### LEGAL NOTICE No. 61

## THE FISHERIES MANAGEMENT AND DEVELOPMENT ACT

(Cap. 378)

# THE FISHERIES MANAGEMENT AND DEVELOPMENT (SAFETY AND QUALITY) REGULATIONS, 2024

Arrangement of Regulations

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### THE FISHERIES MANAGEMENT AND DEVELOPMENT ACT

(Cap. 378)

IN EXERCISE of the powers conferred by section 208(2)(e) of the Fisheries Management and Development Act, 2016, the Cabinet Secretary for Mining, Blue Economy and Maritime Affairs makes the following Regulations—

## THE FISHERIES MANAGEMENT AND DEVELOPMENT (SAFETY AND QUALITY) REGULATIONS, 2024

### PART I—PRELIMINARY

1. These Regulations may be cited as the Fisheries Management and Development (Safety and Quality) Regulations, 2024.

Citation.

2. In these Regulations, unless the context otherwise requires—

Interpretation.

"Act" means the Fisheries Management and Development Act;

Cap 378.

"accredited laboratory" means a laboratory approved by the Kenya Fisheries Service for purposes of testing and analysis of samples of fish, fish product or fish feeds;

"aquaculture facility" means a fishery enterprise undertaking operations related to the farming of fish;

"aquaculture product" means any product or part thereof (including oil) obtained by aquaculture processing, and intended for use as human food, animal feed or raw material ingredient in the manufacture of other commodities of commercial or ornamental value;

"batch" means a quantity of fish or fish 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;

"carrier" means any vehicle, vessel, aircraft, cart, bicycle, motorcycles, train, motorized or hand driven transport system on land or water in or on which fish may be carried by or on behalf of the holder of a permit or certificate to any place for purposes of placing on the market;

"certification" means the process of assurance of compliance with the requirements of these Regulations;

"chilling" means the process of cooling fish and fish products to a temperature approaching that of melting ice;

"clean water" means water from any source where harmful microbiological contamination and substances or toxic planktons are not present in such quantities that may affect the safety of fish, shell fish and their products intended for human consumption;

"competent authority" means the Ministry responsible for the Service and official control of the safety of fish, fish products and fish feed as provided in section 58 of the Act; "compound feed" means a manufactured feedstuff containing two or more ingredients blended together;

"consignment" means fish, fish products or fish feed on transit from one point to another either locally, regionally or internationally and assigned one set of authorization document;

"container" means any box, detachable compartment, receptacle or any other arrangement in which fish may be carried by or on behalf of the holder of a permit or certificate to any place for purposes of placing on the market or selling;

"control plan" means a description established by the competent authority detailing the structure and organization of official control system, operation, and planning of official controls;

"control system" means a system comprising the competent authority and the resources, structures, arrangements and procedures set up to ensure that official controls are performed in accordance with these Regulations;

"control verification procedures" means arrangements put in place and actions performed by the competent authority for the purposes of ensuring that official controls are consistent and effective;

"County Executive Committee Member" means the County Executive Committee Member responsible for Fisheries in a respective County Government;

"critical control point" means any point, step or procedure at which control can be applied and a food safety hazard is prevented, eliminated or reduced to acceptable levels;

"designated fish landing stations" means a fish landing station designated as such pursuant to section 50 of the Act;

"designated person" includes a fisheries inspector or a beach management unit official;

"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;

"factory vessel" means any vessel on board which fish and fish products undergo processing wrapping and packing if necessary;

"farming" in relation to any fish means the breeding, cultivating and rearing of such fish or the cultivating of any such vegetation, as the case may be;

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

"fisheries inspector" means a person appointed under the Act;

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

"fish product" has the same meaning as assigned under the Act;

"freezer vessel" means any vessel in which freezing of fish and fish products is carried out on board and where appropriate, wrapping or packaging is done;

"frozen product" means any fish and fish product which has undergone a freezing process to reach a core temperature not exceeding minus eighteen degrees centigrade after temperature stabilization;

"hazard" means any agent or condition with the potential to have an adverse effect on human, animal or plant health, animal welfare or the environment;

"hazard analysis critical control point" means a system which identifies, evaluates and controls hazards which are significant for food safety;

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

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

"official control" means activities performed by the competent authority to verify compliance by fishery enterprise with these Regulations;

"official control activities" means activities performed by the competent authority in granting approvals;

"packaging" means the procedure of protecting fish and fish 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 fish products for the purpose of sale locally and for export or any other form of transfer undertaken as provided under these Regulations;

"potable water" means water suitable for human consumption and safe to use in any fishery enterprise for the manufacture, processing, preservation or marketing of products or substances intended for human consumption;

"processed products" means any fish and fish products which have undergone the processing;

"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 effect on human, animal or plant health, animal welfare or the environment and the severity of that effect, consequential to a hazard;

"risk assessment" means a scientifically based process consisting of four steps; hazard identification and characterization, exposure assessment and risk characterization;

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

"Technical Committee" means the Technical Committee on Fish Quality and Safety established pursuant to section 58 (2) of the Act;

"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 function or behaviour;

"veterinary officer" means a veterinary officer within the meaning of the Animal Diseases Act; and

Cap. 364.

"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 allowable residue levels.

3. These Regulations shall apply to the control of the safety and quality of fish, fish products and fish feeds in order to safeguard human and animal health.

Scope of application.

### PART II—OFFICIAL CONTROL ENTITIES

4. (1) Where the competent authority is assessing compliance to official control and official control activities, the assessment procedure for fish, fish products and fish feeds shall be—

Assessment by the competent authority.

- (a) based on food safety risks assessment or on other appropriate measures where circumstances and nature do not allow risk assessment;
- (b) effective, equitable and proportionate to the risk; and
- (c) scientifically conducted in an independent, objective and transparent manner.

- (2) Where upon assessment, any fish, fish products or fish feeds present a risk to human or animal health, the competent authority shall take appropriate steps to—
  - (a) inform the general public of the nature of the risk to health;
  - (b) identify as far as possible the fish, fish product or fish feed;
  - (c) identify the risk that such fish, fish product or fish feed may present; and
  - (d) identify the measures to be taken to prevent, reduce or eliminate that risk.
- (3) In safeguarding public health in accordance with subregulation (2), any information obtained by the competent authority in the performance of its functions under these Regulations may be disclosed without the written consent of the fishery enterprise.
- 5. (1) Each county government shall prepare an annual inspection report containing the following information—

County report on official control.

- (a) number and type of inspections carried out in the county;
- (b) the number and type of infringements identified;
- (c) actions taken in cases of non-compliance; and
- (d) any other relevant matter.
- (2) One month after the end of each calendar year, every county shall submit an annual inspection report on official control activities within the county to the competent authority in the Form set out in the First Schedule.
- 6. (1) At the end of every calendar year, the competent authority shall prepare an annual report on official control activities specifying—

Annual report on official control.

- (a) the number and type of inspections carried out;
- (b) the number and type of infringements identified;
- (c) actions taken in cases of non-compliance and;
- (d) any other relevant matter.
- (2) The inspection report prepared by the competent authority shall form part of the annual report on official control prepared under this regulation.
- 7. (1) Pursuant to section 58(2) of the Act, the Technical Committee on Fish Quality and Safety shall consist of—

Technical committee on fish quality and safety.

- (a) the Director-General of the Service, who shall be the Chairperson;
- (b) one person with knowledge and experience in matters relating to fish safety and quality assurance, nominated by the Council of Governors and appointed by the Cabinet Secretary;
- (c) the Head of Fish Safety and Quality Assurance, who shall be the Secretary; and

- (d) not more than four persons, appointed in writing by the Cabinet Secretary, with skills in fish safety and quality assurance.
- (2) The persons appointed under sub regulation (1)(d) shall represent the following—
  - (i) fish exporters;
  - (ii) fish processors;
  - (iii) fisheries inspectors' associations; and
  - (iv) academia and research.
- 8. The functions of the Technical Committee shall be as set out in section 58 (3) of the Act.

Functions of the Technical Committee.

9. The conduct of business and affairs of the Technical Committee shall be as provided for in the Second Schedule.

Conduct of business and affairs.

10. (1) A fisheries inspector appointed under the Act or county legislation shall—

Functions of a fisheries inspector.

- (a) inspect and audit approved fishery enterprises to assess the implementation of internal checks with respect to—
  - (i) hazard analysis critical control point system;
  - (ii) good hygiene practices;
  - (iii) traceability;
  - (iv) training in hygiene and in work procedures;
  - (v) water quality; and
  - (vi) good manufacturing practices;
- (b) collect samples for official control and submit to accredited laboratories to verify the effectiveness of implementation of quality and safety assurance systems by the fishery enterprises;
- (c) report to the respective appointing authorities in accordance with these Regulations;
- (d) certify upon a request in writing, the health conditions relating to any batch of fish products;
- (e) conduct the detailed health controls and monitoring of production conditions in accordance with the Third Schedule;
- (f) grant approval of trucks for issuance of the fish movement permits; and
- (g) perform such other functions as may be assigned from time to time.
- (2) Without prejudice to the provisions of section 84 (4) of the Act, a fisheries inspector shall be responsible to the competent authority for the performance of their functions.

11. (1) In the performance of their functions, a fisheries inspector shall have all the powers conferred on an authorized officer under the Act.

Powers of fisheries inspectors.

- (2) Without prejudice to sub-regulation (1), a fisheries inspector may—
  - (a) enter and search, at any reasonable hour, any premises wherein fish, fish products or fish feed are likely to be produced, handled, processed, packaged and stored or kept, to determine the existence, nature and extent of any trade or business in fish, fish products or fish feed;
  - (b) examine any fish, fish product, aquaculture product or fish feed in any fishery enterprise;
  - (c) take samples of any fish, fish product or fish feed in the course of undertaking inspections under these regulation;
  - (d) examine anything used or capable of being used for the preparation of any fish, fish product or fish feed in any fishery enterprise;
  - (e) stop, search or detain any carrier likely to contain any fish, fish product, or fish feed;
  - (f) open and examine any container, package or any other area likely to contain any fish, fish product, or fish feed and examine the products and take samples thereof;
  - (g) examine and take copies of any book, document, equipment or tools or any other record in any form likely to contain any information relevant to the enforcement of these Regulations;
  - (h) seize, condemn or destroy any fish, fish product or fish feed that is unfit for human consumption, diseased or otherwise contaminated; and
  - (i) temporarily withdraw an approval number allocated to a fishery enterprise in the register pursuant to section 58(3)(g), until they comply with requirements of these Regulations.
- 12. (1) In the exercise of powers or in the performance of the functions specified under these Regulations, a fisheries inspector shall produce a certificate of identification.

Identification of fisheries inspectors.

- (2) The certificate of identification of a fisheries inspector shall be issued by the Director-General in Form KeFS/FS/A1 set out in the Fourth Schedule.
- 13. (1) A fisheries inspector shall report to the respective appointing authority on—  $\,$ 
  - (a) status of any approved fishery enterprise, landing stations or carriers;
  - (b) any temporary or permanent closure of any fishery enterprise that contravenes these Regulations; and

Records and reports by a fisheries inspector.

- (c) any matter necessary for the implementation of these Regulations.
- (2) Any record made under these Regulations by a fisheries inspector shall be preserved by the competent authority for a period of thirty-six months.

## PART III—OFFICIAL CONTROL OF ESTABLISHMENT AND OPERATIONS

14. (1) No person shall establish or use a fishery enterprise for the production, aquaculture, keeping, processing, storage, packaging, transporting or placing on the market of fish or fish products intended for human or animal consumption without approval from the competent authority and a licence from the County Executive Committee Member.

Approval for establishment and use of a fishery enterprise.

- (2) The approval under this regulation shall be granted subject to the conditions specified under these Regulations or such other conditions as the competent authority may determine.
- (3) The approval for the establishment of the fishery enterprise shall be granted upon compliance with the application and health requirements.
- (4) An approval issued under this regulation in respect of any means of transport for fish, fish products and fish feed shall have the same effect as a fish movement permit.
- 15. (1) The competent authority may refuse to issue the approval under regulation 14 where it is satisfied that—

Refusal to grant approval.

- (a) the raw material available is not adequate to support such fishery enterprise;
- (b) such fishery enterprise shall have an adverse effect on the fisheries resources, biodiversity, health, hygiene and the environment; or
- (c) the fish has been legally caught and reported.
- (2) The competent authority may issue conditional approval to a fishery enterprise which meets some of the infrastructure and equipment requirements.
- (3) A conditional approval under this regulation shall be issued to a fishery enterprise for a period of not less than three months and not exceeding six months.
- (4) A conditional approval under this regulation shall be construed to be a fish processing licence issued under section 87 (4) of the Act and the fishery enterprise shall pay the fish processing licence fee set out in the Sixth Schedule.
- 16. (1) No person shall construct or refurbish a fishery enterprise without approval by the Director-General.
- (2) An application for an approval under sub-regulation (1) shall be made to the Director-General in Form KeFS/FS/A2 set out in the Fourth Schedule.

Construction or refurbishing of fishery enterprise.

- (3) The approval shall be granted upon compliance with the application requirements.
- (4) During the construction or refurbishing of the fishery enterprise, the applicant shall comply with the health conditions specified in Part I and Part II of the Fifth Schedule.
- (5) Upon completion of the relevant works for which an approval is sought under this regulation, the Director-General shall undertake a site inspection to inform issuance of a fish processing licence.
- 17. (1) No person shall operate an export oriented fishery enterprise without a valid certificate of compliance.

Export fishery enterprises.

