

**FISHERIES (SAFETY OF FISH, FISHERY
PRODUCTS AND FISH FEED) REGULATIONS, 2007**

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FISHERIES (SAFETY OF FISH, FISHERY PRODUCTS AND FISH FEED) REGULATIONS, 2007

[L.N. 170/2007, L.N. 15/2009.]

PART I – PRELIMINARY

1. Citation

These Regulations may be cited as the Fisheries (Safety of Fish, Fishery Products and Fish Feed) Regulations, 2007.

2. Other written laws to apply

These Regulations shall be in addition to and not in derogation from any other written law for the time being in force related to food safety and public health.

3. Interpretation

In these Regulations, unless the context otherwise requires—

“**batch**” means a quantity of fish or fishery products of the same species collected from the same production area during the same fishing or harvesting operation and accorded a similar identity;

“**bivalve molluscs**” means filter feeding lamellibranch molluscs;

“**chilling**” means the process of cooling fish and fishery products to a temperature approaching that of melting ice;

“**clean water**” means clean sea water and fresh water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food;

“**competent authority**” means the authority designated as such under regulation 4;

“**compound feed**” means a manufactured feedstuff containing two or more ingredients blended together;

“**cooking**” means sterilization in hermetically sealed containers or by immersion in boiling water for the period required to raise the internal temperature of the product to not less than 90°C and maintenance of this minimum temperature for a period of not less than ninety seconds, or cooking in an enclosed vessel for at least three to five minutes at a temperature of not less than 120°C and not more than 160°C and a pressure of not less than 2 kg/cm² and not more than 5 kg/cm²;

“**diseased fish**” means a fish on or in which pathological changes or other abnormalities are apparent;

“**disinfection**” means the application of hygienically satisfactory chemical or physical agents and processes to clean surfaces with the intention of eliminating micro-organisms;

“**export**” means commercial trade with a natural or legal person outside the territory of Kenya;

“**factory vessel**” means any vessel on board which fish and fishery products undergo shelling, shucking, mincing or any other processing followed by wrapping or packing if necessary;

“fish consignment” means fish, fishery products or fish feed on transit from one point to another either locally or overseas and assigned one set of authorization document(s);

“fish culture” has the meaning assigned by the Fisheries (General) Regulations and **“fish culture premises”** shall be construed accordingly;

“fish culture products” means all fishery products produced in controlled conditions until placed on the market as foodstuffs and includes fish and seaweeds harvested in their natural environment when juvenile and kept until they reach the desired commercial size for human consumption;

“fish feed” means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding in fish culture systems producing fish for human and animal consumption;

“fish inspector” means a person appointed under regulation 15;

“fish meal” means any milled, minced, fermented fish and fishery product intended for use as an animal feed or as a raw material for production of animal feed;

“fish processing establishment” means any premises where fish and fishery products are prepared, processed, chilled, frozen, packaged or stored, but does not include fish landing stations, auction or wholesale markets or catering premises;

“fishery enterprise” means any premises, public or private and whether for profit or not, where operations related to production, culture, handling, manufacture, processing, storage, packaging, transport or distribution and marketing of fish, fishery products and fish feed for human and animal consumption are undertaken;

“fishery products” includes products that are primarily composed of sea water and fresh water animals, either wild or cultured, or parts thereof, including their roes, but does not include aquatic mammals, reptiles and frogs;

“freezer vessel” means any vessel on board which freezing of fish and fishery products is carried out where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and where necessary followed by wrapping or packaging;

“fresh products” means unprocessed fish and fishery product, whether whole or prepared, including live fish, fishery products packaged under vacuum or in a modified atmosphere that have not undergone any treatment to ensure preservation other than chilling;

“frozen product” means any fish and fishery product which has undergone a freezing process to reach a core temperature not exceeding minus 18°C;

“hazard” means biological, chemical or physical agent in, or condition of fish, fishery products or fish feed which can cause an adverse effect on human and animal health;

“internal control system” means all those actions undertaken by a fishery enterprise aimed at ensuring and demonstrating that a fishery product satisfies the requirements of product safety as laid down in these Regulations;

“marine biotoxins” means poisonous substances accumulated by fish and bivalve molluscs in particular as a result of feeding on plankton containing toxin;

“means of transport” means the parts set aside for fish and fishery products in road vehicles and rail wagons and aircraft, holds of vessels and containers for transport of fish or fishery products by land, sea or air;

“mechanically separated fishery product” means any product obtained by removing flesh from fishery products using mechanical means resulting in the loss or modification of the flesh structure;

“official control” means any form of control that the competent authority performs for the verification of compliance with these Regulations;

“packaging” means the procedure of protecting fish and fishery products by a wrapper, a container or any other suitable material or device;

“placing on the market” means the holding, displaying or offering of fish or fishery products for the purpose of sale locally and for export or any other form of transfer undertaken as provided for under these Regulations;

“potable water” means water suitable for human consumption and all water used in any fishery enterprise for the manufacture, processing, preservation or marketing of products or substances intended for human consumption;

“processed products” means any fishery products which have undergone the processing as defined in the Act;

“prepared fish and fishery products” means unprocessed fish or fishery products that have undergone an operation affecting their anatomical wholeness such as gutting, heading, slicing, filleting and chopping;

“public health officer” means a public health officer within the meaning of the Public Health Act (Cap. 242);

“relaying” means moving bivalve molluscs from polluted waters to areas approved by the competent authority;

“risk” means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

“risk analysis” means a process consisting of three interconnected components; risk assessment, risk management and risk communication;

“risk assessment” means a scientifically based process consisting of four steps: hazard identification and characterisation, exposure assessment and risk characterisation;

“risk characterisation” means the estimation of the incidence and severity of the adverse effects likely to occur in a population or environmental compartment due to actual or predicted exposure to a substance. These may include risk estimation, i.e. quantification of that likelihood. It serves as a summary and description of the results of a risk analysis or a risk manager or the public and other interested parties;

“risk communication” means the interactive exchange of information and opinion throughout the risk analysis process as regards hazards and risk, risk related factors and risk perceptions among risk assessors, risk managers, consumers, enterprises, the academic community and other interested parties including the explanation of risk assessment findings and the basic risk management decisions;

“risk management” means the process distinct from risk assessment of weighing policy alternatives in consultation with interested parties considering risk assessment and other legitimate factors and if need be selecting appropriate prevention and control options;

“seaweed culture” means propagating, breeding or raising of aquatic plants under confinement by man;

“**traceability**” means the ability to trace and follow fish, fishery product, fish feed, materials in direct contact with fishery product or any other substance intended, or expected to be incorporated into a fishery product or fish feed, through all stages of production, processing and distribution;

“**traditional preservation**” means hot smoking, sun drying, salting, fermentation or any other method undertaken to prolong the shelf life under controlled storage conditions;

“**transhipment**” means transfer of fish and fishery products from one vessel to another;

“**verification**” means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled;

“**veterinary drug**” means any substance applied or administered to any food-producing animal whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviour;

“**veterinary health officer**” means a veterinary officer within the meaning of the Animal Diseases Act (Cap. 364) and Public Health Act (Cap. 242);

“**viscera**” means the internal organs of fish or fishery products and includes the heads of crustaceans;

“**withdrawal period**” means the duration of time between the last dose given to the fish and the time when the level of residues in the tissues or products falls below the maximum residue levels.

PART II – DESIGNATED COMPETENT AUTHORITY

4. Establishment of the competent authority

(1) The Ministry responsible for fisheries shall be the competent authority responsible for the official control of the safety of fish, fishery products and fish feed.

(2) The management of the competent authority in matters related to these regulations shall be the responsibility of a standing committee and a technical committee.

(3) The standing committee shall comprise—

- (a) the Permanent Secretary to the Ministry or an appointed by him, who shall be chairman;
- (b) the Director of Fisheries or an officer appointed by him, who shall be the secretary and chairman of the technical committee;and
- (c) the Director of Veterinary Services; and
- (d) any other competent person appointed in writing by the Permanent Secretary to be a member as the need may arise.

(4) The technical committee shall comprise—

- (a) the Director of Fisheries who shall be the chairman and responsible for the routine management of all technical operations of the competent authority;
- (b) the head of fish safety assurance as committee secretary;
- (c) the heads of fish safety assurance responsible for freshwater, marine and aquaculture fisheries; and
- (d) any other competent person appointed in writing by the Director of Fisheries.

5. Functions of the competent authority

(1) The functions of the competent authority shall be to—

- (a) convene on a regular basis the meetings of the standing and technical committees;
- (b) monitor fish production, fish, fishery products and fish feed with a view to assessing risks to human health;
- (c) control fish handling, landing, transportation, processing and marketing;
- (d) work in collaboration with other Government agencies in matters related to these regulations;
- (e) assess and approve plans and structures of intended fishery enterprises;
- (f) carry out inspection of operational fishery enterprises for compliance with these regulations;
- (g) lay down all the procedures to be followed for compliance with these regulations;
- (h) specify conditions for the placing on the market of fish, fishery products and fish feed;
- (i) maintain a register of fishery enterprises approved under these regulations;
- (j) issue health certification of fish, fishery products and fish feed subject to the consignment meeting the requirements of these regulations;
- (k) grant approval for the fishery enterprises that meet applicable requirements specified in the First Schedule of these regulations; and
- (l) perform such other functions as may be necessary or expedient for safety assurance of fish, fishery products and fish feed in accordance with these Regulations.

(2) The control and nature of the measures applied by the competent authority under this regulation shall be based on an assessment of the food safety risks and shall be effective, equitable and proportionate to the risk or on other appropriate measures where circumstances and nature do not allow risk assessment.

(3) Assessment of the food safety risks as specified in paragraph (2) shall be scientifically conducted and undertaken in an independent, objective and transparent manner.

(4) Where there are reasonable grounds to suspect that any products to which these Rules relate may present a risk to human or animal health, then the competent authority shall take appropriate steps to inform the general public of the nature of the risk to health, identifying as far as possible the fish, fishery product or fish feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

(5) Without prejudice to the requirement to protect public health specified in paragraph (4) of this subparagraph, information which is obtained by the competent authority during the course of the performance of its functions under these Regulations regarding any individual business, or of risk analysis shall not be disclosed without the consent in writing of the person carrying on the business, except—

- (a) in accordance with specific directions of the Minister, so far as may be necessary for the purposes of these Regulations; or
- (b) for the purposes of any legal proceedings for an offence under these Regulations or any other law.

(6) Any person who discloses any information in contravention of subparagraph (5) shall be guilty of an offence and liable to a penalty in accordance to provisions of regulation 28 of these Regulations.

PART III – APPROVAL OF FISHERY ENTERPRISES

6. Requirement for approval

(1) No person shall establish or use a fishery enterprise for the purpose of production, culture, keeping, processing, storage, packaging, transporting or placing on the market of fish or fishery products intended for human or animal consumption unless he has applied for and obtained prior approval to do so from the competent authority.

(2) An approval under this regulation shall be granted on application in the prescribed form upon payment of the prescribed fee and subject to specific conditions and requirements as provided for under the Eleventh Schedule or such other conditions as the competent authority may determine.

(3) The competent authority, where it considers it expedient for ensuring the safety of fish, fishery products and fish feed, may at any time vary the conditions referred to in subparagraph (2).

(4) An approval issued under sub paragraph (1) of this regulation in respect of any means of transport for fish, fishery products and fish feed shall have the same effect as a fish movement permit issued under Regulation 18 of the Fisheries (General) Regulations.

(5) Export oriented fishery enterprises shall require a certificate of compliance with these Regulations per product line, issued by the competent authority and applied for in Form DF/A4 set out in the Twelfth Schedule.

(6) The certificate of compliance shall be in a Form prescribed by the competent authority and shall be issued on payment of such fees as prescribed in the Eleventh Schedule subject to conditions as the competent authority may determine.

(7) A certificate of compliance issued under this regulation shall be renewable annually after national inspection and approval by the competent authority, or—

- (a) every time there is a resumption of processing after a lapse for any reason in the operations of the fishery enterprise to which it relates;
- (b) when there is a change in the method of fish processing used; or
- (c) when there is a change in the kind of raw material used in the fish processing plant.

(8) Notwithstanding subparagraph (6), the competent authority may withdraw a certificate of compliance where—

- (a) the owner or operator of the fishery enterprise to which it relates carries out activities other than those for which the enterprise is established; or
- (b) investigations by the competent authority reveal non-compliance with the provisions of these Regulations or any other written law.

