CONSOLIDATED TO 30 JUNE 2012

LAWS OF SEYCHELLES

Act 18 of 1996
Act 2 of 2003
Act 32 of 2010

CHAPTER 77A

EXPORT OF FISHERY PRODUCTS ACT

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1. This Act may be cited as the Export of Fishery Products Act, 1996 and shall come into operation on the 3rd February 1997.

2. In this Act -

"authorised officer" means an officer appointed under section 9;

"C.E.O" means the Chief Executive Offcier of the Seychelles Bureau of Standards established by the Seychelles Bureau of Standards Act;

"establishment" means any premises where fishery products intended for export are prepared, processed, chilled, frozen, packaged or stored but does not include any auction or wholesale market where fishery products are only displayed and sold by wholesale;

"factory vessel" means any vessel on which fishery products intended for export undergo any one or more of the following operations, namely, filleting, slicing, skinning, mincing or processing followed by packaging, chilling or freezing;

"fishery products"-

(a) means any cold blooded aquatic animal or part or product derived therefrom, intended as food for human consumption and includes any fish, crustacean, mollusc, echinoderm, holothurian or acquatic reptile but does not include live fish other than shellfish

(b) includes aquaculture feed, fish oil and fish meal;

"freezer vessel" Means any vessel on which freesing of fishery products intended for export is carried out after preparatory work such as bleeding, heading, gutting and removal of fins and where necessary wrapping and packaging;

"Minister" means the Minister charged with the portfolio responsibility for Industry.

3. (1) A person shall not use, operate or be in charge of an establishment or a factory vessel except under and in accordance with a permit granted under this Act by the C.E.O.

(2) A permit granted under this Act shall be in such Form as the C.E.O may provide and may be granted -

(a) for such period;

(b) in respect of such fishery products; and

(c) subject to such conditions,

as may be specified in the permit.

4. (1) An application for a permit required under this Act shall be made to the C.E.O and shall be accompanied by the prescribed fee.

(2) Where an application for a permit is refused by the C.E.O, the C.E.O shall refund the fee to the applicant.

5. (1) Before granting a permit under this Act the applicant shall satisfy the C.E.O that the establishment or the factory vessel in respect of which the application is made conforms to the general operating and management requirements as may be prescribed relating to -

(a) the design, layout and construction of the establishment or factory vessel;

(b) the design and construction of any equipment used therein;

(c) the conduct of any person entering the area of the establishment or factory vessel where fishery products are handled; and

(d) the design and application of appropriate systems for controlling product quality.

(2) In prescribing the general operating and management requirements, the Minister shall have regard to -

(a) the Fisheries Act;

(b) the Food Act;

(c) Seychelles Bureau of Standards Act; and

(d) the Licences Act,

as may be relevant to fishery products.

6. Where it is expedient for ensuring the quality of fishery products intended for export, the C.E.O may vary any conditions of a permit granted under this Act.

7. The C.E.O may, where the C.E.O is satisfied that a holder of a permit granted under this Act -

(a) has contravened any provisions of the Food Act or any regulations made thereunder in relation to fishery products intended for export;

(b) has contravened any conditions of the permit; or

(c) has failed to maintain the quality of the fisheries products intended for export,

suspend or revoke the permit.

7A. The C.E.O shall cause any scientific test or investigation required for the purposes of this Act to be carried out by the Seychelles Bureau of Standards.

8. (1) Any person who is aggrieved by a decision of the C.E.O -

(a) to refuse the grant of a permit under this Act;

(b) to vary the conditions of a permit under section 6; or

(c) to suspend or revoke a permit under section 7,

may, within 14 days after the decision is communicated to the holder, appeal to the Minister against the decision.

(2) The Minister may on an appeal under subsection (1), affirm, vary or revoke the decision.

9A. (1) There shall be established, for the purposes of this Act, a unit within the Seychelles Bureau of Standards to be known as the Fish Inspection and Quality Control Unit.

(2) The Unit shall aim to facilitate through inspection and certification of fishery products, internal and international trade in such products.

(3) The C.E.O. shall appoint as the manager of the Unit a competent person experienced in the inspection and quality assurance of fishery products and ensuring compliance with relevant international standards.

(4) The C.E.O. may appoint one or more officers of the Unit or such other persons as the C.E.O. thinks fit to be authorised officers and issue toe ach authorised officer a certificate of authority to act as such.

10. (1) An authorised officer may -

(a) at any reasonable hour or whenever work is in progress in any establishment or factory vessel -

(i) enter and search the establishment or factory vessel;

(ii) examine any fishery product therein or any other things which the officer has reasonable grounds to believe is used or capable of being used in the preparation of a fishery product;

(iii) take samples of the fishery product or other thing examined under subparagraph (ii),

to ensure quality of the fishery product and compliance with this Act or any permit issued under this Act, or the Food Act;

(b) stop, search or detain any vehicle, vessel or aircaft in which the officer has reasonable grounds to believe is conveying any fishery product and to examine and take samples thereof;

(c) open and examine any receptable or package which the officer has reasonable grounds to believe contains any fishery product, examine and take samples thereof;

(d) seize and detain any fishery product in relation to which the officer has reasonable grounds to believe that this Act or any permit issued under this Act or the Food Act has been contravened;

(e) call for any books, documents or other records which the officer has reasonable grounds to believe contain any information relevant to the enforcement of the Act in respect of any fishery product, make copies thereof or take extracts therefrom;

(f) issue health certificates certifying that fishery products are fit for export;

(g) exercise any other functions assigned to the officer by the C.E.O.

(2) Where an authorised officer is satisfied that any fishery product seized under subsection (1)(d) has not contravened this Act, any permit issued under this Act or the Food Act, the officer shall forthwith release the products to its owner or the person from whose possession it was seized.

(3) Where an authorised officer is satisfied that any fishery product seized under subsection (1)(d) has contravened this Act, the permit granted under this Act, or the Food Act, the product may -

(a) with the consent of the owner or the person from whose possession it was seized, be destroyed or otherwise disposed of as the authorised officer may direct;

(b) where it is not possible to obtain the consent required under paragraph (a), produce, with notice to the owner or the person from whose possession the product was seized, the product before a magistrate's court, and the court may, after giving the owner or the other person an opportunity to show cause -

(i) release the fishery product to the owner or other person where the court is satisfied that the product has not contravened this Act, a permit granted under this Act or the Food Act;

(ii) order the destruction or disposal of the fishery products where the court is satisfied that the product has contravened this Act, a permit granted under this Act or the Food Act.

(4) An authorised officer shall, in the exercise of the powers under subsection (1), produce if requested by any person affected by such exercise, the certificate of authority issued to the officer under section 9.

10A. Any person who, in the performance of any official function under this Act, obtains confidential information relating to the activities of another person shall not disclose such information except-

(a) to any person who requires it for the performance of that person's functions udner this Act;

(b) when directed by any court of law;

(c) for the purpose of a criminal investigation; or

(d) on the authorisation of the Minister or the C.E.O.

11. (1) The owner, occupier, or the person in charge of any establishment or the master of a factory vessel or any employee of such establishment or factory vessel or any other person who, if requested by an authorised officer in the exercise of the officer's functions under section (10) to give any information or assistance -

(a) fails, without reasonable excuse, to give the information or assistance so requested;

(b) knowingly makes any false or untrue statement,

is guilty of an offence.

(2) Any person who wilfully obstructs an authorised officer in the exercise of the officer's functions under section 10 is guilty of an offence.

(3) Any person who without the written permission of an authorised officer removes, alters or interferes in any way with any fishery product seized under this Act is guilty of an offence.

(4) A holder of a permit granted under this Act who exports or attempts to export any fishery product without a health certificate issued in respect of that product is guilty of an offence.

11A. All officers and other employees of the Fish Inspection and Quality Control Unit shall be deemed to be employed in the public service for the purposes of sections 91 to 96 of the Penal Code.

12. (1) Any person found guilty of an offence under this Act is liable on conviction -

(a) in the case of the first offence, to a fine of SCR15,000 and imprisonment for 12 months;

(b) in the case of any subsequent offence, to a fine of SCR150,000 and imprisonment for 24 months.

(2) Where any person is convicted of an offence under this Act, the court may, in addition to any other penalty -

(a) order that the fishery product by means of which or in relation to which the offence was committed be forfeited and upon such order being made the fishery product may be disposed of as the court may direct;

(b) order that a permit granted under this Act be suspended or revoked as the court may direct.

13. The Minister may make regulations for carrying into effect the purposes and provisions of the Act and without prejudice to the generality of the foregoing may -

(a) prescribe the general operating and management requirements of establishments and factory vessels;

(b) prescribe the fees for the grant of permits,

(c) prescribe anything required or necessary to be specified under this Act.

14. The provision of this Act shall be in addition to and not in derogation of the provision of any other written law relating to fishery products.

15. A person performing any function under this Act shall not be liable in respect of any loss arising from the performance of such function in good faith and without negligence.

CHAPTER 77A

SI. 10 of 2006

EXPORT OF FISHERY PRODUCTS ACT

SUBSIDIARY LEGISLATION

Export of Fishery Products (Sanitary) Regulations

[20th March 2006]

1. These Regulations may be cited as the Export of Fishery Products (Sanitary) Regulations,

2. All approved fish exporting establishments, factory and freezer vessels and other fishing vessels and personnel engaged in the business of export of fish or fishery products shall-

(a) abide by all operational and managerial requirements relating to that business as prescribed by the Codex Alimentarius of the Food and Agriculture Organisation and the World Health Organisation; and

(b) comply with any additional sanitary requirements prescribed by the importing country or community which are not covered by the standards set by the said Codex Alimentarius.

Export of Fishery Products (Sanitary) Regulations, 2010

SI. 82 of 2010
SI. 55 of 2011

[6th December 2010]

ARRANGEMENT OF REGULATIONS

Regulations

Schedule 13: Requirement for traceability and recall procedures

Schedule 14: Requirements for potable water

Export of Fishery Products (Sanitary) Regulations, 2010

1. These Regulations may be cited as the Export of Fishery Products (Sanitary) Regulations, 2010.

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

3. In these Regulations —

"batch" means a quantity of fish or fishery products of the same species and collected from the same production area during the same fishing or harvesting operation;

"bivalve molluscs" means filter feeding lamellibranch mollusks;

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

"clean sea water" means sea water or brackish water which is free from microbiological contamination and toxic or objectionable substances occurring naturally or as a result of discharge into the environment;

"competent authority" means the Fish Inspection and Quality Control Unit of the Seychelles Bureau of Standards;

"disinfection" means the application of hygienically satisfactory chemical or physical agents and

processes to clean surfaces with the aim of eliminating micro-organisms;

"export" means commercial trade with a person outside the territory of Seychelles;

"fishery enterprise" means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of fishery products for human consumption;

"fish landing site" means place at which fishing or transport vessels discharge a catch of fish to land;

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

"hazard" means biological, chemical or physical agent in, or condition of, fishery products or feed with the potential to cause an adverse effect on human health;

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

"marine biotoxins" mean poisonous substances accumulated by fish and bivalve molluscs which feed on plankton containing toxin;

"means of transport" means the parts set aside for fish in road vehicles, trains and aircraft, holds of vessels and containers for transport of fish by land, sea or air, and includes means of transport used for conveying products to their destination market;

"monitoring" means conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with the requirements of these Regulations;

"official control" means any form of control that the competent authority performs for the verification of compliance with the Act and regulations made thereunder;

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

"placing on the market" means the holding of food or feed for the purpose of export from the territory of Seychelles, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer from the territory of Seychelles;

"potable water" means water which complies with the specifications set out in Schedule 14 of these Regulations;

"processed products" means any chilled or frozen fishery products which have undergone a chemical or physical process of heating, smoking, salting, dehydration or marinating or a combination of processes, whether or not mixed with other foodstuffs;

"preservation" means the process whereby products are packaged in hermetically sealed containers and subjected to heat treatment to the extent that any micro-organisms that might proliferate therein are destroyed or inactivated, irrespective of the temperature at which the product is to be stored;

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

"the Act" means the Export of Fisheries Product Act of 1996;

"traceability" means the ability to trace and follow a fishery product, or other substance intended, or expected to be incorporated into a fishery product, through all stages of production, processing and distribution;

"viscera" means the internal organs of fish or fishery products and includes the head of crustaceans.

4. (1) No person shall export fishery products for human consumption from Seychelles unless they are prepared, processed or packed in an establishment, a freezer vessel, or a factory vessel subject to a permit granted in accordance with section 3 of the Act.

(2) Every establishment or vessel requiring a permit under the Act shall be subject to conditions regarding the general operating and management requirements prescribed in the permit.

(3) The territory to which the establishment or vessel will export shall be taken into account in determining the conditions prescribed in the permit.

(4) Unless otherwise specified in the permit, for each activity in Column 1 of Table 1 in Schedule 1, the conditions in Column 3 shall be prescribed in accordance with the territories defined in Column 2 of Table 1, and Table 2 of Schedule 1.

(5) Where the requirements for conditions to be applied to the award of permit are not defined by Schedule 1, the relevant Seychelles legislation shall apply.

(6) No person shall export fishery products for human consumption from Seychelles unless they are landed at a landing site designated by the Competent Authority as meeting the requirements of these Regulations.

(7) The Competent Authority shall publish from time to time as may be required the list of landing sites designated under Paragraph (6) in the Official Gazette.

5. (1) Operators of establishments and freezer and factory vessels subject to these Regulations shall ensure that fishery products under their control satisfy the requirements of these Regulations at all stages of production, processing and distribution, and shall verify that such requirements are met.

(2) If an operator of an establishments and freezer and factory vessels subject to these Regulations considers or has reason to believe that a fishery product which it has imported, produced, processed, manufactured or distributed is not in compliance with the requirements of these Regulations or may be injurious to human health, where the fishery product has left the immediate control of the operator it shall immediately initiate procedures to withdraw the food in question from the market, and shall inform the Competent Authority thereof.

(3) Operators of establishments and freezer and factory vessels subject to these Regulations shall collaborate with the Competent Authority on actions taken to investigate, avoid or reduce risks posed by a food which they supply or have supplied.