- (2) The certificate of compliance under sub-regulation (1), shall be issued  $\,$ 
  - (a) upon application to the Director-General in Form KeFS/FS/A3 set out in the Fourth Schedule;
  - (b) by the Director-General in respect of each export product line in the fishery enterprise; and
  - (c) upon payment of the fees set out in the Sixth Schedule.
- (3) Where the application under sub regulation (2) is not approved—
  - (a) the Director-General shall furnish the applicant with reasons for the decision within thirty days of receipt of the application; and
  - (b) the applicant may reapply upon fulfilling the requirements stated by the Director-General under paragraph (a).
- (4 A certificate of compliance issued under this regulation shall be renewed annually after inspection and approval by the competent authority.
- (5) The renewal procedure for a certificate of compliance shall be made in accordance with the procedure in sub regulation (2) and (3).
- (6) The competent authority may revoke a certificate of compliance where -
  - (a) the owner or operator of the fishery enterprise carries out activities other than those for which the enterprise is established; or
  - (b) investigations by the Director-General reveal noncompliance with the provisions of these Regulations or any other written law.
- (7) Where a certificate of compliance is revoked under subregulation (5), all operations in the fishery enterprise to which it relates shall cease forthwith.
- (8) Where a certificate is revoked or replaced, the applicant shall meet the cost of revocation or replacement.
- 18. (1) The competent authority shall ensure that the management of approved fishery enterprises implement quality management

Internal controls.

programs as provided in the respective Manuals relating to manufacturing practice, aquaculture practice, sanitation standard operating manuals and hazard analysis critical control point manuals as set out in the following schedules—

- (i) Fifth Schedule;
- (ii) Seventh Schedule;
- (iii) Eighth Schedule;
- (iv) Ninth Schedule;
- (v) Tenth Schedule;
- (vi) Eleventh Schedule;
- (vii) Twelfth Schedule; and
- (viii) Thirteenth Schedule.
- (2) The management of an approved fishery enterprises shall—
- (a) have at least one person competent in food production and safety to be in charge of fish safety and quality;
- (b) ensure that all employees responsible for internal checks receive adequate training for effective implementation of the quality management program;
- (c) construct an in-house laboratory or secure the services of an accredited laboratory, approved by the competent authority, to verify the effectiveness of the quality and safety system;
- (d) collect samples in accordance with the Seventh Schedule to analyze and verify the quality and safety of fish, fish products and fish feed.
- (3) A fishery enterprise of fish, fish products and aquaculture business shall implement the system of internal controls set out in the Seventh Schedule.
- 19. (1) Any approval granted under this Part may be suspended, withdrawn or cancelled by a written order of the competent authority where—
- Suspension, withdrawal and cancellation of approval.
- (a) the operations of a fishery enterprise are in conflict with the conditions set out in the approval or in these Regulations;
- (b) such action is deemed necessary or expedient for the purpose of protecting human and animal health; or
- (c) there is an imminent risk to public health.
- (2) Where the competent authority suspends an approval under this Part, the competent authority shall notify the entity of the suspension and give notice of revocation of the approval unless the entity fulfils such conditions as may be specified in the notice, within such period as may be specified.

- (3) The competent authority may confirm, vary or cancel an approval granted to a fishery enterprise under these Regulations, upon expiry of the period specified under sub-regulation (2).
- (4) Where there is an imminent risk to public health, a fisheries inspector may, by a written order and without notice, suspend any approval granted under this Part and the suspension shall be communicated to the competent authority within twenty-four hours of the suspension:

Provided that a suspension which is not be reported in accordance with this sub-regulation shall be void.

- (5) Upon receipt of the communication of suspension under subregulation (4), the competent authority shall, within seven days of receipt of the communication, formally confirm or rescind the decision of the fisheries inspector and indicate the reasons thereof.
- 20. The competent authority may temporarily or permanently close a fishery enterprise that contravenes these Regulations.

Closure of fishery enterprise.

21. (1) No person shall establish or operate an ice plant or a cold store for fish or fish products without the approval of the competent authority.

Establishment of an ice plant or a cold store.

(2) Any person intending to establish an ice plant or a cold store for fish or fish products shall meet the requirements set out in Part II paragraph D of the Fifth Schedule.

# $\begin{array}{c} \mathsf{PART}\:\mathsf{IV}-\:\mathsf{OFFICIAL}\:\mathsf{CONTROL}\:\mathsf{OF}\:\mathsf{LANDING}, \mathsf{MOVEMENT}\\ \mathsf{AND}\:\mathsf{HANDLING} \end{array}$

22. (1) Fish shall be hygienically handled from the vessel, landed and weighed at designated fish landing stations.

Landing station.

- (2) The control of activities at the landing stations shall be—
- (a) the role of designated persons; and
- (b) undertaken in accordance with the health requirement set out in the Third Schedule.
- 23. (1) No person shall transport, cause to be transported any fish unless such a person holds a valid permit to transport fish.

Movement permit.

- (2) The movement permit shall be in Form KeFS/FS/A4 set out in the Fourth Schedule and shall be issued at the county of origin.
- (3) The holder of a movement permit shall operate in accordance with the provisions of the Eighth Schedule and in particular shall ensure that the carrier or container is—
  - (a) durable, easy to clean and sanitize, with food grade internal lining, and proper sealing to protect fish products from contamination, sunlight and physical damage; and
  - (b) regularly inspected by a fisheries inspector to ensure that the approval conditions of approval are maintained.

- (4) Prior to transportation of fish and fish products from a landing station, a person shall obtain a local fish health certificate.
- (5) The local fish health certificate obtained under sub-regulation (3) shall—
  - (a) be issued in Form KeFS/FS/A6 set out in the Fourth Schedule:
  - (b) be certified by a local fisheries inspector prior to transportation from the landing station;
  - (c) accompany the consignment to the point of destination; and
  - (d) facilitate traceability of fish from the source to the market, fishery enterprise and point of destination.
- (6) Any person who contravenes sub-regulation (1) commits an offence and shall be liable, on conviction, to a fine not exceeding twenty thousand shillings or to imprisonment for a term not exceeding three months, or to both.
- 24. Any person intending to move live fish to place on the market for consumption shall—  $\,$

Live fish movement.

- (a) obtain a live fish movement permit issued in Form KeFS/FS/A5 set out in the Fourth Schedule; and
- (b) transport live fish in clean, sanitized and adequately aerated containers.
- 25. Any fish maws or fish by-products shall be handled and processed—

Handling of fish maws and fish by-products.

- (a) at authorized fishery enterprises;
- (b) hygienically to ensure the quality of product; and
- (c) in compliance with relevant environmental and public health requirements and these Regulations.
- 26. Any fish declared unfit for human consumption that cannot be used for animal feed shall be incinerated or buried.

27. An operator of a fish enterprise shall keep and maintain traceability data from capture and aquaculture at every step of handling fish and fish products in the manner set out in the Ninth Schedule.

Handling of fish unfit for human consumption. Traceability.

## PART V-INSPECTION

28. (1) A fisheries inspector shall conduct an inspection for official control of fish, fish products and fish feed—

Inspection of a fishery enterprise.

- (a) regularly and according to priorities determined by risk assessment carried out by the competent authority;
- (b) where there is reasonable suspicion of non-compliance; and
- (c) when required for the purpose of official certification.
- (2) An inspection under this regulation shall cover—

- (a) all stages of production, fish farming, handling, manufacturing processing, packaging, storage, transportation, distribution, retailing and wholesale trade; and
- (b) the export and import of fish, fish products and fish feed from and into Kenya.
- (3) The frequency of inspection shall be informed by the level of the rating of the fishery enterprise and conducted in accordance with these Regulations as set out in Part 1 of the Third Schedule.
- 29. (1) An inspection of a fishery enterprise shall examine the following—

Areas to be inspected.

- (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 fishery enterprise dealing in fish products and fish feed;
- (b) the raw materials, ingredients, technological aids and other products used for the preparation and production of fish products and fish feed;
- (c) semi-finished fish products;
- (d) finished fish products and fish feed;
- (e) the materials, surfaces and items intended to come into contact with fish, fish products and fish feed;
- (f) the products and processes used for cleaning and maintenance,
- (g) pesticides used for pest control;
- (h) the processes used for the manufacture and processing of fish, fish products and fish feed;
- (i) labelling and presentation of fish, fish products and fish feed;
- (i) preservation methods; and
- (k) transportation of fish, fish products and fish feed.
- (2) The inspection under sub-regulation (1) may be supplemented by—
  - (a) interviews with persons dealing in fish, fish products and 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; and
  - (d) information contained in manual and electronic materials held by the fishery enterprise.

30. (1) Where a fishery enterprise is in a state of construction, disrepair or in a location that may expose fish, fish products and fish feed to contamination or deterioration, the management of the fishery enterprise may be served with a written notice from the Director-General or the County Executive Committee Member requiring the enterprise—

Notification of non-compliance.

- (a) to implement corrective action within an agreed specified time; or
- (b) to cease operations in the fishery enterprise until the noncompliance issues are addressed to the satisfaction of a fisheries inspector.
- 31. An inspection of any consignment of fish, fish products, or fish feed shall be undertaken to determine the following—

Inspection of a consignment.

- (a) whether the conditions in which the batch was produced, processed, stored, packed, transported or placed on the market are proper;
- (b) whether the batch or consignment satisfies the standards set out under these Regulations; and
- (c) the fitness of that batch for the purpose for which it is intended.
- 32. (1) No person shall place on the market or export a consignment of fish, fish product, fish feed or aquaculture products without a valid health certificate.

Health certificate.

- (2) A health certificate shall be issued—
- (a) upon inspection of the consignment in accordance with regulation 31;
- (b) as a local fish health certificate or an export health certificate in Form KeFS/FS/A6 or KeFS/FS/A7 set out in the Fourth Schedule; and
- (c) upon payment of the fee set out in the Sixth Schedule.
- (3) A heath certificate under this regulation shall not be issued where  $\,$ 
  - (a) the consignment is contaminated with any biological or chemical agent, foreign matter or other substances which may compromise food safety or suitability;
  - (b) the contamination level in the consignment is beyond the acceptable levels;
  - (c) the consignment does not comply with packaging and labelling requirements;
  - (d) the fishery enterprise does not adhere to its internal control system; and

- (e) fish safety requirements under these Regulations have not been complied with.
- (4) The competent authority shall communicate to the applicant the reasons for refusal to issue a certificate within fourteen days from the date of the decision.
- (5) A health certificate issued under this regulation may be withdrawn or replaced.
- (6) Where a certificate is withdrawn or replaced, the applicant shall meet the cost of withdrawal or replacement.
- 33. The Director-General may recall any batch or consignment of fish, fish products or fish feed which fails to meet the requirements under these Regulations.

Consignment recall.

34. Pursuant to section 93(3) of the Act, the Director-General or the County Executive Committee Member shall charge the licence holders fees for inspection and any other service rendered.

Inspection fees.

35. Any owner, occupier, person in-charge or employee of a fishery enterprise who obstructs a fisheries inspector in the performance of an inspection commits an offence and shall be liable, on conviction, to the penalty provided under section 156 of the Act.

Obstruction during inspection.

# PART VI—HEALTH CONDITIONS FOR PRODUCTION AND PLACING ON THE MARKET

36. (1) Any fish or fish products intended to be placed on the market shall be —  $\,$ 

Placing on the market of fish and fish products.

- (a) inspected and sampled to verify the quality and safety in accordance with the Third Schedule;
- (b) hygienically handled, prepared, processed and stored and transported at appropriate temperatures in accordance with the Eighth Schedule;
- (c) chilled with ice and transported from the landing station at the temperature of melting ice;
- (d) transported under sanitary conditions in approved transport carriers or containers in accordance with these Regulations;
- (e) transported upon obtaining a movement permit in accordance with these Regulations;
- (f) packaged in accordance with the Tenth Schedule; and
- (g) labelled in accordance with the Eleventh Schedule.
- (2) Any person who contravenes the provisions of this regulation shall be liable, on conviction, to the penalty provided under section 60 (2) of the Act.
- 37. (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 out in the Twelfth Schedule.

Prohibited harvest areas for bivalve molluscs.

- (2) Any person who contravenes sub-regulation (1) commits an offence and shall be liable, on conviction, to a fine not exceeding twenty thousand shillings or to imprisonment for a term not exceeding three months, or to both.
- 38. (1) No person shall possess, consign or transfer any batch or consignment of bivalve molluscs to another person unless the consignment is accompanied by a certificate of origin.

Certificates of origin for bivalve molluses.

- (2) The certificate of origin shall
- (a) be issued by the competent authority upon payment of the fees set out in the Sixth Schedule; and
- (b) accompany the consignment of bivalve molluscs during distribution, transportation and placing on the market.
- (3) The fisher and any person receiving a batch or consignment of bivalve molluscs shall keep an original copy of the certificate of origin for a period of twelve months from the date of issue or transfer thereof.
- (4) Any person who contravenes sub-regulation (1) commits an offence and shall be liable, on conviction, to a fine not exceeding twenty thousand shillings or to imprisonment for a term not exceeding three months, or to both.
  - 39. (1) No person shall place on the market—

Prohibition on placing on the market of certain species.

- (a) fish species of the families *Tetradontidae*, *Molidae*, *Diodontidae*, *Canthigasteridae*, *Gempylidae*; with the exception of Escolar and Oilfish (*Ruvettus pretiosus*) in the family *Gempylidae* which can be placed on the market with strict labelling instructions; and
- (b) fish products commonly containing biotoxins of marine origin.
- (2) Any poisonous fish shall be—
- (a) identified immediately upon landing of harvest; and
- (b) immediately returned to the sea upon being identified.
- (3) Any poisonous fish identified at the landing station shall be disposed of by burying or incineration.
- (4) The Director-General or the County Executive Committee Member shall be informed of all cases of poisonous fish identified under this regulation.
- 40. (1) Any aquaculture facility, fishery enterprise or any person intending to place on the market any aquaculture products shall—
  - (a) observe the requirements for placing on the market fish and fish products provided in the Thirteenth Schedule;

Placing on the market of fish and fish products from aquaculture.

