

GENERAL REGULATION FOR HYGIENE CONTROL ON FOODSTUFFS OF AQUATIC ORIGIN

CHAPTER I

GENERAL PROVISIONS

ARTICLE 1 (Object)

This regulation establishes the following for foodstuffs of aquatic origin:

- a) Hygic-sanitary and quality management requirements pertaining to the handling and/or processing activities, distribution and trading;
- b) The standards for official controls.

ARTICLE 2 (Definitions)

Notwithstanding the provisions in the Fisheries Act, and for the purpose of this regulation, the following expressions mean:

1. **ACCREDITATION:** procedure by a competent body onto another body, institution or person, to assign formal recognition for executing specific tasks or functions;
2. **ANIMAL FEED:** any food for aquatic aquaculture animals;
3. **ANIMAL WELFARE:** the physical, psychological and nutritional status of the animal, acquired by proper feeding, accommodation and transportation conditions that do not cause unnecessary lesions, or intense or prolonged suffering.
4. **AUDIT:** independent control to determine if official control activities and their results comply with the foreseen provisions and if they are effectively applied;
5. **COMPETENT AUTHORITY:** the entity that ensures compliance with the provisions in this regulation and other related pieces of legislation;
6. **DECEPTIVE OR FRAUDULENT PRODUCTS:** packaged products whose information shown in the labels does not match the contents, namely in terms of calibration or classification, weight, quantity, type of glazing, species, *inter alia*;
7. **ESTABLISHMENT:** autonomous production unit;
8. **FISH INSPECTOR:** State agent representing the Competent Authority, with mandate to find, apply, control, verify, supervise, disseminate and promote enforcement of, and compliance with, the provisions in this regulation and other applicable provisions;
9. **FISHERY PRODUCT TRANSPORTATION:** circulation of foodstuffs of aquatic origin and feed used for aquatic animals for human consumption, produced from fishery products captured in the national territory, third countries or international waters, within the country or passing through the country for other markets;
10. **FISHERY PRODUCTS:** any aquatic species, or part thereof, animal or vegetal, from seawater or freshwater, captured during the fishery activity or with origin in aquaculture, produced for commercial purpose, excluding marine mammals, reptiles and amphibian;
11. **FOOD HYGIENE:** hygienic-sanitary measures and conditions required to control risks inherent to foodstuffs of aquatic origin, in order to ensure appropriateness for human consumption, taking their use into account;
12. **FOODSTUFFS OF AQUATIC ORIGIN:** products and sub-products resulting from the handling and processing of fishery products for human consumption;
13. **HACCP:** "Hazards Analysis and Critical Control Points", own-checks system that identifies specific hazards, defines preventive measures and establishes control of such hazards;
14. **HANDLING:** actions related to the treatment of foodstuffs of aquatic origin between capture and processing or between capture and sale, which comprise care taken during evisceration, washing, storage, transportation and off-loading operations, or any other movement operations;
15. **HAZARD:** any biological, chemical or physical agent present in the product that may potentially damage consumer's health;
16. **HEALTH CERTIFICATION:** procedure through which the Competent Authority supplies a written, electronic or equivalent guarantee of compliance with the provisions in this regulation and other applicable provisions, attesting that the product complies with the hygienic-sanitary requirements;
17. **HEALTH LICENSING:** Procedure carried out by the Competent Authority to record and approve procedures for the installation, modification and operation of production units and establishments;
18. **MANUFACTURING:** the action that determines a substantial change of the initial product by heating, smoking, cure, maturation, drying, extraction, extrusion or a combination of such procedures;
19. **MARKET(S):** the domestic market and the external market;
20. **OFFICIAL CONTROL:** actions carried out by the Competent Authority to ensure compliance with the provisions in this regulation and other applicable provisions;
21. **OPERATOR:** natural or corporate person directly or indirectly involved in any phase of the production chain, including distribution and marketing, of foodstuffs of aquatic origin for human consumption and feeds for aquaculture;
22. **PROCESSING:** anatomic or other alteration, or transformation, of fishery products for human consumption;
23. **PRODUCTION UNIT:** any infrastructure and fishing or fishery-related operations vessel and vehicle, operating directly or indirectly in any stage of the production chain including distribution and marketing, of feed and foodstuffs of aquatic origin for human consumption;
24. **RECURRENCE:** repetition, by the operator onto whom a sanction was imposed under the provisions in this regulation, of a new infraction of the same severity within six months from the date of definite fixation of the previous sanction;
25. **REFERENCE LABORATORY:** the laboratory that makes one or more tests using highly sensitive and specialised analytical techniques, with performance criteria, levels of uncertainty of measurements, procedures to validate methodologies and protocols internationally recognised and

accepted;