(9) Where a certificate of compliance is withdrawn under subparagraph (8) all operations in the fishery enterprise to which it relates shall cease forthwith.

(10) An approval issued under this regulation shall be a prior condition for gazetting a fish landing station.

(11) Where the competent authority refuses to grant approval or certificate under this Regulation it shall communicate its decision to the applicant within thirty days stating the grounds for refusal, and the applicant may reapply after fulfilling the requirements thereby stated by the competent authority.

7. Conditions for approval

(1) The competent authority shall consider every application made to it under regulation 6(2) and may refuse to issue such authority where it is satisfied that—

- (a) the raw material available is not adequate to support such establishment; or
- (b) such establishment shall have an adverse effect on the fisheries resources, biodiversity and the environment.

(2) Every fishery enterprise shall be subject to the conditions regarding the general operating requirements as prescribed in the Schedules to these Regulations.

8. Conditional approval

(1) The competent authority may issue conditional approval to a fishery enterprise which meets some of the infrastructure and equipment requirements as provided for in the Schedules of these Regulations.

(2) A conditional approval under this regulation shall be issued to a fishery enterprise for a period of not less than 3 months and not exceeding 6 months.

(3) A conditional approval under this regulation shall be construed to be a fish processing licence issued under Regulation 14 of the Fisheries (General) Regulations.

9. Suspension, withdrawal and cancellation of approval or certificate

(1) Any approval granted in accordance with Regulations 6 and 8 may be suspended, withdrawn or cancelled by a written order of the competent authority signed by the secretary at any time without notice where—

- (a) an establishment has been used in contravention of this regulation or in contravention of any of the conditions attached thereto; or
- (b) such action is deemed necessary or expedient for the purpose of protecting human and animal health.

(2) The competent authority shall, upon suspending approval under subparagraph (1), notify the establishment concerned accordingly and give notice of revocation thereof unless the establishment fulfils such conditions as may be specified in the notice, within such period as may be prescribed.

(3) The competent authority may confirm, vary or cancel an approval granted to an establishment under these Regulations upon expiry of the period prescribed under subparagraph (2).

(4) Where there is an imminent risk to public health any approval granted in accordance with Regulations 6 and 8 may be suspended at any time and without notice by a written order of a fish inspector and the action communicated to the competent authority within 12 hours.

(5) The fishery enterprise upon suspension under paragraph (2) of this regulation shall stop the operations immediately and shall within 24 hours confirm with the competent authority whether the action taken by the inspector has been communicated.

(6) On issuance of the suspension order in paragraph (4) of this regulation, the inspector shall recommend the withdrawal of approval.

(7) In the event that the order has not been complied with, the inspector shall recommend the withdrawal of approval.

(8) The suspension of an approval under paragraph (2) of this Regulation which shall not be reported within the stipulated time shall be considered null and void.

(9) Where an approval is suspended under paragraph (2) or a recommendation for withdrawal has been made under paragraph (5) of this regulation, the competent authority shall formally confirm or rescind the inspector's decision within 5 working days, giving reasons for the decision.

(10) Where a decision has been made to withdraw the approval under paragraph (7) of this regulation, the competent authority shall initiate process for withdrawal of the approval.

PART IV – ADDITIONAL HEALTH CONDITIONS FOR PRODUCTION AND
PLACING ON THE MARKET OF PARTICULAR FISHERY PRODUCTS

10. Prohibited harvest areas for bivalve molluscs

(1) No person shall harvest bivalve molluscs and shellfish for human and animal consumption from any area other than those specified by the competent authority and which meet the conditions set down in Fourth Schedule.

(2) The competent authority may from time to time in the *Gazette* publish the name, location and boundary co-ordinates of designated harvest areas for purposes of paragraph (1) and the permissible uses of the bivalve molluscs harvested therefrom.

(3) The competent authority shall by order published in the *Gazette* notice prohibit the harvest of bivalve molluscs from any defined area or areas where such action is deemed necessary for conservation of the fishery or the protection of public health.

11. Certificates of origin for bivalve molluscs

(1) No person shall consign or transfer any batch of bivalve molluscs to another person unless they are accompanied by a certificate of origin prescribed and issued by the competent authority upon payment of such fees as prescribed in the Eleventh Schedule.

(2) The certificate of origin shall accompany the batch of bivalve molluscs during its distribution, transportation and placing on the market.

(3) No person shall be in possession of any batch of bivalve molluscs unless the batch is subject to and accompanied by a certificate of origin.

(4) The fisherman as defined under the Fisheries (General) Regulations and any person to whom the batch is transferred shall keep an original of the certificate of origin for a period of twelve months from the date of the issue thereof or transfer thereof.

(5) Any person who contravenes the provisions of paragraph (1) of this Regulation shall be guilty of an offence.

12. Prohibition on placing on the market of certain species

No person shall place on the market—

- (a) fish species of the families *Tetradontidae*, *Moridae*, *Diodontidae*, *Canthigasteridae*, *Gempylidae*; or
- (b) fishery products commonly containing biotoxins of marine origin.

PART V – CONDITIONS FOR EXPORT AND IMPORT
OF FISH, FISHERY PRODUCTS AND FISH FEED

13. (1) The competent authority shall specify the conditions for export and import of fish, fishery products and fish feed under these Regulations with due regard to—

- (a) the law relating to fish, fishery products and fish feed in Kenya;

- (b) the organization of the competent authority and the competence of its authorized fish inspectors, the powers of such inspectors and the supervision to which they are subject, as well as their facilities for effectively verifying the implementations of the legislation in force;
 - (c) the actual health conditions during the production, storage and dispatch of fishery products intended for export;
 - (d) the assurance on the compliance with the standards laid down in the Second Schedule.
- (2) The export conditions referred to in paragraph (1) shall include—
- (a) the procedure for obtaining a health certificate which shall accompany the consignment of fishery products when forwarded to the importing country; and
 - (b) the placing of marks identifying the fishery products, with the registration number of the fish processing plant of origin, including imported frozen fishery products, landed immediately for canning and bearing the certificate provided for under subparagraph (a) from the country of origin.

(3) The provisions of the foregoing subregulations shall apply *mutatis mutandis* to fish and fishery products imported into the country.

PART VI – OFFICIAL CONTROL OF FISH, FISHERY PRODUCTS AND FISH FEED

14. Official control of fishery product and feed

(1) The competent authority shall be responsible for official control of fish, fishery products and fish feed.

(2) In exercising its powers of official control under these Regulations the competent authority may authorize the persons appointed under Regulation 15 in such a manner as it may deem appropriate to carry out the following functions—

- (a) inspection and approval of intended and operating fishery enterprises;
- (b) monitoring of approval conditions;
- (c) audit and verification of good hygiene practices and Hazard Analysis Critical Control Point (HACCP) procedures;
- (d) auditing conditions as set out in the Schedules to these Regulations;
- (e) conducting the detailed health controls and monitoring of production conditions described in the Fourth Schedule; and
- (f) certifying on request in writing the health conditions relating to any batch of fishery products.

PART VII – FISH INSPECTORS

15. Appointment of fish inspectors

(1) The competent authority shall appoint such number of suitably qualified fisheries officers, public health officers and veterinary officers as it may deem sufficient to act as fish inspectors.

(2) The competent authority shall issue to every fish inspector a certificate of identification as set out in Thirteenth Schedule to carry out the inspection of fish and fishery products placed on the market and other official control in accordance with these Regulations.

16. Functions of fish inspector

(1) A fish inspector appointed under regulation 15 shall be responsible to the competent authority for the performance of the functions of the competent authority as set out in regulation 5.

(2) All records maintained under paragraph (1) shall be preserved by the competent authority for a period of thirty-six months.

(3) A fish inspector shall for the purpose of the exercise of his functions as specified in this regulation and regulation 14 have access to all parts of a fishery enterprise.

(4) A fish inspector shall ensure that the owner of a fishery enterprise applies procedures continuously and properly as provided for in these Regulations with respect to—

- (a) Hazard Analysis Critical Control Point (HACCP) system;
- (b) good hygiene practices;
- (c) traceability;
- (d) training in hygiene and in work procedures;
- (e) water quality;
- (f) written records of the observation of the matters specified in (a) and (e) above and that the same are preserved for a period of thirty-six months; and
- (g) records maintained as provided for under these Regulations, which should be readily available for verification.

17. Powers of fish inspectors

(1) In the performance of the functions under these Regulations, a fish inspector may—

- (a) at any reasonable hour, or whenever work is in progress in any fishery enterprise in which fish, fishery products or fish feed are believed to be produced, handled, processed, packaged and stored or kept, enter and search those premises for the purposes of determining the existence, nature and extent of any trade or business in fish, fishery products or fish feed;
- (b) examine any fish, fishery product or fish feed in any fishery enterprise to which this Regulation applies, take samples thereof and examine anything believed to be used or capable of being used for the preparation of any fish, fishery product or fish feed;
- (c) stop, search or detain any vehicle, vessel or aircraft in which it is believed that any fish, fishery product or fish feed to which this Regulation applies is conveyed, and examine the fish, fishery products or fish feed and take samples thereof;
- (d) open and examine any receptacle, package or any other area believed to contain any fish, fishery product or fish feed to which this Regulation applies, and examine the products and take samples thereof;
- (e) require to be produced, examine and take copies of any book, document, equipment or tools or any other record in any form believed to contain any information relevant to the enforcement of this Regulation;
- (f) issue a notice of seizure as provided for under section 18 of the Fisheries Act;

- (g) issue a suspension order as provided for under regulation 9(2) of these Regulations; and
- (h) exercise any other functions assigned to him by the competent authority.

(2) A fish inspector shall in the exercise of his powers under paragraph (1), if required to do so by any person affected thereby, produce his certificate of identification issued to him under regulation 15(2).

(3) A fish inspector shall, upon request and examination of any batch of fish, fishery products or fish feed in accordance with these Regulations, issue a certificate in such form and language as may be prescribed by the competent authority attesting to—

- (a) the conditions in which the batch was produced, processed, stored, packed, transported or placed on the market;
- (b) whether the batch satisfies the standards prescribed by these Regulations; and
- (c) the fitness of that batch for the purpose for which it is intended.

18. Obstruction

The owner or occupier or person in charge of any fishery enterprise or any employee found therein, or any person who, when requested to give information or any assistance to a fish inspector pursuant to section 18 of the Act and Regulation 17 of these Regulations fails to do so, or any person who wilfully obstructs a fish inspector in the performance of his functions, shall be guilty of an offence and liable to a penalty as provided for under Regulation 28 of these Regulations.

19. Frequency of inspections

(1) Inspections for official control of fish, fishery products and fish feed shall be carried out—

- (a) regularly and according to priorities determined by risk assessment carried out by the competent authority;
- (b) when non-compliance is suspected; and
- (c) when required for the purpose of certification.

(2) Inspection shall cover all stages of production, culture, handling, manufacture, processing, packaging, storage, transport, distribution, retail and wholesale trade, and the export and import of fish, fishery products and fish feed from and into Kenya.

(3) Whenever practicable, inspections shall be carried out without prior warning.

20. Investigation by fish inspectors

(1) Inspections for official control of fish, fishery products and fish feed shall include an investigation of—

- (a) the state and use of the site intended or occupied by a fishery enterprise, offices, plant surroundings, means of transport, machinery and equipment, fish and business operators dealing in fishery products and fish feed;
- (b) the raw materials, ingredients, technological aids and other products used for the preparation and production of fishery products and fish feed;
- (c) semi-finished fishery products;
- (d) finished fishery products and fish feed;
- (e) the materials, surfaces and items intended to come into contact with fish, fishery products and fish feed;

- (f) the products and processes used for cleaning and maintenance, and also pesticides used for pest control;
- (g) the processes used for the manufacture and processing of fish, fishery products and fish feed;
- (h) labelling and presentation of fish, fishery products and fish feed; and
- (i) preservation methods.

(2) The operations enumerated in paragraph (1) may, where necessary, be supplemented by—

- (a) interviews with persons dealing in fish, fishery products or fish feed, and their employees;
- (b) the reading of values recorded by calibrated measuring instruments installed in the fishery enterprise;
- (c) measurements carried out by the competent authority, with its institutional calibrated instruments, or with calibrated instruments installed by the fishery enterprise; and
- (d) information contained in documentary and electronic materials held by fishery enterprises.

