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SATURDAY 15TH JULY, 2023

THE OFFICIAL GAZETTE 15TH JULY, 2023
LEGAL SUPPLEMENT — B

GUYANA **No. 11 of 2023**

REGULATIONS

Made Under

THE FISHERIES ACT

(CAP. 71:08)

IN EXERCISE OF THE POWERS CONFERRED UPON ME BY SECTION 79 OF THE FISHERIES ACT, I MAKE THE FOLLOWING REGULATIONS:-

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PART I

PRELIMINARY

Citation.

1. These Regulations may be cited as the Fisheries (Products) Regulations 2023.

Interpretation.
Cap. 71:08.

2. In these Regulations–

"Act" means the Fisheries Act;

"adulterated" means any carcass, part thereof, fish or fish food product under one or more of the following circumstances if it bears or contains any such poisonous or deleterious substance which may render it injurious to health;

"Antimicrobial agent" means a substance in or added to a ready-to-eat product that has the effect of reducing or eliminating a microorganism, including a pathogen such as L. monocytogenes, or that has the effect of suppressing or limiting growth of L. monocytogenes in the product throughout the shelf life of the product such as antimicrobial agents added to ready-to-eat products that are potassium lactate and sodium diacetate;

"approved" means approved by the Director of the Veterinary Public Health Unit in writing;

"aquaculture" means the rearing or cultivation of aquatic organisms using techniques designed to increase the production of those organisms beyond the natural capacity of the environment and where the organisms remain the property of one or more natural or legal persons throughout the rearing or culture stages, up to and including harvesting;

"aquaculture production business" means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to the rearing, keeping or cultivation of aquaculture animals;

"aquaculture licence" means the licence to operate an aquaculture production business;

"aquaculture animal" means any aquatic animal such as but not limited to fish, crustaceans, mollusks, amphibians and algae at all its life stages, including eggs and sperm or gametes reared in a farm or mollusk farming area, including any aquatic animal from the wild intended for a farm or molluscs farming area;

"aquaculture product" means all aquaculture animals that are harvested, transported, prepared or processed for the purpose of placing on the market for human consumption;

"autocontrol" means the quality and safety assurance systems implemented by the management of the establishment;

"batch" means the quantity of fishery product obtained under practically identical circumstances, during a period of time from an identifiable processing line and indicated by a specific code;

"beta-agonist" shall mean a beta adrenoceptor agonist;

"brine" means a mixture of potable water or clean seawater and foot grade salt;

"CCP (Critical Control Point)" means factor, practice, procedure, process or location that can be controlled in order to prevent, reduce or eliminate a hazard;

"chiller" means a chamber used for reducing the temperature of fish;

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

"chill storage room" means a chamber or room for the storage of chilled fish;

"clean water" means clean seawater and freshwater of similar quality;

"clean sea water" means sea water or brackish water which is free from microbiological contamination, harmful substances or toxic marine plankton in such quantities as may affect the health quality of fishery products and which is used under the conditions stipulated in these Regulations;

"code of best practices" describes the quality assurance system on structural and operational level, not related to food safety;

"cold storage room" means a chamber or room used for the storage of frozen fishery products (-18° C or colder);

"colours" means food additives which add or restore colour in a food;

"Competent Authority" means the Veterinary Public Health Unit of the Ministry of Health;

"container" means any box, can, tin, cloth, plastic, or any other receptacle, wrapper, or the principal covering in which fish or fishery products are packed;

"contamination" means to make impure or unclean by contact or mixture.

"consignment" means the quantity of fishery products bound for one or more customers in the country of destination and conveyed by one means of transport only;

"corrective action" means action taken when the results of monitoring at the CCP indicates a loss of control;

"CP" means control point, a processing step where the company may wish to address a quality concern not related to food safety;

"critical limit" means a standard or criterion which separates acceptability from unacceptability;

"domestic distribution system" means the pipe work fittings and appliances which are installed between the taps that are normally used for human consumption and the distribution network but only if they are not the responsibility of the water supplier;

"entry" means the point at which an imported product offered for entry receives inspection or reinspection and is marked with the official shipment mark of inspection in accordance with these Regulations;

"exportation" means to carry out from within the territorial limits of Guyana whether that departure is accomplished by land, air, or water;

"establishment" means any premises or facility where fishery products are prepared, processed, chilled, frozen, packaged or stored but it does not include any premises which auctions for fish occurs or where fish is displayed for sale by wholesale;

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

"fail safe control system" means a system to ensure control and monitoring against a standard and by implementing corrective actions;

"farm" means any premises, enclosed area, or installation operated by an aquaculture production business in which aquaculture animals are reared with a view to their being placed on the market;

"fishery products" means all sea water or fresh water animals or parts thereof regardless of the order capable to use as human food, including their roes, excluding aquatic mammals and turtles, regardles of the order;

"fishing grounds" shall be interpreted as the customary name given by the fishing industry to the place in which fishery product has been taken;

"fish product" means any derivate of fish;

"further processing" means smoking, cooking, canning, curing, refining, or rendering in an official establishment of product previously prepared in official establishments;

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

"freezer" means a chamber used for the purpose of reducing fish temperature to –18° C or colder;

"freezing of fish" the term freezing is applied to the continuous and quick process of reducing the thermal core temperature of fish or fishery products from an ambient temperature to –18° C or colder;

"frozen products" means products which have undergone a freezing process to reach a core temperature of –18° C or lower after temperature stabilization;

"gully trap" means siphon system installed in the drainage of premises to cut off an open drainage system from the outside air and avoid entrance of pests;

"HACCP (Hazard Analysis Critical Control Points)" describes the safety assurance system related to food safety;

"ice room" means a chamber used only for the manufacture or

storage of ice;

"illegal treatment" mean the use of pharmacological active substances or veterinary medical products that are prohibited or not registered for use in connection with aquaculture animals;

"importation" means the introduction in to the territory of fishery products from other countries;

"inedible" means adulterated, uninspected or not intended for use as human food;

"ingredient" means any substance used in the processing of fish that ends up in the final product;

"Inspectorate" means the Veterinary Public Health Unit responsible for the inspection of the quality control and safety assurance systems;

"inspected and passed" or "Veterinary Public Health Unit, Guyana Inspected and Passed" means that the product so identified has been inspected and passed under these Regulations and at the time it was inspected, passed, and identified, it was found to be not adulterated or contaminated;

"label" means a display of written, printed or graphic matter upon the immediate container not including package liners of any article;

"labeling" all labels and other written, printed or graphic matter-

(a) upon any article or any of its containers or wrappers or the principle covering in which fish or fishery product are packed; or

(b) accompanying that article;

"production lot" means a quantity of fishery products of a given species which have been subjected to the same treatment on sea and may have come from the same fishing grounds and the same vessel;

"management" includes any person in charge of an establishment;

"means of transport" means those parts set aside for goods in automobile vehicles and aircraft, the holds of vessels, and containers for transport by land, sea or air;

"misbranded" means any carcass, part thereof, fish or fish food product under one or more of the following circumstances if its labeling is false or misleading in any particular;

"monitoring" means conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with legal requirements on feed, food, animal health or animal welfare;

"objectionable industry" means any industry neighbouring the fish preparation or processing plant that could cause contamination of the product either directly or indirectly and includes a coal loading facility, cemetery, rubbish tip or sewerage treatment plant;

"official export health certificate" means an official certificate was produced in accordance with the regulatory requirements in fish and fishery products regulations and inspection manual or in accordance with foreign regulatory authorities regulations;

"official control" means any form of control that the competent authority performs for the verification of compliance of fish and fishery products with these Regulations or the law relating to Aquaculture;

"official analysis" means analysis carried out by an official laboratory;

"official laboratory" means the laboratory which is approved by the competent authority and is by that able to carry out official analyses;

"official sample" means a sample taken by the Competent Authority which bears, for the purposes of examination of the residues or substances it contains with a view to assessing compliance with this regulation;

"Official shipment mark" means the official inspection legend or any other symbol prescribed by the regulations in this sub-chapter to identify the status of any article, fish, or fish product under the Act or at stipulated in the inspection manual procedures;

"potable water" means water that is fit for human consumption and is complying with the standards laid down in Schedule Five either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, from a tanker, or in bottles or containers;

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

"prepared products" means any fishery product which has undergone an operation affecting its anatomical wholeness, such as gutting, heading, slicing, filleting,chopping, etc.;

"placing on the market" means the holding or displaying for sale, offering for sale, selling, delivering, or any other form of

placing on the market excluding retail sales;

"presentation" means the form in which the fish is marketed, such as whole, gutted and headless;

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

"processed products" means any fishery product which has undergone a chemical or physical process such as the heating, smoking, salting, dehydration or marinating, of chilled or frozen products, whether or not associated with other food stuffs, or a combination of these various processes;

"production methods" means a production method which shall consist of one of the following expressions according to whether the product in question is wild caught at sea or inland freshwater or resulted from aquaculture;

"production day" means a chain of activities conducted with a twenty-four hours span at a fishery product processing facility;

"production shift" a chain of activities done with a eight hour production period at a fishery product processing facility or establishment;

"ready-to-eat food" means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern;

"refrigerated brine" means brine cooled by a suitable refrigeration system;

"refrigerated seawater" means clean seawater cooled by a suitable method;

"residue" means a residue of substances having a pharmacological action, of their metabolites and of other substances transmitted to animal products and likely to be harmful to human health;

"salt" means food grade sodium chloride;

"sound" means free from disease, mould, decay or deterioration and is fit for human consumption;

"surveillance" means a careful observation of one or more feed or food business operators or their activities;

"sweeteners" means food additives which are used to impart a sweet taste to foodstuffs or table-top sweeteners;

"traceability" means the ability to trace and follow a food, feed, food producing animal or substance intended to be or expected to be incorporated into a food or feed through all stages of production, processing and distribution;

"unauthorised substances or products" means substances or products the administering of which to aquaculture products is prohibited under the law relating to Aquaculture;

"verification" means the application of methods, procedures and tests, in addition to those used in monitoring, to determine

compliance with the HACCP plan and whether the HACCP plan needs modification;

"visible parasite" means a parasite or group of parasites which has a dimension, colour or texture which is clearly distinguishable from fish tissues;

"visual inspection" means a non destructive examination of fish or fishery products without optical means of magnifying and under good light conditions for human vision, including if necessary, candling;

"wild catch" means fish harvested from seas, rivers and other natural bodies of water or environment;

"withdrawal times" has the same meaning as in the law relating to aquaculture.