- (b) register with the competent authority; and
- (c) source aquaculture fish and fish products from an aquaculture production facility that has implemented the internal system to control safety hazards in the farmed fish and guarantees the traceability of fish during harvesting, transportation and storage.
- (2) every entity in sub regulation(1) shall ensure that all aquaculture fish that is ready for harvesting shall not show any clinical signs of disease.
- (3) Any harvesting, introduction into a dispatch centre or purification centre, further processing or any other related operations involved in the preparation of aquaculture products for entry into the food chain shall be carried out under conditions that prevent the spread of pathogens responsible for causing disease.
- (4) Every dispatch centre, purification centre and other similar businesses shall be equipped with effluent treatment facilities capable of inactivating disease-causing pathogens and reducing the risk of transmission of the disease to natural water bodies to acceptable levels.
- (5) In addition to the requirements under sub-regulation (1), commercial aquaculture facilities intending to place on the market fish and fish products shall put in place the following measures—
  - (a) use a bio-security plan that is adaptable, addresses local disease threats, prevents environmental degradation and prevents the introduction of any infectious organism by controlling infectious diseases within the facility;
  - (b) engage a qualified veterinarian or fish pathologist to undertake diagnostics, treatment and relevant monitoring in accordance with these Regulations;
  - (c) keep records of monitoring the production process for the purposes of preventing misuse and detection of residues and contaminants in accordance with section 70 of the Act;
  - (d) not use any drug, pharmaceutical antibiotic or other chemical without the written approval of the Director-General; and
  - (e) maintain proper records of its activities which shall be—
    - (i) availed to the Director-General or the County Executive Committee Member on request or inspection; and
    - (ii) retained for a period of at least three years.
- (6) Any person intending to transfer aquaculture fish to a fisher enterprise shall obtain an aquaculture movement permit in Form KeFS/FS/A8 set out in the Fourth Schedule.
- (7) The competent authority shall authorize the fishery enterprise slaughtering aquaculture products for disease control purposes.

- (8) Any person who contravenes the provisions of this regulation commits an offence and shall be liable to the penalty prescribed under section 70(2) of the Act.
- 41. (1) Where any drug, pharmaceuticals, antibiotics or other chemicals are administered on any aquaculture fish and fish products in accordance with section 70 of the Act, a withdrawal period of thirty days after administering the pharmaceuticals antibiotics or other chemicals shall be observed before placing the aquaculture fish or fish products in the market.

Use of pharmaceuticals, drugs, antibiotics, etc in aquaculture.

- (2) The concentration of any drug, pharmaceutical antibiotics or other chemicals residue in the harvested fish shall not exceeded the maximum residue limit specified in any applicable law.
- (3) Any aquaculture fish and fish products shall be accompanied by a declaration stating whether drug, pharmaceuticals, antibiotics or other chemicals have been used in the farming of fish and whether the withdrawal period has been observed.
- (4) Where contaminated products or prohibited substances are identified in an aquaculture facility or fishery enterprise handling aquaculture products, the management of the facility shall cooperate with the competent authority to safely dispose the contaminant or the substance.
- 42. (1) Any fishery enterprise intending to place on the market fish feed for commercial aquaculture shall register with the Director-General or the County Executive Committee Member.

Placing on the market of aquaculture feeds.

- (2) The management of the fishery enterprise shall—
- (a) use safe and quality feeds;
- (b) submit samples of fish feed to an accredited laboratory for analysis to determine the safety and quality as required; and
- (c) keep proper records of all fish feeds produced or used by the fishery enterprise.
- (3) Any fish feed ingredients containing toxins and contaminants shall not be used in aquaculture.
- (4) Fish feed treated with veterinary medicinal supplements including hormones and antibiotics shall not be used unless approved under the terms of the Veterinary Surgeons and Veterinary Paraprofessionals Act and the Veterinary Surgeons and Veterinary Paraprofessionals (Veterinary Medicine Directorate) Regulations.
- Cap. 366 L.N. 209 of 2015.
- (5) Fish feeds shall be used before the expiry date and expired feeds shall be disposed of under the supervision of the Director-General or the County Executive Committee Member, as the case may be.
- (6) Medicated feed shall be used in aquaculture in accordance with instructions of an authorised veterinary surgeon or veterinary paraprofessional.
- (7) Fish feed shall be stored in properly constructed and well-ventilated facilities with protection from pests and vermins.

# PART VII—EXPORT AND IMPORT OF FISH, FISH PRODUCTS AND FISH FEED

43. (1) Fish, fish products and fish feed shall meet conditions for export and import specified by the Director-General with regards to—

General conditions.

- (a) safety and having met the conditions stated in sub regulation(2);
- (b) the actual health conditions during production, storage and dispatch of fish products intended for export and import; and
- (c) the assurance on the compliance with the standards laid down in the Fifth Schedule.
- (2) The export and import conditions referred to under sub-regulation (1) include—
  - (a) possession of a health certificate which shall accompany the consignment of fish or fish products to the importing country; and
  - (b) labelling of the fish and fish products, with the reference number of the fishery enterprise of origin, including imported fish and fish products, for further processing and accompanied by the certificate referred to in paragraph (a) from the country of origin.
- 44. (1) No person shall import a batch or consignment of fish or fish product, without a fish import permit and a fish sanitary or health certificate issued by the competent authority of the exporting country in respect of the batch or consignment.

Imports.

- (2) Any applications for a fish import permit shall be—
- (a) made to the Director-General in Form KeFS/FS/A12 set out in the Fourth Schedule or any other approved electronic format; and
- (b) in the case of live fish imports, accompanied by a letter of notification from the authorized person responsible for fisheries in the country of origin.
- (3) All imported live fish shall be placed under quarantine for a period of forty days and thereafter confirmatory laboratory diagnosis tests to confirm that they are free from diseases and parasites.
- 45. All foreign vessels or reefer vessels shall be subjected to import inspection and issued with a foreign vessel import inspection certificate in Form KEFS/FS/A9 set out in the Fourth Schedule.

Import inspection.

- 46. (1) No person shall export a batch or consignment of fish, fish products or fish feed without the following approval documents in respect of the batch or consignment—
  - (a) an export permit;

Exports.

(b) a fish processing licence;

- (c) a certificate of registration of local fishing vessel in the case of fishing vessels;
- (d) a certificate of compliance with Kenyan standards for fish handling and processing; and
- (e) a valid sanitary health certificate.
- (2) Any applications for an export permit shall be made to the Director-General in Form KeFS/FS/A12 set out in the Fourth Schedule.
  - (3) An export permit shall be valid for a period of—
  - (a) fourteen days for fresh fish and fish products; and
  - (b) twenty-one days for other fish, fish products and fish feeds.
- 47. Any person intending to import marine fish for raw materials for further processing shall make an import declaration in Form KEFS/FS/A10 set out in the Fourth Schedule.

Export and import from marine waters.

(2) Fish and Fish products from marine waters and intended for export or import shall be accompanied by a catch certificate issued in Form KeFS/FS/A11 set out in the Fourth Schedule.

### PART VIII-LABORATORIES

48. The Director-General shall maintain a list of accredited laboratories specifying the particular test or group of tests that may be undertaken in the specified laboratory.

Accredited laboratories.

49. The laboratories referred to in regulation 48 shall—

Standards for accredited laboratories.

- (a) comply with the requirements of the International Organization for Standardization Standard Number 17025 or such other standards as the Director-General may specify from time to time;
- (b) participate in appropriate proficiency testing programmes;and
- (c) use methods of analysis and performance criteria specified by the Director-General from time to time.
- 50. (1) For each test required for the purposes of official control of fish, fish products or fish feed, the Director-General shall select one laboratory from the list under regulation 48 for each type of test required for purposes of official control.

Selection of a laboratory.

- (2) A laboratory selected under this regulation shall be responsible for—
  - (a) advising the Director-General on the designation and nomination of official laboratories to conduct analysis 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 standardized 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 Director-General and other laboratories carrying out the testing of fish, fish products and fish feed, whether or not for the purposes of official control; and
- (g) providing scientific and technical assistance to the Director-General in the implementation of co-ordinated control plans.

### PART IX-LICENCES, PERMITS AND CERTIFICATES

51. (1) Unless otherwise provided, a person who requires a licence, permit or certificate under these Regulations shall make an application in the appropriate Form set out in the Twelfth Schedule or in such other form as the Director-General or County Executive Committee Member shall specify.

Issuance of licence, permit or certificate.

- (2) The Director-General or County Executive Committee Member may attach any necessary conditions to any licence, permit, or certificate issued under these Regulations which are necessary for carrying into effect the objects and purpose of the Act and these Regulations.
- 52. (1) The Director-General or County Executive Committee Member may refuse to issue any licence, permit or certificate required under these Regulations.

Power to refuse a licence, permit or certificate.

- (2) Any person aggrieved by the decision to refuse licence, permit or certificate may appeal in accordance with the provisions of regulation 60.
- 53. (1) The Director-General or the County Executive Committee Member may modify a licence, permit or certificate issued under these Regulations.

Power to modify.

- (2) Where a licence, permit or certificate is modified, the licensee shall be notified of the modification and surrender the licence, permit or certificate to the licensing officer for endorsement within seventy-two hours of a written notice on modification.
- (3) Where a licence, permit, or certificate is not surrendered under sub-regulation (2), such licence, permit or certificate shall be considered withdrawn and invalid.
- 54. (1) The Director-General or the County Executive Committee Member may suspend a licence, permit or certificate issued under these Regulations where—

Power to suspend.

- (a) it is necessary or expedient for proper management of the fishing industry; and
- (b) the licence has been used in contravention of any regulation or any conditions therein.
- (2) Where a licence, permit or certificate is suspended, under these Regulations, the Director-General or the County Executive Committee Member shall repossess the licence, permit or certificate.
- (3) Where the licence is repossessed under sub-regulation (2), the Director-General or the County Executive Committee Member if satisfied that the circumstances which resulted in the suspension no longer apply, may authorize that the licence, permit or certificate be returned to the licensee.
- 55. (1) A licence, permit or certificate issued under these Regulations, shall be valid up to the date stated therein or, where no such date is specified, up to the 31<sup>st</sup> December in each year in which it is issued.

Validity.

- (2) Notwithstanding sub-regulation (1), the validity of an export permit shall be for a period of fourteen days for fresh fish and fish products and twenty-one days for other fish, fish products and fish feeds and can be extended as appropriate.
- 56. A licence, permit or certificate issued under these Regulations shall not be transferable.

Transferability.

57. (1) Where any licence, permit or certificate issued under these Regulations is lost, defaced or mutilated, a licencee may be issued with a duplicate copy of the licence, permit, or certificate upon payment of the fee set out in the Sixth Schedule.

Replacement.

(2) Where a duplicate copy of a licence, permit or certificate has been issued pursuant to this regulation, the original shall cease to be valid.

58. The Director-General or County Executive Committee Member shall cause to be kept and maintained, a separate register for each type of licence, permit or certificate issued under these Regulations.

Register.

59. (1) The conviction of the holder of a licence, permit, or certificate for any offence under the Act shall, unless the Director-General or County Executive Committee Member in writing otherwise directs, result in—

Effect of a conviction.

- (a) a cancellation of the licence, permit or certificate from the moment of conviction; and
- (b) a disqualification of the holder from holding a licence, permit, or certificate related to the provisions under which he has been convicted, for a period of two years from the date of conviction.
- (2) The holder of any licence, permit or certificate which is cancelled pursuant to sub-regulation (1), shall, within fourteen days

from the date of conviction, surrender the licence, permit or certificate or any document evidencing permission or authority to engage in business for which authority is required under the Act or these Regulations to the Director-General or the County Executive Committee Member.

- (3) Pursuant to section 81 of the Act, the surrender of the licence, permit or certificate shall be recorded in the appropriate register.
- (4) A person who contravenes this regulation commits an offence and shall be liable to the penalty provided in section 94(6) of the Act.
- 60. A person aggrieved by the action of the Director-General or the County Executive Committee Member to-
  - (a) refuse to approve or issue a licence, permit or certificate;
  - (b) suspend or withdraw a licence, permit or certificate;
  - (c) refuse to grant a conditional approval; or
  - (d) attach conditions to a licence, permit or certificate,

may, in writing, appeal to the Board and further to the Cabinet Secretary in accordance with section 97 of the Act.

61. The fees applicable in respect of any licence, permit or certificates issued under these Regulations shall be as set out in the Sixth Schedule.

## PART X-FINAL PROVISIONS

62. (1) The Director-General or the County Executive Committee Member shall design and implement annual monitoring programmes for fish, fish 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 sub regulation (1), the Director-General shall design and implement a monitoring programme for the harvest areas of bivalve molluscs in accordance with the conditions provided in the Twelfth Schedule.

- (3) The monitoring programmes undertaken under sub regulation (1) shall consider the hazards and criteria provided in the Third and Seventh Schedules and shall include monitoring the presence of the following hazards in the fish, fish products and fish feed and production areas-
  - (a) heavy metals;
  - (b) residues of drugs, pharmaceuticals, antibiotics or other chemicals permitted in aquaculture under the terms of the Veterinary Surgeons and Veterinary Paraprofessionals Act;

(c) residues of substances banned in aquaculture under the terms of the Veterinary Surgeons and Veterinary Paraprofessionals Act;

Cap. 366.

Appeals.

Fees.

Monitoring.

Cap. 366.

(d) pesticides residues;

Feeds) Regulations, 2007 are revoked.

- (e) parasites in fish of significance to public health; and
- (f) other hazards in fish, fish products and fish feed.
- (4) The monitoring programmes shall specify the sampling plan, the methods of analysis to be used and, where applicable, the performance criteria.
- (5) The Technical Committee shall prepare a report on annual monitoring programmes undertaken under this regulation and submit it to the competent authority.
- 63. A person who commits an offence under these Regulations where no penalty is prescribed is liable, on conviction, to the penalty under section 60 (2) of the Act.