21. Annual inspection programme and report

(1) The competent authority shall prepare an annual inspection programme of official control activities, specifying—

- (a) the criteria applied in drawing up the programme; and
- (b) the number and type of inspections to be carried out in the ensuing year.

(2) The competent authority shall at the end of each year prepare an annual report on official control activities, specifying—

- (a) the number and type of inspections carried out;
- (b) the number and type of infringements identified; and
- (c) actions taken in cases of non-compliance.

(3) An annual programme on official control of safety of fish, fishery products and fish feed prepared by the technical committee shall be presented to the standing committee for approval.

PART VIII – OFFICIAL LABORATORIES

22. Laboratory analysis of samples

(1) The competent authority may designate in writing suitable laboratories for analyzing samples collected for purposes of official control.

(2) The competent authority may designate a laboratory for a particular test or group of tests.

(3) All samples collected under these Regulations shall be taken and transmitted to the designated laboratory.

(4) The competent authority shall maintain a list of designated laboratories for different types of analysis in connection with official control.

23. Standard for designated laboratories

(1) The laboratories designated under Regulation 22 shall comply with the requirements laid down in International Organization for Standardization (ISO) Standard 17025 or its updated versions, or in such standards as the competent authority may from time to time prescribe.

(2) The testing laboratories designated by the competent authority under regulation 22(1) shall from time to time participate in appropriate proficiency testing programmes.

(3) The designated testing laboratories shall use methods of analysis and performance criteria specified by the competent authority from time to time.

24. Nomination of reference laboratories

(1) For each test required for the purposes of official control of fish, fishery products or fish feed the competent authority shall designate one laboratory as a reference laboratory for each type of test required for purposes of official control.

(2) A reference laboratory designated under this Regulation shall be responsible for—

- (a) advising the competent authority on the designation nomination of official laboratories whose task is to conduct analyses for the purpose of official control;
- (b) co-ordinating and supporting the activities of official laboratories in respect of the technical standards and methodologies of the testing services for which they are appointed;
- (c) offering training to technical personnel of the official testing laboratories;
- (d) organizing and participating in comparative tests of standardised samples, on a national and international basis, with a view to monitoring the proficiency of official laboratories;
- (e) ensuring that all official laboratories maintain internal systems of quality assurance including method validation, record keeping, reagent storage, safety, and routine calibration of equipment;
- (f) disseminating information from the reference laboratories to the competent authority and other laboratories carrying out the testing of fish, fishery products and fish feed, whether or not for the purposes of official control;
- (g) providing scientific and technical assistance to the competent authority for the implementation of coordinated control plans.

PART IX – MONITORING PROGRAMMES FOR THE SAFETY OF FISH, FISHERY PRODUCTS AND FISH FEED

(1) The competent authority shall design and implement annual monitoring programmes for fish, fishery products and fish feed with the objective of assessing the nature and extent of the safety hazards associated with these products.

(2) Without prejudice to the generality of the provisions of paragraph (1) of this Regulation, the competent authority shall also design and implement a monitoring programmer for the harvest areas of bivalve molluscs as provided for in Regulation 10 and as set out in the Fourth Schedule of these Regulations.

(3) The monitoring programmes described in paragraph (1) shall take into account the hazards and criteria described in the Fifth and Ninth Schedules and shall include monitoring the presence of the following hazards in the fish, fishery products, fish feed and production areas—

- (a) heavy metals;

- (b) residues of veterinary medicines whose use in fish culture is permitted under the terms of the Pharmacy and Poisons Act (Cap. 244);
- (c) residues of substances whose use in fish culture is banned under the terms of the Pharmacy and Poisons Act;
- (d) residues of pesticides;
- (e) parasites in fish which are of significance to public health; and
- (f) other hazards in fish, fishery products and fish feed which may from time to time arise.

(4) The monitoring programmes shall specify the sampling plan and the methods of analysis to be used, and the performance criteria where applicable.

(5) A report on annual monitoring programmes shall be prepared by the technical committee and presented to the standing committee for approval.

PART X – GENERAL PROVISIONS

26. Fees for inspection and certification

Upon approval, fees in respect of licences, permits and certificates shall be payable to the competent authority as set in the Eleventh Schedule.

27. Appeals

Any person aggrieved by the action of the competent authority to—

- (a) refuse to approve or issue a licence, permit or certificate;
- (b) suspend or withdraw a licence, permit or certificate under Regulation 9; or
- (c) refuse to grant a conditional approval; or
- (d) attach conditions to a licence, permit or certificate may appeal as provided for under Regulation 34 of the Fisheries (General) Regulations.

28. Offences

(1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable to a fine not less than twenty thousand shillings and not exceeding five hundred thousand shillings or to imprisonment for a term not exceeding two years, or to both.

(2) The effect of conviction of any person in these Regulations shall be dealt with as provided for under Regulation 39 of the Fisheries (General) Regulations.

29. Revocation of L.N. 100 of 2000

The Fisheries (Quality Assurance) Regulations, 2000 are revoked.

FIRST SCHEDULE

[Regulation 5(1)(k).]

CATEGORY OF FISHERY ENTERPRISES
TO WHICH APPROVAL CONDITIONS APPLY

<i>Category of fishery enterprise</i>	<i>Schedules containing approval conditions</i>
Factory vessels	2 (I, III), 5, 7, 8, 9, 10
Freezer vessels	2 (I, II), 7, 8, 9, 10
Other fishing vessels	2 (I)
Vehicles and fish transport vessels	6
Landing stations, auctions and wholesale markets	2 (IV)
Processing establishments	2 (V, VI), 7, 8, 9, and 10 inclusive
Other processing establishments with a capacity of < 25 employees	2 (V, VI), 7, 8
Processing establishments for smoked and dried fish	2 (VI), 8 (section 1 (1), (4) and section 2), 9 (section (6), (7) and (8))
Fish culture premises	5, 12 and 13

SECOND SCHEDULE

[Regulation 13(1)(d).]

I. HEALTH CONDITIONS FOR FISHING VESSELS

PART 1 – DESIGN AND CONSTRUCTION OF FISHING VESSELS

A General hygienic design

1. The fishing vessel shall be constructed and made of such materials as to minimise any damage or contamination of the catch and shall be designed for rapid and efficient handling (and if appropriate, freezing) of fish and to ease cleaning and disinfection.
2. Fishing vessels, and in particular their water intake and discharge systems, shall be designed and constructed so as to avoid contamination of fish with sewage, smoke, fuel, oil, grease, bilge water and other objectionable substances.
3. Toilet facilities and all waste disposal lines and discharge points shall be so constructed as not to contaminate the fish or sea or lake water which could come into contact with fish.
4. All surfaces with which the fish might come into contact shall be of suitable corrosion-resistant material which is smooth and easily cleanable. Wooden decks are permissible, provided they are kept clean and in good condition.
5. Cleaning materials, disinfectants and chemicals used in the treatment or processing of fish and fishery products shall be stored separately from any area in which fish is handled.

6. Vessels which spend more than twenty-four hours at sea shall be provided with adequate sanitary facilities, including a flush toilet and hand-wash basin supplied with water, and an adequate supply of soap.

7. A legible notice shall be prominently displayed adjacent to the flush toilet instructing personnel to wash their hands after use.

B Fresh fish storage facilities

1. Fish holds and other rooms in which fish is handled, processed or stored shall be constructed in such a manner as to facilitate cleaning, and if constructed of wood they shall be lined with a suitable impervious, non-toxic material which is easy to clean and to disinfect.

2. Where pounds on deck or in the hold are used for the bulk storage of fish, dividing boards shall be constructed with a suitable impervious, non-toxic material, other than wood, which is easy to keep clean and to disinfect. They shall be fitted in such a way that they can be easily removed and cleaned. Pound boards shall be designed to permit the drainage of water from the pound.

3. All equipment used for handling, processing or storage of fish and ice on board fishing vessels shall be designed to facilitate cleaning and disinfection, and constructed so as not to cause contamination of the catch.

4. Containers used for the transfer of fish or for storage on board shall be made of corrosion-resistant material with smooth waterproof surfaces which are easy to clean and disinfect. The use of wood or galvanised steel is not permitted.

5. The fishing vessels shall be equipped with suitable equipment and materials for washing and disinfecting the vessel and fish handling equipment.

PART 2 – GENERAL HYGIENE CONDITIONS

A General

1. Effective measures shall be taken to protect the fishing vessels against infestations by rodents, insects and other vermin.

2. Dogs, cats and other animals are not permitted on board the fishing vessels.

3. Fish carried as bait shall be kept in a separate area from fresh fish for human consumption, or in special containers kept exclusively for this purpose.

4. Only potable water or clean sea or lake water shall be used for the washing of fish and surfaces which come into contact with fish.

5. Potable water shall be used in cleaning and hosing operations while the vessel is in port.

6. Ice which comes into contact with fish shall be made from potable water or clean sea or lake water.

7. The vessel shall be provided with a first aid box, which shall contain as a minimum, a sufficient quantity of impermeable dressings, antiseptic cream, cotton wool and adhesive tape, and a suitable wound disinfectant.

B Hygiene conditions for personnel

1. Persons who handle fish or materials which come into contact with fish or who enter rooms or areas in which fish is handled shall maintain a high level of personal hygiene, and keep themselves and their clothes clean.

2. Personnel handling fish in any area in which fish is handled or stored shall be prohibited from—

- (a) using any form of tobacco;
- (b) spitting;
- (c) blowing or picking the nose;
- (d) eating or drinking.

3. Before commencing the handling of fish, all crew shall wash their hands with soap or detergent and water and shall be provided with protective clothing.

4. After going to the toilet, all personnel shall wash their hands with soap or detergent and clean water.

5. Any person who has an open wound or cut shall cover it with an impermeable dressing that is food safe, i.e. visually and metal detectable.

6. Any member of the crew who suffers from, or shows symptoms of any of the following conditions shall report the fact to the master, and shall not handle fish or any materials which come into contact with fish—

- (a) food poisoning;
- (b) diarrhoea and vomiting;
- (c) dysentery;
- (d) intestinal parasites;
- (e) infected wounds;
- (f) throat infection;
- (g) contagious skin conditions.

7. All crew shall take all reasonable precautions to prevent contamination of the fishery products and to maintain their quality, by—

- (a) conducting themselves in a responsible manner with respect to the product and equipment to ensure compliance with the provisions of this Schedule; and
- (b) informing the master of any failure in hygienic practices or the existence of any risk of contamination.

C Deck preparation

1. Areas of the vessel where fish are unloaded and handled, or the fish hold where fish are stowed, shall be used exclusively for these purposes. All such areas shall be readily capable of being maintained in a clean condition and shall be cleared of unnecessary equipment before the catch is brought on board.

2. After the catch is sorted and stowed, decks, boards and all deck equipment which come into contact with the fish shall be hosed down with clean water, followed by cleaning with detergent and disinfectant.

D Landing, sorting and stowing of fish

1. Line caught fish should, wherever practicable, be stunned and bled.
2. Large fish shall be landed by hooking under the gills rather than gaffing in the body or lifting by the tail.
3. Handling the catch shall be undertaken rapidly and as soon as it comes on board. The fish shall be separated from the parts of the catch unsuitable for human consumption as soon as possible after coming on board.
4. Fish on board shall be protected against physical damage, exposure to high temperatures and the drying effects of the wind and sun.
5. The fish shall, as quickly as possible, be carefully cleaned and cooled down to the temperature of melting ice (0°C). If not frozen it shall be maintained at this temperature until landing.
6. Any fish which is diseased or has deteriorated or which has become unfit for any reason shall be discarded.
7. Cod ends of trawl nets shall be completely emptied of all fish and debris before the net is returned for the next haul.

E Gutting

1. Where the fish is to be gutted or gilled, this shall commence as soon as the catch is brought to the deck.
2. Gutting and gilling shall be complete and carried out with care to avoid contaminating the fish with gut contents.
3. Fish guts shall be disposed off immediately to avoid contamination of other fish on deck, the deck or other equipment.
4. Immediately after gutting, fish shall be thoroughly washed with clean water or potable water to remove all blood, slime and pieces of guts before being chilled.
5. Harbour water shall never be used for washing fish, and if fish is gutted in harbour it shall be washed with potable water.
6. On completion of washing the fish, further handling shall be carried out without delay.