PART II

COMPETENT AUTHORITY

Designation of Competent Authority.

3. (1) The Veterinary Public Health Unit is empowered to enforce these Regulations.

(2) The Organogram of the Competent Authority is set forth in Schedule One to these Regulations.

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(3) Responsibilities of the Competent Authority shall be in accordance with-

(a) the tasks, duties and responsibilities under the Fisheries Act; and

(b)

(c) the responsibilities governing Official Control set out in Part VIII of these Regulations.

Appointment of health inspectors.

Cap. 71:08

4. (1) The Minister of Health, may appoint suitably qualified persons, to perform the functions set out in section 2(3) of the Fisheries Act.

Schedule Twelve

(2) The Competent Authority shall ensure that all of its staff performing official controls receive up to date and appropriate training enabling them to undertake their duties competently and regular additional training in keeping with Schedule Twelve of these Regulations as necessary to carry out official controls in a consistent manner.

PART III
ENFORCEMENT

Compliance with enforcement procedures.

5.Enforcement Procedures laid down in the Fisheries Act and the Regulations made there under shall be complied with by every authorised Officer of the Competent Authority.

PART IV
APPROVAL

Approval of establishments.

6. (1)The following approval procedures for an establishment shall be enforced by the Competent Authority.

(2) No person shall commence to build, rebuild or adapt any establishment, acting on his own initiative and or on the initiative of the Competent Authority, without first making an application to the Competent Authority to inform the Director Veterinary Public Health Unit about the-

(a) activities carried out or proposed to be carried out in the establishment;
(b) lay out (blue print) indicating locations of storage, facilities, equipment, the product flow, the human flow and the plumbing system for potable, non-potable and waste.

(3) After receiving the application, the Director of the Veterinary Public Health Unit shall-

(a) verify whether the proposal submitted has fulfilled the requirements laid down in regulations 46 to 74 of Part XI of these Regulations;
(b) send, within fourteen working days, an invitation to management to discuss the application.

(4) Once the Director of Veterinary Public Health Unit accepts the proposal of the management, his approval shall be signified by affixing the official stamp of the Competent Authority over his signature to the plans and specifications.

(5) On completion of the building, construction or renovation, extension or adoption, the management shall inform the Director of the Veterinary Public Health Unit inviting him in writing, to conduct an audit of the establishment.

(6) After the audit, the Director of the Veterinary Public Health Unit shall-

(a) verify whether the establishment meets the quality assurance and safety assurance conditions laid down in Part XI, XII and XIII with regard to the nature of the activities carried out in the establishment;

(b) within fourteen working days inform the management in writing whether or not the establishment has met the requirements and conditions.

(7) After approval, the establishment shall receive an approval certificate or letter and where necessary a national establishment approval number.

(8) The approval shall be reviewed where management of an establishment decides to carry out activities other than those for which approval has been granted.

Approval of vessels and other facilities.

7. (1) An approval procedure shall be established by the Competent Authority for fishing vessels in accordance with regulation 6 and resulting in registration and the provision of a registration number for these vessels complying with the requirements for fishing vessels laid down in regulations 36 to 42.

(2) An approval procedure shall be established by the Competent Authority for the approval of official and private landing sites, and if applicable for auctions, resulting in a registration and the provision of a registration number for these installations complying with the requirements for landing and unloading of fishery products laid down in Part X of these Regulations.

(3) An approval procedure shall be established by the Competent Authority for the approval of the seaport and airport facilities for offloading, transport and storage for fishery products resulting in registration and the provision of a registration number for these facilities complying with the requirements-

(a) for unloading of fishery products laid down in Part X;

(b) for transport of fishery products laid down in regulations 195 to 208; and

(c) for storage of fishery products laid down in regulations 179 to 194 of these Regulations.

(4) The Competent Authority in cooperation with the Authority as stipulated in the law relating to Aquaculture, and subject to compliance with requirements stipulated in the law relating to Aquaculture, shall provide an approval procedure for aquaculture farms, that will allowed them to supply raw materials to an approved establishment.

(5) The approval procedure laid down in regulation 6 shall apply *mutatis mutandis* to the approval procedures described in regulation 7.

(6) Chemicals used for the following purposes shall be approved by the Competent Authority-

(a) for eradication of pests which include, insects, reptiles and rodents; and

(b) for cleaning and disinfecting premises in the establishments and surroundings.

Monitoring of the approval system.

8.(1) The Competent Authority shall draw up an official list of and placed or affixed the National Approval Number assign to each-

(a) approved establishments;
(b) approved and registered vessels;
(c) approved and registered official and private landing sites and auctions, if applicable;
(d) approved and registered chemicals used as mentioned in regulation 7 (5)-
    (i) for eradication of pests; and
    (ii) for cleaning and disinfecting purposes;
(e) approved and registered seaport and airport facilities;

(f) aquaculture farms that are approved to supply raw materials to approved establishment.

(2) The inspection of establishment, vessel, official and private landing sites and auctions if applicable shall be-

(a) carried out regularly by the Inspectorate to verify whether the facilities still comply with the requirements and whether they are still allowed to keep their official number; and

(b) if such inspection and monitoring reveals that the requirements are not being met anymore, the Competent Authority shall take appropriate action.

(3) The Authority under the law relating to aquaculture with the cooperation of the Inspectorate shall-

(a) regularly inspect aquaculture farms to ascertain continued compliance with the requirements for supplying approved establishments; and

(b) determine whether approval should be withdrawn and appropriate action taken to prevent raw materials being supplied to approve establishment.

(4) The list of approved chemicals shall be updated when necessary.

PART V
PLACING OF FISHERY PRODUCTS ON THE MARKET

General conditions.

9. (1) Fishery products, caught in natural environment and intended to be placed on the market shall-

(a) have been caught and where appropriate handled for bleeding, heading, gutting, and the removal of fins, chilled or frozen, prepared or processed, on board vessels in accordance with the hygiene rules established in regulations 36 to 42 of Part IX;

(b) have been handled, during and after landing, in accordance with the requirements laid down in Part X of these Regulations;

(c) have been handled and, where appropriate packaged, prepared, processed, frozen, defrosted or stored hygienically in plants approved in accordance with regulation 6 of these Regulations in compliance with the requirements of Regulations 46 to 74 of Part XI;

(d) have been appropriately packaged in accordance with the requirements laid down in regulation 173 of these Regulations;

(e) have been given an identification mark in accordance with regulation 173 of these Regulations;

(f) have been certified in accordance with the conditions laid down in regulation 15 of these Regulations;

(g) be stored and transported under satisfactory conditions of hygiene and temperature in accordance with regulations 179 to 208 of Part XI of these Regulations;

(h) be prepared or processed in accordance with the Quality Assurance program established in Part XI and in accordance with the safety assurance program established in Part XIII of these Regulations;

(i) not contain substances or food additives prohibited by these Regulations or not included in the positive list as referred to in Part XII of these regulations;

(j) not contain any substance in excess of any maximum quantity or proportion permitted by the provisions laid down in Part XII of these Regulations;

(k) be dispatched to harbours, for frozen products, and airports, for fresh products, and stored there under satisfactory conditions of hygiene and temperature in accordance with the requirements laid down in regulations 179 to 208 of Part XI of these Regulations.

(2) Aquaculture products intended to be placed on the market shall-

(a) be harvested from farms which are registered and licensed by the Authority in compliance with subregulation 7(4) and which are listed and approved as per subregulation 8(1)(f) and 8(2)(b) of this regulation;

(b) be slaughtered under appropriate conditions of hygiene in compliance with the requirements of regulations 46 to 74 of Part XI;

(c) not be soiled with earth, slime or faeces;

(d) be kept chilled in accordance with the requirements laid down in these regulations if not processed immediately after being slaughtered;

(e) have been handled and, where appropriate packaged, prepared, processed, frozen, defrosted or stored hygienically in plants approved in accordance with regulation 6 of these Regulations in compliance with the requirements of regulations 46 to 74 of Part XI;

(f) have been appropriately packaged in accordance with the requirements laid down in regulation 173 of these Regulations;

(g) have been given an identification mark in accordance with regulation 173 of these Regulations;

(h) have been certified in accordance with the conditions laid down in regulation 15 of these Regulations;

(i) be stored and transported under satisfactory conditions of hygiene and temperature in accordance with regulations 179 to 208 of Part XI of these Regulations;

(j) be prepared or processed in accordance with the Quality Assurance program established in Part XI and in accordance with the safety assurance program established in Part XIII of these Regulations;

(k) not contain substances or food additives prohibited by these Regulations or not included in the positive list as referred to in Part XII of these regulations;

(l) not contain any substance in excess of any maximum quantity stipulated in Part XII and Schedules 4 and 11 of these Regulations;

(m) be dispatched to harbours, for frozen products, and airports, for fresh products, and stored there under satisfactory conditions of hygiene and temperature in accordance with the requirements laid down in regulations 179 to 208 of Part XI of these Regulations.

(3) Where gutting is possible from a technical, commercial and hygienical viewpoint-

(a) it shall be carried out as quickly as possible after the products have been caught or landed;

(b) or, they shall be frozen on the vessel immediately in case the products are not gutted after having been caught.

