SI. 82 of 2010

SI. 55 of 2011

Export of Fishery Products (Sanitary) Regulations, 2010

[6th December 2010]

ARRANGEMENT OF REGULATIONS

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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;

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(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;

(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.

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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.

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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.

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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.

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(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.

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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.

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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.

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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	- -	0.1 -	1.0 -

katsuwonus pelamis.)			
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

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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

Sulphurdioxide

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

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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.

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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.

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IV. Verification

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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.

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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.

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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.