6. (1) The retention on board by a freezer or factory vessel, or the possession by an establishment of the following fishery products is hereby prohibited —

(a) fish of the families *Tetradontidae, Molidae. Diodontidae, Canthigasteridae, Gempylidae;*

(b) fishery products commonly containing biotoxins of marine origin, such as *ciguatera* or other toxins dangerous to human health;

(c) bivalve and gastropod molluscs, tunicates, and echinoderms harvested from areas in which such animals may become contaminated with marine biotoxins, unless production and harvest is subject to a monitoring plan approved by the Competent Authority.

7. The Chief Executive Officer of the Seychelles Bureau of Standard shall implement the Chief Executive Officer's responsibilities under the Act through the Competent Authority.

8. (1) Measures applied by the Competent Authority under these Regulation shall be applied in a non-discriminatory manner and shall be based on an assessment of the food safety risks except where this is not appropriate to the circumstances or the nature of the measure and these measures shall be effective, equitable and proportionate to the risk.

(2) Assessment of the food safety risks shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

(3) Where there are reasonable grounds to suspect that a fishery product or feed subject to these Regulations may present a risk to human health, then, depending on the nature, seriousness and extent of that risk, the Competent Authority shall take steps to identify the fishery product concerned and to implement appropriate measures to prevent, reduce or eliminate that risk.

9. (1) The Competent Authority shall undertake official control and monitoring of food safety conditions in establishments and vessels to which section 3 of the Act applies, and in respect of imports of fishery products for reexport in order to establish whether the requirements laid down in these Regulation are complied with.

(2) The official controls shall at a minimum include the checks set out in regulation 10;

(3) Official control of fishery products and feed shall be carried out —

(a) regularly and according to priorities determined by risk assessment;

(b) where non-compliance is suspected;

(c) when required for the purpose of issue of permits and certificates.

(4) Official control shall be carried out using means proportionate to the end to be attained.

(5) Official control shall cover all stages of production, manufacture, processing, storage, transport, distribution, related to export of fishery products from Seychelles, including imported raw materials where appropriate.

10. (1) Official control of the food safety conditions shall comprise one or more of the following checks and where necessary followed by any consequential actions —

(a) periodic inspection of vessels, landing sites, fish processing establishments and means of transport including transport vessels and other vehicles used to consign fishery products to export markets, and monitoring of compliance with permit conditions;

(b) examination of any control systems that fishery enterprise operators have put in place and the results obtained;

(c) inspection of —

(i) raw materials, ingredients, processing aids and other products used for the preparation and production of fishery products, their sources (including fishing vessels and landing sites) and the conditions under which they are produced;

(ii) semi-finished and finished products;

(iii) materials and articles intended to come into contact with fishery products;

(iv) cleaning and maintenance products and processes;

(v) labelling, presentation and advertising;

(d) assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), and HACCP requirements as set out in the Schedules;

(e) examination of written material and other records which may be relevant to the assessment of compliance with the Act;

(f) interviews with fishery enterprise operators in the supply chain and with their staff;

(g) the reading of values recorded by measuring instruments;

(h) controls carried out with the Competent Authority's own instruments to verify measurements taken by the operator;

(i) any other activity required to ensure that the objectives of the Act and these Regulations are met;

(j) certifying on request in writing the health conditions relating to any batch of fishery products.

(2) Whenever practicable, inspections for the purposes of official control shall be carried out without prior warning.

(3) Inspection of fishery products shall include an examination of the following characteristics in a sample of fishery products at each stage of production —

(a) organoleptic characteristics;

(b) freshness indicators in cases of doubt;

(c) freshness of fishery products;

(d) level of histamine in susceptible species;

(e) level of residues and contaminants;

(f) level of permitted additives; (e) examination of written material and other records which may be relevant to the assessment of compliance with the Act;

(f) interviews with fishery enterprise operators in the supply chain and with their staff;

(g) the reading of values recorded by measuring instruments;

(h) controls carried out with the Competent Authority's own instruments to verify measurements taken by the operator;

(i) any other activity required to ensure that the objectives of the Act and these Regulations are met;

(j) certifying on request in writing the health conditions relating to any batch of fishery products.

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(b) freshness indicators in cases of doubt;

(c) freshness of fishery products;

(d) level of histamine in susceptible species;

(e) level of residues and contaminants;

(f) level of permitted additives;

(g) microbiological contamination;

(h) visual presence of parasites;

(i) presence of poisonous fish species or fishery products.

11. (1) The Competent Authority shall undertake official control of food safety conditions in relation to fishery products which are imported with the intention of processing in Seychelles for subsequent re-export.

(2) The official controls described in paragraph (1) above may include checks on the—

(a) import conditions including the territory of origin;

(b) conditions aboard freezer or factory vessels flying the flag of another country, to confirm compliance with Schedules 3, 4 and 5;

(c) compliance with the food safety conditions described in Schedule 10;

(d) health certification issued by the Competent Authority of the country of origin.

(3) In considering a request for certification for export of fishery products referred to in subsection (1) above, to a territory which applies restrictions on the country of origin of fishery products, the Competent Authority should —

(a) be satisfied that the provisions of Schedule 13 are applied;

(b) confirm compliance with any such restrictions regarding country of origin that may be in place at the time.

12. (1) The Competent Authority shall draw up reports on the inspections for official controls that it has carried out.

(2) These reports shall include a description of the purpose of the official controls, the control methods applied, the results of the official controls and where appropriate the action that the fishery enterprise operator subject to official control should take.

(3) The Competent Authority shall provide the operator concerned with a copy of the report referred to in subregulation (2).

(4) Where the inspection report identifies a case of non-compliance and any corrective actions required they shall be specified in the report, along with a time limit for their implementation.

13. (1) Fishery products are to be considered unfit for human consumption if —

(a) organoleptic, chemical, physical or microbiological checks or checks for parasites have shown that they are not compliant with standards set out in the Schedules;

(b) they contain in their edible parts ontaminants or residues in excess of the limits laid down in the relevant Schedules and other applicable legislation, or at levels where the calculated dietary intake would exceed the acceptable daily or weekly intake for humans;

(c) they derive from —

(i) prohibited fish species described in Regulation 6;

(ii) fishery products not complying with Schedule 10 or;

(d) the Competent Authority considers that they may constitute a risk to public or for any other reason are considered to be not suitable for human consumption.

(2) Possession for the purpose of sale of fishery products which are unfit for human consumption shall be considered to be an offence under the Food Act.

(3) Unfit fishery products may be subject to seizure under the powers granted to authorised officers pursuant to section 10 of the Export of Fishery Products Act of 1996.

14. (1) The Competent Authority shall prepare an annual programme of official control activities, specifying:

(a) the number and type of inspections to be carried out;

(b) the criteria applied in drawing up the programme.

(2) The Competent Authority shall prepare an annual report on official control activities, specifying —

(a) the number and type of inspections carried out in relation to the programme;

(b) the number and type of infringements identified;

(c) actions taken in the case of non-compliance.

(3) The annual programme and report on official control of safety of fishery products and feed will be subject to the approval of the Minister.

(4) The annual inspection programme and the annual report shall be published by the Competent Authority.

15. (1) Samples collected under these Regulations for analysis for the purpose of official control shall be analysed by the official testing laboratory nominated by the Competent Authority.

(2) Samples collected under these Regulations for analysis for the purpose of official control shall be selected and transmitted to the official laboratory by an officer authorised by the Competent Authority.

(3) The costs of the analyses will be borne by the Competent Authority.

16. (1) The testing laboratories nominated for the purposes of analysis in support of official control shall comply with the *General Requirements for the Competence of Calibration and Testing Laboratories* laid down in ISO Standard 17025 in respect of the tests to be conducted.

(2) The accreditation and assessment of testing laboratories referred to in this Regulation may relate to individual tests or groups of tests.

(3) The testing laboratories nominated for the purposes of analysis in support of official control shall participate in appropriate proficiency testing schemes.

17. (1) For each test required for the purposes of official control of fishery products or feed the Competent Authority may nominate one laboratory as a reference laboratory for that test.

(2) Reference laboratories nominated under this Regulation shall be responsible for —

(a) organising and participating in comparative tests of standardised samples, on a national and international basis, with a view to monitoring the proficiency of official establishments;

(b) supporting all testing laboratories maintain internal systems of quality assurance for that test method (to include method validation, record keeping, reagent storage, safety, and routine calibration of equipment);

(c) disseminating information from the reference laboratories in other countries to the Competent Authority and other laboratories carrying out the testing of fishery products and feed, whether or not for the purposes of official control.

(3) The reference laboratory shall be nominated by the Competent Authority by notice in the Official Gazette.

(4) Reference laboratories shall be paid by the Competent Authority for the services which they deliver under the terms of this Regulation.

18. (1) In relation to any defined batch of fishery products or aquaculture feed the Competent Authority may issue a certificate attesting to the —

(a) conditions in which that batch was produced, processed, stored, packed, transported or placed on the market;

(b) compliance of that batch with any standard;

(c) fitness of that batch for any particular purpose.

(2) Applications for the issue of a certificate shall be made on a standard form to be provided by the Competent Authority.

(3) In relation to certification of direct exports from a freezer or factory vessel for which the Competent Authority has no jurisdiction under the Act to determine the facts attested by the certificate, the Competent Authority may undertake one or more of the following measures to determine the facts to be attested as a condition of issue of the certificate —

(a) inspect the vessel;

(b) inspect the consignment of fishery products, including taking samples for laboratory testing;

(c) consult with the Competent Authority of the flag State regarding the food safety conditions onboard the vessel and its approval status.

19. (1) The Competent Authority shall design and cause to be implemented an annual monitoring programme with the objective of assessing the nature and extent of the food safety hazards associated with fishery products produced in Seychelles.

(2) The monitoring programmes described in subparagraph (1) will take into account the risks of different food safety hazards in fishery products and the criteria described in Schedule 10 of these Regulations, and shall include the following parameters —

(a) heavy metals;

(b) residues of veterinary medicines whose use in fish culture is permitted under the terms of the Pharmacy Act;

(c) residues of substances whose use in fish culture is banned under the terms of the Animal Disease and Imports Act of 1981 and the Pharmacy Act;

(d) residues of organochlorine and organophosphate contaminants of the environment;

(e) residues of pesticides and organic pollutants;

(f) visible parasites in fish;

(g) other hazards in fishery products which are identified as relevant to food safety conditions of exported fishery products.

(4) The monitoring programmes will specify the sampling plan and the methods of analysis to be used.

(5) The Competent Authority shall prepare an annual report describing the monitoring programme and the results, which will be subject to the approval of the Minister and published by the Competent Authority.

20. (1) Authorised officers acting in the course of their duties shall at all times act with integrity, transparency and confidentiality.

(2) Information relating to any individual business which is obtained by an officer during the course of official controls or other activities under these Regulations shall not be disclosed without the consent in writing of the person carrying on the business, except —

(a) in accordance with directions of the Minister, so far as may be necessary for the purposes of these Regulations; or

(b) for the purposes of any proceedings for an offence against the law or any report of those proceedings.

21. The Export of Fisheries Products (Sanitary) Regulations 2006 are hereby repealed.

SCHEDULE 1

Reg. 4

CONDITIONS TO BE APPLIED TO THE AWARD OF PERMITS

FOR ESTABLISHMENTS AND VESSELS

Table 1: Conditions to be applied

Activity	**Approval Conditions**
Factory vessels	Schedule 2, 3, 4, 10, 11, 12
Freezer vessels	Schedule 2, 3, 10, 11,12
Fishing vessels	Schedule 2
Landing stations, auctions and wholesale markets	Schedule 5
Vehicles and means of transport	Schedule 6
Processing establishments	Schedules 7, 8, 9, 10, 11, 12, 13, 14

SCHEDULE 2

HEALTH CONDITIONS FOR ALL FISHING VESSELS

I. STRUCTURAL AND EQUIPMENT REQUIREMENTS

A. Requirements for all vessels —

1. All vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, must comply with the structural and equipment requirements laid down in this Schedule.

2. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances.

3. Vessels should be equipped with suitable holds, tanks or containers for the preservation of fishery products on ice or under refrigerated conditions.

4. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.

5. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.

6. When vessels have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water supply.

B. Requirements for vessels designed and equipped to preserve fresh fishery products for more than 24 hours —

1. Holds in which fishery products are stored must be separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the fishery products.

2. Holds tanks, or containers used for the storage of fishery products must ensure their preservation under satisfactory conditions of hygiene and, where necessary, ensure that melt water does not remain in contact with the products, notwithstanding that storage of fish in an ice-water slurry is an acceptable practice.

3. Holds, tanks or containers used for the storage of fishery products comprising fish species which are susceptible to the production of histamine should be equipped with a device for continuous automatic recording of the temperature inside each hold, tank or container.

II. HYGIENE REQUIREMENTS

1. When in use, the parts of vessels or containers set aside for the storage of fishery products must be kept clean and maintained in4. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.

2. As soon as possible after they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source of heat. When they are washed, the water used must be either potable water or, where appropriate, clean seawater.

3. Fishery products must be handled and stored so as to prevent bruising. Handlers may use spiked instruments to move large fish or fish which might injure them, provided that the flesh of the products suffers no damage.

4. Fishery products comprising fish species which are susceptible to the production of histamine, must be chilled immediately after harvest. The mix of fish and clean seawater must reach a temperature of not more than 3°C six after hours after loading and not more than 0°C after 16 hours and allow the monitoring and where necessary, recording of temperatures.

5. Fishery products other than fishery products comprising fish species which are susceptible to the production of histamine, and other than those kept alive, must undergo chilling as soon as possible after harvest. However, when chilling is not possible, fishery products must be landed as soon as possible.

6. Ice used to chill fishery products must be made from potable water or clean seawater.

7. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after harvest, and the products must be washed immediately and thoroughly with potable water or clean seawater.

8. If not to be used for human consumption, the viscera must be removed as soon as possible, and discarded or kept apart from products intended for human consumption.