(4) The placing on the market of the following products shall be forbidden-

(a) poisonous fish of the families Tetraodontidae, Molidae, Diadontidae, Balistidae, Murenidae, Canthigasteridae;

(b) fishery products containing bio-toxins that may endanger human health such as ciguatera toxins or muscle paralysing toxins;

(c) fishery products containing other substances that may endanger human health, such as histamine, environmental contaminants or residues of veterinary medical products in an amount higher than the levels established in regulation 16 to 22 and Schedules 4 and 11 of these Regulations;

(d) fresh, prepared, frozen and processed fishery products belonging to the family Gempylidae, in particular Ruvettus pretiosus and Lepidocybium flavobrunneum, may only be placed on the market in wrapped or packaged

form and must be appropriately labelled to provide information to the consumer on preparation or cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects and the scientific name of the fishery products must accompany the common name on the label.

(5) Detailed requirements on the species concerned by this subject, and concerning levels and methods of analysis are laid down in regulation 16 to 24 of Part VIII of these Regulations.

PART VI

IMPORTATION

Conditions for importation.

10. In application of section 47 of the Fisheries Act, the following additional import conditions are established-

(a) the provisions applied to imports of fishery products from other countries shall in principle be at least equivalent to those governing the production and placing on the market, as described in these Regulations;

(b) specific import conditions may be laid down-

(i) to protect public health of the citizens of Guyana without prejudice to the possibility that imported products may be exported;

(ii) to allow importation of products for local consumption,

under the condition that these products cannot be re-exported or used as raw material in an establishment approved to export fishery products.

Notification by importer.

11. A person who holds an import licence shall notify the Competent Authority of each importation of fishery products in the form and manner prescribed and shall not market the fishery product without the Competent Authority's approval.

Off shore inspection.

12. The Minister may enter into an off shore inspection arrangement with one or more foreign governments, government agencies or trade organisations where he is satisfied, based on verification by the Competent Authority that the legal requirements, fish inspection systems and infrastructure for preparing fish for export in that country and that the fish imported into this country meet the requirements of the laws of Guyana.

Contents of arrangement.

13. An off shore inspection arrangement may include after consultation with the Competent Authority-

(a) issue foreign plant operating license for the purpose of exporting fish to Guyana;

(b) inspect establishments in the other country and the fishery products prepared or processed in those establishments;

(c)establish compliance, monitoring and inspection requirements for imports from

the other country or from establishments in that country;

(d) recognise certificates of inspection issued by other countries;

(e) implement any programme or project related to fishery products inspection and make funding arrangements for the purpose including the sharing of revenues or the recovery of costs so the programme or project; or

(f) fix fees for foreign plant operating certificates or for the recovery of the costs of delivery of off shore Inspectorates.

Foreign Government inspection.

14. The Minister may after consultation with the Competent Authority rely on results of inspections conducted by the inspection agency of a foreign government or foreign trade organisation for the purpose of negotiating or implementing an off-shore arrangement or of determining whether fishery products imported pursuant to an arrangement meet the requirements of these Regulations.

PART VII

EXPORTATION

Conditions for exportation.

15. (1) In addition to the conditions set out under section 47 of the Act, the following shall apply to export of fishery products from Guyana-

(a) except where otherwise agreed upon by a purchaser, no person shall export, process for

export or attempt to export or process for export, any fishery product unless that fishery product is prepared or processed in an establishment in accordance with the requirements laid down in Part XI of these Regulations;

(b) no person shall export, process for export or attempt to export, process for export any fish that is tainted, decomposed or unwholesome or otherwise fails to meet the requirements of these Regulations.

Schedule Two.

(2) All shipments of fishery products of any type, in any presentation, quantity, and by any means, should be accompanied by an Export Health Certificate delivered by the Competent Authority and set forth in Schedule Two of these Regulations.

(3) In case of failure to present this certificate, exportation of product shall be forbidden.

PART VIII

OFFICIAL CONTROL

Official control plan.

16. (1) All fish and fishery products whether caught in natural environment or raised in aquaculture shall be subject to Official Control for the purpose of verifying the compliance with this regulation and related requirements.

(2) The Competent Authority shall establish the system of Official Control including inspection, audits, monitoring and surveillance, sampling and testing.

(3) The frequencies and the methods applied in Official Control shall be decided based on a risk evaluation including at least identified risks, past records of compliance and the reliability

of establishment's quality assurance and food safety control systems.

(4) The frequencies of inspections of establishments approved by the Competent Authority to prepare, process,package,store and transport fish and fishery products of the order of siluriformisfor the purpose of export shall be done by having an inspector presence at least once per eight hours production shift to perform inspection.

(5) The Official Control shall include four programs -

(a) national Monitoring Program for Environmental Contaminants in wild caught fishery products;

(b) surveillance of sanitary soundness of products;

(c) national Monitoring Program for Residues of Veterinary Medicinal Products and Environmental Contaminants in fishery product of aquaculture origin;

(d) the Official Control of "Production Conditions".

The National Monitoring Programme for Environmental Contaminants in wild caught fishery products.

17. (1) The National Monitoring Programme for Environmental Contaminants in wild caught fishery products shall-

(a) be programmed on a yearly base;

(b) have a mid-term or long-term approach.

(2) The Competent Authorities shall draw up and implement a sampling plan which shall include species, substances

to monitor, marine areas to be covered and places for sampling and the plan shall consider at least-

(a) the species related hazards in relation to the commercial species in the region;

(b) chemicals such as herbicides, pesticides, insecticides used in the past and at present in Guyana and neighbouring countries and which may have contaminated the marine environment;

(c) chemicals, produced by industries that could contaminate the sea by effluents;

(d) the presence of heavy metals in marine areas due to natural conditions or industrial contamination.

(3) Sampling and analytical methods shall follow criteria stipulated in Schedule Four to these Regulations.

Surveillance of sanitary soundness.

18. (1) The Competent Authority shall implement a program for surveillance of the sanitary soundness of the fishery products, regarding the presence of parasites, toxins, microbes, viruses, environmental, accidental, intentional contaminants or adulterants present in the fishery products due to-

(a) their natural presence in the aquatic environment; and

(b) the pollution of the aquatic environment and which could endanger human health.

(c) test methods such as atomic absorption spectroscopy, UPLC, UH PLC-MS-MS, LC MS MS or/and any scientifically proven method use for heavy metals such as cadmium, lead, mercury and arsenic.

Parasites.

19. (1) The presence or absence of parasites, in the different commercial fish species, the oceanographic distribution in the region and the risk assessment in relation to human health shall be demonstrated by the Competent Authority, based on scientific studies or research.

(2) Fish or fish species which are obviously infested with parasites shall not be placed on the market for human consumption.

Monitoring plan for Scombrotoxin (histamine).

20. (1) The Competent Authority shall install a monitoring program to verify the efficiency of the auto control system implemented by the management of the establishment and to evaluate the risk of histamine to human health.

(2) In order to put in place a monitoring system for histamine following conditions shall be implemented-

(a) nine samples shall be taken from each batch and shall fulfill the following requirements-

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

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

(iii) no sample may have a value exceeding 200 ppm;

(b) these limits apply only to fish species of the following families: Scrombridae, Clupeidae, Engraulidae and coryphaenidae and fish belonging to these families, which have undergone enzymatic ripening by treatment in

brine, may have higher histamine levels but not more than twice the above values;

(c) examinations shall be carried out in accordance with reliable, scientifically recognized methods, such as "high performance liquid chromatography" (HPLC).

Toxic Species and fish toxins in general.

21. (1) The presence or absence of the different fish-toxins in the different commercial fish species, their oceanographic distribution and seasonal occurrence in the region shall be determined by the Competent Authority, using scientific studies or research.

(2) Surveillance shall be implemented by the Competent Authority to ensure that no poisonous fish is placed on the market-

(a) from the following families: Tetraodontidae, Molidae, Diodontidae, Canthigasteridae;

(b) containing ichthyosarcotoxins, type tetraodotoxin.

(3) Surveillance shall be implemented by the Competent Authority to ensure that species of Gempylidae, in particular Ruvettus pretiosus and Lepidocybium flavobrunneum, are placed on the market only in wrapped or packaged form and appropriately labeled as stipulated in regulation 4(d).

National Monitoring Program for

22. (1) A monitoring program shall be planned and implemented by the Competent Authorities to ensure that

Residues in Products from Aquaculture and Marine species.
Schedule Four
Schedule Eleven

products originating from aquaculture or marine species do not contain residues of veterinary medicines, environmental contaminants or other chemicals in excess of the levels stipulated in Schedule Four and Schedule Eleven of these Regulations.

(2) The purpose of the monitoring program for fishery products originating from aquaculture and marine species shall be to detect potential residues-

(a) due to illegal use of veterinary medicinal products or other chemicals that are prohibited for use;

(b) in excess of established MRL´s due to wrong use of veterinary medicinal products or other chemicals that are allowed for use;

(c) of environmental contaminants such as heavy metals and pesticides in excess of established MRL´s due to contamination of the farming area;

(d) due to illegal use of pesticides that is not allowed for use by the Guyana Pesticide and Toxic Chemical Board.

(3) The monitoring program for fishery products originating from aquaculture and marine species shall be planned and implemented on an annual basis and an annual report shall be prepared and the planning, sampling and reporting shall follow the stipulations in Schedule Eleven to these Regulations.

(4) In the case of non-compliant results, the Competent Authorities shall take immediate action to-

(a) investigate the cause of the non-compliant result;
(b) ensure that the product in question is not placed on the market and where so placed withdrawn from the market;
(c) ensure that appropriate actions are taken against the involved aquaculture business operators with the view to prevent a recurrence of any such non-compliance.

(5) The actions mentioned in sub regulation 22(3) shall be taken in coordination with the Authority as stipulated in the law relating to Aquaculture.