F Chilling and icing of fish

1. During stowage and icing of the catch, deck hatches shall not be left open longer than necessary.
2. Fish from different days' catches shall not be mixed together at any stage.
3. After catching, fish shall be maintained at a temperature as near as possible to 0°C at all times until either discharged or loaded into a freezer.
4. Chilling of fish shall be done rapidly using hygienically crushed block ice, flake ice or by immersion in clean refrigerated or chilled sea or lake water.
5. Iced fish shall be surrounded by adequate quantities of ice, sufficient not only to cool the fish but also to maintain it in a chilled condition until discharge. Icing should be heaviest against the vessel sides and bulkheads.

6. If block ice is used it shall be finely crushed in hygienic conditions to ensure a good chilling effect and avoid physical damage to the fish.

7. Fish stored in ice shall be stowed either in boxes or, if in pounds, in shallow layers separated by pound boards.

8. At the end of each fishing trip, all used ice which has not melted shall be discarded.

G Discharge of the catch

1. The catch shall be unloaded from the fishing vessel rapidly and carefully.

2. The use of hooks, forks and other such implements for unloading is not permitted.

3. During discharge, no fish shall be allowed to touch the deck, or other fishing vessel surfaces, or the ground at the point of discharge.

4. Fish shall not be exposed to direct sunlight.

5. Care shall be taken that fish are not damaged or contaminated during sorting, weighing and transfer.

H Cleaning and sanitation

1. All parts of the vessel and its equipment which come into contact with fish and where fish is handled, processed or stored shall be kept in a clean and sanitized condition.

2. Such parts of the vessel shall be thoroughly cleaned and disinfected at least before and after each fishing trip.

II. HEALTH CONDITIONS FOR FREEZER VESSELS

PART 1- GENERAL

Design and construction of freezer vessels

1. Where fish is frozen on board, the vessel shall be equipped with freezing equipment of sufficient capacity to permit freezing of peak rates of catch, without unreasonable delay.

2. Brine circulating and refrigeration equipment shall be adequate to maintain the temperature of the fish at or below -12°C.

3. The cold store on board the fishing vessel shall be adequate in size for the intended production, and shall be so constructed as to protect the frozen fish from fluctuation in temperature, dehydration and physical damage.

4. The cold storage facilities for fish shall be capable of maintaining a temperature of -18°C or below.

5. Each cold store shall have a thermometer which indicates the interior temperature at the point furthest away from the coolers. The temperature indicator shall be installed in an easy to read position on the exterior of the cold store next to the door. The instrument shall provide a permanent record of the internal temperature.

PART 2- HYGIENIC OPERATING REQUIREMENTS

A Freezing of fish

1. Fish shall be frozen as soon as possible after capture. Fish which is caught first shall be frozen first. Excess fish that cannot be frozen immediately should be chilled in ice.

2. Precise freezing times for fish shall be determined depending on the size and species. The application of refrigeration shall continue until the temperature at the thermal centre of the fish approaches -18°C.

3. On discharge of the freezer, the frozen fish shall be transferred to cold stores without delay.

4. Where brine freezing is used, the brine shall be replaced at the beginning of each voyage.

B Storage of frozen fish

1. The floor and general structure of the cold and chill stores shall be maintained in good condition.

2. All cold and chill stores and blast freezers shall be kept clean and free from accumulations of ice.

3. Cardboard or other absorbent materials shall not be placed on the floor of the cold store.

4. Cold stores for fish and fishery products shall not be used for storage of any other product.

5. The cold store shall be well organized, with separation of different products and batches. A record of batch locations shall be maintained.

C Cleaning and Sanitation Plan

1. Each freezer vessel shall possess a specific, written cleaning and sanitation plan covering the disassembly, cleaning and disinfection of all equipment, tables, fish boxes, tools, fish hold, deck and other materials and areas which come into contact with fish.

2. The plan shall specify a suitable methodology and frequency of cleaning and identify the individuals responsible for each component.

3. Checklists which reflect the plan shall be maintained by the vessel master to ensure that the cleaning schedule is met.

PART 3– HEALTH CONDITIONS FOR FACTORY VESSELS

Design and Construction of Factory Vessels

A. Reception area

1. The fish reception area shall be constructed with easy-to-clean material. It shall be divided into pounds or pens in order to hold each successive catch separately. It shall be designed in such a manner as to protect the fish and fishery products from the sun or the elements and from any source of dirt or contamination.

2. It shall have in it a system which conforms with stipulated health standards for conveying fishery products from the reception area to the work area.

B. Work area

The work areas shall be spacious enough for the preparation and processing of fishery products in proper hygienic conditions. They shall be designed and arranged in such a way as to prevent contamination of the products.

C Storage areas for finished products

1. Storage areas for the finished products shall be spacious enough and designed from material which is easy to clean. A separate hold shall be designated for the storage of by-products where the vessel has a waste-processing unit on board.

2. The vessel shall have a place for storing packaging materials which is separate from the product preparation and processing area.

3. The vessel shall have special equipment for pumping waste or fishery products that are unfit for human consumption either directly into the water or, where circumstances so require, into a water-tight tank reserved for that purpose. If waste is stored and processed on board, separate areas shall be allocated for these purposes.

4. The vessel shall have equipment providing a supply of potable water complying with established standards or pressurized clean sea water. The sea water intake shall be situated in a position where it is not possible for the sea water to be affected by discharges into the sea of water, waste or engine coolant.

D Processing areas

Areas used for the preparation and processing of fishery products shall have—

E Hygiene facilities

The vessel shall have an adequate number of changing rooms, wash rooms and toilets, the latter not opening directly onto areas where fishery products are prepared, processed or stored. They shall be equipped with wash basins, and an adequate supply of single use towels or appliances for drying the hands. The wash basin taps shall not be hand-operable.

F Personnel hygiene

Personnel working in processing areas shall wear suitable working clothes, and headgear which completely covers the hair.

PART 4— GENERAL HEALTH CONDITIONS FOR ISH LANDING STATIONS, AUCTION, WHOLESALE AND RETAIL MARKETS

A. General conditions relating to fish landing stations, auctions or wholesale markets

1. Each fish landing station, auction or wholesale market shall provide working areas which are of sufficient size for work to be carried out under adequate hygienic conditions.

2. The location, design and layout shall be such as to preclude contamination of the products and to allow separation of activities which might give rise to contamination of the fish during landing, sale or storage.

3. In areas where fishery products are handled, displayed or stored there shall be—

- (a) barriers for protection against the entry of animals and unauthorised personnel to areas where fishery products are handled, held or stored;
- (b) measures to prevent the fishery products from being exposed to direct sunlight during periods when they are displayed for sale;
- (c) a waterproof non-slip flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of water;
- (d) if work is to be conducted at night, adequate artificial lighting;
- (e) facilities for hygienic washing and drying of hands;
- (f) facilities for cleaning and disinfecting tools, equipment and fittings; and
- (g) facilities for the cleaning and disinfection of transport vehicles, including fishing vessels.

4. All equipment including, inter alia, weighing scales, work-tables, fish containers and knives, shall be made of corrosion-resistant materials which are easy to clean and disinfect.

5. Special water-tight, corrosion-resistant, containers shall be provided for fishery products not intended for human consumption, and separate premises shall be provided for the storage of such containers if they are not emptied at the end of each working day.

6. Facilities should be provided to ensure adequate supplies of potable water or alternatively of clean water.

7. There should be provided an adequate hygienic waste water disposal system.

8. The fishery enterprise should have an adequate number of toilet facilities. There should be adequate number of facilities for hygienic washing and drying of hands.

B General conditions of hygiene

1. The floors, and all structures and equipment used at the fish landing site, auction or wholesale market shall be kept in a satisfactory state of cleanliness and repair, in order not to constitute a source of contamination for the products.

2. Rodents, insects and any other vermin shall be systematically exterminated in the area of the fish landing site, auction or wholesale market.

3. Potable water or clean sea water shall be used for cleaning purposes.

4. Detergents, disinfectants and similar substances shall be approved by the competent authority and be used in such a way that they do not have an adverse effect on the machinery, equipment and fish and fishery products.

5. Rodenticides, insecticides, disinfectants and any other potentially toxic substances shall be stored in lockable premises or cupboards in order not to present any risk of contamination of the product.

C Personnel hygiene

(1) A high standard of cleanliness is required of all personnel working in the area of the fish landing station, auction or wholesale market areas.

(2) For purposes of subparagraph (1)—

- (a) personnel assigned to the handling of fishery products shall wash their hands at least each time work is resumed;
- (b) wounds shall be covered by a waterproof dressing; and
- (c) smoking, spitting, eating, blowing and picking the nose and drinking in the area of the fish landing site, auction or wholesale market of fishery products shall be prohibited.

2. The operator of the fish landing station, auction or wholesale market shall—

- (a) take all the necessary measures to prevent persons liable to contaminate fish and fishery products from handling such products; and
- (b) nominate a person to be responsible for ensuring that the conditions set down in this Schedule are applied during working hours.

PART 5– SPECIAL CONDITIONS FOR HANDLING
FISH AND FISHERY PRODUCTS ON SHORE

A Conditions for fresh products

1. Where chilled and packaged products are not dispatched, prepared or processed immediately after reaching a fishery enterprise they shall be stored or preserved with adequate quantities of ice to ensure that the temperature does not rise above the temperature of melting ice. Packaged fresh fish and fishery products may be chilled by mechanical refrigeration.

2. Re-icing shall be carried out as often as is necessary. Ice shall be made from potable water or clean sea water and stored under suitable conditions in receptacles or in an area provided for the purpose and such facilities shall be kept clean and in a good state of repair.

3. Preparation of products on shore shall be carried out under hygienic conditions, and the products shall be washed thoroughly with potable water or clean sea water immediately after such operations.

4. Operations such as filleting and slicing shall be carried out in such a manner as to avoid the contamination or spoilage of fillets and slices, and in an area other than that used for heading and gutting operations. Fillets and slices shall not remain on work tables any longer than is necessary for their preparation. Fillets and slices to be sold fresh shall be chilled as quickly as possible after preparation.

5. Viscera and other parts which may constitute a danger to public health shall be separated from and removed from the vicinity of products intended for human consumption. Containers used for dispatch or storage of fresh fish and fishery products shall be designed to ensure both the protection from contamination and their preservation under hygienic conditions and they shall provide adequate drainage of melt water.

6. Unless special facilities are provided for the continuous disposal of waste, the latter shall be placed in leak-proof, covered containers which are easy to clean and disinfect. Waste shall not be allowed to accumulate in working areas and shall be removed either continuously or as soon as the containers are full and at the end of each working day. Care shall be taken to ensure that waste stored as provided for in this paragraph does not constitute a source of contamination or pollution.

7. Containers, receptacles and premises set aside for waste disposal shall be thoroughly cleaned and disinfected after use.

B Conditions for frozen products

1. All establishments producing frozen fishery products shall have—
 - (a) refrigeration equipment sufficiently powerful to achieve a rapid reduction in temperature so that the temperatures laid down in these Regulations are obtained;
 - (b) refrigeration equipment sufficiently powerful to keep products in the storage rooms at temperatures not exceeding those laid down in these Regulations.
2. Whole fish frozen in brine shall be stored at temperatures not higher than -9°C.
3. The temperature indicator shall be installed in an easy-to-read position on the exterior of the cold store next to the door while the temperature sensor shall be located in the warmest area of the cold store. The indicator shall provide a permanent record of the internal temperature. Temperature charts shall be available for inspection by the competent authority during the period in which the products are stored.

C Conditions for thawed products

1. Where fishery enterprises carry out thawing operations they shall ensure that—
 - (a) fish and fishery products are thawed under hygienic conditions to avoid contamination and there shall be adequate drainage for melt water;
 - (b) during thawing, the temperature of the product shall not be increased beyond that of melting ice.
2. After thawing, the fish and fishery products shall be handled in accordance with the requirements of these Regulations as spelt out in health conditions of fish processing establishments of the Second Schedule.
3. Where the products are consigned directly to the market without further processing, particulars as to the thawed state of the fish shall be clearly marked on the packaging, in accordance with the legal requirement relating to labelling, presentation and advertisement of foodstuffs as provided for under the Eighth Schedule.