64. The Fisheries (Safety of Fish, Fishery Products and Fish

65. Notwithstanding the provisions of regulation 64—

- (a) any proceedings taken by the standing committee and the technical committee in the performance of their functions under the Fisheries (Safety of Fish, Fishery Products and Fish Feeds) Regulations, 2007 shall be deemed to be proceedings under these Regulations;
- (b) a licence, certificate or permit issued under the Fisheries (Safety of Fish, Fishery Products and Fish Feeds) Regulations, 2007 shall be deemed to be a licence, certificate or permit under these Regulations;
- (c) any administrative direction, investigation or inquiry instituted in terms of the Fisheries (Safety of Fish, Fishery Products and Fish Feeds) Regulations, 2007 which was pending before the commencement of these Regulations shall be continued or disposed of as if instituted under these Regulations;
- (d) all disciplinary proceedings which immediately before the commencement of these Regulations were pending shall be continued or concluded as if instituted under these Regulations;
- (e) all appeal processes, which immediately before the commencement of these Regulations were pending, shall proceed as if instituted under these Regulations; and
- (f) any proceeding taken in exercise of any of the powers under the Fisheries (Safety of Fish, Fishery Products and Fish Feeds) Regulations, 2007 shall be deemed to be proceedings under these Regulations.

Offences.

Revocation. L. N. 170 of 2007. Savings and Transition.

L. N. 170 of 2007.

# FIRST SCHEDULE INSPECTION REPORT

(r. 5(2))

## REPUBLIC OF KENYA



## MINISTRY/INSTITUTION

## INSPECTION REPORT

1.0	Fishery enterprise Name:
2.0	Location:
	Physical Location:
	Postal Address:
	E-Mail Address:
3.0	Fishery enterprise Représentatives :
4.0	Official Inspectors:
5.0	Inspection code:
6.0	Date of Inspection:
7.0	Scope:
0.8	Objectives:
9.0	Criteria:
0.0	Findings:
0.1	Approval documents:
0.2	Layout of the fishery enterprise:
10.3	Schematic Flow Chart of Product:
0.4	Water:
0.4.1	Sources of water and treatment and storage:
0.4.2	Water distribution/reticulation map:
0.4.3	Free Residual Chlorine:
0.4.4	Alarm System:
0.4.5	Bacteriological examination of water:
0.4.6	Physico-chemical analysis of water:

Hazard Analysis Critical Control Point (HACCP) Policy:

10.5

10.5.1

Internal checks:

1010	Kenya Subsidiary Legislation, 2024
10.5.2	HACCP Team:
10.5.3	Product Description:
10.5.4	Process Flow diagram:
10.5.5	Hazard Analysis:
10.5.6	Identification of Critical Control Points:
10.5.7	Critical Limits:
10.5.8	Monitoring Procedures:
10.5.9	Corrective Actions:
10.5.10	Verification of HACCP System:
10.5.11	Record Keeping:
10.6	Cleaning and sanitation programme:
10.6.1	Cleaning Programme and Schedule:
10.6.2	Visual Checks:
10.6.3	Laboratory Analysis of Swabs:
10.7	Personnel Hygiene and Health Checks:
10.8	Pest Control Programme:
10.9	Temperature Registration:
10.10	Products Entry and Exit:
11.0	Processing and Facilities:
11.1	Cold Room:
11.2	Plate Freezer:
11.3	Blast Freezer:
11.4	Ice plant:
11.5	Utensils washing and storage area:
11.6	Processing area:
11.7	Packaging Material Store:
11.8	Vehicle Washing Bay:
11.9	By- Products area:

11.10

12.

13.

Amenities:

General Environment:

Recommendations:

### SECOND SCHEDULE

(r. 9)

### CONDUCT OF BUSINESS AND AFFAIRS OF THE TECHNICAL COMMITTEE

### 1. Tenure of office

The chairperson or a member of the Technical Committee, other than an *ex officio* member, shall hold office for a period of three years, on such terms and conditions as may be specified in the instrument of appointment, but shall be eligible for reappointment for a further term of three years.

### 2. Meetings of the Technical Committee

- (1)The Technical Committee shall meet at least once in every four months to conduct the business of the Technical Committee.
- (2) The chairperson of the Technical Committee shall preside at every meeting of the Technical Committee at which the chairperson is present but in the absence of the chairperson, the members of the Technical Committee present shall appoint a member from among their number to preside at that meeting.
- (3) The chairperson may, at any time and on requisition in writing by at least four members, convene a special meeting for the transaction of the business of the Technical Committee.

### 3. Notice of meeting

Unless five members of the Technical Committee otherwise agree, at notice of meeting, least seven days' written notice of every meeting shall be given to every member of the Technical Committee.

### 3. Quorum

The quorum for the conduct of the business of the Technical Committee shall be five members including the chairperson or the person presiding.

### 4. Decisions of the Technical Committee

The matters of the Technical Committee shall be decided by a majority of the members present and voting and in the event of equality of votes, the person presiding shall have a casting vote.

6. Vacancy of office of chairperson or members

The office of the Chairperson or member shall become vacant if the holder—

- (a) dies:
- (b) by notice in writing addressed to the Cabinet Secretary, resigns from office; and
- (c) is removed from office under any of the circumstances specified in paragraph 7 of this Schedule.

### 7. Removal of Chairperson and members

The chairperson or member (other than an *ex officio* member), may be removed from the membership of the Technical Committee on any of the following grounds—

(a) is absent from three consecutive meetings of the Technical Committee, without reasonable cause:

- (b) fails to disclose any interest in any contract or matter before the Technical Committee;
- (c) is convicted of a criminal offence and sentenced to imprisonment for a term exceeding six months;
- (d) is incapacitated by prolonged physical or mental illness;
- (e) is declared bankrupt; or
- (f) is otherwise unable or unfit to discharge his function.

### 8. Procedure

Subject to the provisions of this Schedule, the Technical Committee may determine its own procedure.

### THIRD SCHEDULE

(r. 10(1)(e), r.22(2)(b), r.38(3), r.38(a), r.62(3)

### HEALTH CONTROL AND MONITORING OF PRODUCTION CONDITIONS

### PART 1—GENERAL MONITORING

- 1. Audits and inspections shall be undertaken by the Director-General or the director responsible for fisheries at county level as appropriate to establish whether the requirements laid down in this regulation are complied with.
  - 2. During the audits and inspections, the following will be assessed—
  - (a) conditions at landing stations and first sale;
  - (b) conditions at fish auctions and wholesale markets;
  - (c) inspection at regular intervals of fishery enterprises, to establish-
    - (i) whether the conditions for approval are complied with;
    - (ii) whether fish and fish 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 identification of checks to be undertaken and sampling rate to be applied shall be scientifically justified and shall depend on the nature of the hazards involved and risk of their occurrence.

## PART 2 – ORGANOLEPTIC CHECKS

- 1. Fish and fish products shall be inspected at the time of landing or before first sale to establish fitness for placing on the market for human consumption.
- 2. Samples shall be collected for organoleptic checks and any other checks deemed necessary by the fisheries inspector which may include chemical or microbiological analyses as defined in part 4, 5 and 7 below.
- 3. If the organoleptic examination reveals that the fish and fishery are not fit for human consumption, the fisheries inspector shall withdraw them from the market

### PART 3—PARASITE CHECKS

- 1. Fish and fish products for human consumption shall be subjected to visual inspection, to detect any visible parasites.
- 2. The abdominal cavity of eviscerated fish, liver and roe intended for human consumption will be inspected. Candling may be used for flat fish and fillets.
- 3. Whole fish shall be visually inspected on the surface, gills, skin, mouth and fins.
- 4. The abdominal cavity of eviscerated fish, liver and roe intended for human consumption will be inspected. Candling may be used for flat fish and fillets.

- 5. 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.
- 6. On the demand of a fisheries inspector samples from any batch of fish and fish products may be subjected to laboratory analysis for measurement of any scientifically established indicator of the degree of deterioration of the fish and fish products.

### PART 4—TVB

- 1. When organoleptic examination gives cause to suspect the presence of other conditions which may affect human health, appropriate samples will be taken for verification.
- 2. If the freshness of the fish and fish products is suspect, samples shall be subjected to laboratory analysis to determine the levels of total volatile basic nitrogen (TVB-N) and trimethylamine nitrogen (TMA-N).

### PART 5—HISTAMINE

- 1. Samples of fish from any batch of fish products of the following species will be 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, Scombresosidae.
- 2. Where such samples are taken, nine samples shall be taken from each bath 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 fulfill the following requirements-
    - (i) The mean value shall not exceed 100ppm.
    - (ii) Two samples may have a value of more than 100 ppm but less than 200 ppm.
    - (iii) No samples 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 PRESENTS IN THE AQUATIC ENVIRONMENT

- 1. On the demand by a fisheries inspector samples from any batch of fish and fish product may be taken and subjected to laboratory analysis for the measurement of contaminants which may be present in the aquatic environment.
- 2. The Maximum Residual Levels for chemical contaminants in fish and fish products from capture fisheries are specified in the table below:

Table 8. Maximum limits for heavy metals in fish and fish products from capture fisheries

Parameters	Max levels mg/ Kg wet weight
Lead	
Muscle meat of fish	0.3
Crustacean	0.5
Bivalve molluses	1.5
Cephalopods	1
Cadmium	
Muscle meat of fish	0.05
Muscle meat of anchovy, Bonito, Sardine and Tuna	0.1
Muscle meat of swordfish	0.3
Crustacean	0.5
Bivalve molluscs	1
Cephalopods	1
Mercury	
Fish products and muscle meat of fish	0.5
Muscle meat of Bonito, sail fish, rays	1.0
Sword fish Tuna	1.0

Source: EU Regulation 1881/2006

Parameter	Sample type	Maximum levels
Sum of Dioxins	Muscle meat of fish	4.0 pg/g
Sum of Dioxins and Dioxin like PCBs	Muscle meat of fish	8.0 pg/g

## PART 7 – MICROBIOLOGICAL CHECKS

- 1. On the demand of an inspector, samples from any batch of fish and fish products may be taken and subjected to laboratory analysis for the measurement of levels of microbiological contaminants therein, including protozoan and helminthic parasites, bacterial and viral pathogens.
- 2. The sampling plan and microbiological limits for pathogens and indicator organisms in Fish and fish products are specified in the tables 9, 10, 11 below:

Table 9 Sampling plans and limits for pathogens

Type of Organism	Standard
Salmonella spp.	Absent in 25 g
	$n = 5 \qquad c = 0$
Vibrio cholera	Absent in 25 g
	n = 5 $c = 0$
Vibrio parahaemolyticus	Absent in 25 g
	$n=5 \qquad c=0$

Table 10 Sampling plans and limits for indicator micro-organisms

Type of Organisms	Standard (per g)
Coliforms	$m = 10^2$
	$M = 10^4$
	n = 5
	c = 2
E. Coli	m = 10
	$M = 10^2$
	n = 5
	c = 2
Staphylococcus aureus	m = 100
	M = 1000
	n = 5
	c = 2
Mesophilic Aerobic bacteria	$m = 10^4$
(30° C) in whole products	$M = 10^5$
	n = 5
	c = 2
Mesophilic Aerobic bacteria	$m = 10^5$
(30° C) in Crab meat	$M = 10^6$
	n = 5
	c = 2

Where Parameters n, m, M and c are defined as follows —

- n = number of units comprising the sample, (lot or batch;).
- c=Maximum number of the above units that may contain microorganisms for the Batch / lot to be accepted and if above this the batch / lot will be rejected; (bacterial counts between m and M).

- m = the maximum number of micro-organisms per gram that must be contained in not more than C of the n sample units.
- M = the maximum number of micro-organisms per gram that any of n-units may not exceed for the entire lot not to be rejected.
- 3. Batches of cooked crustacean which do not meet the following criteria shall be considered to be unfit for human consumption.

Table 11

Type of bacteria	Standards
Salmonella	absent in 25g
	n= 5
	c= 0
Staphylococcus	m=100
aureus	M=100
	N=5
	C=2
E. coli (on solid	m=10
Medium	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 = no. of units comprising the samples.

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

# PART 8 — CHECKS ON VETERINARY MEDICINES AND CONTAMINANTS IN AQUACULTURE FISH AND FISH PRODUCTS

- 1. On the demand by a fisheries inspector samples from any batch of fish products from an aquaculture facility 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 aquaculture, in accordance with Veterinary Surgeons and Veterinary Paraprofessionals Act No. 29 of 2011 (The Veterinary Medicine Directorate Regulations, 2015).
  - (b) prohibition of use of certain substances as veterinary medicines in aquaculture.

