first-use salt. -

ARTICLE 168 - Once the salting is finished, the product shall be examined by an Inspector of the Institute, who, if the production obtained is deemed fit for human consumption, shall proceed to its sealing using the appropriate element established by INAPE. Any part not indicated by the seal or

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other identification shall be removed immediately. In the case of exports, the corresponding certificate shall be issued. ----

**ARTICLE 169** - The packaging of salted fish or dried salted fish shall be carried out in a way that protects its good sanitary and bromatological conditions. -----

**ARTICLE 170** - For the smoking of fishery products, only firewood, wood shavings or sawdust from hardwoods that do not give off bad odors shall be used. In no case shall resinous woods be used. -----

**ARTICLE 171** - Smoked fish products must be kept at refrigeration temperatures not exceeding 5°C. -----

**ARTICLE 172** - Each unit must be protected by a sanitary container, identified with a label indicating: species used, date of manufacture and expiration date; name, address and manufacturer number and approximate net content. This card shall be a fundamental requirement to market smoked products. Units that do not comply with this requirement shall be removed immediately. -----

**ARTICLE 173** - The Inspection service shall supervise smoking plants, smoking methods, packaging used and maximum marketing periods of these products, as well as their storage conditions.

**CHAPTER IX. SANCTIONS** -----

**ARTICLE 174** - Infractions to the Regulations of Inspection of Fishery Products shall be sanctioned by the National Fisheries Institute, in accordance with laws No. 13833, of December 29, 1969 and No. 16736, of January 5, 1996. -----

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ARTICLE 175 - Let the decree of the Executive Power No. 663/987 of November 4, 1987, be repealed without prejudice to the provisions of Decree No. 315/994, of July 5, 1994. -----

ARTICLE 176 - Let it be communicated, etc. -----

SANGUINETTI -----

CARLOS GASPARRI -----

LUIS MOSCA -----

JULIO HERRERA -----

GUSTAVO AMEN -----

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The undersigned Public Translator declares the foregoing to be a faithful and complete translation of the attached document written in Spanish, /DECREE/ a copy of which is registered in her private file under number 854/19. Montevideo, August 8, 2019. -----



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