D General conditions for processed products

1. Fresh, frozen and thawed products used for processing shall comply with the requirements of section A, B and C of this Part.
2. The person responsible for a fishery enterprise shall keep a register of the processing operations carried out and the associated processing conditions. Depending on the type of process employed, heating time and temperature, salt content, pH, and water content shall be monitored and controlled. Records shall be preserved for at least thirty-six months and be available to the competent authority.
3. For products which are preserved for a limited period by a treatment such as salting, smoking, drying or marinating, the appropriate conditions for storage shall be clearly marked on the packaging.

E Conditions for canned products

In the case of fish and fishery products subjected to sterilisation in hermetically sealed containers—

(g) further checks shall be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat treatment, including—

- (i) an incubation test carried out at 37°C for seven days or at 35°C for ten days, or at any other equivalent combination; and
- (ii) microbiological examination of the contents and the container;

F Conditions for smoked products

1. Smoking shall be carried out in separate premises or in an area used specifically for this purpose, equipped, if necessary, with a ventilation system to prevent the smoke and heat from affecting other premises or places where fishery products are prepared, processed or stored.

2. Materials used to produce smoke for the smoking of fish shall be stored away from the place of smoking and shall be used in such a way that they do not contaminate the product.

3. Smoking by burning wood that is painted, varnished, or glued or has undergone any chemical preservation treatment is prohibited.

4. After smoking, products shall be cooled rapidly to the temperature required for their preservation before being packaged. Cooling shall take place in an area with adequate protection against contamination with vermin.

5. Smoked fish shall be packed in suitable packaging material, which provide a suitable degree of protection from contamination.

6. Storage of products shall be in a well ventilated, cool, dry place.

G Conditions for dried products

1. Drying of fishery products shall be carried out in a premises or area used specifically for this purpose.

2. Areas in which fish is dried shall be adequately protected against the entry of animals and unauthorised persons.

3. Fish shall not be dried on the ground.

4. Smoked fish shall be packed in suitable packaging material, which provide a suitable degree of protection from contamination.

5. Storage of products shall be in a well ventilated cool, dry place.

H Conditions for salted products

1. Salting operations shall be carried out in premises or areas used specifically for this purpose.

2. Salt used in treatment of fishery products shall be clean and stored in such a way as to preclude contamination, and shall not be re-used.

3. Any container used for salting or brining shall be constructed in such a way as to preclude contamination during the salting or brining process.

4. Containers or areas used for salting or brining shall be cleaned before use.

5. Salted fish shall be packed in suitable packaging material, which provide a suitable degree of protection from contamination.

6. Storage of products shall be in a well ventilated cool dry place.

I. Conditions for cooked crustacean and molluscan shellfish products

1. Only potable water or clean sea water shall be used for the cooking of crustaceans and molluscan shellfish.

2. Cooking shall be followed by rapid cooling. If no other method of preservation is used, cooling shall continue until the temperature approaching that of melting ice is reached.

3. Shelling or shucking of cooked products shall be carried out under hygienic conditions, avoiding contamination of the product. Where such operations are done by hand, workers shall pay particular attention to the washing of their hands and all working surfaces shall be cleaned thoroughly. If machines are used, they shall be cleaned at frequent intervals and disinfected after each working day.

4. After shelling or shucking, cooked products shall immediately be frozen or kept chilled at a temperature which precludes the growth of pathogens, and shall be stored in appropriate conditions.

5. Every owner of a fishery enterprise shall carry out microbiological checks on his production at regular intervals.

J Conditions concerning parasites

1. During production and before they are released for human consumption, fish and fishery products shall be subjected to a visual examination by the producer for the purpose of detecting visible parasites.

2. Fish or parts of fish which have obviously been infested with parasites shall not be placed on the market for human consumption.

3. The following fishery products shall be frozen at a temperature of not more than 20°C in all parts of the product for not less than twenty-four hours, this treatment shall be applied to the raw product or the finished product—

- (a) fishery products to be consumed raw, or almost raw;

- (b) fishery products if they are to undergo a cold smoking process at which the internal temperature of the fish is less than 60°C;
- (c) marinated and/or salted fishery products, if the processing is insufficient to destroy nematode larvae.

4. Treatment required under paragraph 3 need not be carried out if epidemiological data is available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites and the competent authority so authorises.

5. The fishery products listed in paragraph 3 shall when they are placed on the market, be accompanied by a document from the manufacturer stating the type of process they have passed through.

K Mechanically separated fishery products

Manufacturing of mechanically separated fishery products shall ensure compliance with the following conditions:

1. The raw materials used shall satisfy the following requirements—
 - (a) only whole fish and bones after filleting may be used to produce mechanically separated fishery products;
 - (b) all raw materials shall be free of guts.

2. Mechanical separation shall take place without undue delay after filleting. Where whole fish is used, these shall be gutted and washed beforehand.

3. After production, mechanically separated fishery products shall be frozen as quickly as possible or incorporated in a product intended for freezing or stabilising treatment.

PART 6– GENERAL HEALTH CONDITIONS FOR FISH PROCESSING ESTABLISHMENTS

Part 1 General conditions relating to premises and equipment

1. Each fish processing establishment shall provide working areas which are of adequate size and space for work to be carried out under adequate hygienic conditions. The location, design and layout shall be such as to preclude contamination of the products and to separate the clean parts of the building from the contaminated areas.

2. In areas where products are handled, prepared and processed there shall be—
 - (a) waterproof non-slip flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of water;
 - (b) walls which have smooth surfaces and are easy to clean, durable and impermeable;
 - (c) ceilings which are easy to clean and designed to avoid the accumulation of dust;
 - (d) adequate natural or artificial lighting;
 - (e) doors made of durable materials which are easy to clean;
 - (f) adequate ventilation and where necessary, proper vapour extraction facilities;
 - (g) an adequate number of hand wash basins with taps that are not hand-operable and an adequate supply of single use towels or appliances for drying the hands;
 - (h) facilities for cleaning and disinfecting tools, equipment and fittings.

3. Appropriate facilities shall be provided for protection against the entry of pests such as insects, rodents and birds.

4. Instruments and working equipment such as cutting boards, work tables, containers, conveyor belts and knives shall be made of corrosion-resistant materials which are easy to clean and disinfect.

5. Special water-tight, corrosion-resistant containers shall be provided for fishery products not intended for human consumption. Separate premises shall be provided for the storage of such containers if they are not emptied at the end of each working day.

6. Facilities shall be provided to ensure adequate supplies of potable water or alternatively of clean sea water, under pressure and in sufficient quantities for processing and cleaning operations.

7. Where a non-potable water supply is provided for the production of steam, fire fighting or the cooling of refrigeration equipment, the pipes installed for the purpose shall preclude the use of such water for any other purpose and present no risk of contamination of the products. Water pipes for non-potable water shall be clearly distinguished from those used for potable water or clean sea water.

8. There shall be provided an adequate hygienic waste water disposal system.

9. There shall be provided adequate facilities in a separate room for personnel to change their clothes. This room shall have smooth, waterproof, washable walls and floors.

10. The establishment shall have an adequate number of flush toilets, the latter not opening directly onto areas where fishery products are prepared, processed or stored. There shall be an adequate number of wash basins and an adequate supply of single use towels or appliances for drying the hands. The wash basin taps shall not be hand-operable.

11. There shall be provided an adequately equipped lockable room for the exclusive use of fish inspectors in cases where the volume of products processed requires their regular or permanent presence.

12. There shall be adequate facilities for cleaning and disinfecting the means of transport delivering raw material to or taking final products from the establishment.

13. Fish establishments keeping live animals such as crustaceans and fish shall provide water supply of a quality such that no harmful organisms or substances are transferred to the animals.

Part 2 General Conditions of Hygiene

1. Floors, walls and partitions, ceilings and roof linings, equipment and instruments used for working on fishery products shall be kept in a satisfactory state of cleanliness and repair, in order not to constitute a source of contamination for the products.

2. Rodents, insects and any other vermin shall be systematically exterminated in the premises or on the equipment.

3. Equipment used in the processing areas shall be used only for work on fish and fishery products.

4. Potable water or clean sea water shall be used for cleaning purposes.

5. Detergents, disinfectants and similar substances used in the establishment shall be of a type approved by the competent authority and shall be used in such a way that they do not have an adverse effect on the machinery, equipment and fishery products.

6. Rodenticides, insecticides, disinfectants and any other potentially toxic substances shall be stored in lockable premises or cupboards in order not to present any risk of contamination of the product.

PART 3– PERSONNEL HYGIENE

1. A high standard of cleanliness is required of personnel working in processing areas. In particular—

- (a) personnel shall wear suitable working clothes, and headgear which completely covers the hair;
- (b) personnel assigned to the handling and preparation of fishery products shall wash their hands at least each time work is resumed;
- (c) wounds shall be covered by a waterproof dressing; and
- (d) smoking, spitting, eating, nose blowing and picking, and drinking in work areas and storage premises of fishery products shall be prohibited.

Employers shall take all the necessary measures to prevent persons liable to contaminate fishery products from handling and working on such products until there is evidence that such persons can do so without risk.

THIRD SCHEDULE

[Regulation 5(1)(k).]

CONDITIONS FOR THE CULTURE AND PLACING ON THE MARKET OF FISH CULTURE PRODUCTS

PART 1– SITE LOCATION AND SELECTION

A General

1. Commercial scale fish culture shall before being undertaken, be subjected to an Environmental Impact Assessment (EIA) by relevant authorities.

2. The management of fish culture systems before constructing, reconstructing or adapting a new technology shall submit to the competent authority for approval, a plan of the establishment and a list of activities to be carried out.

3. Fish culture operations shall be located in areas where the risk of contamination with hazardous chemical effluents is minimal and where sources of pollution can be controlled.

4. Fish culture operations shall be sited at a safe distance from potential sources of water contamination, in order to ensure protection of products from contamination.

5. The immediate vicinity of fish culture operations shall be free from potential sources of water contamination and in particular shall not be located downstream or close to—

- (a) industry and mining;
- (b) intensive agriculture (especially animal husbandry);
- (c) densely populated areas or urban areas;

- (d) hospitals and major laboratories;
- (e) major roads and railways.

(1) Before building a land-based fish culture facility a survey of the soil shall be conducted in order to determine the concentration and extent of any parameters which are of importance for the safety of end products, including heavy metals and pesticide residues.

(2) Results of the survey in subparagraph (1) above shall form the basis of issuance of the permit required under Regulation 7.

7. Cages, pens or any other form of fish culture enclosures or water intakes shall be sited away from routes of water-borne traffic, and preferably upstream of any water borne traffic and any natural or man-made discharges of contamination.

B Fish culture site facilities

1. All fish culture enterprises must provide reasonably accessible sanitary facilities available for the use by people working in the enterprise.

2. Sanitary facilities under this provision may include earth closet facilities.

3. The minimum number of facilities shall depend on the number of personnel at the site, according to the following table:

<i>Number of employees (counted according to gender)</i>	<i>Minimum number of toilets</i>
01 – 09	1
10 – 24	2
25 – 49	3
50 – 100	5
More than 100	for every 30 persons add 01 more toilet

4. Sanitary facilities shall be located away from the place where fish are held to ensure that there is no risk of contamination of fish ponds with human waste.

C Fish feed storage

If fish feed is stored at the fish culture facility it shall be stored in a properly constructed well-ventilated facility, and protected from the entry of vermin.

PART 2– POND CONDITIONING, FERTILIZER AND FEEDS

A Pond preparation

1. Weeds, rubbish and debris shall be removed before preparing fish culture ponds for filling with water.

2. Ponds shall be conditioned with lime and left for a period of at least two weeks before filling and stocking.

3. At least once each year the pond shall be drained, allowed to dry out and re-conditioned with lime.

B Fertilizer

The following materials shall not be used as fertilizer—

2. pig manure, except where it—
 - (a) is added with an equal weight of lime during pond conditioning;
 - (b) has been adequately composted to eliminate trematode eggs; or
 - (c) is derived from enclosed animals living adjacent to the pond as part of an integrated culture system, and those animals are treated regularly with anthelmintic drug and free from zoonotic diseases.

C Feeds and feed materials

1. Slaughterhouse waste and offal from mammalian food animals may only be used as fish feed if it is first cooked.
2. Compound feed shall not be used for feeding fish unless the user is informed of the composition, including any supplements added by the manufacturer.
3. Compound feed treated with veterinary medical supplements (including hormones and antibiotics) are considered to be veterinary medicines to which Part III below applies.
4. Fish feeds shall be used before the expiry date and any remaining feed disposed of on the supervision of a fish inspector.