26. **RISK ANALYSIS:** a procedure comprising three interlinked components: assessment, management and communication of risks;
27. **RISK ASSESSMENT:** process of identification and characterisation of a hazard, assessment of exposure to, and characterisation of the risk to analyse the likelihood and severity of the identified hazard;
28. **RISK:** relation of probability of occurrence of a hazard and the severity of its effect;
29. **SAFE FOODSTUFF:** harmless food, therefore free of chemical, physical and biological contaminants, or foodstuffs showing contamination levels that are harmless to the health and integrity of consumers;
30. **SAMPLE:** units or parts of batches or sub-batches and/or a portion of a foodstuff of aquatic origin, of a ration or any other relevant substance, extracted or taken for examination or analysis;
31. **SEVERITY:** magnitude and/or impact of a hazard on the consumer's health;
32. **TRACEABILITY:** ability to trace a foodstuff of aquatic origin, a feed or a substance to be, or likely to be, incorporated in it, for origin identification purposes, along the whole of the production chain, including distribution and marketing;
33. **VERIFICATION:** systematic assessment of compliance with the specified requirements by the official control.

ARTICLE 3 (Scope)

1. The provisions in this regulation shall be applicable, within the national territory:
 - a) To every food product and sub-product of aquatic origin for human consumption;
 - b) To the operators along the production chain of the industry of foodstuffs of aquatic origin and feed for aquatic animals for human consumption;
 - c) To all phases of production and/or processing, distribution and marketing of foodstuffs of aquatic origin for human consumption, as well as feed for aquaculture aquatic animals;
 - d) To all products transiting unsealed and handled within the national territory;
 - e) To the official controls for verification of compliance by operators.
2. This regulation does not apply to the retail market.

ARTICLE 4 (Objectives)

The following regulation has the objective to assure:

- a) Fulfillment of the market requirements, better consumer protection and human health, regarding whenever adequate the health protection and welfare of animals and of the environment;
- b) Verification of compliance of the standards defined for undertaking official controls to allow preventing, eliminating or reducing to an acceptable level the health risks for human beings and animals.

ARTICLE 5 (General Principles)

The enforcement of this regulation is guided by the principles of:

- a) food safety;
- b) consumer protection;
- c) responsibility;
- d) traceability;
- e) document maintenance;
- f) confidentiality.

ARTICLE 6 (Principle of food safety)

The assurance of safety of foodstuffs for human consumption and of animals of aquatic origin for human consumption is based on a scientific risk analysis and assessment, internationally acknowledged, based on the HACCP principles.

ARTICLE 7 (Principle of consumer protection)

The protection of consumer interests is established as a way to prevent:

- a) fraudulent and deceptive practices;
- b) adulteration of foodstuffs of aquatic origin;
- c) hazards that may damage consumers' health;
- d) any other practices misleading for consumers.

ARTICLE 8

(Principle of responsibility)

3. The operators along the production chain, including distribution and marketing, are responsible for ensuring the production and sale of safe foodstuffs.
4. The Competent Authority is responsible for controlling and verifying compliance with requirements for the production of safe foodstuffs, along all of the production chain, including distribution and marketing, by making use of official controls.

ARTICLE 9

(Principle of traceability)

Traceability of foodstuffs of aquatic origin, feeds and any other substances to be, or likely to be, incorporated in them, shall be ensured along the whole of the production chain.

ARTICLE 10

(Principle of document maintenance)

Operators are obliged to maintain all documents and records in good reading and handling condition for a period defined by the Competent Authority.

ARTICLE 11

(Principle of confidentiality)

The Competent Authority ensures that the execution of official controls takes place in such a manner as to safeguard confidentiality of information on the activities of production units or establishments and operators.

CHAPTER II

OFFICIAL CONTROLS

SECTION I – MANDATE

ARTICLE 12

(Competent Authority)

The Competent Authority is appointed by the Council of Ministers.