9. Livers, roes and other viscera intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice, or be frozen.

10. Where vessels undertake fishing voyages of duration greater than 24 hours, they shall have a programme for the systematic extermination of rodents, insects and any other pests.

SCHEDULE 3

HEALTH CONDITIONS FOR FREEZER VESSELS

1. Freezer vessels and factory vessels must meet the requirements for vessels designed and equipped to preserve fishery products for more than 24 hours laid down in Schedule 1.

2. Freezer vessels must have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -18ºC.

3. In the case of brine freezing of whole fish intended for canning, the vessel must have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than - 9ºC. The brine must not be a source of contamination for the fish.

4. Freezer vessels and factory vessels must have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18ºC. Storage holds must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor shall be located in the area furthest away from the cold source, i.e. where the temperature in the storage room is the highest.

5. Rodents, insects and any other pests shall be systematically exterminated in the vessel.

6. Vessels shall apply a systematic hygiene and sanitation plan which covers all areas where fish is handled, and equipment, tables, fish boxes, knives and other items with which fish comes into contact. A copy of the plan, and evidence of its implementation, shall be available to inspectors during inspections.

SCHEDULE 4

HEALTH CONDITIONS FOR FACTORY VESSELS

1. Factory vessels should comply with the requirements of schedule 3.

2. Factory vessels must have at least —

(a) a receiving area reserved for taking fishery products on board, designed to allow each successive catch to be separated. This area must be easy to clean and designed so as to protect the products from the sun or the elements and from any source of contamination;

(b) a hygienic system for conveying fishery products from the receiving area to the work area;

(c) work areas that are large enough for the hygienic preparation and processing of fishery products, easy to clean and disinfect and designed and arranged in such a way as to prevent any contamination of the products;

(d) storage areas for the finished products that are large enough and designed so that they are easy to clean. If a waste-processing unit operates on board, a separate hold must be designated for the storage of by products;

(e) a place for storing packaging materials that is separate from the product preparation and processing areas;

(f) special equipment for disposing waste or fishery products that are unfit for human consumption directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to its sanitation, separate areas must be allocated for that purpose;

(g) a water intake situated in a position that avoids contamination of the water supply; and

(h) hand-washing equipment for use by the staff engaged in handling exposed fishery products with taps designed to prevent the spread of contamination.

3. Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in Schedule 3.

SCHEDULE 5

GENERAL HEALTH CONDITIONS FOR FISH LANDING SITES

Design and layout

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

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

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

(a) Protection against the entry of animals and unauthorized personnel to areas where fishery products are handled, held or stored;

(b) Measures to prevent the fishery products from being exposed to direct sunlight during periods when they are displayed for sale;

(c) A waterproof non-slip flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of water;

(d) If work is to be conducted at night, adequate artificial lighting;

(e) an adequate number of wash hand basins and an adequate supply of soap, single use towels or appliances for drying the hands;

(f) facilities for cleaning and disinfecting tools, equipment and fittings;

(g) facilities for the cleaning and disinfection of transport vehicles including vessels, and fishing vessels.

4. Equipment shall be made of corrosion-resistant materials which are easy to clean and disinfect. This shall include *inter alia* weighing scales, worktables, fish containers, and knives.

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

6. Facilities shall be provided to ensure adequate supplies of potable water or alternatively of clean sea water treated by an appropriate system, under pressure and in sufficient quantities for processing and hygiene operations.

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

8. The establishment shall have an adequate number of flush toilets. There shall be provided an adequate number of wash basins, and an adequate supply of soap, single use towels or appliances for drying the hands.

General conditions of hygiene

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

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

3. The landing site shall apply a systematic hygiene and sanitation plan which covers all areas where fish is handled, and equipment, tables, fish boxes, knives and other items with which fish comes into contact. A copy of the plan, and evidence of its implementation shall be available to inspectors during inspections.

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

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

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

7. A high standard of cleanliness is required of staff working in the area of the fish landing site, auction or wholesale market areas. In particular —

    (a) staff assigned to the handling of fishery products shall wash their hands at least each time work is resumed;

    (b) staff assigned to the handling of fishery products shall refrain from wearing jewellery, nail polish and other personal items which may contaminate the product;

    (c) wounds to the hands shall be covered by a water proof dressing;

    (d) smoking, spitting, eating and drinking in the area of the fish landing site, auction or wholesale market of fishery products shall be prohibited;

8. The operator of the fish landing site, auction or wholesale market shall —

    (a) take all the necessary measures to prevent persons liable to contaminate fishery products from handling such products;

    (b) nominate a person to be responsible for ensuring that the condition set down in this schedule are applied during working hours3. The landing site shall apply a systematic hygiene and sanitation plan which covers all areas where fish is handled, and equipment, tables, fish boxes, knives and other items with which fish comes into contact. A copy of the plan, and evidence of its implementation shall be available to inspectors during inspections.

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

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

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

7. A high standard of cleanliness is required of staff working in the area of the fish landing site, auction or wholesale market areas. In particular —

    (a) staff assigned to the handling of fishery products shall wash their hands at least each time work is resumed;

(b) staff assigned to the handling of fishery products shall refrain from wearing jewellery, nail polish and other personal items which may contaminate the product;

(c) wounds to the hands shall be covered by a water proof dressing;

(d) smoking, spitting, eating and drinking in the area of the fish landing site, auction or wholesale market of fishery products shall be prohibited;

8. The operator of the fish landing site, auction or wholesale market shall —

(a) take all the necessary measures to prevent persons liable to contaminate fishery products from handling such products;

(b) nominate a person to be responsible for ensuring that the condition set down in this schedule are applied during working hours 9. When chilling is not possible on board the vessel, fresh fishery products, other than those kept alive, must undergo chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice.

SCHEDULE 6

REQUIREMENTS FOR STORAGE AND MEANS OF TRANSPORT

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

(a) fresh or thawed fishery products and cooked and chilled crustacean and molluscan shellfish products shall be kept at the temperature of melting ice;

(b) frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned foods, shall be kept at an even temperature of 18°C or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than 3°C, during transport;

(c) processed products shall be kept at the temperature specified by the manufacturer.

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

3. Means of transport used to transport fishery products should never be used for the transport of products other than food fit for human consumption. Products may not be stored or transported together with other fishery products or with any other goods which may contaminate them or affect their quality, unless they are packaged in such a way as to provide adequate protection.

4. Vehicles and vessels and other means of transport used for fishery products shall be constructed and equipped in such a way that the prescribed temperatures can be maintained through the period of transport. If ice is used to chill the products, adequate drainage shall

be provided in order to ensure that water from melted ice does not stay in contact with the products.

5. The inside surfaces of the means of transport shall be smooth and easy to clean and disinfect, and shall be kept in clean condition so as to avoid contaminating the product during transport.

SCHEDULE 7

GENERAL HEALTH CONDITIONS FOR FISH PROCESSING ESTABLISHMENTS

General conditions relating to premises and equipment

1. Each establishment shall provide working areas which are of sufficient size for work to be carried our 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 laid down in such a way as to facilitate the 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) an adequate ventilation and, where necessary proper vapour extraction facilities; airflow from a contaminated area to a clean area is to be avoided and ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible;

   (g) an adequate number of wash hand basins with taps that are not hand-operable and an adequate supply of soap, single use towels or appliances for drying the hands;

   (h) facilities for cleaning and disinfecting tools, equipment and fittings;

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

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

5. Special water-tight, corrosion-resistant containers shall be provided for fishery products not intended for human consumption. They shall be easily distinguishable from containers used

for fishery products for human consumption. Separate premises shall be provided for the storage of such containers if they are not emptied at the end of each working day;

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

7. Where a non-potable water supply is provided for the production of steam, fire fighting or the cooling of refrigeration equipment, the pipes installed for the purpose should 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 seawater.

8. There shall be provided an adequate hygienic waste water disposal system. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where fishery products likely to present a high risk to the final consumer are handled.

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

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

11. If the volume of products treated requires their regular or permanent presence, there shall be provided an adequately equipped lockable room for the exclusive use of the authorized fish inspectors.

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

13. Establishments keeping live animals such as crustaceans and fish shall be provided with water supply of a quality such that no harmful organisms or substances are transferred to the animals.

General conditions of hygiene

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

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

3. The establishment shall apply a systematic hygiene and sanitation plan which covers all areas where fish is handled, and equipment, tables, fish boxes, knives and other items with which fish comes into contact. A copy of the plan, and evidence of its implementation shall be available to inspectors.

4. Equipment used in the processing areas shall be used only for work on fishery products.

5. Potable water or clean seawater shall be used for cleaning purposes.

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

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

Staff hygiene and training

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

   (a) Staff shall wear suitable working clothes, and headgear which completely covers the hair;

   (b) Staff assigned to the handling and preparation of fishery products shall wash their hands at least each time work is resumed;

   (c) Wounds to the hands shall be covered by a water proof dressing;

   (d) Smoking, spitting, eating and drinking in work and storage premises of fishery products shall be prohibited.

2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle fishery products or enter any area where fishery products are handled in any capacity if there is any likelihood od direct or indirect contamination. Any person so affected and employed in a establishment and who is likely to come into contact with fishery products is to report immediately the illness or symptons, and if possible their causes, to the fishery enterprise operator.

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

4. Operators of fish processing establishments are to ensure —

   (a) that persons handling fishery products undergo a medical examination and posses a certificate of fitness in accordance with Regulation 4 of the Food Act (General Hygiene) Regulations of 1992;

   (b) that persons handling fishery products are supervised and instructed and/or trained in food hugiene matters commensurate with their work activity;

SCHEDULE 8

SPECIAL CONDITIONS FOR HANDLING FISHERY PRODUCTS ON SHORE

Conditions for fresh products

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

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

3. Preparation of products on shore shall be carried out in hygienic conditions, and the products shall be washed thoroughly with potable drinking water or clean seawater immediately after such operations. Clean seawater used for washing fishery products may only be used to wash whole fish, fish from which viscera have been removed, and whole live bivalve molluscs, echinoderms, tunicates and marine gastropods.

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

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

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

7. The containers, receptacles and/or premises set aside for waste shall be always thoroughly cleaned and disinfected after use.

Conditions for frozen products

1. Except as provided in Point 2 below, all establishments producing frozen fishery products shall have:

   (a) refrigeration equipment sufficiently powerful to achieve a rapid reduction in the temperature to -18ºC or below;

(b) refrigeration equipment sufficiently powerful to keep products in the storage rooms at -18ºC or below irrespective of the ambient temperature.

2. Whole fish frozen in brine shall be stored at temperatures not higher than -9°C.

3. Storage rooms for frozen fish shall have a temperature recording device in a place where it can easily be read. The temperature sensor shall be located in the area where the temperature in the storage room is the highest.

4. Temperature charts shall be available for inspection by the Competent Authority during the period in which the products are stored.

Conditions for thawed products

1. Where establishments carry out thawing operations they shall ensure that —

(a) Fishery products shall be thawed under hygienic conditions; their contamination shall be avoided and there shall be adequate drainage for any melt water produced;

(b) During thawing the temperature of the product shall be not be increased excessively.

2. After thawing the fishery products shall be handled in accordance with the requirements of these Regulations.

General conditions for processed products

1. Fresh, frozen and thawed products used for processing shall comply with the requirements of Parts I, II and III of this schedule.

2. The person responsible for a fish processing establishment shall keep a register of the processing operations carried out and the associated processing conditions.. Depending on the type of process employed, heating time and temperature, salt content, pH, water content etc. shall be monitored and controlled. Records shall be kept at least two years and be available to the competent authority.

3. For products which are preserved for a limited period by a treatment such as salting, smoking, drying or marinating, the appropriate conditions for storage shall be kept clearly marked on the packaging.

Conditions for canned products

In the case of fishery products subjected to commercial sterilization in hermetically sealed containers the Food Act (Low Acid Canned Foods) regulations of 1992 shall apply.

Conditions for smoked products

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

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

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

4. After smoking products shall be cooled rapidly to the temperature required for their preservation. Cooling shall take place in area with adequate protection against contamination with insects, their larvae and eggs.

5. Smoked fish should be packed in adequate cartons, which provide a suitable degree of protection from contamination with insects, their larvae and eggs. Cardboard cartons should be lined with waxed paper.

Conditions for dried products

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

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

3. Fish should not be dried on the ground unless the ground is covered with a smooth impermeable surface which is capable of being easily cleaned.

4. Dried fish should be packed in adequate cartons, which provide a suitable degree of protection from contamination with insects, their larvae and eggs. Cardboard cartons should be lined with waxed paper.

Conditions for salted products

1. Salting operations shall carried out in a premises or area used specifically for this purpose.

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

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

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

Conditions for cooked crustacean and molluscan shellfish products

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

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

3. Shelling or shucking of cooked products shall be carried out under hygienic conditions avoiding contamination of the product. Where such operations are done by hand, workers shall pay particular attention to the washing of their hands and all working surfaces shall be

cleaned thoroughly. If machines are used, they shall be cleaned at frequent intervals and disinfected after each working day.

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

SCHEDULE 9

PACKAGING REQUIREMENTS FOR FISHERY PRODUCTS

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

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

   (a) They shall not be such as to impair the organoleptic characteristics of the fishery products;

   (b) They shall not be capable of transmitting to the fishery products substances harmful to human health;

   (c) They shall be strong enough to protect the fishery products adequately.

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

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

5. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.

6. Packaging materials shall be stored in areas separate to the area in fishery products are processed or handles and shall be protected from dust and contamination.

SCHEDULE 10

FOOD SAFETY CONDITIONS FOR FISHERY PRODUCTS

For the purposes of this Schedule and insofar as the parameters specified the following Regulations shall not apply to fishery products intended for export—

(a) Food Act (Contaminants) Regulations 1994;

(b) Food Act (Food Additive) Regulations 1992

Spoilage

Fish and fishery products intended for sale for human consumption shall have organoleptic and chemical characteristics consistent with fitness for human consumption

Conditions concerning parasites

Fish and fishery products shall be free from visible parasites and visible manifestations of parasitic infections.