Table 12 Parameters to be monitored in the Residue Monitoring Plan (RMP) for aquaculture

GROUP OF SUBSTANCES TO BE MONITORED  GROUP A: SUBSTANCES HAVING ANBOLIC EFFECTS		COMPOUND or MARKER RESIDUE	MATRIX ANALYSE D	LEVEL OF ACTION (i.e. concentration above which a result is deemed non-compliant) [µg/Kg]
AND				
SUBS	STANCES			
A1	STILBENES	Diethylstilbestrol	Muscle	Any confirmed
A3	STEROIDS (WITH ANDROGENIC, ESTROGENIC OR	Methyl testosterone	Muscle	Any confirmed
	PROGESTAGENIC	Norethandrolone	Muscle	Any confirmed
	ACTIVITY)	Medroxyprogester one	Muscle	Any confirmed
		Trenbolone	Muscle	Any confirmed
A6	Chloramphenicol + Nitrofurans+ Nitroimidazoles			
	CHLORAMPHENICOL	Chloramphenicol	Muscle	0.3*
	NITROFURANS			
	Nitrofurantoin metabolite	AOZ	Muscle	1*
	Furaltadone metabolite	AMOZ	Muscle	1*
	Furazolidone metabolite	AHD	Muscle	1*

	Nitrofurazone metabolite	SEM	Muscle	1*
	NITROIMIDAZOLES	Metronidazole	Muscle	Presence
ANTI CHEM	JP B: DRUGS, RMACEUTICALS BIOTICS OR OTHER MICALS AND FAMINANTS			
B1	ANTIBACTERIAL	Oxytetracycline	Muscle	100
	SUBSTANCES	Norfloxacin	Muscle	Any confirmed
		Sulphamethoxazol e	Muscle	100
		Trimethoprim	Muscle	50
		Amoxycillin	Muscle	50
		Tylosin	Muscle	100
		Oxolinic acid	Muscle	100
B2a	ANTHELMINTICS	Albendazole	Muscle	Any confirmed
		Ivermectin	Muscle	Any confirmed
B2f	Other pharmacologically active substances			
Sum of B3a + B3c + B3d + B3e				
	ORGANOCHLORINE	Aldrin	Muscle	Various 2-100
	COMPOUNDS INCLUDING PCBS	Chlordan-Alpha- Cis	Muscle	Various 2-100
		Chlordan-Gamma- Trans	Muscle	Various 2-100
		DDE, pp'-	Muscle	Various 2-100
		DDT, op-	Muscle	Various 2-100
		DDT, pp'-	Muscle	Various 2-100
		Dieldrin	Muscle	Various 2-100
		Endosulfan-Alpha	Muscle	Various 2-100
		Endosulfan-Beta	Muscle	Various 2-100
		Endosulfansulfat	Muscle	Various 2-100
		HCH-Alpha	Muscle	Various 2-100
		HCH-Beta	Muscle	Various 2-100

		HCH-Gamma (lindane)	Muscle	Various 2-100
		Heptachlor	Muscle	Various 2-100
		Heptachlorepoxid- Cis-Trans	Muscle	Various 2-100
		Oxychlordane	Muscle	Various 2-100
		PCB 101	Muscle	Various 2-100
		PCB 118	Muscle	Various 2-100
		PCB 138	Muscle	Various 2-100
		PCB 153	Muscle	Various 2-100
		PCB 180	Muscle	Various 2-100
		PCB 28	Muscle	Various 2-100
		PCB 52	Muscle	Various 2-100
ВЗс	CHEMICAL ELEMENTS	Cadmium	Muscle	50
		Lead	Muscle	200
		Mercury	Muscle	500
B3d	MYCOTOXINS	Aflatoxin B1	Muscle	Any confirmed
		Aflatoxin B2	Muscle	Any confirmed
		Aflatoxin G1	Muscle	Any confirmed
		Aflatoxin G2	Muscle	Any confirmed
ВЗе	DYES e.g. Malachite Green	Malachite Green	Muscle	2*
	(+ leucomalachite green), crystal violet etc	Leucomalachite green	Muscle	2*
		Crystal violet	Muscle	Any confirmed

#### PART 9 – CHECKS ON ADDITIVES

- 1. Samples of fish and fish products shall be taken and subjected to laboratory analyses for control of additives in edible parts of fish and fish products for the purposes of protecting public health.
- 2. Batches of fish and fish products which do not meet the following criteria shall be considered to be unfit for human consumption.

Table 13

Type of fish and fish products	Maximum level (mg/kg or mg/1 as appropriate) expressed as SO <sup>2</sup>
Crustaceans and cephalopods; Fresh, frozen and deep frozen	150
Crustaceans111111111[pv b, panaeidae solenceridae	
<ul><li>Aristeidae family</li><li>Up to 80 units</li><li>Between 80 and 120</li><li>Over 120 units</li></ul>	150 200 300
Cooked	50

#### Note

- 1. Maximum levels are expressed as  $\mathrm{SO}^2$  in mg/kg or mg/l as appropriate and relate to the total quantity available from all sources.
- 2. An  $SO_2$  content of not more than 10 mg/kg or 10mg/l is not considered to be present.

# PART 10 — MICROBIOLOGICAL AND PHYSICAL CHECKS OF POTABLE WATER

The Director-General shall prescribe microbiological and physical chemical criteria including sampling plans methods of analysis for potable water in fishery enterprises for the purpose of protecting public health.

# FORMS

	FORMS		
FORM KeFs/FS/A1:			(r.12(2))
CERTIFICATE OF IDENTIFICATION			РНОТО
KEN <sup>*</sup>	YA FISHERIES SERVICE /C	COUNTY	
COAT OF ARMS		F	L OF KENYA ISHERIES ICE/COUNTY
NAME			
FISHERIES INSPECTOR			
	al/County Executive Committ		
S/NO			
Dated the			

Minister for Agriculture, Livestock and Fisheries / County Executive Committee Member

(r.16(2))

# APPLICATION FOR PERMIT TO ESTABLISH, CONSTRUCT OR REFURBISH A FISHERY ENTERPRISE

(To be filled by applicant)

1.	I/We hereby apply for a permit to establish/construct/refurbish a Fishery Enterprise under the Fisheries Management and Development Act No. 35 of 2016 and the Fish, Fish products and Fish Feed Regulations hereunder—
2.	Name of applicant
	Nationality: (ii)Passport No: / ID/No:
	Mailing Address Telephone No
3.	Business Location: Name of Building/Place
	L.R. No
4.	Name and contact addresses of Shareholders/Directors
5.	Other than the business for which this application is made, are you involved in any
	other activity in the fishing/fisheries industry? YES/NO
6.	If the answer to above is yes, specify nature or type of business(es)
7.	Fishery enterprise approval number (if applicable)
8.	Number of employees:
9.	Ice plant capacity
10.	Refrigeration and freezing capacity
11.	Cold Storage capacity
12.	Intended activity:

1024	Kenya Subsidiary Legislation, 2024
Signature	
Name (of signatory):	
	FOR OFFICIAL USE ONLY
Approved/Not approve	ed Date
Reasons for not appro	ving:
	Director-General

(r. 17(2)(a))

# APPLICATION FOR CERTIFICATE OF COMPLIANCE WITH FISHERIES CONSERVATION AND MANAGEMENT (SAFETY AND QUALITY) REGULATIONS, 2024

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)TownDistrict
	(e) (i) Description of premises and details of processing
	(ii) Capacity of the factory / vessel
	(ii) Previous certificate of compliance No.
3.	(a) Other than processing fish for which this application is made, are you involved in any other processing of fish and 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
	(d) If the answer above to (c) is export, please specify the countries you wish to export to
4.	Details to be supplied by corporate body applicants
	(a) (i) Name of Company
	(ii) Number of Certificate of Incorporation of company
(Pl	ease attach copy)
	(b) State:
	(i) Nominal shares of the company
	(ii) Isquad shares

(c) Details of Directors:

(5) Details for mode of transport of fish and fish products.
(a) Specify the form of transport to be used
(b) If mode of transport is own vehicle state:
(i) Make
(ii) Registration mark and No
(iii) Load capacity
(c) If fish processing is vessel, state:
(i) Name of vessel
(ii) Type of vessel
(iii) Type of hull Overall length
(iv) Registration No District of Registration
Registration tonnage
(v) Prime mover
(vi) Engine type
(vii) Hp
(viii) Intended processingTarget fish species
(ix) Intended processing.
(x) Number of processing equipment including other details
(d) Details of crew (Attached crew list showing nationality)

(6) I/We declare that the particulars and information as supplied by me/us herein are true, accurate and correct in every respect. I/We understand clearly that discovery of any false information provided by me/us will render this application invalid.

Signature	Date
Name (of signatory)	
Position (in business)	
	OFFICIAL USE ONLY
Application approved/Not appr	oved
Reasons /Conditions	
Director-General / Authorized	Fisheries Inspector

#### FORM KeFS/A4

(r. 23(2))

#### FISH AND FISH PRODUCTS MOVEMENT PERMIT

PERMIT No
Name:
Address
Nationality: ID. No. /Passport No.:
is hereby authorized to Transport:
From: To:
Type and capacity of carrier/container:
Refrigeration/insulation capacity where applicable:
Reasons for transport
Name of Authorized officer:
County Executive Committee Member
Signature Date
Official Stamp:

(r. 24(a))

MOVEMENT PERM	IT FOR LIVE FISH			
PERMIT No.				
1. Wild fish				
Name				
Address				
Nationality:	ID. No. /Passport No:			
is hereby authorized to move fish species name	ned below:			
Zoological name	Common name			
(a)				
(b)				
FROM	ТО			
County	County			
(Name)	(Name)			
	Physical Location of Recipient			
(a)				
(b)				
Reasons for movement/transfer of live fish				
Contingent to the conditions specified here un	ider:			
2. Farmed fish				
SOURCE: Fish farmer/ Hatchery/ nursery operator/owner	RECIPIENT (Fry/Fingerlings/Post- Larvae/Brood-Stock			
Name:	Name:			
Full Address	Full Address			
Farm Address	Farm Address			
County	County			

Licence Registration No	Licence Registration No
Common Name	Common Name
Scientific Name	Scientific Name
Quality of species transported	Quantity Received Date
Date of harvest	received:
Signature	Quantity/species of dead fish
	Reason
	Signature
Reasons for movement/transfer of live fish	
Contingent to the conditions specified here un	
Border Inspection Post:	
Name of Authorised Officer:	
Director-General/County Executive Committe	
Signature	. Date
Official Stamp:	

		FORM		(r.23(5), 32(2)(b))					
Refe	Reference No								
	HEALTH (	CERTIFICATE FOR	R WHOLE FISH	AT THE LAND	ING STATIONS				
I.	Compiled History Record								
	Name/Co	de of Landing Beach	n						
	County		Sub-Coun	ty					
	Date	Name of supplier	Boat reg. No.	Origin of fish	Quantity supplied				
II.	Details id	entifying the fish an	d Destination						
		Owner of the Vehic	le:	Vehicle Regi	istration Number:				
Qua	antity of fish	n (Number):		Approximate w	Approximate weight:				
			Approximate ratio of fish: ice:						
Nuı	nber of fish	Inspected:		Species:					
				Buyer:	Buyer:				
				Destination:					
III.	Health At	testation							
	The under	rsigned official fishe	eries inspector he	ereby certifies that	t				
		the fish specified a esome. The fish is the			und organoleptically ;				
	(b) That the fish compartment of the transporting Vehicle is in good state of repair and cleanliness;								
(c) That the ice used had previously been packed in gunny bags or any other appropriate packages.									
	Done at (Place) on (Date)								
Nan	ne of Fisher	ies Inspector		Designa	ation				
	a.				Official Stamp				
	Signature								

Original to the owner of the Vehicle
Duplicate to the Director of Fisheries
Triplicate to the Regional Assistant Director of Fisheries
Quadruplicate to remain in the book

(r.32(2)(b))

#### FISH AND FISH PRODUCTS EXPORT HEALTH CERTIFICATE



EN-HC

#### For exports of fishery products intended for human consumption

			Tor exports or fishery							
1.1.	Consignor				1.2. Certi	ficate reference	e number		1.2.a.	
	Name Address					1.3. National Competent Authority				
	Postal code				1.4. Coun	ty Competent A	Authority			
	Tel. No.:									
1.5.	Consignee				1.6.					
	Name									
	Address									
	Tel. No.:									
1.7.	Country of origin	ISO code	1.8. Region of origin	Code	1.9. Co	untry of destina	ation	ISO Code	1.10.	
1.11	Place of origin									
					1.12.					
	Name:									
	Approval number									
	Address:									
1.13	. Place of Loading				1.14 Date of departure					
1.15	. Means of transport				1.16 Entry BIP in EU					
4	Aeroplane	Ship	Railway w	agon						
	Road vehicle		Other		1.17.					
	Identification:									
	Documentary reference	es:								
1.18	8 Description of com	modity				1.19 Comm	odity code	e (HS code)		
					·		1.20 Q	uantity		
1.21	1 Temperature of pro Ambient		illed Frozen				1.22 N	umber of packag	ges	
1.23	1.23 Identification of container/Seal number						1.24 T	ype of packagin	g	
1.25	5 Commodities certif	ied for								
	Human consun	nption								
1.26	b				1.27 For	export or admi	ssion into	EU		
1.28	3 Identification of the o	commodities								
					Approval	number of estal	blishments	s		
		Nature of co			nufacturing	plant Nu	ımber of p	oackages	Net weight	
									Page 1 of 3	
									-	

# Part 11: Certification

# II. Health attestation II.a. Certificate reference number II.b.

#### II.1. (1) Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of the Fish, Fishery Products and Fish Feed Safety and Quality Regulations, 2019 and certify that the fishery products described above were produced in accordance with those requirements, in particular that they:

- come from (an) establishment(s) implementing a programme based on the HACCP principles;
- have been caught and handled on board vessels, landed, handled and where appropriate prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Part V and the Second Schedule of the Regulations;
- satisfy the health standards laid down in Part III, IV, V, VI, IX and the Fourth and Fifth Schedules of the Regulations;
- Have been packaged, stored and transported in compliance with Part V, VI and the Sixth and Seventh Schedules of the Regulations;
- Have been marked in accordance with Part VI, V and the Eighth and Tenth Schedules of the Regulations;
- The guarantees covering live animals and products thereof, if from aquaculture origin, provided by the residue plans submitted in accordance with Part IV, VI, IX and the Fourth Schedule of the Regulations are fulfilled; and
- Have satisfactorily undergone the official controls laid down in Part V, IX and the Ninth Schedule of the Regulations
- II.2. (²)(4) [Animal health attestation for fish and crustaceans of aquaculture origin
- II.2.1 (²)(4) [Requirements for susceptible species to Epizootic ulcerative syndrome (EUS), Epizootic haematopoletic necrosis (EHN), Taura syndrome and Yellowhead disease
  - I, the undersigned, official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:
  - (5) originate from a country/territory, zone or compartment declared free from (4)[EUS] (4) [EHN] (4)[Taura syndrome] (4)[Yellowhead disease]in accordance with the relevant OIE Standard by the competent authority of my country,
  - (i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant diseases must be immediately investigated by the official services,
  - (ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and
  - (iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases]
- II.2.2 (³)(¹) [Requirements for species susceptible to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon amaemia (ISA), Koi herpes virus (KHV) and White spot disease intended for Country, zone or declared disease free or subject to a surveillance or eradication programme for the relevant disease
  - I, the undersigned, official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:
  - $\label{eq:continuous} \begin{tabular}{ll} (6) originate from a country/territory, zone or compartment declared free from (4)[VHS] (4) [IHN] (4)[ISA] (4)[KHV] (4)[White spot disease] in accordance with the relevant OIE Standard by the competent authority of my country, \end{tabular}$
  - (i) Where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant diseases must be immediately investigated by the competent authority,
  - (ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and
  - (iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases]
- II.2.3 Transport and labelling requirements
  - I, the undersigned official inspector hereby certify that:
- II.2.3.1 the aquaculture animals referred to above are placed under conditions, including with a water quality, that do not alter their health status;
- II.2.3.2 the transport container or well boat prior to loading is clean and disinfected or previously unused; and
- II.2.3.3 the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes 1.7 to 1.11 of Part I of this certificate, and the following statement:
  - "(4) [Fish](4)[Crustaceans] intended for human consumption".