ARTICLE 13

(Standards applicable to official controls)

1. The competent Authority carries out the official controls in compliance with the provisions in this regulation and every other specific procedures and legal instruments that might be approved.
2. To determine the nature and intensity of official controls, the Competent Authority shall assess:
 - a) Risks for public health and, if appropriate, for animal health;
 - b) The type and capacity of procedures in the production units;
 - c) The operator's background in terms of compliance with requirements.

ARTICLE 14

(Mandate of the Competent Authority)

Within the scope of Official Controls, the Competent Authority's mandate is to:

- a) Authorise the installation and/or modification, licensing of production units and certify foodstuffs of aquatic origin and sub-products for the market or transit of fish products;
- b) Implement research programmes related to hazards and risks of foodstuffs of aquatic origin;
- c) Analyse and assess risks of hazards in foodstuffs of aquatic origin;
- d) Carry out planning, development, implementation, supervision and control actions for all activities pertaining to official controls;
- e) Carry out fish inspection training, research and dissemination actions;
- f) Establish and disseminate specific technical standards pertaining to official controls including the preparation or adaptation of specifications, harmonised with the national and international laws.
- g) Verify and audit the compliance with hygio-sanitary requirements by production units, along all production chain phases including distribution and marketing;
- h) Create and maintain documental records of licensing, certification and other related;
- i) Carry out internal audits;
- j) Disseminate national and international legislation on food safety and legislation concerning general and specific requirements of importing markets and

- of fish inspection;
- k) Carry out laboratory analyses on the safety of foodstuffs of aquatic origin or official controls;
 - l) Instruct lab accreditation procedures and maintain the accreditation level;
 - m) Appoint the reference labs for analyses of official controls and own-checks of production units and operators, with regards to safety of foodstuffs of aquatic origin;
 - n) Other as may be superiorly defined within the scope of Fish Inspection.

SECTION II – CRITERIA, OBLIGATIONS, APPLICABILITY AND EXECUTION OF OFFICIAL CONTROLS

ARTICLE 15 (Official Controls)

1. The Competent Authority establishes the System of Official Controls that precedes verification of compliance with the provisions in this regulation and other, by production units and operators.
2. The Official Controls used by the Competent Authority should ensure:
 - a) effectiveness, efficiency and adequacy in their use and compliance;
 - b) access to accredited or reference laboratories;
 - c) existence of qualified staff, in sufficient number and with adequate experience;
 - d) existence of appropriate facilities and equipment and adequate maintenance;
 - e) coordination and co-operation, in case official control functions are assigned onto different control units.
3. The Competent Authority shall integrate emergency plans into Official Controls, and be ready to use them.

ARTICLE 16 (Approval and register)

1. The Competent Authority authorises the installation, construction, modification, operation of, and issues health licenses to, production units and establishments.
2. Approved and licensed production units and establishments shall be registered at the Registry of the Competent Authority, upon which they receive a health registration number.
3. The Competent Authority shall only approve, register and license a production unit or establishment if the operator demonstrates compliance with the relevant requirements of applicable hygio-sanitary legislation.
4. Production units and establishments shall be approved by the Competent Authority following at least one visit, and in every case following the required operational procedures.
5. The operators shall make sure that the Competent Authority has, at all times, updated information on the production units or establishments, including information on any change in structure, procedures and equipment with implications on the production chain, as well as of a possible shutting down.
6. The Competent Authority shall submit all specific requirements for licensing production units and establishments to approval by the Minister responsible for fisheries.

ARTICLE 17 (Service fee)

1. Service provision, including health certification and licensing and the related laboratory analyses, are performed against payment of fees to be set forth by a joint order from the ministers responsible for the areas of fisheries and finance.
2. The amounts collected as fees shall be the Competent Authority's own revenue.

ARTICLE 18 (Duties of the Competent Authority)

1. The Competent Authority shall ensure that official controls are undertaken regularly, depending on risks and with the appropriate frequency, taking into account namely:
 - a) Identified risks associated with aquatic animals, feeds or foodstuffs of aquatic origin, with the activity or operation, which may influence safety of these products or human health or the welfare of aquatic animals;
 - b) The operators' background in regards to compliance with legislation pertaining to feeds or foodstuffs of aquatic origin, or standards pertaining to human health, and the welfare of aquatic animals;
 - c) The reliability of any self-controls that may have been carried out previously;
 - d) Any other information that may indicate noncompliance.
2. The Competent Authority shall keep itself informed and updated about the requirements pertaining to the official controls of destination countries, in what concerns the export of foodstuffs of aquatic origin.