Histamine

1. A consignment of fishery products comprising a fish species which is susceptible to the production of histamine shall not be placed on the market if the level of histamine in nine samples selected at random from the consignment exceeds the minimum levels specified in below.

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

   (a) the mean value shall not exceed 100 ppm;

   (b) two samples may have a value of more than 100 ppm but less than 200 ppm;

   (c) no sample may have a value exceeding 200 ppm.

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

4. Examinations for official control shall be carried out in accordance with the high-performance liquid chromatography (HPLC) method described in the following publications:

   (a) Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49; and

   (b) Duflos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination of biogenic amines in plaice (Pleuronectes platessa) and whiting (Merlangus merlangus). J. AOAC Internat. 1999, 82, 1097-1101.

Heavy metal contaminants present in the aquatic environment

1. Batches of fishery products in which the levels of heavy metal contaminants exceed the maximum limits indicated in the following table shall be regarded as unfit for human consumption.

Substrate	Maximum Limit (ppm)

	Lead	Cadmium	Mercury
Muscle meat of all fish except where indicated below:	0.3	0.05	0.5
Little tuna (Euthynnus app.) Tunas (thunnus spp, and katsuwonus pelamis.)	-	0.1	1.0
Marlin (Maraira spp.) Sail fish (Istiophorus platypterus) Rays (Raja species) Shark and dogfish (all species)	-	0.05	1.0
Bullet tuna (Auxis species)	-	0.2	1.0
Swordfish (Xiphias gladius)	-	0.3	1.0
Crustaceans (excluding brown meat of crabs and thorax meat of lobsters of the genus Palinuridae)	0.5	0.5	0.5
Bivalve Molluscs	1.5	1.0	0.5
Cephalopods (without viscera)	1.0	1.0	0.5

———————

Substrate	**Maximum Limit (ppm)**
	Tins (Inorganic)
Canned fishery products:	200

1. Sampling and analysis should be conducted in accordance with CEN Standard 'Foodstuffs Determination of trace elements Performance criteria and general consideration' or other equivalent recognised methodology.

2. Laboratories shall use a validated analytical method with a detection limit at lest one tenth of the MRL indicated in the above Table. The validation shall include a certified reference material in the collaborative trial test materials.

Microbiological standards

1. Batches of ready to eat fishery products which do not meet the following criteria shall be considered to be unfit for human consumption.

Type of bacteria	**Standard**
Salmonella	Absent in 25g n=5 c=0
Coagulase positive Staphylococci	m=100 cfc/g M=1000 cfu/g n=5 c=2
E.coli (on solid medium)	n=1 cfu/g M=10 cfu/g n=5 c=2
Listeria monocytogenes (in samples taken before the product has left the establishment)	Absent in 25g n=5 c=0

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 sample

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

2. In determining compliance with the above microbiological specifications, examinations for official control shall employ the following testing methodologies —

(a) In the case of Salmonella EN/ISO 6579

(b) In the case of Listeria monocytogenes EN/ISO 11290-1

(c) In the case of E.coli ISO TS 16649-3

(d) In the case of coagulase positve staphylococci EN/ISO 6888-1 0r 2

Organochlorine contaminants present in the aquatic environment

1. Batches of fishery products in which the levels of dioxins and dioxin like PCBs and their congeners exceed the limits indicated in the following table shall be regarded as unfit for human consumption.

Substrate	Maximum Level	
	Sum of dioxins (WHO PCDD/F-TEQ)[1]	Sum of dioxins and dioxin like PCBs (WHO PCDD/F-TEQ)
Muscle meat of fishery products, including cru staceans (excluding brown meat of crabs and head and thorax meat of lobsters of the genus *Palinuridae*)	4.0 pg/g wet weight	8.0 pg/g wet weight
Fish liver	n/a	25 pg/g wet weight
Marine oils for human consumption	2.0 pg/g fat	10.0 pg/g fat

1. Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), expressed as World Health Organisation (WHO) toxic equivalent using the WHO-toxic equivalency factors (WHO-TEFs)) and sum of dioxins and dioxin-like PCBs (sum of PCDDs, PCDFs and polychlorinated biphenyls (PCBs), expressed as WHO toxic

equivalent using the WHO-TEFs), as described in the WHO-TEFs for human risk assessment based on the conclusions of the WHO meeting in Stockholm, Sweden, 15 to 18 June 1997 (Van den Berg et al., (1998) Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and for Wildlife. Environmental Health Perspectives, 106 (12), 775)

In the case of canned fish liver, the maximum level applies to the whole edible content of the can

2. Methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in fishery products shall follow established international practices where they are available.

Permitted Additives

1. The additives listed in Table 1 are permitted in fishery products, insofar as they may be added to fishery products listed in Tables 2 and 3 providing that the maximum limits in the final product are not exceeded.

Table 1: List of permitted additives

Sulphur dioxide
Sodium sulphite
Sodium hydrogen sulphite
Sodium metabisulphite
Potassium metabisulphite
Calcium sulphite
Calcium hydrogen sulphite
Potassium hydrogen sulphite
Triphosphates of sodium and potassium
Polyphosphates of sodium, potassium and calcium

Table 2: Maximum limits of SO

Fishery products	**Maximum level (mg/kg) expressed as SO2**
Fresh, frozen crustacean and cephalopods	150
Cooked crustacean	50

Table 3: Maximum limits of tri-phosphates and polyphosphates

Fishery products	Maximum level (g/kg)
Frozen fishery products	5

SCHEDULE 11

IDENTIFICATION MARKS FOR FISHERY PRODUCTS

1. Fishery products which are packed and consigned to market by an establishment shall bear the following information on the packaging —

   (a) The name of the country of origin of the products;

   (b) The name and official registration number of the establishment in which the products were processed or packed;

   (c) A description of the product, including the common name and the latin name of the species and its state (fresh, frozen), weight grade;

   (d) Packaging method (chilled/frozen/canned etc);

   (e) The date on which it was packed by the establishment and the Batch identification number;

   (f) Any special storage instructions required to maintain the safety and quality of the fishery product, including storage temperature;

   (g) Production method (capture fisheries or aquaculture);

   (h) If capture fisheries, the catch area (according to FAO Areas);

   (i) Name of any food additives administered to the product and code number if appropriate.

SCHEDULE 12

REQUIREMENT FOR HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM

Part 1: General requirements

1. Fishery enterprise operators shall implement a system of own checks based on the principles of Hazard Analysis and Critical Control Point System, which shall include the following actions;

(a) identification of fish and fishery product safety hazards associated with their products and processes, and identification of critical points in their establishment on the basis of the manufacturing processes used;

(b) establishing and implementing methods for monitoring and checking such critical points, and for taking corrective actions to prevent or minimize the risk of hazards arising;

(c) taking samples for analysis for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the fish and fishery product safety requirements established by this Regulation;

(d) keeping a written record or a record registered in an indelible fashion of the preceding points with a view to making them available to the relevant competent authority. The results of the different checks and tests will be kept for a period of at least two years.

2. The detailed requirements for the implementation of the system are defined in Part 2 of this schedule.

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

(a) validation of the system of own checks when first set up;

(b) if necessary, revalidation of the system in case of a change to the characteristics of the product or to the manufacturing process;

(c) verification, at specified intervals, that all provisions are still appropriate and properly applied.

4. If the results of the own checks referred to in this Schedule reveal the existence of a significantly elevated risk to the health of consumers in respect of a batch of fish or fishery products then the products concerned will be considered to be not in compliance with the requirements of Section 4 of the Food Act and shall be treated accordingly.

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

6. The documentation referred to in paragraph 1 (d) must include two types of information to be kept for submission to the competent authority on request —

(a) a detailed and comprehensive document including —

(i) description of the product;

(ii) description of the manufacturing process indicating critical points;

(iii) for each critical point, identified hazards, assessment of risks and control measures;

(iv) procedures for monitoring and checking at each such critical point, with indication of critical limits for parameters that need to be controlled and corrective action to be taken in case of loss of control;

(v) procedures for verification and review.

(b) records of the observations and/or measurements referred to in paragraph 1 (b), results of the verification activities referred to in paragraph 3, plus reports and written accounts of decisions relating to corrective action when taken. An appropriate document management system must provide, in particular, for the easy retrieval of all documents relating to an identified production batch.

7. Operators of fish processing establishments are to ensure that those responsible for the development and maintenance of the procedures referred to in this Schedule have received adequate training in the application of the HACCP principles.

Part 2: Specific requirements for the own checks system

1. The own checks system will represent an approach internal to the establishment, developed and implemented by persons within that establishment.

2. As part of the internal approach referred to in paragraph 1.1 of this part of the Schedule, establishments may use guides of good manufacturing practice drawn up by appropriate professional organizations and acceptable to the competent authorities.

3. The persons responsible for the establishment must ensure that all staff concerned with the own-checks receive adequate training in order to effectively participate in their implementation.

4. In the design of any system for own-checks the following general approach should be adopted—

(i) identification of hazards, analysis of risks and determination of measures to control them;

(ii) identification of critical points;

(iii) establishing critical limits for each critical point;

(iv) establishing monitoring and checking procedures;

(v) establishing corrective action to be taken when necessary;

(vi) establishing verification procedures;

(vii) validation of the own-checks system;

(viii) documentation of the system and maintaining records of results;

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

Identification of Critical Points

General principles

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

2. All critical points should first be identified by a detailed review of the process (applying knowledge of microbiological and other hazards which may potentially arise). This should be undertaken by a person with specialised knowledge and by reference to existing codes of practice.

3. The information thus generated is used as the basis of the own-checks system to ensure compliance with the hygiene and safety requirements of the process, including those specified in any relevant code of practice.

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

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

Assembly of a multidisciplinary team

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

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

    (a) a quality control specialist who understands the biological, chemical or physical hazards connected with a particular product group;

    (b) a production specialist who has responsibility for, or is closely involved with, the technical process of manufacturing the product under study;

    (c) a technician who has a working knowledge of the hygiene and operation of the process plant and equipment;

    (d) any other person with specialist knowledge of microbiology, hygiene and food technology.

3. One person may fulfil several or all of these roles. The most important factors are that all relevant information should be available to the team and that they are applied effectively to ensure that the own-checks system developed is valid and reliable.

4. Where necessary, the team may be assisted by external specialists who will contribute technical knowledge in areas not adequately covered by the establishment's own personnel. Such advice may be obtained from sources such as consultants or government inspectors.

Description of the product

1. The end product should then be described in terms of —

   (a) composition (e.g. species, raw materials, ingredients, additives);

   (b) structure and physio-chemical characteristics (e.g. whole, portion, Aw, pH,);

   (c) nature and extent of processing (e.g. heating, freezing, drying, salting, smoking and respective process conditions);

   (d) packaging (e.g. hermetic, vacuum, modified atmosphere);

   (e) storage and distribution conditions (temperature control);

   (f) required shelf life (e.g. sell by date and best before date);

   (g) instruction for use;

   (h) any microbiological or chemical criteria applicable to the final product.

Identification of intended use

The multi-disciplinary team should also define the normal or expected use of the product by the customer and the consumer target groups for which the product is intended. In specific cases, the suitability of the product for particular groups of consumers with special needs may have to be considered (whether target market segments or not). For example, this may include such groups as institutional caterers, travellers or children.

Construction of a flow diagram (description of manufacturing process)

Whatever the format chosen, all steps involved in the process, including delays during or between steps, from receiving the raw materials to placing the end product on the market, through preparation, processing, storage and distribution, should be studied in sequence and presented in a detailed flow diagram with technical data to describe process conditions at each stage.

Types of data may include but are not limited to —

- plan of working premises and ancillary premises
- equipment layout and characteristics
- sequence of all process steps (including the incorporation of raw materials)
- ingredients or additives and delays during or between steps)

- technical parameters of operations (in particular time and temperature, including delays, and concentrations of solutions)
- flow of products (including potential cross-contamination)
- segregation of clean and dirty areas (or high/low risk areas)
- cleaning and disinfection procedures
- hygienic environment of the establishment
- personnel routes and hygiene practices product storage and distribution conditions.

On-site confirmation of flow diagram

After the flow diagram has been drawn up, the multi-disciplinary team should confirm it on site during operating hours. Any observed deviation should result in an amendment of the original flow diagram to make it accurate.

Listing of hazards and control measures

1. A hazard is a potential to cause harm to health and is anything covered by the hygiene objectives of legislation and codes of practice relating to the storage, processing and packaging of fishery products.

2. Specifically, a hazard may include any of the following —

    (a) unacceptable contamination (or recontamination) of a biological, chemical or physical nature of raw materials, intermediate products or final products;

    (b) unacceptable survival or multiplication of pathogenic micro organisms and unacceptable generation of chemicals in intermediate products, final products, production line or line environment;

    (c) unacceptable production or persistence of toxins or other undesirable products of microbial metabolism.

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

4. Using the confirmed flow diagram as a guide, the team should then —

    (a) list all potential biological, chemical or physical hazards that may be reasonably expected to occur at each process step (including those resulting from acquisition and storage of raw materials and ingredients and delays during manufacture and any other foreseeable eventuality);

    (b) consider and describe what control measures, if any, exist which can be applied for each hazard.

5. Control measures are those actions and activities that can be used to prevent hazards, eliminate them or reduce their impact or occurrence to acceptable levels.

6. More than one control measure may be required to control an identified hazard and more than one hazard may be controlled by a single control measure. For instance, pasteurization or controlled heat treatment may provide sufficient assurance of reduction of the level of both Salmonella and Listeria hazards.

7. Control measures need to be supported by detailed procedures and specifications to ensure their effective implementation. For instance, this may include detailed cleaning schedules, precise heat treatment specifications (time and temperature combinations), concentrations and quantities of preservatives used.

Methods for identification of critical points

The identification of a critical point for the control of a hazard requires a logical approach. Such an approach can be facilitated by the use of the decision tree in Figure 1. Other methods can be used by the team, according to their knowledge and experience.