Standards for residues of veterinary medicals and Environmental Contaminants. Schedule Four Schedule Eleven

23. (1) Fishery products to be placed on the market for human consumption shall not contain residues of veterinary medical products and environmental contaminants in levels higher than specified in Schedule Four and Schedule Eleven of these Regulations.

(2) The Competent Authority shall ensure that the laboratories are designated according to Regulation 35 of this Regulation and that the methods of analysis used for testing of residues of veterinary medical products and environmental contaminants comply with performance criteria as stipulated in Schedules Four and Eleven to these Regulations.

(3) Methods of sampling stipulated or prescribed in Schedule Four, Part II and Schedule Eleven of these Regulations shall be followed.

(4) Sample preparations and criteria for methods of analysis are stipulated or prescribed in Schedule Four, Part III and Schedule Eleven of these Regulations shall be followed.

Records and data of monitoring programmes.

24. Plans, records and results of the national monitoring programs shall be preserved and made available at any time.

Official Control for Production Conditions.

25. (1) The Official Control of "Production Conditions" shall be done as a daily or regular surveillance activity.

(2) The Official Control of Production Conditions shall target different control points in the production chain, in order to establish whether the sector in the field of work is complying with all the requirements during the whole production chain from catch till dispatch, stipulated in these Regulations.

Official Control before first sale.

26. (1) Arrangements for the organisation implementation and maintenance of the health checks shall be made by the Competent Authority to establish-

(a) an inspection comprising an organoleptic check which shall be carried out to check whether they are fit for human consumption, in accordance with the requirements laid down in Regulations 103 to 117 of these Regulations-

(i) by the Competent Authority of each batch of fishery products at

the time of landing or before first sale; or

(ii) by the quality manager of each batch of fishery products during reception of fish in the establishment, cross checked at regular intervals by the official health inspector;

(b) if the organoleptic examination reveals any doubt as to the freshness of the product, an inspection comprising physical, chemical or microbiological methods in accordance with the requirements laid down in regulation 111 of these Regulations;

(c) an inspection of the physical soundness of the fishery products in accordance with the requirements laid down in regulation 112 of these Regulations;

(d) an inspection of the sanitary soundness of the fishery products in accordance with the requirements laid down in regulation 113 of these Regulations;

(e) sampling and monitoring of water and ice used in contact with fisheries products in accordance with requirements laid down in regulations 98 to 101 of these Regulations.

Official Control of the auto control system guaranteed by the sector on the level of vessels.

27. (1) Arrangements for checking, controlling and monitoring the hygiene rules applicable to fishery products caught on board fishing vessels shall be made by the Inspectorate in order to establish whether the fishery products, have been caught and where appropriately handled for bleeding, heading, gutting and the removal of fins, chilled or frozen, prepared or processed on board vessels in accordance with the hygiene rules established in regulations 36 to 42 of these Regulations.

(2) Such arrangements will include, in particular, a check on factory vessels and fishing vessels, on the understanding that such a check may be carried out during the stay in port. In order to ensure the implementation of a coherent and efficient inspection, the Competent Authority shall-

(a) implement a registration system and should keep up-to-date for control purposes, a list of vessels equipped as: freezing vessels, CSW (chilled sea water) vessels and as RSW (refrigerated sea water) vessels;

(b) the registration, the controls and the checks of the vessels shall be done by-

(i) the Competent Authority of the country of which the vessel is flying the flag; or

(ii) the Competent Authority of another

country on condition-

(A) such country figures on the community list of the third countries authorised to import fishery products into the EC community;

(B) the fishery products are landed regularly on its territory; and

(C) are inspected by its Competent Authority which shall also apply the health conditions to the products, and, issue the export health certificate;

(iii) the Competent Authority of an EC member state;

(c) implement an approval procedure for factory vessels in accordance with the approval procedure for establishments as referred to in regulation 6 of these Regulations;

(d) control the autocontrol (quality assurance : good practices; safety assurance; HACCP) system implemented by the qualified person (quality manager) on board of the factory vessels;

(e) indicate the frequency of inspection;

(f) make records of every inspection.

Official Control of the auto control system guaranteed by the sector on the level of landing and unloading.

28. Arrangements for checking, controlling and monitoring the hygiene rules and conditions of landing and first sale shall be made by the Inspectorate in order to establish whether the fishery products, have been handled during and after landing and in the auction markets in accordance with the hygienic rules and conditions established in Part X of these Regulations.

Official Control of the auto control system guaranteed by the sector on the level of transport.

29. Arrangements for checking, controlling and monitoring the hygiene rules of transport conditions shall be made by the Inspectorate in order to establish whether fishery products, caught in natural environment, have been transported under satisfactory conditions of hygiene and temperature in accordance with the hygienic rules and conditions established in regulations 195 to 209 of Part XI of these Regulations.

Official Control of the auto control system guaranteed by the sector on the level of establishments.

30. Arrangements for checking, controlling, inspection and monitoring at regular intervals of establishments shall be made by the inspectorate to verify the efficient implementation of the quality assurance program, as required in Part XI, the safety assurance program as required in Part XIII and the requirements for the use of sweeteners, food colours or other food additives laid down in Part XII of these Regulations in order to establish-

(a) whether fishery products caught in natural environment have been handled and where appropriate prepared, processed, stored, frozen, defrosted, packaged, identified by a mark;

(b) whether the cleanliness conditions of premises, facilities and instruments and staff hygiene are;

Schedule Five

(c) whether fishery products, prepared or processed from fish species which are estimated to be a potential hazard in relation to regulation 9 of these Regulations, before being released for human consumption are subjected to a visual inspection by way of sample, for the purpose of detecting any parasites that are visible;

(d) whether the water and ice used in contact with fishery products comply with criteria

stipulated in Schedule Five to these Regulations as required in regulations 98 to 101 of these Regulations.

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Official Control of the auto control system guaranteed by the sector on the level of approval conditions.

31. Arrangements for controlling and monitoring the approval and registration conditions and requirements, laid down in regulation 6 of these Regulations shall be made by the Competent Authority in order to establish whether these conditions and requirements are still fulfilled.

Official Control of the auto control system guaranteed by the sector on the level of certification.

32. Arrangements shall be made by the inspectorate to ensure that error or fraud can be excluded and that the declarations on the export certificates are truthful for-

(a) final checking of the guarantees obtained during the whole production chain before certification; and

(b) stipulation of reliable conditions for certification.

Official Control of the auto control system guaranteed by the sector on the level of airports and sea ports.

33. Arrangements for checking, controlling and monitoring the hygiene, chilling storage conditions, and the frozen storage conditions on airport and seaports shall be made by the inspectorate in order to establish whether the fishery products have been handled, stored and dispatched in accordance with the hygienic rules and conditions established in regulations 179 to 208 of Part XI of these Regulations.

Records.

34. Records of official controls shall be kept and available at any time.

Official Laboratories.

35. (1) The Competent Authority shall, after auditing and on the basis of the audit report, approve laboratories and designate these laboratories as official laboratories.

(2) The Competent Authority shall designate the authority responsible for the inspection and audit of the laboratories for compliance with the agreed criteria.

(3) To be approved, laboratories shall be able to carry out non clinical-

(a) microbiological tests (e.g. on food, contact surfaces, residues of antibiotics);

(b) chemical tests (e.g. heavy metals, industrial chemicals, medicinal products, food additives, animal feed additives and pesticides);

(c) biological tests (e.g. detection and identification of parasites, bio assay for the detection of marine biotoxins);

(d) physical and chemical tests for freshness determination of fishery products (e.g. pH measurements, refractometric index of the eye liquid, TVB-N (Total Volatile Basic – N);

(e) equipped to do analyses of-

(i) organic and inorganic chemicals;
(ii) marine and fish toxins;
(iii) biological organisms;
(iv) microbiological organisms;

(f) as described in these Regulations-

(i) able to carry out the different reference methods or to comply with the performance criteria described in Schedules to these Regulations or required by foreign markets;
(ii) accredited to ISO 17025 for the relevant test methods and criteria.

(4)Where foreign laboratories are designated as official laboratories for specific tests, a contract or written agreement shall be made specifying the terms of reference of the agreement.

(5) The Competent Authority shall draw up a list of the approved laboratories and designate, on the basis of the audit report which tests they are assigned to carry out for the purpose of official control.

PART IX

CONDITIONS APPLICABLE TO VESSELS

General conditions applicable to vessels.

36.(1) The following conditions concerning construction and equipment shall apply to vessels-

(a) the sections of the vessels or the containers reserved for the storage of fishery products shall-

(i) be covered and self-draining;

(ii) be well insulated;

(iii) have provision for holding a reasonable quantity of ice or have an alternative means of refrigeration; and

(iv) not contain objects or products liable to transmit harmful properties or abnormal characteristics of the foodstuffs;

(b) these sections or containers shall be designed as to allow them to be cleaned easily and to ensure that melt water cannot remain in contact with fishery products;

(c) decks used for fish handling may be constructed of one or more of the following

materials, namely surface-coated aluminium, fiberglass, timber-sheathed or coated with an epoxy finish or similar;

(d) where fish does not normally come in contact with the deck and the timber is clean, sound and well caulked untreated timber is allowed on exposed decks;

(e) where operations are carried out in daylight hours unenclosed fish handling areas on decks shall be effectively roofed over or protected by a substantial and easily erected awning;

(f) water used at any stage of processing shall comply with the parameters of potable water, laid down in regulations 84 to 102 of Part XI of these Regulations or of clean sea water and sea water intakes for vessels shall be located forward of any toilet or bilge discharge;

(g) sinks, processing tables, equipment used for gutting, heading and the removal of fin and containers and equipment in contact with the fishery products, shall be made of or coated with a material which is waterproof, resistant to decay, smooth and easy to clean and disinfect and when used they shall be completely clean.