ARTICLE 19

(Duties of operators)

Operators should submit to inspections carried out as per this regulation or other applicable legislation and facilitate the execution of official controls by the Competent Authority, namely by:

- a) Allowing access to production units and establishments;
- b) Making available all documentation and records required or deemed necessary.

ARTICLE 20

(Execution of official controls)

1. Official controls based on verification and audit methods focus on:
 - a) Hygieno-sanitary requirements;
 - b) Good hygiene and manufacturing practices;
 - c) Procedures based on the HACCP system;
 - d) Control of deceptive and fraudulent economic practices.
2. Official controls should find whether operators are applying procedures in a consistent and correct manner, at least in terms of:
 - a) Information pertaining to the production chain;
 - b) Design and maintenance of facilities and equipment in production units and establishments;
 - c) Hygiene before, during and after operations;
 - d) Hygiene of staff and facilities;
 - e) Training in hygiene and work methods;
 - f) Parasite controls;
 - g) Water quality;
 - h) Pest control;
 - i) Temperature control;
 - j) Control of raw materials, ingredients, packaging and final products, entering and leaving production units or establishments, and respective documentation;
 - k) Consistent and correct use of procedures based on the HACCP system;
 - l) Observation of provided microbiological criteria;
 - m) Compliance with requirements on residues, contaminants and forbidden substances;
 - n) Absence of physical, chemical and biological hazards in products;
 - o) Compliance verification of staff and activities with legal requirements in all phases of the production chain, at the production unit or establishment;
 - p) Compliance with the calibration, weight, glazing, labelling, presentation and advertising requirements, *inter alia*, ensuring these are not deceptive for the consumer or fraudulent.
3. The implementation of official controls should specifically cover:
 - a) Staff performance assessment;
 - b) Observation and reading of records made by the operator;
 - c) Sampling for laboratory analysis, as necessary;
 - d) Documentation of the elements verified;
 - e) Interviews with operators;
 - f) Findings and conclusions.
4. Official controls shall be made without notice and with immediate access to facilities and documentation, except when for approval of production units.

Article 21

(Checks and tests within the scope of official controls)

1. Official controls of foodstuffs of aquatic origin should, at least, include the following checks:
 - a) Organoleptic check;
 - b) Parasite check;
 - c) Calibration, weight, glazing, labelling, presentation and publicity checks, *inter alia*.
2. They should further include at least the following tests:
 - a) Total volatile basic nitrogen (TVBN) content test;
 - b) Trimethylamine nitrogen (TMAN) test;
 - c) Histamine test;
 - d) Residues and contaminants tests;
 - e) Microbiological tests;
 - f) Biotoxins, sulphites and pH tests.
3. The Competent Authority shall define the limits and criteria for checks and tests.

ARTICLE 22

(Products unfit for human consumption)

Products are unfit for human and animal consumption if they pose a hazard due to:

- a) Serious deficiencies detected by official controls;
- b) Check and test results showing the existence of levels higher than established;
- c) Having originated from species of poisonous fish indicated in article 36.

ARTICLE 23

(Official control reports)

1. The Competent Authority shall prepare reports on the official controls it carries out, which should include:
 - a) Identification of the operator;
 - b) Composition of the inspection team;
 - c) Description of the official control purpose and methods used;
 - d) Description of results;
 - e) Measures to take;
 - f) Findings and deadlines for adjustment.
2. Each report shall be signed by the Inspector and the operator, or proxy, and a copy of the report shall be given to the operator.

ARTICLE 24

(Sampling and laboratory analysis)

1. Sampling and analysis methods used within the context of official controls shall abide by:
 - a) the national standards or, in their absence, international acknowledged and accepted protocols;
 - b) the standards applicable in importing countries.
2. The execution measures to make laboratory analyses shall, at least, consider:
 - a) Performance criteria, parameters of analysis, degree of uncertainty of measurements and procedures to validate methodologies;
 - b) The rules for interpreting the results.
3. Samples shall be collected, handled and labelled in such a way as to ensure their legal and analytical validity.