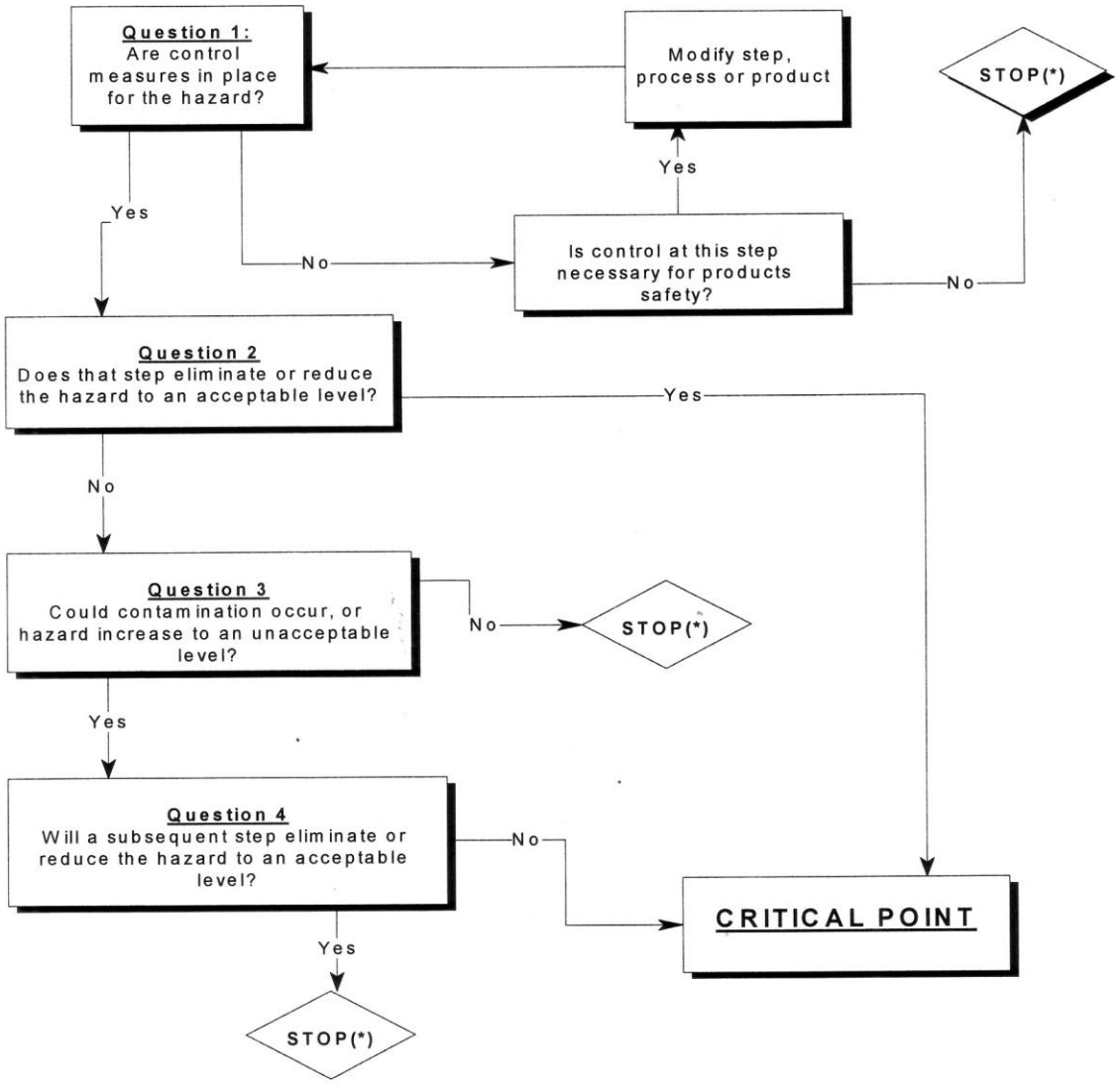

FIGURE 1

DECISION TREE FOR THE IDENTIFICATION OF CRITICAL POINTS

(NB. * indicates that point is not critical; proceed to the next stage of the process)

1. For the application of the decision tree, each process step identified in the flow diagram should be considered in sequence. At each step, the decision tree must be applied to each hazard that may be reasonably expected to occur or be introduced and each control measure identified.

2. The decision as to which stages of the process are to be regarded as critical points requires a flexible and common sense approach. In particular there is a need to apply a pragmatic view of the causes of given hazardous effects to avoid, whenever possible, the listing of unnecessary critical points.

Action to be taken following identification of a critical point

The identification of critical points has two consequences for the multidisciplinary team which should then

- 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 should be modified at that step, or at an earlier or later stage, to include a control measure.

- establish and implement a monitoring and checking system at each critical point.

Monitoring and Checking of Critical Points

General principles

1. An appropriate monitoring and checking system is essential to ensure the effective control of each critical point.

2. Monitoring and checking of critical points includes all those observations and/or measurements necessary to ensure that the key process variables at critical points are kept under control.

3. The following steps are suggested as an appropriate framework for the design of a suitable system for monitoring and checking.

I. Establishing critical limits

1. Each control measure associated with a critical point should give rise to the specification of critical limits.

2. Those critical limits should correspond to the extreme values acceptable with regard to product safety. They separate acceptability from unacceptability. They are determined for observable or measurable parameters which can readily demonstrate whether the critical point is under control; they should be based on substantiated evidence that the chosen values will result in elimination of the hazard.

3. Examples of such parameters include temperature, time, pH, moisture level, additive, preservative or salt level, and sensory parameters such as visual appearance or texture.

4. In some cases, to reduce the risk of exceeding a critical limit due to naturally occurring process variations, it may be necessary to specify more stringent target levels than are necessary to eliminate the hazard, to ensure that process variables remain within the critical limits in a reasonable majority of cases.

5. 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 should ascertain their validity relative to the control of the identified hazards at the critical points.

II. Establishing a monitoring and checking system

1. An essential part of own-checks is a programme of observations or measurements performed at each critical point to ensure compliance with specified critical limits. The programme should describe the methods of measurement, the frequency of observations or measurements and the recording procedures to be followed.

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

3. Observations or measurements may be made continuously or discontinuously.

4. When observations or measurements are not continuous, it is necessary to establish a frequency of observations, or measurements (in terms of a defined sampling plan), which provides information which can be validly used for extrapolation of the resulting measurement data to the behaviour of critical variables between observations.

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

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

   (a) who is to perform monitoring and checking;

   (b) when monitoring and checking is performed;

   (c) how monitoring and checking is performed.

III. Establishing a corrective action plan

1. Observations or measurements may indicate —

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

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

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

3. The corrective action plan should 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

(d) during the period when the process was out of control (e) written records of measures taken

IV. Verification

1. "Verification" refers to those actions taken for the routine confirmation that the HACCP system is working effectively.

2. The multidisciplinary team should specify the methods and procedures to be used for the verification of the own-checks system.

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, and at critical points;

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

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

3. The corrective action plan should 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

(d) during the period when the process was out of control

(e) written records of measures taken

IV. Verification

1. "Verification" refers to those actions taken for the routine confirmation that the HACCP system is working effectively.

2. The multidisciplinary team should specify the methods and procedures to be used for the verification of the own-checks system.

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, and at critical points;

(b) surveys on actual conditions and product characteristics during storage, distribution and sale, and at the point of actual use of the product.

4. Verification procedures may also include —

(a) inspection of operations;

(b) validation of critical limits;

(c) review of deviations and corrective action and measures taken;

(d) additional confirmatory sampling and measurements;

(e) audits of the HACCP system and its records;

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

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

7. In addition it is necessary to review the HACCP system to ensure that it is still valid in case of changes made. Changes in the system of own-checks may arise as a result of —

(a) change in raw material or in product, processing conditions (factory layout and environment, process equipment, cleaning and disinfection programme);

(b) change in packaging, storage or distribution conditions;

(c) change in consumer use;

(d) receipt of any information on a new hazard associated with the product, or any new information on an old hazard.

8. Any amendments to the own-checks system should be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is available.

V. Documentation

1. Documentation requirements

2. A written record of the complete documentation relating to the design and operation of the system of own-checks, should be kept at the establishment and be permanently available for inspection.

3. The written record should include.

(a) own checks system definition —

(i) detailed physical, chemical and microbiological description of the product;

(ii) detailed description of the process (including process flow diagrams);

(iii) identification and definition of hazards;

(iv) identification of critical points;

(v) definition of critical limits to key variables at critical points;

(vi) definition of sampling periods and frequency for measurement of key variables;

(vii) description of measurement methods and procedures for measurement of key variables;

(viii) description of corrective actions in case critical limits are exceeded;

(ix) definition of validation and verification procedures;

(x) results of the validation activities.

(b) results of own checks —

(i) results of all monitoring and checking actions;

(ii) written accounts of any decisions made relating to corrective action when critical limits have been exceeded;

(iii) results of the verification activities.

4. Data retrieval.

5. Results of monitoring and checking actions should be maintained for a period of at least two years.

6. The own checks data management system must provide, in particular, for the easy retrieval of all documents relating to an identified production batch.

SCHEDULE 13

REQUIREMENT FOR TRACEABILITY AND RECALL PROCEDURES

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

2. Operators of fishery enterprises shall be able to identify any person from whom they have been supplied with a fish or fishery product, a feed, or any substance intended to be, or

expected to be, incorporated into a fishery product or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the relevant competent authority on demand.

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

4. Fish and fishery product or feed which is placed on the market or is likely to be placed on the market shall be labelled or otherwise identified through relevant documentation or other information to ensure its traceability.

5. Each operator of a fishery enterprise must prepare a written recall plan detailing the procedures to be followed in the case that a batch of fish or fishery products which has left the possession of the operator should be withdrawn from being placed on the market.

SCHEDULE 14

REQUIREMENTS FOR POTABLE WATER

Where this regulation refers to potable water, it shall mean water which complies with the standards laid down in this schedule.

Public Health (Water Examination) Regulation 1994 shall not apply to establishments to which this Schedule applies.

Operators of fish processing establishments should be in a position to demonstrate with a distribution diagram the distribution of potable water and other water within the establishment. This should show all sources, pipework, tanks and cisterns and outlets of water within the establishments. Outlets should be numbered and identifiable on the plan.

Where water is treated with a process of chlorination, and the fishery enterprise operator relies on that treatment to comply with the microbiological standards set out in Table 1, then the level of residual chlorination will be monitored at least on a daily basis.

At least once every month, water samples from each source should be submitted for a microbiological analysis, to ensure that there is no contamination of the water supply. If numbers of microbes exceed the specifications, then action must be taken to identify the source and stop the contamination.

At least once every year, a sample should be submitted for analysis of other parameters.

Samples of water taken to test for compliance with standards set out in this schedule should be taken from various outlets within the establishment in rotation. Ice shall also be subject to regular testing. The results of the examinations must bear the identification of the outlet from which the sample is taken.

Potable water shall comply with the microbiological standards set out in Table1, and the chemical parameters of Table 2.

Table 1: Microbiological parameters

Parameter	**Parametric value (Number/100ml)**
Escherichia coli (E.Coli)	0
Enterococci	0
Clostridium perfringens (including spores)	0

Note 1: This parameter needs to be tested if the water originates or is influenced by surface water.

_____

Table 2: Chemical Parameters

Parameter	**Parametric value**	**Unit**	**Note**
Acrylamide	0.1	**µg/1**	1
Antimoney	5.0	**µg/1**	
Arsenic	10	**µg/1**	
Benzene	1.0	**µg/1**	
Benzylpyrene	0.01	**µg/1**	
Boron	1.0	**µg/1**	
Benzoate	10	**µg/1**	2
Cadmium	5	**µg/1**	

Chromium	50	**µg/1**	
Copper	2	**mg/1**	3
Cyanide	50	**µg/1**	
1,2 dichloroethane	3.0	**µg/1**	
Epichlorhydrine	0.1	**µg/1**	1
Fluoride	1.5	**mg/1**	
Lead	10	**µg/1**	3,4
Mercury	1	**µg/1**	
Nickel	20	**µg/1**	3
Nitrate	50	**mg/1**	
Nitrite	0.5	**mg/1**	
Pesticides	0.1	**µg/1**	4,5
Pesticides total	0.5	**µg/1**	4.6
Polycyclic aromatic hydrocarbons	0.1	**µg/1**	Sum of concentration of specified compounds Note 7
Selenium	10	**µg/1**	
Tetrachloroetchane and trichloroethane	10	**µg/1**	Sum of concentration of specified compounds

Trihalomethanes	100	**µg/1**	Sum of concentration of specified compounds Note 8
Vinyl chloride	0.5	**µg/1**	1

Note 1: The parametric value refers to the residual monomer concentration in the water as calculated according to specifications of the maximum release from the corresponding polymer in contact with the water.

Note 2: Where possible, without compromising disinfection, a lower value should be aimed for.

Note 3: The value applies to a sample of water intended for human consumption obtained by an adequate sampling method at the tap. Where appropriate the sampling and monitoring methods must be applied to take account of the occurrence of peak levels that may cause adverse effects on human health.

Note 4: 'Pesticides' means:

— organic insecticides,

— organic herbicides,

— organic fungicides,

— organic nematocides,

— organic acaricides,

— organic algicides,

— organic rodenticides

— organic slimicides,

related products (inter alia, growth regulators)

and their relevant metabolites, degradation and reaction products.

Only those pesticides which are likely to be present in a given supply need be monitored.

Note 5: The parametric value applies to each individual pesticide. In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide the parametric value is 0,030 ug/l.

Note 6: Pesticides Total' means the sum of all individual pesticides detected and quantified in the monitoring procedure.

Note 7: The specified compounds are —

— benzo(b)fluoranthene,

— benzo(k)fluoranthene,

— benzo(ghi)perylene,

— indeno(1,2,3-cd)pyrene.

Note 8: Where possible, without compromising disinfection, a lower level should be aimed for. The specified compounds are: chloroform, bromoform, dibromochloromethane, bromodichloromethane.

Export of Fishery Products (Aquaculture) Regulations, 2010

SI. 83 of 2010

[6th December 2010]

1. These Regulations may be cited as the Export of Fishery Products (Aquaculture) Regulations, 2010.

2. These Regulations may be in addition to and not in derogation of any other written law for the time being in force relating to food safety and public health.