(2) The following conditions concerning use and maintenance shall apply to the vessel-

(a) when used, the section of vessels or the containers reserved for the storage of fishery products shall

be completely cleaned and, in particular, shall not be capable of being contaminated by the fuel used for the propulsion of the vessel or bilge water;

(b) after the fishery products have been unloaded, the containers, equipment and sections of vessels which are directly in contact with the fishery products shall be cleaned with potable water or clean water.

(3) The following conditions shall apply to the handling and storage of fishery products on board-

(a) as soon as they are taken on board, the fishery products shall be protected from contamination and from the effects of the sun or any other source of heat and when they are washed, the water used shall be either fresh water complying with the parameters set out in regulations 84 to 102 of Part XI of these Regulations or clean seawater, so as not to impair their quality or wholesomeness;

(b) the fishery products must be chilled immediately with ice, and stored in insulated containers or holds and however in the case of fishing vessels where cooling in not possible from a practicable point of view the fishery products must not be kept on board for more than eight hours;

(c) the fishery products shall be handled and stored in such a way as to prevent bruising and the use of spiked instruments shall not be tolerated for the moving of large fish or fish, which might injure the handler, provided the flesh of these products, is not damaged;

(d) fishery products shall undergo, if applicable, cold treatment as soon as possible after loading; complying with the conditions laid down in regulation 38(3)(a) of this document;

(e) ice used for chilling of products shall be made from potable water or clean sea water and before use it shall be stored under conditions which prevents its contamination; and

(f) where fish is headed or gutted on board such operation shall be carried out hygienically and the products shall be washed immediately and thoroughly with potable water or clean sea water and the viscera and parts, which may pose a threat to public health, shall be removed and set apart from products intended for human consumption and livers and roes intended for human consumption shall be refrigerated or frozen.

(4) Staff assigned to handling of fishery products shall be required to maintain a high standard of cleanliness for themselves and their clothes.

Additional hygiene conditions.

37. (1) Additional hygiene conditions are applicable to the fishing vessels designed and equipped to preserve fishery products on board under satisfactory conditions for more than twenty-four hours, other than those equipped for keeping fish, shellfish and molluscs alive without other means of conservation on board.

(2) When additional hygiene conditions are applicable for certain vessels, the general hygiene conditions applicable to fishery

products on board all fishing vessels, laid down in regulation 36 of these Regulations are also applicable.

(3) The following conditions concerning construction and equipment shall apply-

(a) fishing vessels shall be equipped with holds, tanks or containers for the storage of refrigerated or frozen fishery products at the temperature laid down by these Regulations and these holds shall be separated from the machinery space and the quarters reserved for the crew by partitions which are sufficiently impervious to prevent any contamination of the stored fishery products;

(b) the inside surface of the holds, tanks or containers shall be water proof and easy to wash and disinfect and it shall consist of a smooth material or failing that, smooth paint maintained in a good condition, not being capable of transmitting to the fishery products substances harmful to human health;

(c) the holds shall be designed to ensure that melt water cannot remain in contact with the fishery products;

(d) containers used for the storage of products shall ensure their preservation under satisfactory conditions of hygiene and, in

particular, allow drainage of water and when used they shall be completely clean;

(e) refrigeration shall be carried out in refrigeration holds, refrigerated sea water tanks or other suitable equipment and refrigeration capacity shall be sufficient to rapidly cool fish from ambient temperature to the temperature of melting ice and hold it at this temperature;

(f) waterproof and separate storage room shall be provided for the storage of cartons, ship to shore containers and the like;

(g) artificial lighting shall be provided where necessary and where handling, processing and inspection takes place at night and below deck and in enclosed processing areas;

(h) the intensity of illumination shall be a minimum of: 220 lux in the processing area, 540 lux where the product is being inspected;

(i) sanitary facilities including toilet and shower facilities shall be sufficient in number for the normal complement of crew and any toilet shall be equipped with not hand or elbow operable wash basin located in the toilet room or immediately outside the door and berth shall be available for each member of the crew and when required for a Fisheries Officer and a Veterinary Public Health Inspector;

(j) hydraulic circuits shall be protected in such a way as to ensure no oil leakages can contaminate product.

(4) The following conditions concerning use and maintenance shall apply to vessels-

(a) the working decks, the equipment and the holds, tanks and containers shall be cleaned each time they are used for this purpose and disinfecting, the removal of insects or rat extermination shall be carried out whenever necessary;

(b) cleaning products, detergents and disinfectants, insecticides, rodenticides and all potentially toxic substances shall be stored in locked premises or cupboards physically separated from fish cartons and ship to shore containers and their use shall not present any risk of contamination of the fishery products.

(5) The following conditions concerning handling and storage of fishery products on board vessels shall apply-

(a) ice for chilling of fishery products shall be used in such a way and in such quantities, so that by unloading of the fishery products, they still have the temperature of melting ice;

(b) the water inlet for vessels, having an intake system for seawater, shall be located in front of the outlet for waste and sewerage water;

(c) fishing vessels that use seawater to wash up and process, shall do so in uncontaminated waters and whilst the vessel is moving in open waters;

(d) fishing vessels that use seawater and anchor at secure harbourages to wash up and process shall ensure that-

(i) waters are uncontaminated and meet the requirements of clean seawater;

(ii) toilet facilities are not operated unless self-contained;

(iii) the vessel is far enough from the shore and in deep water.

(6) Subregulation 37 (5) (d) shall not apply to vessels that use a self-contained water system and the water meets the requirements laid down in regulations 84 to 102 of Part XI of these Regulations.

(7) The following conditions concerning personnel shall apply-

(a) staff assigned to the handling of fishery products shall be required to maintain a high standard of cleanliness for themselves and their clothes;

(b) ship owners or their representatives shall take all the measures necessary to prevent persons liable to contaminate fishery products from working on board handling them, until there is evidence that such persons can do so without risk and the routine medical monitoring of such people shall be governed by the national laws.

Specific hygiene conditions applicable to fishery products caught on board fishing vessels equipped for freezing fishery products on board.

38. (1) General hygiene conditions applicable to fishery products on board all fishing vessels laid down in regulation 36 of these Regulations are applicable to fishery products caught on board fishing vessels equipped for freezing.

(2) Additional hygiene conditions applicable to the fishing vessels designed and equipped to preserve fishery products on board under satisfactory conditions for more than twenty-four hours laid down in regulation 37 of these Regulations are applicable.

(3) If fishery products are frozen on board, this operation shall be carried out in accordance with following conditions-

(a) fishing vessels shall have freezing equipment, sufficiently powerful-

(i) to achieve rapid reduction in temperature to (-18° C);

(ii) to keep products in storage rooms at (-18° C);

(iii) to freeze whole fish in brine intended for canning at (-9° C);

(b) fresh products to be frozen shall comply with the requirements of the conditions for the fresh products laid down in regulation 161 of these Regulations;

(c) temperature recording devices in storage rooms shall be located in a place where they can easily be read and the temperature sensor of the recorder shall be located in the area furthest away from the cold storage, where the temperature in the storage room is the highest and temperature charts shall be available at least during the period in which the products are stored;

(d) a freezer shall be physically separated from the hold in which the frozen food is stored, provided with separated refrigeration;

(e) if the freezer is located within storage hold where frozen food is stored, it shall be separately refrigerated, provided with doors of a material that ensures its efficiency when operating and effectively divides the freezer from the hold;

(f) freezer holds, blast freezers, plate freezers and the like shall be capable of reducing the temperature of fish

undergoing freezing to –18° C or colder;

(g) a waterproof, hygienic and separate storage room shall be provided for the storage of cartons (first and second envelope);

(h) on prawn trawlers, prawns can be packed and frozen whole or headed when the hygienic conditions comply with the requirements laid down in the general, the additional and the specific hygiene conditions laid down in regulation 36, 37 and 38 of these Regulations;

(i) when prawns are headed before packing and freezing, special hygiene measures have to be taken to prevent contamination by the environmental circumstances;

(j) where freezing in brine is used, the brine shall not be a source of contamination for the fish.

Specific hygiene conditions applicable to fishery products caught onboard fishing vessels equipped for chilling of fishery products in cooled seawater either chilled by ice

39. (1) General hygiene conditions applicable to fishery products on board all fishing vessels laid down in regulation 36 of these Regulations are applicable for CSW and RSW vessels.

(2) Additional hygiene conditions applicable to the fishing vessels designed and equipped to preserve fishery products on board under satisfactory condition for more than twenty-four hours, laid down in regulation 37 of these Regulations are applicable.

(CSW) or refrigerated by mechanical means (RSW).

(3) Fishing vessels equipped for chilling of fishery products in cooled seawater (CSW) (chilled by ice) or in refrigerated sea water (RSW) (chilled by mechanical means) shall comply with the following requirements-

(a) tanks shall be equipped with adequate sea water filling and drainage installations and shall incorporate devices for achieving uniform temperature throughout the tanks;

(b) tanks shall have a means of recording temperature connected to temperature sensor positioned in the section of the tank where temperatures are highest;

(c) the operation of the tank or container system shall secure a chilling rate which ensures the mix of fish and seawater reaches 3° C at the most six hours after loading and 0° C at the most after sixteen hours;

(d) after each unloading, the tanks circulation systems and containers shall be completely emptied and thoroughly cleaned using potable or clean seawater and should only be filled with clean seawater, and

(e) the date and the number of the tank shall be clearly indicated on the

temperature recordings, which shall be kept available for the Inspectorate.

Specific hygiene conditions applicable to fishery products caught on board fishing vessels equipped for cooking crustaceans and molluscs on board.

40. (1) Fishing vessels equipped for cooking crustaceans and molluscs on board shall comply with the general hygiene conditions applicable to fishery products on board all fishing vessels, laid down in regulation 36 of these Regulations.

(2) Additional hygiene conditions applicable to the fishing vessels designed and equipped to preserve fishery products on board under satisfactory conditions for more than twenty-four hours laid down in regulation 37 of these Regulations are also applicable.