ARTICLE 25

(Operator assurances)

The Competent Authority shall establish the procedures to ensure the right of operators whose products are subject to sampling and analysis to request an opinion from independent experts, notwithstanding the obligation of the Competent Authority, in case of emergency, to take the appropriate measures.

ARTICLE 26

(Official laboratories)

1. The Competent Authority shall appoint and publish the list of accredited and reference laboratories, according to the international standards applicable to their operation, evaluation and accreditation, that may analyse the samples collected during the official controls.
2. The Competent Authority shall cancel the appointment of laboratories that cease meeting the required accreditation conditions.

ARTICLE 27

(Emergency plans)

1. During the implementation of a health crisis management, the Competent Authority shall prepare operational emergency plans.
2. The operational emergency plans shall specify:
 - a) The measures to apply in case a feed or a foodstuff of aquatic origin shows serious risk, directly or due to environmental factors, to human beings;
 - b) The administrative authorities and other agents that shall intervene, and their respective powers and responsibilities;
 - c) The channels and procedures for information exchange between the various stakeholders;
 - d) The review procedures taking into account experience acquired in simulation exercises;
3. The operators shall have the Competent Authority approve emergency plans that allow manage a health crisis.

ARTICLE 28

(National official controls plan)

1. The Competent Authority shall prepare a National Official Controls Plan, which shall include the following:
 - a) The way to update such Plan according to the evolution of the situation;
 - b) General information on the structure and organisation of official controls along the whole production chain;
 - c) The plan's strategic objectives and the way these are reflected in control prioritisation and resource allocation;
 - d) Risk classification for the activities in question;
 - e) Description of implementation actions from the perspective of human, material and economic/financial resources.

2. The National Official Controls Plan shall be tri-annual and submitted to the social, professional and economic bodies related to the operators for dissemination, and to any importing country upon request.

ARTICLE 29

(Corrective measures in case of non-compliance)

1. In case of finding non-compliances during the official control operation execution, the Fish Inspector shall take measures taking into account the nature of such non-compliance and the operator background, to ensure such non-compliance is resolved.
2. The Fish Inspector, jointly with the operator whenever possible, shall establish an execution deadline for solving the non-compliance problems, which shall be subject to follow up verification.
3. Non-compliance with the deadlines established by the Fish Inspector is an infraction punishable under the terms of this regulation.

CHAPTER III

HYGIO-SANITARY RULES

ARTICLE 30

(Hygiene requirements)

1. The operators along the production, distribution and marketing chain shall observe, when applicable, the following hygio-sanitary requirements:
 - a) Microbiological criteria;
 - b) Temperature requirements;
 - c) Maintenance of the cold chain;
 - d) Collection of samples and analyses;
 - e) Other procedures necessary for complying with the hygiene requirements.
2. The hygiene requirements mentioned in the previous paragraph and the associated sampling methods and analyses shall be determined by the Competent Authority.

ARTICLE 31

(Hazard analysis and critical control points)

1. The operators shall create, apply and maintain one or more permanent procedures based on the HACCP principles:
 - a) Identification of all hazards that may be avoided, eliminated or reduced to acceptable levels;
 - b) Identification of the critical control points in the phases where control is crucial to avoid or eliminate a hazard or to reduce such hazard to acceptable levels;
 - c) Establishment of critical limits for critical control points that separate acceptance from non-acceptance, aiming at the prevention, elimination or reduction of identified hazards;
 - d) Establishment and use of effective monitoring procedures for critical control points;
 - e) Establishment of corrective measures in case the monitoring procedure points out a critical control point that is not under control;
 - f) Establishment of procedures to carry out regularly to check whether the measures mentioned in paragraphs a) to e) are functioning effectively;
 - g) Preparation of documents and records appropriate to the nature and size of the company that demonstrate the effective use of measures mentioned in paragraphs a) to f).
2. Any change to the products, processes or in any production phase of foodstuffs of aquatic origin shall entail a review of such processes and introduction of the necessary changes.
3. The operators shall not be forced to create, apply and maintain HACCP-based procedures if they carry out the following activities:
 - a) Creation, fishing and collection of live fishery products aimed at market placement;
 - b) Handling operations namely slaughter, bleeding, beheading and evisceration, fin removal, refrigeration and packaging, as long as these operations take place on board fishing vessels.
 - c) Transportation and warehousing of products of aquatic origin whose nature has not been substantially altered, including live products in on-shore fish farm enterprises.
4. The operators shall possess documents describing the procedures developed in compliance with this article, and keep such documents updated, as a way to provide evidence of compliance with HACCP procedures, in a manner as may be decided by the Competent Authority.