PART 3– VETERINARY MEDICINES AND WITHDRAWAL PERIODS

A Registration and Distribution of Veterinary Drugs

No veterinary therapeutic-products and medicinal premixes for inclusion in fish feeds may be applied to fish unless they are approved for use under the terms of the Pharmacy and Poisons Act (Cap. 244).

B Handling and Administration of Veterinary Drugs

1. Control of fish diseases in fish culture using drugs shall be carried out only on the basis of a diagnosis by a qualified fish disease specialist.
2. Veterinary medicines for treatment of fish diseases shall only be applied under the supervision of a qualified fish disease specialist.
3. Veterinary drugs shall be used according to the manufacturer's instructions and note shall be taken of all warning statements and contra-indications for use, and in particular instructions in relation to withdrawal periods.
4. Each individual dose and administration of veterinary medicines (including compound feeds containing veterinary supplements) shall be recorded in a special book kept at the facility for that purpose, specifying date and nature of treatment, identification of fish and duration of withdrawal period.
5. The entries in the register are to be signed by the fish disease specialist responsible for administering the drug programme.
6. Fish which are diseased and which are being treated with veterinary medicine shall be isolated and be easy to identify as a separate batch.
7. The health of fish shall be monitored regularly for symptoms of disease or parasitic/fungal infection.

C Harvesting and Withdrawal Period

1. Drugs used for treatment as well as prophylaxis shall not be given to fish for a period of time (withdrawal period) before slaughtering.
2. Withdrawal periods under different conditions shall be established by the supplier of the drug for the fish species and the drug in question, and recorded in the drug register held by the farmer.
3. Fish shall not be harvested before the end of the withdrawal period.
4. The amount of any veterinary drug residue in the harvested fish shall not exceed any maximum residue limit specified under the terms of the Pharmacy and Poisons Act (Cap. 244).
5. If fish which are treated with a veterinary medicine are sold live for on-growing before the end of the withdrawal period, the buyer must be informed in writing by the seller.

D Requirements for marketing

1. If the fish is consigned for placing on the market for human consumption, then the producer shall certify to the processor in writing with a copy to the competent authority that either—
 - (a) no veterinary medicines have been applied; or
 - (b) if they have been applied, that minimum withdrawal periods have been observed for the named medicines.
2. Persons receiving fish culture products for subsequent placing on the market shall undertake their internal controls system in accordance with the Ninth Schedule to ensure that—
 - (a) they do not accept production batches to which undeclared drug treatments have been administered;
 - (b) where veterinary medicines have been applied, minimum withdrawal periods have been observed and maximum residue limits are not exceeded; and
 - (c) no prohibited substances are present.

PART 4– HARVESTING EQUIPMENT AND MATERIALS

1. Harvesting areas and methods within the fish culture facility shall be designed and constructed for easy, fast and hygienically acceptable operations.
2. All equipment used for the harvesting, catching, sorting, grading, conveying and transportation of fish shall be designed for rapid and efficient handling of fish without causing mechanical damage thereto.
3. Equipment, containers and utensils coming into contact with fish shall be designed and constructed so as to ensure that they can be adequately cleaned, disinfected and maintained to avoid contamination.
4. All surfaces of boxes, implements and other equipment which come into contact with fish shall be of corrosive-resistant material which is smooth and easy to clean, or be designed for a single use only.
5. If re-usable boxes are used to carry fish from the pond, suitable means of cleaning with clean water and detergent followed by disinfection shall be provided.

PART 5– HYGIENE

A Personal hygiene

1. Any person working at a fish culture facility shall maintain a reasonable standard of personal hygiene and shall take all necessary precautions to prevent the contamination of the fish.
2. Any cut or wound shall immediately be covered with a suitable waterproof dressing.
3. Persons suffering from infectious diseases, or from a helminthic parasitic infection, or who have infected wounds, boils or other skin infections, or who are suffering from diarrhoea, shall not be permitted to work in a fish culture operation.
4. Personnel who work in fish culture operations shall, on their appointment and at six month intervals thereafter undertake a health examination to ensure that they do not suffer from any of the above conditions. Health documents of every person shall be kept at the facility and shall be available to the competent authority on request.
5. Any person entering a fish culture facility shall refrain from spitting or eating food, or relieving himself, except in areas designated for these purposes, which must be away from fish production areas.

B First aid box

Each fish culture facility shall be provided with a first-aid box, which shall contain sufficient quantities of—

C Exclusion of animals

PART 6– CLEANING, DISINFECTION AND PEST CONTROL

A. Cleaning and Disinfection Schedule

1. Areas around the ponds shall be kept clean and free from rubbish, waste fish and items not associated with the fish culture operation.
2. A cleaning and disinfection schedule bearing the name of the responsible person shall be developed to ensure that all parts of the fish culture facilities and equipment therein are cleaned appropriately and regularly.
3. The schedule shall be made available to the inspector at all times.
4. Fish culture personnel shall be trained in the use of special cleaning tools, and methods of dismantling equipment for cleaning and shall be knowledgeable in the significance of contamination and the hazards involved.
5. The disinfectants applied to fish culture systems shall be approved and applied in accordance with competent authority's and manufacturer's instructions.

B. Pest Control Systems

1. A pest control schedule bearing the name of the responsible person shall be developed to ensure that all parts of the fish culture facilities and equipment remain free from infestations by vermin.

2. The schedule shall be made available to the inspector at all times.

PART 7— RECORD KEEPING AND BATCH IDENTIFICATION

1. The following records of fish culture systems shall be kept—

- (a) date of construction;
- (b) number of fingerlings stocked;
- (c) stocking rate and time;
- (d) anticipated harvest time;
- (e) date of harvest and quantities harvested;
- (f) each batch of fish cultured in each pond, including veterinary drug regimes;
- (g) feeding methods and quantities;
- (h) pond fertilization;
- (i) results of water quality parameters.

2. The records shall be kept for a period of one year after harvest.

3. Each batch of fish leaving the farm for market or for processing shall be allocated a batch number which relates it to the information records described in paragraph 1 above.

4. Each batch of fish leaving the fish culture operation for placing on the market shall be marked to include the following information—

- (a) approval number of the fish culture enterprise;
- (b) name and permanent postal and physical address of the enterprise;
- (c) date of harvesting;
- (d) species; and
- (e) batch number.

5. Managers shall ensure effective procedures are in place to effect the complete traceability in accordance with Tenth Schedule, and rapid recall of any lot of fish from the market.

PART 8— MINIMUM MONITORING REQUIREMENTS FOR THE INTERNAL CONTROL SYSTEM

1. Monitoring programmes shall be developed to ensure that—

- (a) waste and debris does not build up and is disposed of in a hygienic manner;
- (b) personal hygiene and health standards are maintained;
- (c) a pest control programme is implemented;
- (d) cleaning and disinfecting programmes are implemented;
- (e) the quality of water and any supplies of ice are maintained; and
- (f) in fresh water fish culture operations, the farm is maintained free from trematode parasites.

2. The results of all monitoring actions and of any corrective actions taken after monitoring shall be recorded.

FOURTH SCHEDULE

[Regulation 10(1).]

MONITORING OF HEALTH CONDITIONS FOR PRODUCTION AND PLACING ON THE MARKET OF BIVALVE MOLLUSCS

PART 1– HARVEST AND RELAY AREAS

1. Bivalve molluscs for human consumption shall be harvested from areas designated by the competent authority.

2. Permitted harvest areas shall be classified according to the level of faecal contamination as determined by routine monitoring of the microbiological contamination of the product.

3. Any change in the demarcation of harvest areas or in the classification of harvest areas shall be immediately announced by the competent authority through advertisements in the press and in the Kenya Gazette.

4. Harvest areas shall be classified according to the scheme specified in the first and second columns of the following table, and applied for the uses specified in the third column.

<i>Classification</i>	<i>Bacteriological counts* (not more than ...)</i>	<i>Permitted use</i>
A	300 faecal coliforms/100g flesh or 230 E.coli/100g flesh free of <i>salmonella</i> in 25g*	Direct human consumption; Cooking
B	In 90% of samples tested - 6000 faecal coliforms/100g flesh or 4600 E.coli/100g flesh	Direct human consumption after purification or relaying until Class A is achieved; cooking
C	60,000 faecal coliforms/100g flesh 46,000 E.coli/100g flesh	Relaying for at least two months prior to retesting; cooking

* Based on a five tube three dilution mean probable number test or any other equivalent bacteriological procedure.

5. The gathering of shellfish for human consumption shall be prohibited from any area in which the product is found to contain more than the maximum permitted number of coliform bacteria for Class C.

6. The gathering of shellfish for human consumption shall be prohibited from any area in which product is found to contain marine biotoxins with levels greater than those indicated in the following table:

<i>Toxin</i>	<i>Testing method</i>	<i>Limit</i>
Paralytic Shellfish Poison (PSP)	Mouse bioassay or HPLC Saxitoxin	80 microgrammes/100g of Edible portion
Diarrhetic Shellfish Poison (DSP)	Mouse	Not detected in 100g of edible portion
Amnesic Shellfish Poison (ASP)	HPLC for domoic acid	20 microgrammes/gram of edible portion

PART 2– MONITORING OF HARVEST AREAS BY THE COMPETENT AUTHORITY

1. Harvest areas and samples of fishery products from them shall be monitored on a regular basis by the competent authority, according to a written sampling plan, and with respect to the following parameters:

Parameters to be measured in Water samples	<p>Faecal coliforms</p> <p>E.coli</p> <p><i>Salmonella</i> spp</p> <p><i>Vibrio parahaemolyticus</i></p> <p>Marine phytoplankton which produce the toxins which cause PSP (paralytic shellfish poisoning), DSP (diarrhetic shellfish poisoning) and ASP (amnesic shellfish poisoning)</p> <p>Chemical and physical parameters (temperature, pH, salinity)</p>
Parameters to be measured in product samples	<p>Faecal coliforms</p> <p>E.coli</p> <p><i>Salmonella</i> spp</p> <p><i>Vibrio parahaemolyticus</i></p> <p>Marine biotoxins which cause PSP (paralytic shellfish poisoning), DSP (diarrhetic shellfish poisoning) and ASP (amnesic shellfish poisoning)</p> <p>Heavy metals including lead, cadmium and mercury</p>

2. Samples for the measurement of the parameters listed in paragraph 1 above shall be taken as frequently as necessary to identify the potential development of hazards in advance of the occurrence of any significant risk to human health.

3. The sampling frequency shall take into account any features of the fishery concerned in relation to seasonal or irregular fishing.

4. The sampling plan shall define the sampling points within each defined harvest area.

Sufficient sample points shall be defined by taking into account—

- (a) likely variations in the faecal contamination of the production area; and
- (b) possible variations in the development of marine algal blooms.

5. Detection of potential problems shall be followed by a more intensive sampling regime, until the area is closed, or until the potential hazard recedes.

6. If the results of the sampling programme indicate that the placing on the market of products from the harvest area would constitute a hazard to human health, the competent authority shall close the area and put advertisements in the press and Kenya Gazette.

7. Areas which are subject to temporary closure shall be monitored as if the area was not closed, unless they are to be closed permanently.

FIFTH SCHEDULE

[Regulation 13(d).]

REQUIREMENT FOR HEALTH CONTROL AND
MONITORING OF PRODUCTION CONDITIONS

PART 1– GENERAL MONITORING

1. Arrangements for checking and monitoring shall be made by the competent authority in order to establish whether the requirements laid down in this Regulation are complied with.

2. Such arrangements shall include, in particular—

- (a) a check on the conditions at landing and first sale;
- (b) a check on the conditions at fish auctions and wholesale markets;
- (c) an inspection at regular intervals of fishery enterprises, to undertake the activities defined in regulation 6 of these Regulations, with a view to establishing—
 - (i) whether the conditions for approval are all complied with;
 - (ii) whether the fishery products are handled in accordance with the requirements of these Regulations;
 - (iii) the cleanliness of the premises, facilities and instruments and personnel hygiene;
 - (iv) whether identification marks are affixed correctly; and
 - (v) periodical sampling and testing of products during production or after placing on the market.