II.	Health attestation	II.a. Certificate reference number	II.b.						
Note Part									
-	Box reference I.8: Region of origin: For Frozen or processed bive	alve molluses, indicate the production area.							
-	Box reference I.11: Place of origin: name and address of the dispatch establishment.								
-	Box reference I.15: Registration number (railway wagons or controlled in the event of unloading and reloading.	ainer and lorries), flight number (aircraft) or nam	e (ship) Separate information is to be						
-	Box reference I.19: Use the appropriate HS codes: 03.01, 03.02, 0	3.03, 03.04, 03.05, 03.06, 03.07, 05.11.91, 15.04	1, 15.18.00, 16.03, 16.04, 16.05.						
-	Box reference 1.23: Identification of container/seal number: When	e there is a serial number of the seal it has to be	ndicated.						
-	Box reference I.28: Nature of commodity: specify if aquaculture	or wild origin.							
	Treatment type: Specify whether live, chilled, frozen or processed								
	Manufacturing plant: includes factory vessel, freezer vessel, cold	store, processing plant.							
Part	II:								
(1)	Part II.1 of this certificate does not apply to countries with spe other legislation in the Country.	cial special public health certification requirem	ients laid down in equivalence agreements or						
(2)	Part II.2 of this certificate does not apply to:								
	(a) non-viable crustaceans, which means crustaceans no longer at	ole to survive as living animals if returned to the	environment from which they were obtained.						
	(b) fish which are slaughtered and eviscerated before dispatch								
	(c) aquaculture animals and products thereof, which are placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Part VI and Seventh Schedule of the Regulations,								
	(d) crustaceans destined for processing establishments authorised businesses which are equipped with an effluent treatment syst treatment reducing the risk of transmitting diseases to the nature.	em inactivating the pathogens in question, or wh	oatch centres, purification centres or similar ere the effluent is subject to other types of						
	(e) crustaceans which are intended for further processing before has packed and labelled for that purpose in accordance with the So	numan consumption without temporary storage at	the place of processing and						
( <sup>3</sup> ) ( <sup>4</sup> )	Parts II.2.1 and II.2.2 of this certificate apply to species susceptible Keep as appropriate.		title.						
(5)	For consignments of species susceptible to EUS, EHN, Taura sauthorised.	syndrome and/or Yellowhead disease this states	nent must be kept for the consignment to be						
-	The colour of the stamp and signature must be different to that of	other particulars in the certificate.							
	Official inspector								
Nam	ne (in capitals):								
Date		Qualifica	tion and title:						
Stan									
J	T	Signature	n						
Fees	s (Kshs):								

Page 3 of 3

(r.40(6))

# AQUACULTURE FISH DELIVERY PERMIT TO FISH PROCESSING FISHERY ENTERPRISE/ MARKET

PERMIT NO
PART A (To be kept by the fish supplier)
Permission is hereby granted to
(Name of fish supplier) to transport fish and fish products namely (common/ scientific
name) Batch code number
Quantity/Number of pieces type of species
Temperature of fish
TREATMENT HISTORY
Name of Drug
TREATMENT SCHEDULE
Start Date
Withdrawal period
Prescribed by (Name of Veterinarian))
Administered by (Name of personnel)
From (source) to (destination)
Means of transport used
Vehicle/Vessel Registration No Business Licence No
Full name of driver/vessel operator
(Postal address)
Signature of driver/vessel operator
Expected date of dispatch
Signature of fish supplier Date
Full name of Authorized Officer (at point of dispatch)
SignatureDate
Office stamp
This permit is validity until20

PART B
For official use only
(To be kept by the Authorized Officer at point of destination)
This is to confirm that the fish or fish products (type)
described in part A above weighing / number of pieces
have been unloaded/verified for the destined fishery enterprise (name)
at (time)
Name of Authorized Officer/Fisheries Officer at point of destination
Signature Date
Official stamp

Conditions attached to the Permit:

This permit shall be accompanied by the respective fish consignment and shall be presented to an Authorized Officer, as it may deem necessary.

(r.45)

#### FOREIGN FISHING VESSELS IMPORT CERTIFICATE

A. Vessel details		
Name	Type	
Registration No.	Identification Mark	
Permanent Ref No.:		
Vessels owner	s Name & Address	
Port of registration		
Flag		
Date of Present arrival	. Date previous arrival	
B. Product details		
Species	Quantity	
Where fished	- 1	
Storage conditions:		
C. Certification		
I certify that the vessel has satisfied requested Products and Fish Feed Safety and Quality on the list drawn by the Competent Author of another country.	Regulations, 2024 and that	the vessel appears
Inspectors Name:	Signature	Date

(r. 47(1))

	RAW MATERIAL IMP	ORT :	DECLA	RAT	ION F	FORM	
This form should	s.	Refer No.	rence				
Fishery enterpris	e Details						
Name of the fishery enterprise			ress of shery prise				
SE	CTION A			S	ECTI	ON B	
Vessel	Identification		Inform	ation	on R	eefer C	Containers
Vessel Name		Name Merc Vess	hant				
Vessel Type		Date ETA	and at Port				
Flag		Cour Origi	ntry of				
Home Port		Sizes Reef					
Registration No.		Spec					
International Radio Call Sign		Total Quar (Kg)					
International Maritime Organization Number		Fish Prese State	ervation				
Arrival Information			Individual Container Details				
Date and Expected Time of Arrival at Port		S/N Contai o. Numbe			Catcl Certi No.	h ficate	Health Certificate No.
		1					
Common Name a	and Species	2					

Name of Fishing Vessel(s) and Catch Certificate Number(s)	AC	Quant ity (Kg)	Fish Preserva tion State	3			
				4			
				5			
				6			
Inspector's Name	Inspector's Name:-						
Signature and Stamp:							

(r.47(2))

#### CATCH CERTIFICATE

	REPU	UBLIC	OF	K	ENY A	1		
	CAT	CH CI	ERT	IFI	CATE	Ε		
Document Number		Validating Authority (Name, Address Tel., Email address)					me, Address,	
1. Description of Product						Applicable ( Measures	Conser	vation and
Species	Code	ode Verified Weig					Landed (Kg)	
3. List of vessels which have Registration No, etc. ann		d catch	nes a	ınd	the qu	iantities by	each ve	essel, (Name,
4. Name, Address, Tel. and address of Exporter	Email		Sign	atu	ıre	Date		Stamp
5. Flag State Authority Val	idation							
Name/Title			Signature			Date	;	Stamp
6. Transport Details						I.		
7. Importer Declaration								
Name and Address of Importer	Signature		Date			Stamp		Product CN Code
8. Import Control: Authority	Place		mportation Authorized (*)		*)	Importation Suspended		Verification Requested - Date
Customs Declaration	Number			Da	ite		Place	

<sup>(\*)</sup> Tick as appropriate

 $(r\ 44(2)(a), r.46(2))$ 

#### APPLICATION FOR FISH AND FISH PRODUCTS

#### IMPORT/EXPORT PERMIT

In	specto	or's remark										
Si	gnatuı	·e		Date								
Re	ef. No											
1.	I/We	hereby apply for	Import	/Export permit								
2.	Nam	e of applicant	of applicant									
	Nati	onality:	(ii) Passport No	o: /ID/No:								
	Mail	ng Address		Telephone No								
3.	Busi	ness Location: Name o	of Building/Place									
	L.R.	NoStree	t/RoadTo	own County								
4.				is made, are you involved in any								
	If th	_		e of business(es)								
	_	ify any other gainful o	ecupation(s) you are eng	aged in								
5.		FISH AND FISH PRO										
٥.	(a)	Fish/Fish Products	DDUCIS	O.,4'4								
,	Value	FISH/FISH Froducts		Quantity								
	, ara-c											
	(b)	LIVE FISH										
		Species	Common Name	Number								
Va	alue											

5.	Name and address of Consignee/supplier
6.	I /We declare that the particulars and information supplied by me/us herein are true, accurate and correct in every respect. I/We understand clearly that discovery of any false information provided by me/us render this application invalid.
,	Signature Date
Na	me (of signatory):
Red	commended/Not Recommended Date
	 Director-General

#### FIFTH SCHEDULE

#### HEALTH CONDITIONS FOR FISHERY ENTERPRISES

(r. 16(4), 18(1), r.21(2), r. 43(1)(c))

#### PART I-GENERAL HYGIENE CONDITIONS

#### A-General

- 1. Effective measures shall be taken to protect fishing vessels from infestation by rodents, insects and other pests.
  - 2. Dogs, cats and other animals are not permitted on board fishing vessels.
- 3. Fishing baits shall be kept in exclusive containers in a separate area from fish for human consumption.
- 4. Only potable water or clean water shall be used for washing fish and surfaces which come into contact with fish the fish and fish products.
- 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 water (lake and Sea).
- 7. The vessel shall be provided with a first aid box, which shall contain as a minimum, 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.
  - 2. Fish handlers shall be prohibited from-
  - (a) using any form of tobacco;
  - (b) spitting;
  - (c) blowing or picking the nose; or
  - (d) eating or drinking in the fish handling area.
- 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 wear and headgear which completely covers the hair.
  - 4. All personnel shall wash and sanitize their hands after going to the toilet.
- 5. Any member of the crew who suffers from or shows symptoms of any of the following conditions shall report 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; or
- (h) coughing.
- 6. All crew shall take reasonable precautions to prevent cross contamination between fish and fish products, by-
- (a) conducting themselves responsibly 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. Fish handling areas shall be used exclusively for the purpose, maintained clean and cleared of unnecessary equipment.
- 2. After the catch is sorted and stowed, decks, boards and all deck equipment which come into contact with the fish shall be cleaned 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 or lifting by the tail.
- 3. The catch shall be handled rapidly and sorted as soon as possible.
- 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 cleaned and chilled down to the temperature of melting ice (0°C). If not frozen it shall be maintained at this temperature until landing.
  - 6. Any spoilt or diseased fish 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 carried out with care to avoid contaminating the fish with gut contents.
- 3. Fish guts shall be disposed of immediately to avoid contamination of fish, the deck and other equipment.
- 4. Immediately after gutting, fish shall be thoroughly washed with clean water or potable before chilling.
- 5. Harbor water shall never be used for washing fish; if fish is gutted in harbor it shall be washed with potable water.

6. After washing the fish, further handling shall be carried out without delay.

#### F-Chilling and icing of fish

- 7. During stowage and icing of the catch, deck entrances shall not be left open longer than necessary.
  - 8. Fish from different days' catches shall not be mixed together.
- 9. 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.
- 10. Fish shall be rapidly and hygienically chilled with finely crushed block ice, flake ice or by immersion in clean refrigerated or chilled sea or lake water.
- 11. 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.
- 12. 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.
- 13. Fish chilled with ice shall be stowed either in containers or, if in pounds, in shallow layers separated by pound boards.
  - 14. At the end of each fishing trip, all used ice shall be discarded.

#### F.- 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, fish shall be handled carefully to avoid damage and contamination from contact surfaces.
  - 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. The catch shall be unloaded from the fishing vessel rapidly and carefully.

#### G. —Cleaning and Sanitation

- 1. All parts of the vessel and equipment which come into contact with fish and where fish is handled, processed or stored shall be maintained cleaned and sanitized.
  - 2. Such parts of the vessel and equipment shall be thoroughly cleaned.
  - 3. Disinfected at least before and after each fishing trip.
- 4. 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.
- 5. The plan shall specify methodology and frequency of cleaning and identify the individuals responsible for each component.
- 6. Check lists which reflect the plan shall be maintained by the vessel master to ensure that the cleaning schedule is adhered to.

#### PART II- HEALTH CONDITIONS FOR FISH PROCESSING ENTERPRISES

#### A—General conditions for constructing or refurbishing a fishery enterprise

- 1. The following information shall be submitted to the Director-General or County Executive Committee Member as the case may apply:
  - (a) full name and address of the fisher enterprise;
  - (b) copy of certificate of incorporation;
  - (c) activities to be carried out by the enterprise;
  - (d) description and composition of finished product;
  - (e) number of employees;
  - (f) production and storage capacities;
  - (g) source of water;
  - (h) approved architectural plan minimum size 1:200 detailing:
    - (i) facilities and utilization, clear separation between clean and dirty areas;
    - (ii) the flow of products, by products and waste
    - (iii) movement and flow of personnel, utensils and ice;
    - (iv) equipment lay-out and utilization;
    - (v) refrigeration and freezing equipment and capacity;
    - (vi) sanitary facilities, shower rooms, hand wash basins, changing rooms and toilets:
    - (vii) water reticulation map including water outlets or taps, serially numbered, storage tanks, treatment.
    - (viii) The flow of waste water and solid waste; and
    - (ix) air and moisture exhaust systems.
  - 2. Pest control system.
- 3. Waste water and solid waste disposal system prepared in accordance with Environmental Management and Co-Ordination (Waste Management) Regulations 2006, (Legal Notice No. 121 of 2006).
- 4. Good Manufacturing Practice (GMP) manual, Hazard Analysis Critical Control Point Manual, Sanitation Standard Operating Procedures Manual.
- 5. Environmental Impact Assessment Report approved by the relevant authority in accordance with Environmental Management and Coordination Act, 1999
- B—General conditions relating to premises and equipment
- 1. Each fishery enterprise 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) water-proof non-slip flooring which is easy to clean and disinfect and adequate drainage of water;
- (b) walls which have smooth surfaces and 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 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.
- 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 fish 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 clean water, with adequate pressure and in sufficient quantities for processing and cleaning operations.
- 7. Where non-potable water supply is provided for the production of steam, firefighting 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 water.
  - 8. There shall be an adequate hygienic waste water disposal system.
- 9. There shall be adequate facilities in a separate room for personnel to change their clothes. This room shall have smooth, waterproof, washable walls and floors.
- 10. The fishery enterprise shall have an adequate number of flush toilets, the latter not opening directly onto areas where fish 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 adequate facilities for cleaning and disinfecting the means of transport delivering raw material to or taking final products from the fishery enterprise.
- C General Conditions for live fish handling fishery enterprise
  - 12. A fishery enterprise handling live fish shall meet the following requirements—
  - (a) The construction and design of holding units shall be smooth, and non-corrosive to prevent injury to the live fish.