3. In these Regulations —

"aquaculture" means the managed production in artificial enclosures of aquatic organisms which are used for human consumption, and includes the production of intermediate stages of the life cycle including eggs and larval stages of fish, crustacean and molluscs. It does not include the holding of live animals for short periods for the purpose of collecting for market or for purification;

"aquaculture establishment" means a place at which aquaculture is undertaken whether for profit or not with a view to placing aquaculture products on the market for human consumption;

"aquaculture feed" means feed provided to aquaculture animals, including larval stages;

"aquatic organism" has the meaning assigned by the Fisheries Act;

"competent authority" means the Fish Inspection and Quality Control Unit of the Seychelles Bureau of Standards;

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

"export" means commercial trade with any person outside the territory of Seychelles;

"official control" means any form of control that the competent authority exercises for the verification of compliance with these Regulations;

"traceability" means the ability to trace and follow a aquaculture product, aquaculture feed or other substance intended or expected to be incorporated into an aquaculture product or aquaculture feed, through all stages of production, processing and distribution;

"withdrawal period" means the minimum time before harvest during which treatment with a veterinary medicine must cease to ensure that any residues of veterinary medicines in the edible parts of the aquaculture product are within the limits established for the safety of consumers.

4. (1) No person shall export aquaculture products for human consumption from Seychelles unless they are produced in an aquaculture establishment under and in accordance with a permit granted under these Regulations by the Chief Executive Officer of the Seychelles Bureau of Standards.

(2) Every aquaculture establishment shall satisfy the conditions contained in Schedules 1 and 2 unless otherwise specified in the permit.

5. (1) Operators of aquaculture establishments shall ensure that aquaculture products under their control satisfy the requirements of these Regulations at all stages of production.

(2) If an operator of an aquaculture establishment has reason to believe that an aquaculture product which the operator has produced or distributed is not in compliance with the Regulations or is injurious to human health, the operator shall immediately take steps to withdraw the product in question from the market, and shall inform the competent authority thereof.

(3) Operators of aquaculture establishments shall collaborate with the competent authority on actions taken to investigate, avoid or reduce risks posed by any product which they have supplied.

6. (1) Notwithstanding the prohibition of specific veterinary medicines and medicinal premixes described in subregulation (2) of this regulation, the following substances shall not be applied to aquaculture products —

(a) Chloramphenicol and derivatives, e.g. thiamphenicol (TAF);

(b) Dimetridazole;

(c) Metronidazole;

(d) Compounds which produce a nitrofuran metabolite;

(e) Anabolic substances for growth promotion purposes;

(f) Malachite green and leucomalachite green.

(2) Veterinary medicines and medicinal premixes for inclusion in aquaculture product feeds shall not be used if their active ingredients are prohibited for use in food animals under the Animal Diseases and Imports Act of 1981.

7. (1) No veterinary therapeutic products and medicinal premixes for inclusion in aquaculture products feeds may be applied to living aquaculture products unless they are

approved for such use under the terms of relevant legislation controlling the import, distribution and use of medicines.

(2) Where no specific legislation is in place controlling the import, distribution and use of medicines, the medicines listed in column 1 of Table 1 in Schedule 2 shall be permitted to be applied to living aquaculture products, on the condition that residues present in the aquaculture product placed on the market does not exceed the limit indicated in column 2 of that Table.

8. (1) Aquaculture products are to be considered to be unfit for human consumption if —

(a) they derive from aquaculture products which have been treated by a substance whose use is prohibited under the Animal Diseases and Imports Act of 1981; or

(b) they derive from aquaculture products which have not been produced in accordance with Schedule 2;

(2) Unfit aquaculture products intended for sale for human consumption are subject to seizure under the powers granted to authorised officers referred to in section 10 of the Export of Fishery Products Act.

9. The Chief Executive Officer may delegate the Chief Executive Officer's functions under these Regulations to the Fish Inspection and Quality Control Unit (hereinafter referred to as the competent authority).

10. (1) The competent authority shall undertake control and monitoring of food safety conditions in aquaculture establishments and ascertain whether the requirements of these Regulations are complied with.

(2) The official controls shall include relevant checks set out in the Export of Fishery Products (Sanitary) Regulations, 2010.

11. The competent authority shall draw up reports on the inspections for official controls that it has carried out under these Regulations in accordance with Regulation 12 of the Export of Fishery Products (Sanitary) Regulations, 2010.

12. (1) The competent authority shall design and cause to be implemented an annual monitoring programme with the objective of assessing the nature and extent of the compliance of aquaculture establishments with these Regulations.

(2) The monitoring programmes described in subregulation (1) shall take into account the risks of different food safety hazards in aquaculture feeds and aquaculture products and the criteria described in Schedule 2, and shall include the following parameters —

(a) heavy metals;

(b) residues of veterinary medicines whose use in aquaculture is permitted under the Pharmacy Act;

(c) residues of substances whose use in aquaculture is banned under the Animal Disease and Imports Act of 1981 and the Pharmacy Act;

(d) residues of organochlorine and organophosphate contaminants of the environment;

(e) mycotoxins;

(f) other hazards in aquaculture products which are identified as relevant to food safety conditions of products.

(4) The monitoring programme shall specify the sampling plan and the methods of analysis including detection limits to be applied, along with the residue levels which will precipitate follow up actions.

(5) The competent authority shall prepare an annual report describing the monitoring programme, the results and the outcome of any follow up action, and submit the report to the Minister.

13. The competent authority shall prepare an annual programme and annual report of official control and monitoring activities it has carried out under these Regulations in accordance with the Export of Fishery Products (Sanitary) Regulations, 2010.

14. (1) Authorised officers acting in the course of their duties shall at all times act with integrity, transparency and confidentiality.

(2) Information relating to any individual business which is obtained by an officer during the course of official controls or other activities under these Regulations shall not be disclosed without the consent in writing of the person carrying on the business, except —

(a) so far as may be necessary for the purposes of these Regulations; or

(b) for the purposes of any legal proceedings.

SCHEDULE 1

Reg. 4(2)

Hygiene and management requirements of aquaculture establishments

Site location and selection

1. Aquaculture operations should be located in areas where the risk of contamination with hazardous chemical effluents is minimal and where sources of pollution can be controlled.

2. Aquaculture operations should be sited at a safe distance from potential sources of water contamination in order to ensure protection of products from contamination.

3. The immediate vicinity of aquaculture operations should be free of potential sources of water contamination and in particular should not be located downstream and close to —

   (a) industrial activity;

   (b) intensive agriculture (especially animal husbandry);

(c) densely populated areas or urban areas;

(d) hospitals;

(e) major roads.

4. Before building a land-based aquaculture facility, a survey of the soil should be conducted in order to determine the concentration and extent of any parameters which are of importance for the safety of end products, including heavy metals and pesticide residues. Such an analysis should be conducted as a condition of the permit required under Regulation 4.

5. Cages, pens or any other form of aquaculture enclosures or water intakes should be sited away from routes of water-borne traffic, and preferably upstream of any water-borne traffic.

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6. Cages, pens or any other form of aquaculture enclosures or water intakes should be sited away from, and preferably upstream of, any natural or artificial discharges of contamination.

Aquaculture site facilities

7. All aquaculture establishments shall have an adequate number of flush toilets for the use of staff.

8. There shall be an adequate number of wash hand basins, and an adequate supply of single use towels or appliances for drying the hands.

9. Sanitary facilities should be located so as to ensure that there is no risk of contamination of fish ponds.

Pond preparation

10. Weeds, rubbish and debris should be removed before preparing aquaculture ponds for filling with water.

11. If necessary ponds should be conditioned with lime and left for a period of at least two weeks before filling and stocking.

12. At least once each year the pond should be drained, allowed to dry out and, if required, re-conditioned with lime.

Aquaculture feeds and feed materials

13. Aquaculture feed stored at the aquaculture facility should be held in a properly constructed and well-ventilated facility, and protected from the entry of insects, birds and rodents.

14. Slaughterhouse waste and offal from mammalian food animals may only be used as a food for fish if it is first cooked.

15. Compound feed should not be used for feeding fish unless the user is informed of the composition, including any supplements added by the manufacturer.

16. Compound feed treated with veterinary medical supplements (including hormones and antibiotics) are considered to be veterinary medicines to which Schedule 2 applies.

Harvesting, equipment and materials

17. Harvesting areas and methods within the aquaculture facility should be designed and constructed for easy, fast and hygienic operation.

18. All equipment used for harvesting, catching, sorting, grading, conveying and transporting of aquaculture products should be designed for their rapid and efficient handling without causing mechanical damage.

19. Equipment, containers and utensils coming into contact with aquaculture products should be designed and constructed to ensure that they can be adequately cleaned, disinfected and maintained to avoid contamination.

20. All surfaces of boxes, implements and other equipment which come into contact with aquaculture products should be of corrosive resistant material which is smooth and easy to clean, or be designed for a single use only.

21. If re-usable boxes are used to carry aquaculture products from the production area, then a suitable means of cleaning with water and detergent, and disinfection should be provided

Personal hygiene

22. Any person working at an aquaculture facility shall maintain a reasonable standard of personal hygiene and take all necessary precautions to prevent the contamination of the aquaculture products.

23. Any cut or wounds on hands and forearms shall immediately be covered by a suitable water-proof dressing.

24. Persons suffering from infectious diseases, or from a helminthic parasitic infection, or who have infected wounds, boils or other skin infections, or who are suffering from diarrhoea are not permitted to work in an aquaculture operation.

25. Personnel who work in aquaculture operations shall, on their appointment and in one year intervals thereafter, undertake a health test 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.

26. Any person entering an aquaculture establishment must refrain from spitting or eating food, urinating or defecating, except in areas or locations designated for these purposes, which must be away from production areas.

First aid box

27. Each aquaculture facility shall be provided with a first aid box, which should contain at the minimum —

    (a) a sufficient quantity of impermeable dressings;

    (b) antiseptic cream or disinfectant;

    (c) cotton wool and adhesive tape.

Exclusion of animals

28. Domestic animals should be excluded from aquaculture operations and areas adjacent to ponds.

Cleaning and Disinfection schedule

29. Areas around the ponds should be kept clean and free from rubbish, waste aquaculture products and items not associated with the aquaculture operation.

29. A permanent written cleaning and disinfection schedule should be drawn up to ensure that all parts of the aquaculture facilities and equipment therein are cleaned appropriately and regularly.

30. A named person should be responsible for implementation of the schedule.

31. The schedule should be available for inspection at all times.

32. Aquaculture personnel should be trained in the use of special cleaning tools, methods of dismantling equipment for cleaning and should be knowledgeable in the significance of contamination and the hazards involved.

Pest control systems

33. A permanent written pest control schedule should be drawn up to ensure that all parts of the aquaculture facilities and equipment remain free from infestations of insect and rodent pests.

34. A named person should be responsible for implementation of the schedule.

35. The schedule should be available for inspection at all times.

Record keeping and batch identification

36. Effective records should be kept of each batch of aquaculture products grown in each pond, and of veterinary drug regimes, feeding methods and quantities, pond fertilisers added and any results of water quality parameters.

37. The records should be kept for a period of one year after harvest.

38. Each batch of aquaculture products leaving the farm for market or for processing should be allocated a batch number which relates it to the information records described below.

39. Each batch of aquaculture products leaving the aquaculture operation for placing on the market should be marked to include the following information —

    (a) Permit number of the aquaculture establishment;

    (b) Name of the enterprise;

    (c) Date of harvesting;

    (d) Species;

    (e) Batch number.

Traceability

40. The traceability of aquaculture products, feeds used in aquaculture systems, and any other substance intended to be, or expected to be, incorporated into an aquaculture product or aquaculture feed shall be established at all stages of production, processing and distribution.

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

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

43. Aquaculture products or aquaculture feed which is placed on the market or is likely to be placed on the market shall be labelled or otherwise identified through relevant documentation or other information to ensure its traceability.

44. Each operator of an aquaculture establishment must prepare a written recall plan detailing the procedures to be followed in the case that a batch of aquaculture products which has left the possession of the operator should be withdrawn from being placed on the market.

Minimum monitoring requirements for the internal control system

45. Monitoring programmes should be implemented by the operator of an aquaculture establishment to check that —

    (a) waste and debris e.g. dead or diseased aquaculture products do not build up and are disposed of in a hygienic manner;

    (b) personal hygiene and health standards are maintained;

    (c) the pest control programme is implemented;

    (d) cleaning and disinfecting programmes are implemented;

    (e) quality of water and ice supply is maintained;

    (f) aquaculture feeds, feed supplements and other additives applied to aquaculture products do not contain any substances whose use is prohibited by law;

    (g) withdrawal periods observed in relation to treatment of aquaculture products by permitted veterinary medicines are effective in relation to meeting the requirements for maximum residue limits of those medicines in the final product.

46. The results of all monitoring actions and of any corrective actions taken after monitoring must be recorded.

SCHEDULE 2

Reg. 4(2)

VETERINARY MEDICINE CONDITIONS FOR AQUACULTURE ESTABLISHMENTS

Permitted Veterinary Medicines

Table 1: Permitted veterinary medicines for use in aquaculture and Maximum Residue Limits in aquaculture products

Compound	**Maximum Residue Limit 1**
Penicillins	
Amoxicyllin	50µ/kg
Ampicillin	50µg/kg
Quinolones	
Flumequin	600µg/kg
Sarafloxacin	30µg/kg
Oxolinic acid	300µg/kg
Tetracyclines	
Chlorotetracyline	100µg/kg
Oxy tetracycline	100µg/kg
Tetracycline	100µg/kg
Acyl urea derivatives	
Diflubenzuron	1 000 µg/kg
Teflubenzuron	500µg/kg
Pyrethroids	

Cypermethrin	50µg/kg
Macrolides	
Erythromycin	200µg/kg
Others	
Sulphonamides	100µg/kg
Trimethroprim	50µg/kg
Tosylchloramide sodium	Not subject to MRL
Tricaine mesilate (MS222)	Not subject to MRL
Formalin	Not subject to MRL
Methyltestosterone 2	Not subject to MRL

Notes: [1] *All MRLs in skin and muscle in commercial proportions*

[2] *Permitted for tilapia hatchery operations*

Handling and administration of Veterinary Medicines

1. Therapeutic treatment with veterinary medicines of diseases in aquaculture should be carried out only on the basis of a diagnosis by a veterinarian, a qualified fish disease specialist or a qualified aquaculture technician.