(3) Any cooking shall be followed by rapid cooling and water used for this purpose shall be potable water or clean seawater and cooling shall continue until the temperature approaching that of melting ice is reached if no other method of preservation is used.

(4) Shelling or sucking shall be carried out under hygienic conditions avoiding the contamination of the product.

(5) Where such operations are done by hand, workers shall pay attention to the washing of their hands and that all working surfaces are cleaned thoroughly.

(6) If machines are used, they shall be cleaned at frequent intervals and disinfected after each working.

(7) After shelling or shucking, cooked products shall immediately be frozen or kept chilled at a temperature which will

preclude the growth of pathogens and be stored in appropriate premises.

(8) Every manufacturer shall carry out micro-biological checks on his production at regular intervals, complying with the following-

(a) the microbiological standards set forth in Schedule Three to these Regulations shall be checked by the manufacturer during the manufacturing process and before the crustacean and molluscan shellfish products, cooked in the processing plant, are placed on the market;

(b) sampling programs-

(i) shall be established by the responsible staff of the fishing vessel in relation to-

(A) the nature of products (whole, shelled or shucked);

(B) the temperature;

(C) the time of cooking;

(D) the risk evaluation;

(ii) shall meet the principles of the autocontrol system; and

(iii) shall contain, in the event of failure to comply with the

standards laid down under the following headings- pathogens (1) organisms indicating poor hygiene;

(c) the manufacturer shall-

(i) notify the Competent Authority of the findings made and the action taken with regard to unsatisfactory batches;

(ii) review the methods of supervising and checking the critical points so as to identify the contamination source and to carry out analyses more frequently;

(iii) not market for human consumption batches found to be unsatisfactory on account of the discovery of pathogens or where the M-value for staphylococcus is needed.

Conditions concerning design and equipment of factory vessels.

41. (1) The minimum requirements for design and equipment needed on factory vessels are the following-

(a) a reception area set aside for taking fishery products on board designed and arranged into pounds or pens that are large enough to allow each successive catch to be separated and the reception area and its movable parts shall be easy to clean it shall

be designed in such a way as to protect the products from the sun or the elements and from any source of dirt or contamination;

(b) a system for conveying fishery products from the reception area to the work area that conforms with rules of hygiene;

(c) work areas that are large enough for the preparation and processing of fishery products in proper conditions of hygiene and they shall be 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 and if a waste processing unit operates on board, a separate hold shall be designated for the storage of these by-products;

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

(f) special equipment for pumping waste or fishery products that are unfit for human consumption either directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose

and if waste is stored and processed on board with a view to cleaning, separate areas shall be allocated for that purpose;

(g) equipment providing a supply of potable water within the meaning of Regulations 84 to 102 of Part XI of these Regulations relating to the quality of water intended for human consumption or pressurised clean seawater and the seawater intake shall be situated in a position where it is not possible for the water being taken in, to be affected by discharges into the sea of waste water, waste and engine coolant outlets;

(h) a suitable number of changing rooms, wash basins and toilets, the latter not opening directly into areas where fishery products are prepared, processed or stored and the wash basins shall be equipped with appliances for washing and drying the hands that comply with hygiene requirements; the wash basin taps shall not be hand or elbow-operable.

(2) Areas used for the preparation and processing or freezing or quick freezing of fishery products shall have-

(a) a non-slip floor that is also easy to clean and disinfect and equipped for easy drainage of water and structures and fixtures shall have limber holds

that are large enough not to be obstructed by fish waste and to allow water to drain freely;

(b) walls and ceilings that are easy to clean, particularly where there are pipes, chains or electricity conduits;

(c) the hydraulic circuits shall be arranged or protected in such ways as to ensure that it is not possible for any leakage of oil to contaminate fishery products;

(d) adequate ventilation and, where necessary, proper vapour extraction;

(e) adequate lighting;

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

(g) appliances for cleaning and disinfecting the hands with taps that are not hand or elbow-operable and with single use towels.

(3) Equipment and tools such as cutting benches, containers, conveyors, gutting or filleting machines, etc., shall be resistant to seawater corrosion, easy to clean and disinfect and well-maintained.

(4) Factory vessels which freeze fishery products shall have-

(a) a refrigeration plant sufficiently powerful to lower the temperature rapidly so as to

achieve a core temperature that complies with the specification of these Regulations;

(b) refrigeration plants sufficiently powerful to keep fishery products in the storage hold at a temperature that complies with the specifications of these Regulations and the storage holds shall be equipped with a temperature recording system placed so that it can easily be consulted.

Conditions of hygiene relating to on board handling and storage of fishery products.

42. (1) A qualified person on board the factory vessel shall be responsible for applying best practices and that person shall have the authority to ensure that the provisions of this Division are applied and shall make available to inspectors the program for inspecting and checking control points and critical control points as supplied on board, a register containing that person's comments and the temperature recordings that may be required.

(2) The general conditions of hygiene applicable to areas and equipment shall be the following-

(a) floors, walls and partitions, ceilings or roof linings, equipment and instruments used for working on fishery products shall be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the products;

(b) rodents, insects and any other vermin shall be systematically exterminated in the premises or on the equipment; rodenticides, insecticides, detergents, disinfectants and any other potentially toxic substances shall be stored in premises

or cupboards which can be locked; their use shall not present any risk of contamination of the products;

(c) working areas, instruments and working equipment shall be used only for work on fishery products;

(d) potable water, within the meaning within regulations 84 to 102 of Part XI of these Regulations, or clean seawater shall be used for all purposes. However, by way of an exception, non-potable water may be used for steam production, firefighting and the cooling of refrigeration equipment, provided that the pipes installed for purpose preclude the use of such water for other purposes and present no risk of contamination of the products;

(e) detergents, disinfectants, rodenticides, insecticides and similar substances shall be approved by the Competent Authority and used in such a way that they do not have adverse effects on the machinery, equipment and products.

(3) The general conditions of hygiene applicable to staff shall be the following-

(a) the highest possible standard or cleanliness is required of staff and more specifically-

(i) staff shall wear suitable clean working clothes and headgear which completely

enclosed the hair and this applies particularly to persons handling exposed fishery products;

(ii) staff assigned to the handling and preparation of fishery products shall be required to wash their hands and at least each time work is resumed; wounds to the hands shall be covered by a waterproof dressing;

(iii) smoking, spitting, eating and drinking in work and storage premises of fishery products shall be prohibited;

(b) the employer shall take all the requisite measures to prevent persons liable to contaminate fishery products from working on and handling them, until there is evidence that such persons can do so without risk and when recruited, any person working on and handling fishery products shall be required to prove, by a medical certificate, that there is no impediment to such employment.

(4) Heading, gutting and filleting shall be carried out under the following conditions of hygiene-

(a) operations such as heading and gutting shall be carried out hygienically and the products shall be washed thoroughly with potable water or clean seawater immediately after such operations;

(b) 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 place other than that used for heading and gutting operations and fillets and slices shall not remain on work tables any longer than is necessary for their preparation and shall be protected from contamination by appropriate packaging and fillets and slices to be sold fresh shall be chilled as quickly as possible after preparation;

(c) guts and parts that may constitute a danger to public health shall be separated from and removed from the vicinity of products intended for human consumption.

(5) On-board freezing of fishery products shall be carried out under the following conditions of hygiene-

(a) fresh products to be frozen or quick-frozen shall comply with the requirements for fresh products laid down in regulation 162 of these Regulations;

(b) storage rooms shall have temperature recording devices in a place where it can easily be read and the temperature sensor of the recorder shall be located in the area furthest away from the cold source that is where the temperature in the storage room is the highest and temperature charts shall be available for inspection by the

supervisory authorities at least during the period in which the products are stored.

(6) On-board processing of fishery products shall be carried out under the following conditions of hygiene-

(a) the conditions of hygiene for fresh products laid down in regulation 160 of these Regulations;

(b) the conditions of hygiene for frozen products laid down in regulation 161 of these Regulations;

(c) the conditions of hygiene for thawing products laid down in regulation 162 of these Regulations;

(d) the conditions of hygiene for processed products laid down in regulation 170 to 171 of these Regulations;

(e) the conditions concerning parasites laid down in regulation 171 of these Regulations.

(7) Fishery products shall be wrapped and packaged under the following conditions of hygiene-

(a) packaging shall be carried out under satisfactory conditions of hygiene, to preclude contamination of the fishery products;

(b) packaging materials and products liable to enter into contact with fishery products shall comply with all the rules of hygiene, and in particular-

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

(ii) they shall not be capable of transmitting to the fishery products substances harmful to human health; they shall be strong enough to protect the fishery products adequately;

(c) with the exception of certain containers made of impervious, smooth and corrosion-resistant material which are easy to clean and disinfect, which may be re-used after cleaning and disinfecting, packaging materials may not be re-used;

(d) unused packaging materials shall be stored in premises away from the production area and be protected from dust and contamination.

(8) On-board storage of fishery products shall be carried out under the following conditions of hygiene-

(a) fishery products shall, during storage be kept at the temperatures laid down in these Regulations and in particular-

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

(ii) 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;

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

(b) products may not be stored with other products which may contaminate them or affect their hygiene, unless they are packaged in such a way as to provide satisfactory protection.

PART X

REQUIREMENTS FOR LANDING AND UNLOADING OF FISHERY PRODUCTS

General conditions for landing and unloading.

43. (1) Unloading and landing equipment shall be constructed of material which is easy to clean and disinfect and shall be kept on a good state of repair and cleanliness.

(2) During unloading and landing, contamination of fishery products shall be avoided and it shall in particular be ensured that-

(a) unloading and landing operations proceed rapidly;

(b) fishery products are placed without unnecessary delay in a protected environment at the temperature required on the basis of the nature of the product and, where necessary, in ice in transport, storage or market facilities, or in plant;

(c) equipment and handling practices that cause unnecessary damage to the edible parts of the fishery products are not authorised.