ARTICLE 32

(Water use)

1. An adequate potable or, when allowed, clean water supply shall be provided, and such water shall be used whenever necessary to ensure products are not contaminated.
2. Ice that comes into contact with the products or that may contaminate such products should be made from potable water or, when used to refrigerate whole fishery products, clean water, and should be handled and stored in conditions that prevent such ice from becoming contaminated.

3. To remove all possible contamination from the surface of products, the operators shall use potable water or, when allowed, clean water, except in cases where the Competent Authority authorises the use of other substances.

ARTICLE 33
(Traceability)

1. The operators of foodstuffs of aquatic origin and feeds shall be able to:
 - a) Identify the supplier of a product, feed or any other substance to be, or likely to be, incorporated in such product or feed;
 - b) Identify the operators to whom his products have been supplied;
 - c) Have systems and procedures available that allow the information mentioned in the previous paragraphs is made available to the Competent Authority whenever requested.
2. Foodstuffs of aquatic origin and feeds placed, or likely to be placed, in the market should be properly identified in order to facilitate traceability.

CHAPTER IV

ABOUT THE MARKET

ARTICLE 34
(List of production units)

The Competent Authority shall regularly disseminate a list of production units, establishments and operators:

- a) National, approved to operate with foodstuffs of aquatic origin to be placed in the market;
- b) Foreign, approved to place foodstuffs of aquatic origin in the national market.

ARTICLE 35
(Requirements for market placement)

1. The batches of foodstuffs of aquatic origin proposed for market placement shall comply with the following general principles:
 - a) They must have been handled and/or processed according to the general and specific requirements in these and other related regulations;
 - b) They must have passed the official controls;
 - c) They must comply with statements on the package or label, according to applicable standards.
2. The batches of foodstuffs of aquatic origin proposed for export must comply with the requirements in the previous number, notwithstanding the requirements of the importing country.
3. The Competent Authority shall approve the specific requirements for packaging and labelling in separate legal instruments.

ARTICLE 36
(Forbidden products)

1. No products originating from poisonous species of fish, namely from the families *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*, may be placed in the market.
2. The Competent Authority may, upon justification, propose the ban of other species that may be considered harmful or poisonous.

ARTICLE 37
(Health certification)

1. The Competent Authority issues health certification of foodstuffs of aquatic origin and feeds used for aquatic animals for human consumption to be placed in the domestic or external markets, including those used or not used for commercial promotion.
2. The conditions and quantities to certify, aimed or not aimed to commercial promotion, shall be approved by ministerial diploma, by proposal from the Competent Authority.

ARTICLE 38
(Internal circulation)

1. In-country circulation of foodstuffs of aquatic origin and feeds for aquatic animals for human consumption shall be subject to health verification by the Competent Authority at ports, airports, and road and railway checkpoints, or at maritime or river landing sites.
2. Notwithstanding the national public health standards, by proposal from the Competent Authority, the conditions and ways of in-country health verification of foodstuffs of aquatic origin and feeds used for aquatic animals for human consumption shall be set forth by ministerial diploma.

ARTICLE 39
(Health requirements for imports)

1. Foodstuffs of aquatic origin and feeds for aquatic animals for human consumption to be imported must comply with the hygio-sanitary requirements in this regulation and other applicable legal provisions.
2. The importers of foodstuffs of aquatic origin and feeds for aquatic animals for human consumption are responsible for acquiring products legally produced in the country of origin and whose production takes place according to the hygio-sanitary requirements in this regulation and other

related provisions.

3. The Competent Authority shall establish, in legal instruments, the official controls execution rules on the import of foodstuffs of aquatic origin and of feeds for aquatic animals for human consumption, including those pertaining to the import procedure.