3. The selection of the checks to be undertaken and the sampling rate to be applied shall be scientifically justifiable and shall depend on the nature of the hazards involved and the risk of their occurrence.

PART 2– ORGANOLEPTIC CHECKS

1. On the demand by a fish inspector each batch of fish and fishery products shall be subject to inspection at the time of landing or before first sale to establish whether it is fit for human consumption.

2. This inspection will comprise an organoleptic check carried out by sampling, plus any other checks deemed by the fish inspector to be appropriate including chemical checks or microbiological analyses as defined in Parts 4, 5 and 7 below.

3. If the organoleptic examination reveals that the fish and fishery products are not fit for human consumption, the fish inspector shall withdraw them from the market as provided for in Regulation 17 of these Regulations.

PART 3– PARASITE CHECKS

1. Before they are released for human consumption, fish and fishery products shall be subject to visual inspection, by way of sample, for the purpose of detecting any parasites that are visible.

2. Fish or parts of fish which are obviously infested with parasites which cannot be readily removed, shall not be placed on the market for human consumption.

FIFTH SCHEDULE—*continued*

3. On the demand of a fish inspector samples from any batch of fish and fishery products may be taken and subjected to laboratory analysis for the measurement of any scientifically established indicator of the degree of deterioration of the fish and fishery products.

PART 4— TVB

PART 5— HISTAMINE

1. On the demand of an authorised fish inspector samples from any batch of fishery products of the following species may be taken and subjected to laboratory analysis for the measurement of histamine—

- (a) *fish of the family Scombridae;*
- (b) *fish of the family Clupeidae;*
- (c) *fish of the families Engraulidae, Coryfenidae, Pomatomidae, Scombrosidae.*

2. Where such samples are taken, nine samples shall be taken from each batch and submitted for analysis.

3. Examinations shall be carried out in accordance with the high-performance liquid chromatography (HPLC) or any other reliable, scientifically recognized methods.

4. The results of the analysis shall fulfil the following requirements—

- (i) the mean value shall not exceed 100 ppm;
- (ii) two samples may have a value of more than 100 ppm but less than 200 ppm;
- (iii) no sample may have a value exceeding 200 ppm.

5. Fish belonging to the above families which have undergone enzyme-ripening treatment in brine are permitted higher histamine levels, but not more than twice the above values.

PART 6— CONTAMINANTS PRESENT IN THE AQUATIC ENVIRONMENT

1. On the demand by a fish inspector samples from any batch of fish and fishery products may be taken and subjected to laboratory analysis for the measurement of contaminants which may be present in the aquatic environment.

2. Batches of fish and fishery products in which the levels of heavy metal contaminants exceed the maximum residue limits indicated in the manual of Standard Operating Procedures for Inspection and Quality Assurance in Capture Fisheries and Aquaculture in Use in Kenya.

FIFTH SCHEDULE—*continued*

PART 7— MICROBIOLOGICAL CHECKS

1. On the demand by an authorised fish inspector samples from any batch of fishery products may be taken and subjected to laboratory analysis for the measurement of levels of microbiological agents therein, including protozoan and helminthic parasites, bacteria and viral pathogens.

2. Batches of cooked crustacean which do not meet the following criteria shall be considered to be unfit for human consumption.

<i>Type of bacteria</i>	<i>Standard</i>
<i>Salmonella</i>	Absent in 25g n = 5 c = 0
<i>Staphylococcus aureus</i>	m = 100 M = 1000 N = 5 C = 2
<i>E. coli</i> (on solid medium)	m = 10 M = 100 n = 5 c = 1

Where:

m = limit below which all results are considered satisfactory

M = acceptability limit beyond which the results are considered unsatisfactory

n = number of units comprising the sample

c = number of sample units giving bacterial counts between m and M

PART 8— CHECKS ON VETERINARY MEDICINES

1. On the demand by a fish inspector samples from any batch of fishery products produced by fish culture systems may be taken and subjected to laboratory analysis for the measurement of levels of residues of veterinary medicines therein.

2. This monitoring will establish compliance with—

- (a) limits on the maximum residue levels of veterinary medicines permitted for use in fish culture, in accordance with the Pharmacy and Poisons Act (Cap. 244);
- (b) prohibition of the use of certain substances as veterinary medicines in fish culture, in accordance with the Pharmacy and Poisons Act.

PART 9— CHECKS ON ADDITIVES

1. Samples of fish and fishery products shall be taken and subjected to laboratory analyses for control of additives in edible parts of fish and fishery products for the purpose of protecting public health.

2. Batches of fish and fishery products which do not meet the following criteria shall be considered to be unfit for human consumption.

FIFTH SCHEDULE—continued

Type of fish and fishery product	Maximum level (mg/kg or mg/l as appropriate) expressed as SO ₂
Crustaceans and cephalopods; Fresh, frozen and deep frozen	150
Crustaceans, <i>panaeidae</i> <i>solenceridae</i> , <i>aristeidae</i> family	
– up to 80 units	150
– between 80 and 120 units	200
– over 120 units	300
Cooked	50

Note:

1. Maximum levels are expressed as SO₂ in mg/kg or mg/l as appropriate and relate to the total quantity available from all sources.
2. An SO₂ content of not more than 10 mg/kg or 10 mg/l is not considered to be present.

PART 10– MICROBIOLOGICAL AND PHYSICAL CHECKS OF POTABLE WATER

SIXTH SCHEDULE

[Regulation 5(1)(k).]

REQUIREMENTS FOR STORAGE AND TRANSPORT

1. Fishery products shall, during storage and transport, be kept at the prescribed temperature, and, in particular—

- (a) fresh or thawed fishery products and cooked and chilled crustacean and molluscan shellfish products shall be kept at the temperature of melting ice;
- (b) frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned foods, shall be kept at an even temperature of -18°C or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than 3°C during transport;
- (c) processed products shall be kept at the temperature specified by the manufacturer.

2. Paragraph 1(b) shall not apply where frozen fishery products are transported from a cold storage plant to an approved processing plant to be thawed on arrival for the purpose of preparation or processing and where the journey is shorter than two hours.

3. Products may not be stored or transported together with other fishery products or with any other goods which may contaminate them or affect their quality, unless they are packaged in such a way as to provide adequate protection.

4. Vehicles used for the transportation of fishery products shall be constructed and equipped in such a way that the prescribed temperatures can be maintained through the period of transport. If ice is used to chill the products, adequate drainage shall be provided in order to ensure that water from melted ice does not stay in contact with the products.

5. The inside surfaces of the means of transport shall be smooth and easy to clean and disinfect without contaminating the products.

SEVENTH SCHEDULE

[Regulation 5(1)(k).]

PACKAGING REQUIREMENTS FOR FISHERY
PRODUCTS PROCESSING ESTABLISHMENTS

1. Packaging of fish and fishery products shall be carried out under satisfactory conditions of hygiene, to preclude contamination.

2. Packaging materials and products liable to enter into contact with fishery products shall comply with all the rules of hygiene, and in particular—

- (a) they shall not be such as to impair the organoleptic characteristics of the fishery products;
- (b) they shall not be capable of transmitting to the fishery products substances harmful to human health;
- (c) they shall be strong enough to protect the fishery products adequately.

3. With the exception of containers made of impervious, smooth and corrosion-resistant, durable material which may be re-used after cleaning and disinfecting, packaging materials shall not be re-used.

4. Packaging materials used for fresh products held under ice shall provide adequate drainage for melt water.

5. Unused packaging materials shall be stored in premises away from the production area and be protected from dust and contamination.

EIGHTH SCHEDULE

[Regulation 5(1)(k).]

IDENTIFICATION MARKS FOR FISHERY PRODUCTS

Where fishery products are packed and consigned to the market by an establishment, the following information shall appear on the packaging—

NINTH SCHEDULE

[Regulation 25(3).]

REQUIREMENT FOR AN INTERNAL SYSTEM TO CONTROL
FISH AND FISHERY PRODUCT SAFETY HAZARDS

PART 1– GENERAL REQUIREMENTS

1. Fish and fishery product business operators shall implement a system of internal controls (an own-checks system) based on the following principles—

- (a) identification of fish and fishery product safety hazards associated with their products and processes, and identification of critical points in their establishment on the basis of the manufacturing processes used;
- (b) establishing and implementing methods for monitoring and checking such critical points, and for taking corrective actions to prevent or minimise the risk of hazards arising;
- (c) taking samples for analysis for the purpose of checking, cleaning and disinfection methods and for the purpose of checking compliance with the fish and fishery product safety requirements established by this Regulation;
- (d) keeping a written record or a record registered in an indelible fashion of the preceding points with a view to making them available to the relevant competent authority. The results of the different checks and tests shall be preserved for a period of at least two years.

2. The persons responsible for the establishment must make provision for a sampling programme which, though not concerning systematically every production batch, nevertheless allows—

- (a) validation of the system of internal controls when first set up;
- (b) if necessary, revalidation of the system in case of a change to the characteristics of the product or to the manufacturing process;
- (c) confirmation, at specified intervals, that all provisions are still appropriate and properly applied.

3. If the results of the internal controls referred to in this Schedule reveal the existence of a significantly elevated risk to the health of consumers in respect of a batch of fish or fishery products, the products concerned shall be deemed not to be in compliance with the requirements of section 3 of the Food, Drugs and Chemical Substances Act (Cap. 254) and shall be treated accordingly.

4. In order to keep a written record or a record registered in an indelible fashion, as referred to in paragraph 1(d) of this Part of the Schedule, the persons responsible for the establishment must document all information relating to the implementation of internal control system and its verification.

5. The documentation referred to in paragraph 1 shall include the following two types of information to be kept for submission to the competent authority on request—

- (a) a detailed and comprehensive document including—
 - (i) a description of the product;

- (ii) a description of the manufacturing process indicating critical points;
 - (iii) for each critical point, identified hazards, assessment of risks and control measures;
 - (iv) procedures for monitoring and checking each such critical point, with an indication of critical limits for parameters that need to be controlled and the corrective action to be taken in case of loss of control; and
 - (v) procedures for verification and review;
- (b) records of the observations or measurements referred to in paragraph 1(b), results of the verification activities referred to in paragraph 3, and reports and written accounts of decisions relating to corrective action when taken. An appropriate document management system must provide, in particular, for the easy retrieval of all documents relating to an identified production batch.

PART 2– SPECIFIC REQUIREMENTS FOR THE INTERNAL CONTROL SYSTEM

1. The internal control system shall be developed and implemented by persons within the establishment to which it relates.

2. As part of the internal approach referred to in paragraph 1 an establishment may use guides of good manufacturing practice drawn up by appropriate professional organizations and acceptable to the competent authority.

3. The proprietor of the establishment shall ensure that all personnel concerned with the internal control receive adequate training in order to effectively participate in their implementation.

4. In the design of any system for internal control the following general approach shall be adopted—

- (i) identification of hazards, analysis of risks and determination of measures to control them;
- (ii) identification of critical points;
- (iii) establishment of critical limits for each critical point;
- (iv) establishment of monitoring and checking procedures;
- (v) establishment of corrective action to be taken when necessary;
- (vi) establishment of verification procedures;
- (vii) validation of the system; and
- (viii) documentation of the system and maintaining records of results.

5. This general approach shall be used with flexibility appropriate to each situation.

PART 3– IDENTIFICATION OF CRITICAL POINTS

A General principles

1. **“Critical point”** means any point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels.

2. All critical points shall first be identified by a detailed review of the process, based on knowledge of microbiological and other hazards which may potentially arise, undertaken by a person with specialised knowledge and with reference to existing codes of practice.

3. The information generated under paragraph 2 shall be used as the basis of the internal control system to ensure compliance with the hygiene and safety requirements of the process, including those specified in any relevant code of practice.

4. The critical points shall be specific to each establishment, depending on the raw materials it uses and on its manufacturing processes, structure and equipment, end products and marketing system.

5. The sequential steps described below may be followed in order to identify and characterize the critical points in the process.

B Assembly of a multi-disciplinary team

1. A multi-disciplinary team shall be drawn from all parts of the establishment concerned with the product, and shall include a wide range of specific knowledge and expertise appropriate to the product under consideration, its production process, viz manufacture, storage and distribution, its consumption and the associated potential hazards.