General conditions for auctions.

44. (1) If fishery products are displayed for sale in auctions, parts of auctions shall-

(a) be covered and have walls which are easy to clean;

(b) have water-proof flooring which is easy to wash and disinfect and laid in such a way to facilitate the drainage of water and have a hygienic waste water disposal system;

(c) be equipped with sanitary facilities with an appropriate number of wash basins and flush lavatories. Wash basins shall be supplied with materials for cleaning the hands and single use hand towels;

(d) be well lit to facilitate the inspection of fishery products provided for in regulation 26 of these Regulations;

(e) when they are used for display or storage of fishery products, not be used for other purposes; vehicles emitting exhaust fumes which may impair the quality of the fishery products shall not be admitted to markets; crates shall, after each sale, be cleaned and rinsed inside and outside with drinking water or clean sea water; where required, they shall be disinfected and undesirable animals shall not be admitted;

(f) have displayed in a prominent position, signs prohibiting smoking, spitting, eating or drinking;

(g) be kept closed when the Competent Authority considers it necessary;

(h) have facilities to provide adequate supplies of drinking water within the meaning of regulations 84 to 102 of part XI of these Regulations or alternatively of clean seawater or seawater treated by an appropriate system, under pressure and in sufficient quantity and by way of exception, a supply of non-drinking water is permissible for steam

production, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purpose and present no risk of contamination of the products and non-drinking water pipes shall be clearly distinguished from those used for drinking water or clean sea water;

(i) have special watertight receptacles made of corrosion-resistant materials for fishery products which are unfit for human consumption; and

(j) in so far as they do not have their own premises on the spot or in the immediate vicinity on the basis of the quantities displayed for sale, have, for the purpose of the Competent Authority, an adequately-equipped lockable room, and the equipment necessary for carrying out inspection.

(2) After landing or, where appropriate, after first sale, fishery products shall be transported without delay, under the conditions laid down in regulations 195 to 208 of Part XI of these Regulations to their place of destination.

(3) If the conditions laid down in subregulation (2) are not fulfilled, the markets in which fishery products may be stored

before being displayed for sale or after being sold and pending transport to their place of destination shall have sufficiently large cold or chill storage rooms which satisfy the following conditions-

(a) waterproof flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of the water or provided with equipment to remove water;

(b) walls, which have, smooth surfaces and are easy to clean, durable and impermeable;

(c) ceilings or roof linings which are easy to clean;

(d) doors in durable materials which are easy to clean;

(e) adequate natural or artificial lighting, and

(f) where necessary a sufficiently powerful refrigeration plant to keep products at temperature prescribed in these Regulations.

(4) In such cases, fishery products shall be stored at a temperature approaching that of melting ice.

General hygiene conditions for auctions.

45. (1) General conditions of hygiene for auctions and markets in which fishery products are displayed for sale or stored are-

(a) floors, walls and partitions, ceilings or roof linings, equipment and instruments

used for working on fishery products shall be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the products;

(b) rodents, insects and any other vermin shall be systematically exterminated in the premises or on the equipment; rodenticides, insecticides, disinfectants and any other potentially toxic substances shall be stored in premises or cupboards which can be locked; their use shall not present any risk of contamination of the products;

(c) working areas, instruments and working equipment shall be used only for work on fishery products however, following authorisation by the Competent Authority, they may be used at the same time or other times for work on other foodstuffs;

(d) potable water, satisfying regulations 84 to 102 of Part XI of these Regulations shall be available and by way of an exception, non-drinking water may be used for steam production, all fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use

of such water for other purposes and present no risk of contamination of the products;

(e) detergents, disinfectants and similar substances shall be approved by the Competent Authority and used in such a way that they do not have adverse effects on the machinery, equipment and products.

(2) General conditions of hygiene applicable to staff are-

(a) the highest possible standard of cleanliness is required of staff more specifically-

(i) staff shall wear suitable clean working clothes;

(ii) staff assigned to the handling and preparation of fishery products shall be required to wash their hands at least each time work is resumed; wounds to the hands shall be covered by a waterproof dressing;

(iii) smoking, spitting, eating and drinking in work and storage premises of fishery products shall be prohibited;

(b) the employer shall take all the requisite measures to prevent persons liable to contaminate fishery products from

working on and handling them, until there is evidence that such persons can do without risk.

(3) When recruited, any person working on and handling fishery products shall be required to prove, by a medical certificate, that there is no impediment to such employment.

PART XI

QUALITY ASSURANCE SYSTEM AND PRODUCTION CONDITIONS

BEST PLANT PRACTICES
Location of an establishment.

46. (1)Establishments, preparing or processing fishery products should be located on sites-

(a) which can be maintained free of floods, smells, dust, smoke and other types of pollution or contamination, whether physical, chemical or microbiological;

(b) where neighboring buildings, operations and land use present no source of potential contamination for the hygienic operation of the establishment;

(c) where -

(i) there is access to water, power and all-weather roads;

(ii) good evacuation possibilities for waste and waste water are available.

(2) Existing establishments, exposed to pollution should possess satisfactory means of preventing contamination of the fishery products.

(3) An implementation plan of the establishment in the environment shall be available for any inspection body.

Surroundings of the establishment.

47. (1) The areas directly surrounding the establishment (patios, passages, pathways, access ways, yards, roads, parking lots, buildings and other areas connected to the establishment shall be-

(a) suitably graded, grassed or landscaped and it is required that-

(i) the grass and weeds shall be cut regularly to prevent dust and litter build up;

(ii) the grounds shall be provided with adequate drainage;

(b) suitably paved or concreted and it is required that –

(i) the surrounding grounds and concreted surfaces should be inclined towards trapped gullies and provided with adequate drainage to permit rapid evacuation of rainwater;

(ii) the surroundings should be properly maintained, that is-

(A) the grounds should be kept clean, tidy at all times and free of accumulation of water;

(B) equipment should be stored properly;

(C) litter, rubbish and waste should be regularly removed.

(2) If guard dogs are present, they should not have access to any area in which fish is handled, including the loading and unloading areas.

(3) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described supra in this regulation, care shall be exercised in the plant by the inspection, extermination or other means to exclude pests, dirt and filth that may be a source of food contamination.

(4) Operating systems for waste treatment and disposal shall be installed in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

(5) Where vehicles are cleaned on the premises, a paved and drained area shall be provided for this purpose.

Requirements for an establishment.

48. (1) The building shall protect the processing line and the products against contamination (water, dust, air, heat, pests, etc), should be of solid construction with adequate materials and should never be a source of contamination (condensation, moulds, flaking paint, drains, etc).

(2) The processing line (reception – processing – dispatch) should be directly connected with the input lines (ice, water, ingredients, cleaned containers, packing materials, personnel, etc) and output lines (by-products, waste products, offal, dirty containers and recipients, etc); Appropriate storage capacity for the side inputs and outputs shall be available.

(3) The construction and the processing design has to be conceived in a way that-

(a) there is separation by walls, location, air flow, enclosed systems or other effective means-

(i) between clean and dirty areas;

(ii) between dry and wet areas;

(iii) between cold and hot areas;

(iv) between precooking and post-cooking areas; and

(v) between operations which may cause cross contamination of food;

(b) there is a good lay-out and flow from raw materials through finished products and dispatch and the processing layout should be designed-

(i) so that the distribution of equipment and processing activities facilitates the rapid processing of fishery products;

(ii) in such a way that fish is not exposed to contamination by toxic materials, bacteria from the plant environment or by cross contamination during processing.

(c) all possible preventive measures and provisions shall be taken already on construction level-

(i) to avoid cross-contamination during production between final and raw products;

(ii) to minimise the risk of food contamination by contact surfaces, packing material, offal, drainage systems, etc;

(iii)to minimise maintenance;

(iv) to facilitate cleaning and disinfection;

(v) to build in the passive pest-control systems;

(vi) to minimise airborne contamination;

(viii) to guarantee safety and a healthy work environment to the workers;

(ix) to provide adequate working space to allow for satisfactory performance of all operations connected with the preparation and or processing of food;

(x) to dispose of all liquid and solid waste, storm water and sewerage;

(xi) to implement an adequate potable water supply, it may be necessary to install an in plant chlorination system to ensure the supply of potable water at all times;

(xii) to install an adequate electrical supply to maintain normal and efficient operation of all electrically powered equipment and lighting;

(xiii) to ensure that-

(A) product flow takes place from dirty areas to clean areas (raw to final with no cross over);

(B) drains flow from clean to dirty areas, away from food handling areas;

(C) airflow is directed from clean to dirty areas;

(xiv) to avoid dripping or condensation from fixtures, ducts, pipes and ceilings contaminating food, food-contact surfaces or food packing materials.

(4) A ground plan, the layout of the establishment and a schematic flow-chart for each product shall be available for any inspection body.

Conditions and requirements for working, handling and storage rooms and for facilities and equipment in these rooms.

49. (1) The different working, handling and storage rooms needed in the establishments as described in regulation 50 shall comply with the minimum conditions and requirements laid down in regulation 51 to 65 of these Regulations.

(2) The establishments shall afford in the working and storage rooms mentioned in regulation 50 (1) a number of facilities complying with the minimum requirements and conditions laid down in regulations 66 to 74 of these Regulations.

General conditions for working rooms.