ARTICLE 40
(International transit)

1. The international transit of foodstuffs of aquatic origin and of feeds for aquatic animals for human consumption to third countries is allowed under the following conditions:
 - a) They must be duly kept and sealed, placed in a warehouse under responsibility of the customs authority;
 - b) Warehousing location must be approved by the Competent Authority.
2. Products in international transit that do not comply with the requirements in the previous number shall be subject to mandatory health inspection.

ARTICLE 41
(Customs clearance)

Customs authorities at the various customs station countrywide shall require the importer or exporter show health certification documents and shall check for a match between documents and goods shown.

CHAPTER V

HEALTH INSPECTION, INFRACTIONS AND SANCTIONS

ARTICLE 42
(Health inspection)

1. Health inspection shall be carried out by staff from the Competent Authority mandated as Fish Inspectors.
2. The Competent Authority appoints, by order, staff members mandated as Fish Inspectors authorised to sign the documentation pertaining to health certification and licensing.

ARTICLE 43
(Staff expertise)

1. The Competent Authority, in its inspection function, shall maintain competent and qualified staff for official controls in the following areas:
 - a) Audit, inspection and sampling, and respective procedures;
 - b) Legislation related to foodstuffs of aquatic origin and feeds for aquatic animals for human consumption;
 - c) Phases of the production chain, distribution and marketing, and potential hazards and risks for human health and, if appropriate, the health of aquatic animals and the environment;
 - d) Assessment of HACCP, respective pre-requisites or other equivalent own-checks systems;
 - e) Official certification systems;
 - f) Intervention provisions in case of emergency;
 - g) Verification of written documents and other records, including analytical test results;
 - h) Any other area necessary to ensure that official controls are made in compliance with the provisions in these and other applicable regulations.
2. Staff in charge of official controls should be qualified to carry out multi-disciplinary activities, and maintain themselves up to date in the sphere of their competence and regularly receive supplementary documentation.

ARTICLE 44
(Powers of the Fish Inspector)

1. In order to ensure enforcement of the provisions in this regulation and other applicable provisions, Fish Inspectors, using their competences, may:
 - a) Inspect, open or order opening of production units and establishments;
 - b) Verify hygienic conditions of production units and establishments;
 - c) If necessary, order closure of production units and establishments;
 - d) Collect product samples for analysis;
 - e) Inspect, along the whole production chain including transport, documentation pertaining to foodstuffs of aquatic origin and feeds for aquatic animals for human consumption;
 - f) Prohibit circulation of suspicious products or products unfit for human consumption.
2. If, during an inspection and verification, the Fish Inspector has acceptable reasons to assume an infraction to this regulation or other applicable

provisions, he may, for prevention:

- a) Seize any vessel or vehicle with foodstuffs of aquatic origin e feeds for aquatic animals for human consumption, including batches thereof, that are adulterated or unfit for human consumption;
- b) Withdraw health licenses from production units and establishments whose hygio-sanitary conditions are not compliant with this regulation and other applicable provisions;
- c) Seal holds, production units and establishments suspected to contain adulterated products;
- d) Collect proof elements deemed necessary, including Fishing Vessel Logs and Engine Logs.

ARTICLE 45
(Surveillance)

1. Notwithstanding mandates assigned by law to other entities, the Competent Authority is responsible for surveillance and supervising compliance with the provisions in this regulation and with specific associated standards.
2. The Competent Authority is responsible for imposing the sanctions resulting from infractions found during the official controls and deemed proved.
3. Customs authorities at the various border posts countrywide are responsible for imposing the sanctions as result of the control activities carried out as per article 41 of this regulation.

ARTICLE 46
(Accumulation of infractions)

1. The operator found practising more than one infraction at the same occasion shall be punished by accumulation of infractions.
2. In case of accumulation of infractions, the amount of the fine is the arithmetical sum of the amounts of each accumulated sanction.
3. The corresponding ancillary sanctions shall be also applicable in case of accumulation of infractions.

ARTICLE 47
(Administrative nature of infractions)

1. The instruction of infractions in fisheries has an administrative nature.
2. The instruction of infractions to no.2 of article 51 of this regulation is the mandate of criminal investigation.

ARTICLE 48
(Recurrence)

1. In case recurrence, the maximum amounts of fines are doubled; these become the minimum limits and the maximum limits are adjusted *pro rata*.
2. The ancillary sanction is applicable in recurrence.