2. The team may consist of one or more of—

- (a) a quality control specialist with an understanding of the biological, chemical or physical hazards connected with a particular product group;
- (b) a production specialist with responsibility for, or who is closely involved with, the technical process of manufacturing the product under study;
- (c) a technician who has a working knowledge of the hygiene and operations of the plant and equipment; or
- (d) any other person with specialist knowledge of microbiology, hygiene or food technology.

3. Where necessary, the team may be assisted by external specialists with technical knowledge in areas not adequately covered by the establishment's own personnel.

C Description of the product

The end product shall be described in terms of—

D Description of manufacturing process

1. The establishment shall develop and maintain a detailed description of the premises and all steps involved in the manufacturing process, from the raw material to the finished product including but not limited to—

- (a) the layout and characteristics of the premises and the equipment;
- (b) the sequence of all steps in the manufacturing process, including the incorporation of raw materials;

- (c) the ingredients or additives and delays during or between steps in the process;
- (d) technical parameters of operations in particular time and temperature, and concentrations of solutions;
- (e) the flow of products, including potential cross-contamination;
- (f) the segregation of clean and dirty areas;
- (g) the cleaning and disinfection procedures;
- (h) the hygienic environment of the establishment;
- (i) the personnel routes and hygiene practices; and
- (j) product storage and distribution conditions.

2. The description may be amended at any time when a deviation occurs in the manufacturing process.

E Listing of hazards and multi-disciplinary control measures

1. The multi-disciplinary team of an establishment shall make a list of all potential health hazards relating to the storage, processing and packaging of fishery products.

2. A list prepared under paragraph 1 may include matters which are likely to lead to—

- (a) unacceptable contamination (or recontamination) of a biological, chemical or physical nature of raw materials, intermediate products or final products;
- (b) unacceptable survival or multiplication of pathogenic micro-organisms and unacceptable generation of chemicals in intermediate products, final products, production line or line environment;
- (c) unacceptable production or persistence of toxins or other undesirable products of microbial metabolism.

3. For inclusion in the list of hazards, matters must be of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe fishery products.

4. The multi-disciplinary team shall—

- (a) list all potential biological, chemical or physical hazards that may be reasonably expected to occur at each step of the manufacturing process (including those resulting from acquisition and storage of raw materials and ingredients and delays during manufacture and any other foreseeable eventuality);
- (b) consider and describe what control measures, if any, exist which can be applied to counter each hazard.

5. Where the multi-disciplinary team identifies a critical point for the control of a hazard, it shall take the following steps, viz.—

- (a) ensure that appropriate control measures are effectively designed and implemented. In particular, if a hazard has been identified at a step where control is necessary for product safety and no control measure exists at that step or at any other, then the product or process shall be modified at that step, or at an earlier or later stage, to include a control measure;
- (b) establish and implement a monitoring and checking system at each critical point.

*F Monitoring and checking of critical points
General principles*

1. The following steps shall be taken as the framework for the design of a suitable system for monitoring and checking critical points—

Establishing critical limits

- (a) Each control measure associated with a critical point shall give rise to the specification of critical limits.
- (b) The critical limits shall correspond to the extreme values acceptable with regard to product safety. Critical points are determined for observable or measurable parameters including temperature, moisture level, additive, preservative or salt level, which can readily demonstrate whether the critical point is under control; they shall be based on substantiated evidence that the chosen values will result in elimination of the hazard.
- (c) To reduce the risk of exceeding a critical limit due to naturally occurring process variations, it may be necessary to specify more stringent target levels than are necessary to eliminate the hazard, to ensure that process variables remain within the critical limits in a reasonable majority of cases.
- (d) Critical limits may be derived from a variety of sources. They may be defined by regulatory standards or from existing and validated guides of good manufacturing practices. In all cases the team shall ascertain their validity relative to the control of the identified hazards at the critical points.

Establishing a monitoring and checking system

2. An essential part of an internal control system is a programme of observations or measurements performed at each critical point to ensure compliance with specified critical limits, which describes the methods of measurement, the frequency of observations or measurements and the recording procedures to be followed.

3. Observations or measurements must be able to detect loss of control at critical points and provide information in sufficient time for corrective action to be taken.

4. It is necessary to establish a frequency of observations or measurements (in terms of a defined sampling plan) which provides information which can be validly used for extrapolation of the resulting measurement data to the behaviour of critical variables between observations.

5. Any decision on the periods between observations of critical variables at critical points shall be based on a detailed knowledge of the behaviour of those variables (and in particular their rate of change under all foreseeable circumstances).

6. A written programme of observations or measurements shall properly identify for each critical point—

- (a) the person to perform monitoring and checking;
- (b) the time when monitoring and checking is performed; and
- (c) how monitoring and checking is performed.

7. Observations or measurements may indicate—

- (a) that the parameter monitored is tending towards, although not exceeding, its specified critical limits, indicating a trend toward loss of control. Appropriate corrective action to maintain control must be taken before the occurrence of a hazard; and

- (b) that the parameter monitored has exceeded its specified critical limits, indicating a loss of control. It is necessary to take appropriate corrective action to regain control and decide on an appropriate action with respect to the products subject to the process conditions exceeding the critical limits.

8. Corrective action must be planned and documented in advance by the multi-disciplinary team, for each critical point and for each of the above cases, so that the necessary action may be taken without hesitation when the event is observed.

9. The corrective action plan shall include—

- (a) proper identification of the person(s) responsible for the implementation of the corrective action;
- (b) description of means and action required to correct the observed deviation;
- (c) action to be taken with regard to products that have been manufactured during the period when the process was out of control; and
- (d) written records of measures taken.

10. Although sampling for laboratory analysis may be included in the monitoring and checking of critical points, this specifically does not include verifying that the end product conforms with any standards or set of product criteria either externally or internally determined.

11. If the system of monitoring and control of critical control points is substantially dependent on sampling and laboratory analysis, then a system of internal control must be applied within the laboratory to ensure that the results generated are valid and reliable, including inter alia—

- (a) the preparation of a written and defined programme of instrument calibration;
- (b) checking of reagent activity and concentrations; and
- (c) verification that written laboratory methods are followed.

G Verification General principles

1. “**Verification**” refers to those actions taken for the routine confirmation that the provisions laid down for the operation of the internal control system are being properly applied.

2. Verification is necessary to ensure that the internal control system in routine operation is executed in the manner specified by the multi-disciplinary team. The multi-disciplinary team shall specify the methods and procedures to be used for the verification of the own-checks system.

Implementation of verification programmes

3. The person responsible for the establishment shall implement the verification programme at specified intervals. Government inspectors may also undertake a routine verification as part of any accreditation scheme.

4. On a basic level, verification will entail an audit of the own-checks system and its records. This may include random sampling and analysis to confirm that own-checks are being made, and that sampling, measurement and recording of results are being carried out correctly.

5. Verification procedures may also include—

- (a) inspection of operations;
- (b) review of deviations and corrective action and measures taken; and
- (c) additional confirmatory sampling and measurements.

H Validation
General principles

1. “**Validation**” refers to those actions taken to ensure that the system has correctly identified—

- (a) the hazards;
- (b) the critical points at which they arise;
- (c) the critical limits to key variables which give rise to the hazard;
- (d) the sampling and measurement methods which detect whether critical limits have been exceeded; and
- (e) corrective action in such cases which will eliminate the hazard or reduce it to acceptable levels.

2. When an internal control system is first introduced the operator of the establishment shall make provision for a programme of sampling and analysis intended to demonstrate the validity of the system following the methods and procedures specified.

3. The validation procedure may include—

- (a) a reinforced sampling and analysis (both more intensive and extensive than the systems established for the routine application of own-checks) of intermediate or final products;
- (b) surveys on actual conditions and product characteristics during storage, distribution and sale, and at the point of actual use of the product.

4. Changes in the system of internal control may arise as a result of—

- (a) a change in raw material or in product, processing conditions (factory layout and environment, process equipment, the cleaning and disinfection programme);
- (b) a change in packaging, storage or distribution conditions;
- (c) a change in consumer use;
- (d) the receipt of any information on a new hazard associated with the product, or any new information on an old hazard.

5. Any change in the system of internal control shall be followed by a re-validation of the internal control system.

6. Any amendments to the internal control system shall be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is available.

Documentation

1. The operator of an establishment shall keep a written record of the complete documentation relating to the design and operation of the system of internal control, which shall at all times be available for inspection.

2. The written record shall include—

- (a) a description of the internal control system including—
 - (i) a detailed physical, chemical and microbiological description of the product;
 - (ii) a detailed description of the process (including process flow diagrams);
 - (iii) an identification and definition of hazards;
 - (iv) an identification of critical points;
 - (v) a definition of critical limits to key variables at critical points;
 - (vi) a definition of sampling periods and frequency for measurement of key variables;
 - (vii) a description of measurement methods and procedures for measurement of key variables;
 - (viii) a description of corrective actions in case critical limits are exceeded;
 - (ix) a definition of validation and verification procedures;
 - (x) the results of the validation activities;
- (b) the results of internal controls, including—
 - (i) the results of all monitoring and checking actions;
 - (ii) a written account of any decisions made relating to corrective action when critical limits have been exceeded; and
 - (iii) the results of the verification activities.

3. The results of monitoring and checking actions shall be maintained for a period of at least two years.

4. The internal control data management system shall provide, in particular, for the easy retrieval of all documents relating to an identified production batch.

**TENTH SCHEDULE
REQUIREMENT FOR TRACEABILITY AND RECALL PROCEDURES**

1. The traceability of fish, fishery products and fish feed used in fish culture systems, and any other substance intended to be, or expected to be, incorporated into a fish, fishery product or feed shall be established at all stages of production, processing and distribution.

2. Operators of fishery establishments shall be expected to be able to identify any person from whom they have been supplied with fish, fishery products or fish feed, or any substance intended to be, or expected to be incorporated into a fishery product or feed. Such operators shall have in place systems and procedures which allow for this information to be made available to the competent authority on demand.

3. Operators of fishery establishments shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authority on demand.

4. Fish, fishery products or fish feed which are placed on the market or are likely to be placed on the market shall be labelled or otherwise identified through relevant documentation or other information to ensure its traceability.

5. Each operator of a fishery establishment shall prepare a written recall plan detailing the procedures to be followed in a case where a batch of fish or fishery products which has left the possession of the operator shall not be placed on the market, or, where it has been so placed, shall be withdrawn therefrom.

ELEVENTH SCHEDULE

[Regulation 6(2), L.N. 15/2009.]

FEEES FOR APPROVALS, HEALTH CERTIFICATION AND OTHER CHARGES REGARDING FISH, FISHERY PRODUCTS AND FISH FEEDS

	KSh.
1. Certificate of Compliance per product	35,000
2. Certificate of Compliance following withdrawal	70,000
3. Certificate of origin for bivalve molluscs	100,000
4. Fish and Fishery Products Export Health Certificate	1,500
5. Local Health Certificate for whole fish at landing sites—	
(a) quantities of fish less or equal to 1000 kgs	50,00
(b) more than 1000 kgs	30,00 for every 1000 kgs

TWELFTH SCHEDULE

Form DF/A4

(r. 6(5))

APPLICATION FOR CERTIFICATE OF COMPLIANCE WITH SAFETY OF FISH,
FISHERY PRODUCTS AND FISH FEED REGULATIONS, 2007

1. I/We hereby apply for a certificate of compliance with Kenya Standards for handling and processing of fish and fish products.
2. (a) Name of applicant
- (b) Mailing address
- (c) Location L.R. No. Street
- (d) Town District
- (e) (i) Description of premises and details of processing
- (ii) Capacity of the factory/vessel
- (iii) Previous certificate of compliance no.
3. (a) Other than processing of fish for which this application is made, are you involved in any other processing of fish and fish products? Yes/No
- (b) If answer to (a) above is yes, please specify the nature and type of processing
- (c) Do you intend to process fish for local or export market? Yes/No

TWELFTH SCHEDULE, FORM DF/A4—continued

FOR OFFICIAL USE ONLY

Application approved/not approved
Reasons/Conditions
.....
.....
.....

.....
Director of Fisheries/Authorized Fish Inspector

THIRTEENTH SCHEDULE

[Regulation 15(2).]

Form DF/CAI

CERTIFICATE OF IDENTIFICATION

FISHERIES DEPARTMENT



NAME

FISH INSPECTOR

EST. NO.



Signature of Permanent Secretary/

Director of Fisheries

S/NO.