2. Prophylactic and therapeutic treatment with veterinary medicines of fish diseases in aquaculture should be carried out under the supervision of a veterinarian, a qualified fish disease specialist or a qualified aquaculture technician.

3. Veterinary medicines should be used according to manufacturers' instructions and note should be taken of all warning statements and contra-indications for use, and in particular instructions in relation to withdrawal periods.

4. Each individual dose and administration of veterinary medicines (including compound feeds containing veterinary supplements) should be recorded in a book kept at the facility for that

purpose, specifying date and nature of treatment, identification of aquaculture products and duration of withdrawal period.

5. The entries in the register are to be signed by the veterinarian, a qualified fish disease specialist or a qualified aquaculture technician responsible for administering the drug programme.

6. Aquaculture products which are being treated with a veterinary medicine should be kept separate from those which are not being treated, and be easy to identify as a separate batch.

Harvesting and withdrawal period

7. Withdrawal periods under different conditions of each veterinary medicine used and for each species to which it is applied must be established by the operator of the aquaculture establishment and recorded in the register held by the operator of the aquaculture establishment.

8. Aquaculture products must not be harvested before the end of the withdrawal period.

9. The amount of any veterinary drug residue in the harvested aquaculture product must not exceed any maximum residue limit specified under this or other legislation.

10. If aquaculture products which are treated with a veterinary medicine are sold live for on-growing before the end of the withdrawal period, then the buyer must be informed in writing by the seller.

Requirements for marketing

11. If the Aquaculture products is consigned for placing on the market for human consumption, then the producer should certify to the processor in writing that either:

    (a) no veterinary medicines have been applied; or

    (b) if they have been applied, that minimum withdrawal periods have been observed for the named medicines.

12. Persons receiving aquaculture products for subsequent placing on the market, in addition to the checks defined in Schedule 1, must undertake checks to ensure that —

    (a) they do not accept production batches in which undeclared drug treatments have been administered;

    (b) where veterinary medicines have been applied, that minimum withdrawal periods have been observed and maximum residue limits are not exceeded;

    (c) No prohibited substances are present.

SI. 84 of 2010

Export of Fishery Products (Aquaculture Feed) Regulations, 2010

[6th December 2010]

1. (1) These Regulations may be cited as the Export of Fishery Products (Aquaculture Feed) Regulations, 2010.

(2) These Regulations shall be in addition to and not in derogation of any other written law for the time being in force relating food safety and public health.

2. In these Regulations —

"Competent Authority" means the Fish Inspection and Quality Control Unit referred to in the Export of Fishery Products Act;

"feed" or "feedstuff" means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding of animals or fish;

"feed business" means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed and includes any persons producing, processing or storing feed for feeding of animals on that person's own holding;

"feed business operator" means the person responsible for ensuring that the requirements of law are met within the feed business under their control;

"fishmeal" means any substance or product originating from seafood products and including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding of animals;

"by-product" means any material or product that is not the primary product of a specific processing operation, yet may be used in the production of secondary products for either for human consumption or as an ingredient in the manufacture of other products intended for consumption by humans or in the manufacture of animal feed;

"fishery waste" means material originating from fishery products, whole fish or parts thereof, that have been identified as either being potentially harmful to the consumer or of no commercial value *and* are permanently and irreversibly removed from the human and animal supply chain;

"processing" means any action that substantially alters the initial product, including but not limited to heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes.

3. (1) Feed shall not be placed on the market or fed to any food producing animal if it is unsafe for consumption.

(2) Feed shall be declared to be unsafe for its intended use if it is considered to —

(a) have an adverse effect on human or animal health;

(b) make the food derived from food-producing animals unsafe for human consumption.

(3) Where a feed that has been identified as being unsafe is part of a batch, lot or consignment from the same processing conditions, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless the establishment can demonstrate to the Competent Authority the product safety of the rest of the batch, or consignment and so satisfy the feed safety requirement.

4. (1) Feed business operators at all stages of production, processing and distribution within businesses under their control shall ensure that, feeds satisfy the requirements of the Export of Fishery Products Act which are relevant to their activities and verify that such requirements are satisfied.

(2) The Competent Authority shall enforce this regulation, and monitor and verify that the relevant requirements are fulfilled by the feed business operators at all stages of production, processing and distribution.

5. (1) The Competent Authority shall —

(a) perform its functions in a non-discriminatory manner;

(b) assess the food safety risks on the available scientific evidence in an independent, objective and transparent manner; and

(c) where there are reasonable grounds to suspect that a fishery product or feed may present a risk to human health, take steps to identify the fishery product in question and to implement appropriate measures to prevent, reduce or eliminate that risk.

6. (1) The Competent Authority shall undertake official control and monitoring of food safety conditions in establishments and vessels to which section 3 of the Act applies, and of imports of fishery products for re-export to ensure compliance with these Regulations.

(2) The official controls shall include the checks set out in Schedule 2.

(3) Official control of fishery products and feed shall be carried out —

(a) regularly and according to priorities determined by risk assessment;

(b) where non-compliance is suspected; and (c) for the purpose of issue of permits and certificates.

(4) Official control shall be carried out using means proportionate to the end to be attained.

(5) Official control shall cover all stages of production, manufacture, processing, storage, transport, distribution and production of aquaculture feeds.

7. (1) Feed business operators shall conduct their manufacturing operations according to the requirements set out in Schedule 1.

(2) Feed business operators shall put in place, implement and maintain permanent written procedures based on the HACCP principles, as set out in Schedule 12 of the Export of Fishery Products (Sanitary) Regulations, 2010.

(3) If a feed business operator has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the relevant public authorities thereof. In these circumstances or, where the batch, lot or consignment does not satisfy the feed safety requirements, that feed shall be destroyed, unless the Competent Authority determines otherwise.

(4) The feed business operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

8. (1) The traceability of raw materials, ingredients and additives, and any other substance intended to be incorporated in the feed shall be established at all stages of production, processing and distribution by the feed business operator.

(2) Feed business operators shall know the identity of persons who have supplied them with raw materials, and any ingredients or additives used or to be used in the production of aquaculture feeds.

(3) The feed business operators shall have in place systems and procedures which allow for such information to be made available to the Competent Authority on request.

(4) Feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the Competent Authority on demand.

(5) Feed which is placed on the market or is likely to be placed on the market shall be adequately labelled or identified to facilitate its traceability.

9. (1) Aquaculture feeds shall not be placed on the market unless the following particulars are indicated by labelling —

(a) type of feed: e.g. “shrimp feed”, “complete feed” or “complementary feed"”, as appropriate;

(b) name or business name and address of the feed business operator responsible for labeling particulars;

(c) establishment approval number;

(d) batch or lot reference number;

(e) net quantity expressed in units of mass in the case of solid products, and in units of mass or volume in the case of liquid products;

(f) list of feed additives preceded by the name and the content expressed as 'additives per kg;

(g) moisture content if greater than 8%;

(h) fat/oil content if greater than 5%;

(2) In addition the product labelling may include the following details —

(a) the country of production or manufacture;

(b) the description or trade name of the product;

(c) an indication of the physical condition of the feed or the specific processing it has undergone;

(d) the moisture content;

(e) the date of manufacture;

(f) special storage conditions;

(g) the price of the product.

(3) Feed may be placed on the market only in sealed packages or containers. Packages or containers shall be sealed in such a way that when the package or container is opened the seal is damaged and cannot be reused.

SCHEDULE 1

Regulation 7

Conditions of Manufacturing of Aquaculture Feeds

1. (1) Feed processing and storage facilities, equipment, containers, crates, vehicles and their immediate surroundings shall be kept clean, and effective pest control programmes shall be implemented.

(2) The lay-out, design, construction and size of the facilities and equipment shall —

(a) permit adequate cleaning;

(b) be such as to minimise the risk of error and to avoid contamination, cross-contamination and any adverse effects generally on the safety and quality of the products and machinery coming into contact with feed shall be dried following any wet cleaning process.

(3) Facilities and equipment to be used for mixing and manufacturing operations shall undergo appropriate and regular checks, in accordance with written procedures preestablished by the manufacturer.

(4) All scales and metering devices used in the manufacture of feeds shall be appropriate for the range of weights or volumes to be measured and shall be tested for accuracy regularly.

(5) All mixers used in the manufacture of feeds shall be appropriate for the range of weights or volumes being mixed, and shall be capable of manufacturing suitable homogeneous mixtures and homogeneous dilutions and operators shall demonstrate the effectiveness of mixers with regard to homogeneity.

(6) Facilities must have adequate natural artificial lighting.

(7) Drainage facilities must be adequate for the purpose intended and must be so designed and constructed as to avoid the risk of contamination of feeding stuff.

(8) Water used in feed manufacture shall be of suitable quality for animals and the conduits for water shall be of an inert nature.

(9) Sewage, waste and rainwater shall be disposed of in a manner which ensures that equipment and the safety and quality of feed are not affected. Spoilage and dust shall be controlled to prevent pest invasion.

(10) Windows and other openings must, where necessary, be proofed against pests. Doors must be closefitting and proofed against pests when closed.

(11) Where necessary, ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles that can affect the safety and quality of feed.

2. Feed businesses must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the products concerned. An organisation chart setting out the qualifications (e.g. diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the Competent Authority.

(2) All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, so as to obtain the desired product quality.

3. (1) A qualified person responsible for production must be designated.

(2) Feed business operators must ensure that the different stages of production are carried out according to preestablished written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process.

(3) Technical or organisational measures must be taken to avoid or minimise, as necessary, any cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.

(4) The presence of prohibited feed, undesirable substances and other contaminants in relation to human or animal health shall be monitored, and appropriate control strategies to minimise the risk shall be put in place.

(5) Waste and materials not suitable as feed should be isolated and identified. Any such materials containing hazardous levels of veterinary drugs, contaminants or other hazards shall be disposed of in an appropriate way and not used as feed.

(6) Feed business operators shall take adequate measures to ensure effective tracing of the products.

(7) Where appropriate, a qualified person responsible for quality control must be designated.

(8) Feed businesses must, as part of a quality control system, have access to a laboratory with adequate staff and equipment.

(9) A quality control plan must be drawn up in writing and implemented, including in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications and the destination in the event of non-compliance from processed materials to final products.

(10) Documentation relating to the raw materials used in final products must be kept by the manufacturer in order to ensure traceability. Such documentation must be available to the Competent Authority for a period appropriate for the use to which the products are placed on the market. In addition, samples of ingredients and of each batch of products manufactured and placed on the market or of each specific portion of production (in the case of continuous production) must be taken in sufficient quantity using a procedure preestablished by the manufacturer and be retained, in order to ensure traceability (on a regular basis in the case of manufacture solely for the manufacturer's own needs). The samples must be sealed and labelled for easy identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any adulteration. They must be kept at the disposal of the Competent Authority for a period appropriate to the use for which the feed is placed on the market. In the case of feeding stuff for animals not kept for food production, the manufacturer of the feeding stuff must only keep samples of the finished product.

4. (1) Processed feeds shall be separated from unprocessed feed materials and additives, in order to avoid any cross contamination of the processed feed and proper packaging materials shall be used.

(2) Feeds shall be stored and transported in suitable containers. They shall be stored in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorised by the feed business operator have access.

(3) Feeds shall be stored and transported in such a way as to be easily identifiable, in order to avoid any confusion or cross contamination and to prevent deterioration.

(4) Containers and equipment used for the transport, storage, conveying, handling and weighing of feed shall be kept clean. Cleaning programmes shall be introduced, and traces of detergents and disinfectants shall be minimised.

(5) Any spillage shall be minimised and kept under control to reduce pest invasion.

(6) Where appropriate, temperatures shall be kept as low as possible to avoid condensation and spoilage.

5. All feed business operators, including those who act solely as traders without ever holding the product in their facilities, shall keep in a register relevant data, comprising details of purchase, production and sales for effective tracing from receipt to delivery, including export to the final destination.

6. Feed businesses must have a system of documentation designed to define and ensure mastery of the critical points in the manufacturing process and to establish and implement a quality control plan. They must keep the results of the relevant controls. This set of documents must be kept so that it is possible to trace the manufacturing history of each batch of products put into circulation and to establish responsibility, if complaints arise.

7. (1) Feed business operators shall implement a system for registering and processing complaints.

(2) They shall put in place, where this proves necessary, a system for the prompt recall of products in the distribution network. They shall define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality control reassessment.

———————

SCHEDULE 2

Reg. 6

General principles of inspection

1. Official control of the food safety conditions shall comprise one or more of the following checks and where necessary any consequential actions —

    (a) periodic inspection of aquaculture feed manufacturing establishments and monitoring of compliance with permit conditions;

    (b) examination of any control systems that aquaculture feed manufacturing establishments have put in place and the results obtained;

    (c) inspection of —

        (i) raw materials, ingredients, processing aids and other products used for the preparation and production of fishery products, their sources (including fishing vessels and landing sites) and the conditions under which they are produced;

        (ii) semi-finished and finished products;

        (iii) cleaning and maintenance of facilities, equipment products and processes;

    (d) labelling, presentation and advertising;

    (e) assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP)

SCHEDULE 3

Maximal levels of contaminants in aquaculture feeds

1. These levels are maximal levels designated beyond which the product is declared unsafe for use as aquaculture feed.

2. Analysis shall only be required for the purposes of verifying product safety where contamination is thought to have occurred, where it is the responsibility of the processor to demonstrate product safety.