- (b) Adequate supply of quality clean water shall be provided to prevent the transfer of harmful organisms or substances to the fish.
- (c) The fishery enterprise shall have an adequate supply of clean water which shall be free of pollutants.
- (d) The fishery enterprise shall be equipped with a water purification system that is supplied with good water aeration system.
- (e) The water shall be monitored regularly and records kept.
- (f) Chemicals shall not be used to treat the water; the water shall be changed regularly and spent water shall either be treated or drained back to the sea or be disposed off in septic tanks.
- (g) The surroundings of the holding premises shall be clean and protected from vermin and vectors.
- (h) Fish will be handled in a manner that prevents injury.
- (i) If fish are to be marked, it shall be done in a manner that causes minimum damage to fish.
- (j) Injured fish shall be separated from the rest of the stock.
- (k) holding facilities shall be provided.
- (l) Fish shall not be held in holding tanks for more than 3 days; if it happens, the fish shall be placed in cages and put in the sea/Lake water until the appropriate time for packaging and dispatch.
- (m) The fish shall not be given supplementary feed in the holding tanks.

#### D- Ice Plants and Cold Storage facilities

The following information shall be provided by the applicant to construct and operationalize an ice plant and/or a Cold storage facility—

- (a) Full name and address of the fishery enterprise
- (b) Copy of certificate of incorporation.
- (c) Activities to be carried out by the enterprise.
- (d) Number of employees.
- (e) Capacities of equipment for ice production and cold storage capacity and description of products to be stored.
- (f) Source of water and treatment.
- (g) Source of water and treatment.
- (h) type of ice to be produced.
- (i) Ice distribution and handling procedure.
- (j) product handling procedure.
- (k) The ice plant and /or cold storage facility layout plan, minimum scale 1:200 indicating:
  - (i) the facilities and respective utilization;

- (ii) refrigeration equipment;
- (iii) sanitary facilities;
- (iv) water reticulation map; and
- (v) waste water disposal system.
- (1) Pest control system.
- (m) Sanitation standard operating procedures.
- (n) Good hygiene practice and good manufacturing practice manuals.
- (o) An environmental Impact Assessment report where applicable.
- (p) Number of employees.

#### E—General conditions of hygiene

- 1. Floors, walls and partitions, ceilings and roof linings, equipment and instruments used for handling fish and fish products shall be kept in a satisfactory state of cleanliness and repair to prevent contamination.
  - 2. Pest and rodent control measures shall be implemented.
- 3. Equipment used in the processing areas shall only be used for handling fish and fish products.
  - 4. Potable water or clean seawater shall be used for cleaning purposes.
- 5. Detergents, disinfectants and similar substances used in the fishery enterprise shall be approved by the competent authority and shall not have adverse effects on the machinery, equipment and fish and fish products.
- 6. Rodenticides, insecticides, disinfectants and any other potentially toxic substances shall be stored under lock and key to eliminate the risk of contamination of the products.

#### F- 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 fish and fish products shall wash their hands at least each time work is resumed;
  - (c) wounds shall be covered by waterproof dressing; and
  - (d) smoking, spitting, eating, nose blowing and picking, and drinking in work areas and storage premises of fish products shall be prohibited.
- 2. Employers shall take all the necessary measures to prevent persons liable to contaminate fish products from handling and working on such products until there is evidence that such persons can do so without risk.

#### SIXTH SCHEDULE

(r.15(4), r.17(2)(c), 32(2)(c), (38)(2)(a), (57(1), r.61)

#### **FEES**

Particulars of fees	Amount (KShs)	
Certification of compliance (export)	35,000	
Certificate of compliance following withdrawal (export)	70,000	
Certification of origin for bivalve mollusks	100,000	
Fish and fish products Export Health Certificate	1,500	
Fish export fees	0.5% ad volerem the value of fish	
Fish import fees	5% ad volerem the value of fish	
Replacement of licence, permit or certificate	20% of the application fee	
Fish Processing licence	200	
Live fish movement permit	100	
Shell collectors Licence	100	
Local health certificate for whole fish at landing sites		
Fish of less or equal to 1000 kilograms	100	
Fish of more than 1000 kilograms	1,000	

#### SEVENTH SCHEDULE

### INTERNAL SYSTEM TO CONTROL FISH AND FISH PRODUCT SAFETY HAZARDS

(r.18, r.62(3))

#### PART 1: GENERAL REQUIREMENTS

- 1. Fish, fish products and aquaculture fishery enterprise operator shall implement a system of internal controls (an own-checks system).
  - 2. The internal controls shall be based on the following principles;
  - (a) identification of safety hazards associated with the products and processes, and identification of critical points on the basis of the manufacturing processes;
  - (b) establishing and implementing methods for monitoring critical points, and for corrective actions to prevent or minimize the risk of hazards;
  - (c) taking samples for analysis for the purpose of verifying the effectiveness of cleaning and disinfection methods and for the purpose of checking compliance with fish and fish product safety requirements in the regulations;
  - (d) keeping a written record or a record registered with indelible ink 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.
- 3. The management of the fishery enterprise shall make provision for a sampling programme which, 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 in the characteristics of the product or the manufacturing process;
  - (c) confirmation, at specified intervals, that all provisions are still appropriate and properly applied.
- 4. If the results of the internal controls reveal the existence of a significantly elevated risk to the health of consumers in respect of a batch of fish or fish products, the products concerned shall be deemed to be in non-compliant with requirements.
- 5. The persons responsible for the fishery enterprise shall document all information relating to the implementation of internal control system and verification shall keep written records or records registered in indelible ink, as referred to paragraph 1 (d) of this schedule.
- 6. The documentation referred to in paragraph 1 above shall include the following two types of information to be kept for submission to the Director-General on request—
  - (a) a detailed and comprehensive document detailing—
    - (i) a description of the product;
    - (ii) description of the manufacturing process and critical points;
    - (iii) for each critical point, identified hazards, assessment of risks and control measures:

- (iv) procedures for monitoring each critical point, and critical limits for parameters that need to be controlled and the corrective action to be taken in case of deviation; and
- (v) procedures for verification and review.
- (b) records of the observations or measurements referred to in paragraph 1 (b), of this schedule, 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 facilitates 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 fishery enterprise to which it relates.
- 2. As part of the internal approach referred to in paragraph 1, a fishery enterprise may use guides of good manufacturing practice drawn up by appropriate professional organizations and acceptable to the competent authority.
- 3. The management of the fishery enterprise shall ensure that all personnel concerned with internal controls are adequately trained to effectively participate in the implementation.
- 4. In the design of any system for internal control the following general approach shall be adopted—
  - (a) identification of hazards, analysis of risks and determination of measures to control the hazards:
  - (b) identification of critical points;
  - (c) fishery enterprise critical limits for each critical point;
  - (d) fishery enterprise monitoring and checking procedures;
  - (e) fishery enterprise corrective action to be taken when necessary;
  - (f) fishery enterprise verification procedures;
  - (g) validation of the system; and
  - (h) 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 points" means any point, step or procedure at which control applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels.
- 2. Critical points shall first be identified by a detailed review of the process, based on knowledge and with reference to existing codes of practice.
- 3. The information generated under paragraph 2 (1) shall be used as the basis of the requirements of the process, including those specified in any relevant code of practice.
- 4. The critical points shall be specific to each fishery enterprise, depending on the raw material, 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 multidisciplinary team

- 2. A multi-disciplinary team shall be drawn from all departments of the fishery enterprise concerned with the products and shall include a wide range of specific knowledge and expertise appropriate to the product under consideration, the production process, viz manufacture, storage, and distribution, consumption and the associated potential hazards.
  - 3. The team may consist of one or more of-
  - (a) a quality control specialist with an understanding of the biological, chemical or physical hazards associated with a particular product group;
  - (b) a production specialist with responsibility for, or who is involved with the technical process of manufacturing the products under review;
  - (c) a technician who is knowledgeable in the hygiene and operation of the fishery enterprise's equipment; or
  - (d) any other person with specialist knowledge of microbiology, hygiene or food technology.
- 4. Where necessary, the team may be assisted by external experts with technical knowledge in areas not adequately covered by the fishery enterprise's own personnel.

#### C — Description of the product

- 1. The end product shall be described in terms of –
- (a) the composition viz, species raw materials ingredients, and additives;
- (b) the structure and physio-chemical characteristics (e.g. whole, portion, Aw, PH,);
- (c) the nature and extent of processing viz. heating, freezing, drying, salting, smoking and respective process conditions;
- (d) the packaging (viz, hermetic, vacuum, or modified atmosphere;
- (e) the storage and distribution conditions (temperature control);
- (f) the required shelf-life viz:sell by date and best before date;
- (g) the instructions for use;
- (h) any microbiological or chemical criteria applicable thereto; and
- (i) the normal or expected use of the product by the targeted consumer, including classes of consumers with special needs.

#### D - Description of manufacturing process

- 1. The fishery enterprise 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 in particular time and temperature, and concentrations of solutions;
- (e) the flow of products, potential cross-contamination;
- (f) the segregation of clean and dirty areas;
- (g) the cleaning and disinfection procedures;
- (h) the hygienic environment of the fishery enterprise;
- (i) the personnel routes and hygiene practices; and
- (j) product storage and distribution conditions.
- 2. The description may be amended at any time when there is a change in the manufacturing process.
  - E— Listing of hazards and multidisciplinary control measures
- 1. The multidisciplinary team shall make a list of all potential health hazards relating to the storage, processing and packaging of fish and fish products.
- 2. A list prepared under paragraph 1 may include hazards 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 microorganisms and unacceptable generation of chemicals in intermediate products, final predicts, production line or environment;
  - (c) unacceptable production or persistence of toxins or other undesirable products of microbial metabolism.
    - 3. The identified hazards must be those that their elimination or reduction to acceptable levels is essential to the production of safe fish products.
      - 4. The multidisciplinary team shall—
  - (a) list all potential biological, chemical or physical hazards that are expected to occur at each step of processing (including those resulting from acquisition and storage of raw materials, ingredients, delays during processing and any other foreseeable eventuality).
  - (b) consider and describe control measures, which can be applied to eliminate or reduce each hazard.
- 5. In identifying the critical point for the control of the hazard, take the following steps—
  - (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 variable 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

- 1. An essential part of internal control system is a programmed 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 observation s or measurements and the recording procedures to be followed.
- 2. Observations or measurement must be able to detect loss of control at critical points and provide information in sufficient time for corrective action to be taken.
- 3. It is necessary to establish a frequency of observation 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 behavior of critical variables between observations.
- 4. Any decision on the periods between observations of critical variables at critical points shall be based on a detailed knowledge of the behavior of those variables (and in particular their rate of change under all foreseeable circumstances).
- 5. A written programme of observations or measurements shall properly identify for each critical point-
  - (a) the person monitoring and checking;
  - (b) the time when monitoring and checking is performed; and

- (c) how monitoring and checking is performed.
- 6. Observations or measurements may indicate—
- (a) that the parameter monitored is tending towards, although not exceeding its specified critical limits, indicating a tread towards loss of control Appropriate corrective action to maintain control must be taken before the occurrence of a hazards; and
- (b) that the parameter monitored has exceeded its specified critical limits, indicating a loss of control and decide on an appropriate action with respect to the products subject to the process conditions exceeding the critical limits.
- 7. Corrective action must be planned and documented in advance by the multidisciplinary 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.
  - 8. 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 control; and
  - (d) written records of measures taken.
- 9. 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 products criteria either externally determined.
- 10. 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 for 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.
- 3. The person responsible for the fishery enterprise shall implement the verification programme at specified intervals. Government inspectors may also undertake a routine verification as part of any accreditation scheme.

- 4. On the basic level verification will entail as audit of the own-checks system and 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 measurement.

#### H- VALIDATION

#### PART I- 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 variable 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 fishery enterprise 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) change in raw material or in product, processing conditions (factory layout and environment, process equipment, the cleaning and disinfection programme);
  - (b) change in packaging, storage or distribution conditions;
  - (c) 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 revalidation 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.

## PART 2—DOCUMENTATION

- 1. The operator of a fishery enterprise 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; and
    - (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.

## EIGHTH SCHEDULE

(r.18, r.23(3), r.36(1)(b))

#### STORAGE AND TRANSPORT

- 1. Fish and Fish products shall during storage and transport, be preserved at the prescribed temperature and, in particular—
  - (a) fresh or thawed fish products and cooked and chilled crustacean and molluscan shellfish products shall be preserved at the temperature of melting ice;
  - (b) frozen fish products with the exception of frozen fish in brine intended for the manufacture of canned foods, shall be kept at a temperature of minus eighteen degrees-centigrade or less in all parts of the product, allowing for the possibilities of brief upward fluctuations of not more than three degreescentigrade during transport.
  - (c) processed products shall be kept at the temperature specified by the manufacturer.
- 2. Paragraph 1 (b) shall not apply where frozen fish products are transported from a cold storage facility to an approved fishery enterprise to be thawed on arrival for the purpose of preparation or processing and where the journey is shorter than two hours.
  - 3. Live fish shall be transported under suitable conditions that minimize mortality
- 4. Fish and fish products will not be transported with other goods which may contaminate them or affect their quality, unless they are packaged in such a way as to provide adequate protection.
- 5. Carriers and containers used for transportation of fish and fish products shall be constructed and equipped to maintain prescribed temperatures throughout the period of transport. If ice is used to chill the fish, adequate drainage shall be provided to ensure that water from melted ice drains away.
- 6. The inside surfaces of the carrier or container shall be smooth and easy to clean and disinfect.