ARTICLE 49
(Appeal)

1. A hierarchical appeal may be filed against decisions made within the scope of this regulation within eight days upon notification.
2. In case no settlement is achieved, an appeal may be filed at Administrative Tribunal within the time period established by law.
3. Appeals filed within the scope of this regulation have a devolution effect.

ARTICLE 50
(Disposal of seized products)

Products seized administratively may be:

- a) If good for human consumption, sold in public auction or given to kindergartens, hospitals or other social institutions;
- b) If unfit for human consumption, destroyed.

ARTICLE 51
(Infractions)

1. The following are infractions to this regulation:
 - a) The operation of production units and establishments without operation license;
 - b) The operation of production units and establishments with expired or suspended license;
 - c) The placement of foodstuffs of aquatic origin in the market incompliant with requirements in articles 30 and 35 and/or without health certificate;
 - d) Incompliance with hygio-sanitary requirements prescribed in this regulation or in specific regulations;
 - e) The lack of documents and records or forgery of such documents and records, submission of false information or non-submission of information to the Competent Authority;
 - f) Obstruction or raising obstacles to official controls;

- g) The operation of production units and establishments that don't comply with the structural or equipment requirements established in specific standards;
 - h) Deliberate placement of, or attempt to place, contaminated fishery products that contain toxins harmful to human health;
 - i) Non-compliance with the deadlines that may be set forth by the Fish Inspector within the scope of official controls.
2. In case someone assaults or obstructs with violence or threatens the activity of the Fish Inspector in the line of duty, such person shall be punished according to the ordinary law in force.

ARTICLE 52
(Applicable sanctions)

1. Infractions to this regulation and other applicable provisions shall be punished cumulatively with fines and ancillary sanctions.
2. The following are ancillary sanctions:
 - a) Loss to the State of the products produced in violation of the law;
 - b) Closure of the production unit or establishment;
 - c) Suspension of authorisations and health licenses.
3. Fines shall be paid in national currency.
4. Fines applied to foreigners, non-residents or persons with no representative in Mozambique shall be paid in freely exchangeable hard currency.

ARTICLE 53
(Cases of infraction)

1. Cases of infraction shall be instructed by the Competent Authority.
2. Fines and ancillary sanctions pertaining to the identified violations and deemed proved shall be applied by the Competent Authority.

ARTICLE 54
(Notification)

1. In case a violation is found, staff in charge of official controls shall issue a Notification, which should at least include the identification of the operator and the production unit, an objective explanation of facts and circumstances.
2. The Notification shall be signed by the Fish Inspector and, if possible, by two witnesses.
3. If necessary, the Competent Authority should also notify its decision to the Competent Authority of the country of dispatch.

ARTICLE 55
(Sanctions)

1. Infractions in article 51 shall be punishable by the following sanctions:
 - a) Infraction to paragraph a) shall be punished by fine 20 a 50 times the amount of the corresponding operation license and by the ancillary sanction of closure of the production unit or establishment;
 - b) Infraction to paragraph b) shall be punished by fine 10 a 30 times the amount of the corresponding operation license and by the ancillary sanction of temporary closure of the production unit or establishment;
 - c) Infraction to paragraph c) shall be punished by fine 100 a 150 times the amount of the health certification corresponding to the product and by the ancillary sanction of loss to the State of the products in question;
 - d) Infraction to paragraph d) shall be punished by fine 30 a 50 times the amount of the corresponding operation license and by the ancillary sanctions of suspension of the corresponding health license until compliance is regained, and loss to the State of the products illegally produced;
 - e) Infraction to paragraph e) shall be punished by fine 2 a 10 times the amount of the corresponding operation health license;
 - f) Infraction to paragraph f) shall be punished by fine 30 a 50 times the amount of the corresponding operation health license;
 - g) Infraction to paragraph g) shall be punished by fine 20 a 30 times the amount of the corresponding operation license and by the ancillary sanction of suspension of the corresponding health license until compliance is regained;
 - h) Infraction to paragraph h) shall be punished by fine 30 a 50 times the amount of the corresponding operation health license of the establishment and by the ancillary sanction of loss of products to the State;
 - i) Infraction to paragraph i) shall be punished by fine 2 a 10 times the amount of the corresponding operation health license.