	Mg/kg	**Notes**
Arsenic	15 mg/kg	Feeding stuffs obtained from the processing of fish or other marine animals
Lead	5.0 mg/kg	Complete feeding stuffs
Flourine	0.5 mg/kg	Complete feeding stuffs for fish
Mercury	0.5 mg/kg	Feeding stuffs produced by the processing of fish or other marine animals
Cadmium	2.0 mg/kg	Feed materials of animal origin
Aflatoxin B1	0.01 mg/kg	Other complete feeding stuffs
Aldrin	0.02 mg/kg	Fish feed
Dieldrin Camphechlor	0.05 mg/kg	Feeding stuffs for fish (1)
Dioxins	2.25 ng WHO- PCDD/F- TEQ/kg	Feed for fish
Sum of dioxins and dioxins and dioxin-	7.0 ng. WHO-	Feed for fish (sum of plychlorinated dibenzoparadioxins (PCDDs), polychlorinated dibenzofurans (PCDF's) and polychlorinated

like PCBs	PCDD/F- PCB/kg	biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO – TEFs (toxic equivalency factors, 1997 (3)

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Export of Fishery Products (By-Products) Regulations, 2010

[6th December 2010] SI. 85 of 2010

1. These Regulations may be cited as the Export of Fishery Products (By-Products) Regulations, 2010.

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

3. In these Regulations the definitions of terms in the Export of Fisheries Products (Sanitary) Regulations, 2010 shall apply in addition to the following definitions —

"by-product" means any material or product that is not the primary product of a specific processing operation, yet may be used in the production of secondary products either for human consumption or as an ingredient in the manufacture of other products intended for consumption by humans or the manufacture of animal feeds;

"fishery waste" means material originating from fishery products, whole fish or parts thereof that have been identified as either being potentially harmful to the consumer or of no commercial value and are permanently and irreversibly removed from the human and animal supply chain.

4. (1) Type 1: Fishery By-Products shall consist of parts of fishery products (which are fit for human consumption in accordance with Seychelles legislation), intended for —

(a) human consumption;

(b) use as an ingredient in products intended for human consumption;

(c) use as a raw material that will undergo further processing before being used for either (a) or (b).

(2) Type 2: Fishery By-Products shall be one or more of the following, namely

(a) whole or parts of fishery products, which are fit for human consumption in accordance with Seychelles legislation, but are not intended for human consumption for commercial reasons;

(b) former fishery products other than catering waste, which are no longer intended for human consumption for commercial reasons or due to problems

of manufacturing or packaging defects or other defects which do not present any risk to humans or animals;

(c) fishery products that have been declared as unfit for human consumption as defined in regulation 13 parts (a) and (d) of the Export of Fisheries Products (Sanitary) Regulations, 2010, provided that it can be demonstrated that the final product composition is safe for the intended use;

(d) fresh by-products from fish from plants manufacturing fish products for human consumption;

(e) whole fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production.

(3) Type 3: Fishery By-Products are those by-products that are not used either as ingredients or raw materials in food or feed. Examples of such products may include but are not limited to fish skins for the tannery industry.

(4) Type 4: Fishery Waste Products shall be one or more of the following namely, material derived from fishery product processing —

(a) that has no commercial value and as such is removed from the food supply chain;

(b) that is unsafe for human consumption due to contamination in excess of limits defined in Schedule 10 of the Export of Fisheries Products (Sanitary) Regulations 2010;

(c) that is suspected of being infected with diseases or parasites communicable to humans or animals;

(d) that has been mixed with any potentially unsafe products, whether derived from products of fishery, animal origin or non animal origin;

(e) that has been handled, processed or stored in any way that may make it unsafe for human or animal consumption.

5. (1) All raw materials shall —

(a) originate from establishments, including vessels, registered and approved by the Competent Authority according to the Export of Fisheries Products Regulations 2010;.

(b) meet the requirements for food safety conditions as set out in Schedule 10 of the Export of Fisheries Products Regulations 2010;

(c) be derived from fishery products which are fit for human consumption as defined by the appropriate organoleptic and/or chemical standards for freshness.

(2) They shall be transported and stored with respect to conditions of hygiene as set out in Schedule 6 of the Export of Fisheries Products Regulations 2010.

(3) All processing shall be in accordance with the requirements for all other fishery product as set out in the Export of Fisheries Products Regulations 2010 and its Schedules.

(4) Specific products may also need to comply with additional measures as set out the Schedules to these Regulations.

6. (1) All raw materials shall —

(a) originate from establishments, including vessels registered and approved according to the Export of Fisheries Products (Sanitary) Regulations 2010;

(b) such premises shall be used for the sole purpose of processing Type 2 Fishery by-products.

(2) Traceability and recall procedures shall be implemented for all raw materials and final products as set out in Schedule 14 of the Export of Fisheries Products (Sanitary) Regulations 2010.

(3) The processing facility must meet the requirements set out in —

(a) Schedules 7 (General plant hygiene);

(b) Schedule 12 (HACCP requirements);

of the Export of Fisheries Products (Sanitary) Regulations 2010.

(4) The processing facility must be separated from any other food processing operations (although it may be linked by either a conveyor system or doorways for reception of raw material).

(5) The processing plant must have clearly defined and separated areas for handling of raw materials, processing and final product handling and storage, to prevent cross contamination between raw material and final product. The "unclean" raw material areas must include a covered reception area to receive fishery by-products and must be constructed in such a way that it is easy to clean and disinfect.

(6) The unclean sector shall include, where appropriate—

(a) areas for reception and storage of raw materials;

(b) equipment to reduce the size of animal byproducts;

(c) equipment for loading the crushed animal byproducts into the processing unit.

(7) Where heat treatment is required, all installations must be equipped with —

(a) measuring equipment to monitor temperature against time and, if necessary, pressure at critical points;

(b) recording devices to record continuously the results of these measurements; and

(c) an adequate safety system to prevent insufficient heating.

(8) The processing plant must have its own laboratory or make use of the services of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved by the Competent Authority.

General hygiene requirements

(9) Fishery by-products must be processed as soon as possible after arrival. They must be stored under appropriate conditions until processed.

(10) Containers, receptacles and vehicles used for transporting unprocessed material must be cleaned in a designated area. That area must be situated or designed to prevent the risk of contamination of processed products.

(11) There must be clear physical separation of personnel and equipment between those areas in which raw materials ("unclean") and post heat treatment product ("clean") areas are handled to prevent cross contamination of final product. Documented procedures must be established to control the movement of personnel and equipment between areas with appropriate controls prescribed (e.g. foot baths, cleaning & disinfection of equipment).

(12) Installations and equipment must be kept in a good state of repair and measuring equipment must be calibrated at regular intervals.

(13) Processed products must be handled and stored at the processing plant in such a way as to preclude recontamination.

Plants' own-checks

(14) Hygiene control must include regular own checks of the environment and equipment. Internal inspection schedules and results must be documented and maintained for at least two years.

(15) Operators and owners of processing plants shall put in place, implement and maintain permanent procedures for the application of HACCP system and own checks.

(16) Where the results of a tests on samples taken, do not comply with the provisions of these Regulations, the operator of the processing plant must —

(a) notify the Competent Authority immediately of the full details of the nature of the sample and the batch from which it was derived;

(b) establish the causes of failure of compliance;

(c) reprocess or dispose of the contaminated batch under the supervision of the Competent Authority;

(d) ensure that no material suspected or known to be contaminated is moved from the plant before being reprocessed under the supervision of the

Competent Authority and re-sampled officially in order to comply with the standards laid down in these Regulations, unless destined for disposal;

(e) increase the frequency of sampling and testing of production;

(f) investigate animal by-products records appropriate to the finished sample; and

(g) instigate appropriate decontamination and cleaning procedures within the plant;

(h) specific products may also need to comply with additional measures as set out in the Schedules.

7. (1) Products once dispatched from the fishery facility shall not re-enter the food or feed supply chain.

(2) The controls and requirements for further processing of such products are beyond the scope of this regulation.

8. (1) The fishery waste shall be —

(a) disposed of in accordance with the provisions of the Environment Protection Act 1994 and all regulations regarding the disposal of food or animal waste;

(b) unless special facilities are provided for the continuous disposal of waste, placed in leak proof, covered containers which are easy to clean and disinfect. Waste shall not be allowed to accumulate in working areas. It shall be removed either continuously or as soon as the containers are full and at least at the end of each working day in the containers or premises specifically set aside for that purpose. Care shall be taken to ensure that waste stored as provided for in this regulation does not constitute a source of contamination or pollution.

(2) The containers, receptacles and/or premises set aside for waste shall be —

(a) always thoroughly cleaned and disinfected after use;

(b) clearly labelled as Type 4 fishery waste and the containers shall not be used for any other fishery products or by-products.

(3) The waste shall be transported to disposal site in trucks and or containers specifically used for the sole purpose of waste disposal.

9. (1) The Competent Authority shall at regular intervals carry out inspections and supervision at plants approved in accordance with these Regulations. Inspections and supervision of processing plants shall take place in accordance with Export of Fishery Products (Sanitary) Regulations, 2010.

(2) The frequency of inspections and supervision shall depend on the size of the plant, the type of products manufactured, risk assessment and guarantees offered in accordance with the principles of the system of hazard analysis and critical control points (HACCP).

(3) If the inspection carried out by the competent authority reveals that one or more of the requirements of these Regulation are not being met, the Competent Authority shall take appropriate action as described under the Export of Fishery Products Act (Cap 77A).

(4) The Competent Authority shall draw up a list of plants approved in accordance with the Regulations and shall assign an official number to each plant, which identifies the plant with respect to the nature of its activities.

SCHEDULE 1

Specific Requirements for Production of Fish Oil

1. Fish oil shall be classified as either crude or refined product, where —

(a) crude fish oil shall be used only as —

(i) a product that will undergo further refining or processing before being incorporated in a food product;

(ii) an ingredient in feed manufacture, but the requirements for production of all crude fish oils irrespective of its use shall remain the same;

(b) refined fish oils shall have undergone further processing and laboratory analysis to demonstrate its safety. It can be used as an ingredient or component in food products;

(c) all fishery products used for production of fish oil shall be fit for human consumption as determined by organoleptic or TVB-N determination;

(d) the processor is responsible for conducting "own checks" on raw materials, including the determination of TVB-N, and documenting such checks as part of the HACCP plan;

(e) the maximal permitted levels for TVB-N in raw materials for production of fish oil are —

(i) 25 mg of nitrogen/100 g of flesh for species Sebastes spp., Helicolenus dactylopterus, Sebastichthys capensis;

(ii) 30 mg of nitrogen/100 g of flesh species belonging to the Pleuronectidae family;

(iii) 35 mg of nitrogen/100 g of flesh for Salmo salar, species belonging to the Merlucciidae family, species belonging to the Gadidae family;

(iv) 60 mg of nitrogen/100 g of flesh for whole fish of species that are caught for the sole and direct purpose of fish oil production;

(f) all fish to be used for the production of fish oil shall, be stored, transported and handled in conditions that are the same as for any fishery product according to the Export of Fishery Products (Sanitary) Regulations 2010, except that where whole fish of species that are caught for the sole and direct purpose of fish oil production are used they may be processed without chilling provided that the organoleptic criteria and TVB-N criteria are met and processing occurs within 36 hours of capture.

2. These levels are maximal levels designated beyond which the product is declared unsafe for use as a crude product. Analysis shall only be required for the purposes of verifying product safety where contamination is thought to have occurred.

Arsenic		
Aldrin		
Dieldrin	0.1 mg/kg	
Camphechlor		
Dioxins	6.0 pg/g	WHO-PCDD/F-TEQ/kg (1)
Sum of dioxins and dioxinlike PCBs	24.0 pg/g	WHO-PCDD/F-PCB-TEQ/kg

(1) WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation meeting in Stockholm, Sweden, 15-18 June 1997 (Van den Berg et al., (1998) Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, and PCDFs for Humans and for Wildlife. Environmental Health Perspectives, 106(12), 775).

SCHEDULE 2

Specific Requirements for Fish Meal Production

1. Processing plants must have an installation to check the presence of extraneous matter, such as packaging material, metallic pieces, etc. in the animal byproducts.

The fishery by-products must undergo an appropriate heat treatment process dependant on the particle size the raw materials have been reduced to. The processing parameters (flow rate

time and temperature etc) of this heat treatment must be proven by laboratory analysis, to ensure the final product meets the microbial standards in part 2 of this schedule.

The critical control points must at least include —

(a) raw material particle size;

(b) temperature achieved in the heat treatment process;

(c) pressure applied to the raw material, if applicable; and

(d) duration of the heat treatment process or feed rate to a continuous system.

Minimum process standards must be specified for each applicable critical control point.

When using a continuous flow system, the progression of the product through the heat converter must be controlled by means of mechanical commands limiting its displacement in such a way that at the end of the heat treatment operation the product has undergone a cycle which is sufficient in both time and temperature as verified by microbial analysis of final product.

Records must be maintained for at least two years to show that the minimum process values for each critical control point are applied.

Accurately calibrated gauges/recorders must be used to monitor continuously the processing conditions. Records must be kept for at least two years to show the date of calibration of gauges/recorders.

Material that may not have received the specified heat treatment (for example, material discharged at start up, or leakage from cookers) must be recirculated through the heat treatment or collected and reprocessed.

2. Microbial analysis for Salmonella is required to verify the effectiveness of the heat treatment,

		n	c	m	M
Salmonella	Absence in 25 g	5	0	0	0
Enterobacteriaceae		5	2	10	300 in 1 g

Where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and

c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.

3. These levels are maximal levels designated beyond which the product is declared unsafe for use as feed. Analysis shall only be required for the purposes of verifying product safety where contamination is thought to have occurred.

Arsenic	60 mg/kg	(expressed as) sodium nitrite)
Aldrin	0.1 mg/kg	
Dieldrin		
Camphechlor		
Dioxins	6.0 pg/g	WHO-PCDD/F-TEQ/kg (1)
Sum of dioxins and dioxin-like PCBs	24.0 pg/g	WHO-PCDD/F-PCB-TEQ/kg (1)

(1) WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation meeting in Stockholm, Sweden, 15-18 June 1997 (Van den Berg et al., (1998) Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, and PCDFs for Humans and for Wildlife. Environmental Health Perspectives, 106(12), 775).