## NINTH SCHEDULE

## TRACEABILITY AND RECALL PROCEDURES (r.18, r.27)

- 1. The traceability of fish and fish products, and fish feed used in fish culture systems, and any other substance intended to be, or expected to be, incorporated into a fish or fish product or feed shall be established at all stages of production, processing and distribution.
- 2. An operator of a fishery enterprises shall be expected to be able to identify any person who supplies them with fish, fish products, fish feed, or any substance intended to be, or expected to be, incorporated into a fish, fish product or fish feed.
- 3. An operator of a fishery enterprises shall have in place systems and procedures allow for traceability information to be made available to the competent authority and the Director-General on demand.
- 4. An operator of a fishery enterprise shall have in place systems and procedures to identify businesses to which their products have been supplied. This information shall be made available to the competent authority and the Director-General on demand.
- 5. Fish and fish products or fish feed which are placed on the market or are likely to be placed on the market shall be labelled or identified through relevant documentation to ensure its traceability.
- 6. Each operator of a fishery enterprise shall prepare a written recall plan detailing the procedures to be followed when a batch of fish, fish product or fish feed which has left his possession shall be withdrawn before and after placing on the market.

## TENTH SCHEDULE

## WRAPPING AND PACKAGING REQUIREMENTS FOR FISH AND

#### FISH PRODUCTS

(r. 18, r.36(1)(f))

- 1. Packaging of fish and fish products shall be carried out hygienically, to preclude contamination.
- 2. Packaging materials and products likely to come into contact with fish and fish products shall comply with all hygiene and sanitary requirements including□
  - (a) they shall not impair the organoleptic characteristics of the fish products;
  - (b) they shall not transmit harmful substances to fish products intended for human and animal consumption;
  - (c) they shall be durable to protect the fish and fish products adequately.
- 3. Packaging materials shall not be re-used with the exception of containers made of smooth, impervious, and corrosion-resistant, durable material which may be re-used after cleaning and disinfection.
- 4. Packaging materials used for fresh fish and fish products chilled with ice shall be water resistant and designed to provide adequate drainage for melt ice water.
- 5. Unused packaging materials shall be stored in premises away from the production area and be protected from dust and contamination.

#### **ELEVENTH SCHEDULE**

(r.18, r.38(1)(g)

## LABELLING AND IDENTIFICATION MARKS FOR FISH PRODUCTS

- 1. Where fish products are packaged and consigned for placing on the market by a fishery enterprise the following information shall be printed on the packaging—
  - (a) the country of origin;
  - (b) the name and official registration number of the fishery enterprise where the fish and fish products were processed or packaged;
  - (c) the description of the product, common and scientific name, of the fish or fish product and the state (fresh, chilled, frozen, cooked etc.);
  - (d) the date of production, use before date, expiry date;
  - (e) the date of consignment from the fishery enterprise;
  - (f) any special storage instructions required to maintain the safety and quality of the fish or fish product.

## TWELFTH SCHEDULE

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

(r.18, r.37(1), r.51(1), r.62(2))

## PART 1-HARVEST AND RELAY AREAS

- 1. Bivalve molluscs for human consumption shall be harvested from areas designated by the Director-General.
- 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 Director-General in the Kenya *Gazette*.
- 4. Harvest areas shall be classified according to the scheme specified in the first and second columns in table 3, and applied for the uses specified in the third column.

Table 3

Classification	Bacteriological counts*	Permitted use
	(not more than)	
A	300 faecal coliforms/100g flesh	Direct human consumption;
	or 230 E. coli/100g flesh	Cooking.
	Free of salmonella in 25g*	
В	In 90% of samples tested –	Direct human consumption after
	6000 faecal coliforms/100g flesh	purification or relaying until Class A is achieved: Cooking
	or 4600 E. coli/100g flesh	,
С		Relaying for at least two months
	Flesh 46,000 E. coli/100g flesh	prior to retesting; Cooking

<sup>\*</sup>Based on a five tube three dilution mean probable number test or any other equivalent bacteriological procedure.

- 5. The harvesting 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 coliforms 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 table 4.

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

## PART 2 – MONITORING OF HARVEST AREAS BY THE DIRECTOR-GENERAL

1. Harvest areas and samples of fish products from these areas shall be monitored on a regular basis, according to a written sampling plan, and with respect to the parameters in table 5.

Table 5

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

- 2. Samples for measurement of the parameters listed in paragraph 1 above (table 5) 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 consider 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.
  - 5. Sufficient sample points shall be defined by considering—
  - (a) likely variations in the faecal contamination of the production of the production area; and
  - (b) possible variations in the development of marine algal blooms
- 6. Detection of potential problems shall be followed by more intensive sampling regimes, until the area is closed, or until the potential hazard recedes.
- 7. 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 Kenya *Gazette*.
- 8. Areas which are subject to temporary closure shall be monitored as if the area was not closed unless they are to be closed permanently.

#### THIRTEENTH SCHEDULE

(r. 42(1)(a))

## CONDITIONS FOR AQUACULTURE AND PLACING ON THE MARKET OF AQUACULTURE PRODUCTS

## PART 1-SITE LOCATION AND SELECTION

## A-General

- 1. Commercial aquaculture shall be subjected to an Environmental Impact Assessment by relevant authorities in accordance with the Environmental Management and Coordination Act, 1999.
- 2. The management of aquaculture facility before constructing, reconstructing or adapting a new technology shall submit to the Director-General or County Executive Committee Member for approval, a plan of the fishery enterprise and a list of activities to be carried out.
- 3. Aquaculture operations shall be sited away from potential sources of pollution and contamination.

## B-Biosecurity programme

The Biosecurity Programme shall incorporate:

- (a) Disease prevention,
- (b) Disease monitoring,
- (c) Management of disease outbreaks,

- (d) Cleaning and disinfection between production cycles and
- (e) General security precautions.

## C-Aquaculture site facilities

- 1. Aquaculture facilities shall be inspected prior to approval to ensure compliance with requirements for—
  - (a) Site location and selection.
  - (b) Production system design.
  - (c) Facilities and equipment.
  - (d) Fish feed storage.
  - (e) Pond conditioning, fertilizer and feeds.
  - (f) Veterinary medicines, harvesting and withdrawal period.
  - (g) Hygiene and fish handling procedures.
  - (h) Exclusion of animals and pest control.
- 2. All aquaculture facilities must provide reasonably accessible sanitary facilities for use by the people working in the facility.
- 3. Sanitary facilities shall be located away from the place where fish are held to ensure that there is no risk of contamination of fishponds with human waste.
- 4. The minimum number of facilities shall depend on the number of personnel at the site, according to the following table—

Table 2.

Number of employees (Counted according to gender)	Minimum number of toilets
01-09	01
10-24	02
25-49	03
50-100	05
More than 100	for every 30 persons add 01 more toilet

## C-Fish Feed storage

- 1. Fish feed shall be stored in a properly constructed well-ventilated facility, and protected from exposure to pests, vandals, heat, light and humidity.
- 2. Fish feeds shall be stored according to manufacturers' instructions and stock records maintained

#### PART 2 - POND CONDITIONING, FERTILIZER AND FEEDS

## A-Pond preparation

- 1. Aquaculture ponds shall be free of weeds, rubbish and debris before filling with water.
- 2. Ponds shall be conditioned with lime and given a rest 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 reconditioned with lime.

#### B - Fertilizer

The following materials shall not be used as fertilizer:

- 1. Human waste:
- 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 aquaculture system, and the animals are treated regularly with anthelminthic drugs 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 after proper treatment.
- 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 feeds shall be packaged in airtight and suitable weather resistant material with adequate tamper proof labels detailing composition, date of manufacture and expiry date, origin, contact address and batch numbers.
- 4. Fish feed treated with veterinary medical supplements (including hormones and antibiotics) shall be considered to be veterinary medicines and shall be approved for use under the terms of Veterinary Surgeons and Veterinary Paraprofessionals Act No. 29 of 2011 (The Veterinary Medicine Directorate Regulations, 2015.
- 5. Fish feeds shall be used before the expiry date and any remaining feed disposed of.

## PART 3-VETERINARY MEDICINES AND WITHDRAWAL PERIODS

A-Registration and Distribution of Drugs, pharmaceuticals, antibiotics or other chemicals

No Veterinary therapeutic-products and medicinal premixes for inclusion in fish feeds shall be used unless they are approved under the terms of Veterinary Surgeons and Veterinary Paraprofessionals Act, 2011 and the Veterinary Surgeons and Veterinary Paraprofessionals (The Veterinary Medicine Directorate) Regulations, 2015.

- B-Handling and Administration of Drugs, pharmaceuticals, antibiotics or other chemicals
- 1. Control of fish diseases in aquaculture facility using drugs shall be carried out only after diagnosis by a qualified fish disease specialist.
- 2. Veterinary medicines for treatment of fish diseases shall only be administered under the supervision of a qualified fish disease specialist.
- 3. Drugs, pharmaceuticals, antibiotics or other chemicals shall be used according to the manufacturer's instructions.
- 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 aquaculture facility, specifying date and nature of treatment, fish identity 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.
  - 6. Diseased fish shall be isolated for treatment and shall be easy to identify.
- 7. The health of fish shall be monitored regularly for symptoms of disease or parasitic/fungal infection.

## C-Harvesting and Withdrawal Period

- 1. Withdrawal period shall be observed before harvesting and placing the fish on the market.
- 2. Supplier instructions on administration of drugs, pharmaceuticals s or other chemicals in regard to Withdrawal periods under different conditions and specific fish species shall be recorded in the drug register at the aquaculture facility and observed.
- 3. The veterinary drug residue in the harvested fish shall not exceed maximum residue limit specified under the terms of the Veterinary Surgeons and Veterinary Paraprofessionals (Veterinary Medicine Directorate) Regulations, 2015.
- 4. When live fish that has been treated with veterinary medicine is sold for onward growth before the end of the withdrawal period, the seller must declare so in writing to the buyer.

## D-Requirements for marketing

- 1. If the fish from an aquaculture facility is placed on the market for human consumption, the producer shall disclose to the processor in writing with a copy to the Director-General/director responsible for fisheries at county level that either—
  - (a) no veterinary medicines have been used; or
  - (b) that the withdrawal period(s) has/have been observed.

- 2. Persons receiving fish and fish products from aquaculture for subsequent placing on the market shall undertake internal controls in their facility in accordance with Ninth Schedule to ensure that—
  - (a) they do not accept fish and fish products from aquaculture which are not accompanied by written declaration on treatment;
  - (b) where veterinary medicines have been used, withdrawal periods have been observed and maximum residue limits are not exceeded; and
  - (c) no prohibited substances are present.
- 3. When fish and fish products from aquaculture are delivered to a fishery enterprise, the supplier shall provide the following information□
  - (a) fish species;
  - (b) date of harvest;
  - (c) name of aquaculture facility/facilities of origin;
  - (d) name of the recipient fishery enterprise;
  - (a) quantity of fish harvested;
  - (b) fish consignment batch number;
  - (c) where applicable, treatment records.

## Part 4—Harvesting equipment and materials

- 1. Harvesting areas and methods within the aquaculture facility shall be designed and constructed for easy, fast and hygienically acceptable operations.
- 2. All equipment used for 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 constructed with non-corrosive material which is smooth and easy to clean, disinfect and maintain or be designed for single use only.
- 4. 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 an aquaculture facility shall maintain reasonable standards of personal hygiene and shall take all necessary precautions to prevent contamination of fish.
- 2. Any cut or wounds shall immediately be covered with suitable water-proof dressing.
- 3. Persons suffering from infectious diseases, helminthic parasite infection, have infected wounds, boils or other skin infections, or who are suffering from diarrhea, shall not be permitted to work in an aquaculture facility.
- 4. Personnel who work in an aquaculture facility shall, on their appointment and at six months 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 an aquaculture facility shall refrain from spitting or eating food, or relieving himself, except in areas designed for these purposes, which must be away from fish production areas.

#### B-First aid box

1. Each aquaculture facility shall possess a well-equipped first aid box.

#### C-Exclusion of animals

Except in an integrated aquaculture facility where food animals are deliberately introduced, domestic animals shall be excluded from the facility and areas adjacent to ponds.

## PART 6— CLEANING, DISINFECTION AND PEST CONTROL

## A-Cleaning and Disinfection

- 1. Areas around the ponds shall be kept clean.
- 2. A cleaning and disinfection schedule bearing the name of the responsible person shall be developed to ensure that all parts of the aquaculture facility and equipment therein are cleaned appropriately and regularly.
  - 3. The schedule shall be made available to the inspector at all times.
  - 4. Equipment and tools shall be dismantled for cleaning and disinfection.
- 5. The disinfectants used in an aquaculture facility shall be approved and applied in accordance to manufacturer's instructions.

## B-Pest Control

- 1. A pest control schedule shall be developed.
- 2. The schedule shall be made available to the inspector at all times.

## PART 7—RECORD KEEPING AND BATCH IDENTIFICATION

- 1. The following records 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 regimens;
- (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 aquaculture facility for placing on the market or for processing shall be allocated a batch number which traces it to the information in the records as described in paragraph 1 above.
- 4. Each batch of fish leaving the aquaculture facility for placing on the market shall be labelled as follows—
  - (a) approval number of the aquaculture facility;
  - (b) name and permanent, postal and physical address of the enterprise;
  - (c) date of harvesting;
  - (d) species; and
  - (e) batch number.
- 5. The management of the aquaculture facility shall ensure that effective procedures are in place to facilitate traceability in accordance with Tenth Schedule, and rapid recall of any batch 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 does not accumulate 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 ice are maintained; and
- (f) in fresh water aquaculture, the farm is free from trematode parasites.
- 2. The results of monitoring and of any corrective actions taken after monitoring shall be recorded.

Made on the 13th February, 2024.

SALIM MVURYA,

Cabinet Secretary, Ministry of Mining, Blue Economy and Maritime Affairs.