50. The establishment shall provide, at least the following conditions for working rooms-

(a) working rooms shall be of sufficient size to permit the processing of fishery products without overcrowding of personnel and equipment and shall be designed for work to be carried out in logical sequence and under satisfactory conditions;

(b) in general and pending the preparation or processing activities, completely separated working rooms could be needed such as-

(i) reception room;
(ii) chill storage room for fresh raw material (directly connected with the reception or by means of transport)

(iii) cold storage room for frozen raw material (directly connected with the reception or by means of transport;

(iv) ice maker or storage room;

(v) processing rooms, depending on the activities: preparation or processing (smoking, salting, cooking, canning, etc);

(vi) freezing facilities or rooms (blast freezers, plate freezers, tunnel freezers, etc.) for freezing prepared or processed products;

(vii) chilling facilities or rooms for chilling prepared or processed products;

(viii) freezing facilities or rooms for freezing raw whole fish in brine at – 9° C;

(ix) dry room for packaging;

(x) dry room for the storage of packing material;

(xi) dry room for the storage of chemicals;

(xii) room for cleaning and disinfecting recipients and small equipment, connected with a room for the storage of it;

(xiii) laboratory;

(xiv) chill storage room for finished fresh products;

(xv) cold storage room for finished frozen products both connected with the dispatch room;

(xvi) storage room for storage of finished products at ambient temperature;

(xvii) dispatch room;

(xviii) social amenities with-

(A) changing room for city clothes and shoes;

(B) showers (optional);

(C) changing room for uniforms and boots;

(D) toilet block;

(E) hand-washing room;

(F) eventually laundry and canteen;

(c) the main processing area in which fish is handled should have only one entrance for personnel and this entrance should be separate from any entrances and exits used for raw materials, finished products and other materials used during process.

Conditions for preparation and processing rooms.

51. (1) In rooms where products are handled, prepared and processed, the establishment shall afford at least the following facilities-

(2) Floors-

(a) shall have hard impact resistant surfaces, impermeable to grease and water, which permit easy cleaning and disinfection and laid down in such a way as to facilitate the drainage of the water and concrete floors shall have a high

density, impermeable finish which is maintained in good condition;

(b) shall be sufficiently graded and have a gradient of at least 1 : 100 towards drainage channels;

(c) shall have floor joints sealed with impervious materials, finished flush with the surface;

(d) shall have junctions between floor and walls curved to facilitate cleaning;

(e) shall have all drainage channels, gullies and gully traps covered with removable grills.

(3) Effluent disposal systems and drains shall comply with following requirements and the establishment shall have-

(a) an efficient and hygienic effluent and waste water disposal system maintained in good order and repair;

(b) effluent lines (sewerage, storm water, processing) large enough to carry peak loads and constructed so as to avoid contamination of the potable water supply;

(c) an adequate drainage system, especially in the areas and rooms that involve wet operations;

(d) a storm water drainage system, if applicable, not connected to the effluent treatment system;

(e) floor drains shall-

(i) be adequate in size, number and location;

(A) to allow the rapid removal of all liquid wastes arising from all processing operations;

(B) to cope with the maximum flow of water under normal working conditions but also to carry peak loads;

(ii) be effectively sealed by gully traps installed in every room;

(A) to prevent the return of gases and odours from the drainage system;

(B) to prevent the entry of rodents;

(C) an open drainage system vented through an opening in the wall, without sealed outlet by gully traps is not allowed;

(iii) have solid traps to prevent the passage of solid materials to the external sewage system and solid traps installed in conjunction with floor drains or with gully traps shall be designed to enable adequate cleaning;

(iv) have adequate access for cleaning;

(v) flow from clean to dirty areas;

(vi) not be connected to sanitary drainage;

(vii) not be connected to the storm water and site drainage system and where this occurs they shall be designed and maintained to ensure that flooding of the premises cannot occur due to backflow.

(f) sanitary drainage-

(i) shall not be connected with any other drains within the facility and be directed to a septic tank or sewerage system;

(ii) sanitary drainage, septic tanks, waste and solid trap systems shall be located in such a way to avoid a hygiene hazard to the product and located away from any processing area or entrance to the building.

(4) Walls shall comply with following requirements-

(a) walls should be of solid construction and prevent the entry of insects, rodents, birds and other animals;

(b) the interior surfaces of walls and the partitions shall-

(i) be constructed of water-proof, non-absorbent, durable, impermeable and washable materials;

(ii) be smooth, of a light colour and free from gaps;

(iii) have all joints (e.g. laminates) sealed that might allow the ingress of water, pests or contaminants (with an impermeable compound);

(iv) be impact resistant or protected from impact;

(v) be resistant to damage;

(vi) be easy to clean and disinfect.

(c) angles between walls, between walls and floors and between walls and ceilings, shall be sealed and coved to facilitate cleaning;

(d) where internal walls are painted or surface coated-

(i) any paint materials applied to the walls shall be non-toxic, durable and of light colour;

(ii) the surface shall withstand hosing with hot water and detergents and withstand a reasonable impact;

(e) any piping or tubing should be located either within the wall or fixed at least four cm from the wall, in order to permit easy cleaning behind;

(f) if any facility or room (including a cold storage room) is built within a preparation, processing or a food handling room, inaccessible cavities formed between the walls or ceilings of the inner and outer rooms shall be made pest and dust proof;

(5) Ceilings shall comply with following requirements-

(a) in buildings in which the roof frame is exposed, the installation of a suspended ceiling should be considered and otherwise all parts of the structure shall be smooth and painted in a light colour

and there should be easy access to all parts of the roof structure to facilitate cleaning;

(b) ceilings shall be designed, constructed, sealed and finished so as to-

(i) provide a height of at least 2.2 metres in all rooms where fish is handled;

(ii) be of a light colour, smooth and impervious to moisture;

(iii) prevent or minimises accumulation of dust and dirt;

(iv) be capable of being effectively cleaned;

(v) have all overhead machinery and pipes located above ceiling;

(vi) minimise condensation, mould development and flaking.

(6) Doors shall comply with the following requirements-

(a) the doors of the reception room through which enters raw material, and the doors of the dispatch room, by which the finished products leave, shall be of adequate size and well-constructed, using suitable materials to protect them from impact damage and these doors should possess either plastic curtains or air curtains or a self-closing curtain or a self-closing device, in order to minimise the entry of flying insects, when they are opened;

(b) the doors and hatches inside the factory shall-

(i) be well constructed, using suitable, durable materials which are easy to clean;

(ii) have smooth, impermeable and non-absorbent surfaces;

(iii) be close fitted;

(iv) be impact resistance or protected from impact damage;

(c) where doors are painted or surface coated-

(i) any paint materials applied to the doors shall be nontoxic, durable and of light colour;

(ii) the surface shall withstand hosing with hot water and detergent, and withstand a reasonable impact;

(d) if air locks are installed they shall be designed to minimise movement of air into or between areas where food is exposed, processed or packed.

(7) Windows and external openings shall comply with following requirements-

(a) on construction level-

(i) window frames shall be made of a smooth impermeable material;

(ii) window sills shall be as small as possible and inclined in order to prevent the accumulation of dust, and their use for the storage of articles;

(b) on pest-proofing level-

(i) windows, hatches, ventilation openings and other openings to the outside of the building or where physical separation is

required shall be constructed to render the opening pest proof;

(ii) any window which may be opened, or which does not have glass (plexiglass) and vents shall be covered with an insect-proof mesh screen-

(A) kept in good repair;

(B) which are easily removable for easy cleaning;

(iii) windows without pest-proofing that open are not permitted in areas where food is exposed, processed or packed;

(iv) if any services, chutes, conveyors or the like pass through external walls, the gap where they pass through, if any, shall be sealed against the entry of pest and dust.

(8) Stairs, catwalks, platforms, stands to raise personnel to the level of the work tables, ladders and the like in processing areas shall be-

(a) of a construction and material that is impervious, non-slip, non-corrodible, easy to clean and impact resistant;

(b) situated and constructed so as not to cause contamination of food processing areas, equipment and product by allowing potential contamination items to fall onto them.

(9) The ventilation system shall comply with following requirements-

(a) adequate and sufficient ventilation shall be provided to minimise the accumulation of odours, vapours, gases, dust and to prevent excessive buildup of heat, steam, condensation, contaminated air and other hazards where they may contaminate fishery products;

(b) where cooking, canning or boiling operations are carried out, extractor fans and canopies shall be installed and have capture velocities capable of conveying all heat, fumes and other aerosols through the exhaust canopy opening;

(c) the flow of air within the establishment shall always be directed from clean, hygienic area (e.g. where cooked fish is handled) to dirty or less hygienic areas;

(d) where fans, air conditioning systems and other air-blowing equipment are located and operated-

(i) it shall be done in a manner that minimises the potential for contaminating food, food packing materials and food-contact surfaces;

(ii) the installation of an overpressure system shall be recommended whereby the inlets are controlled and the outlets are uncontrolled;

(iii) all extraction fans, blowing fans and air conditioners shall be protected with filters and meshes to

prevent the entry of dust, insects and birds.

(10) Illumination-

(a) adequate natural or artificial lighting shall be provided throughout the establishment and light produced shall not distort colours and be shadow free at work and inspection surfaces;

(b) the intensity of illumination at the task area floor shall be a minimum of-

(i) 400 lux in the processing areas;

(ii) 600 lux where the product is being inspected;

(iii) 250 lux in other areas;

(c) light fittings shall be equipped with a diffuser or other means or protection so that breakage will not contaminate the product;

(i) recessed into or flush fitted against the ceiling so that no exposed ledge is created;

(ii) readily accessible for cleaning purposes.

(d) where light fittings cannot be installed as mentioned above, they may be suspended from the ceiling by cables provided that the top of the fitting is sloped at approximately 45 degrees.

(11) Hand washing facilities-

(a) all areas in which fishery products are handled shall be provided with hand washing facilities;

(b) the location of these hand washing facilities shall be arranged in a way that they are-

(i) sufficient in number;

(ii) provided in accessible locations throughout the preparation and processing areas, readily accessible from work areas for all staff to wash their hands;

(iii) also located adjacent to the social amenities and just before personnel is entering the preparation or processing room;

(c) these hand washing facilities shall be provided with-

(i) taps of the non-hand or elbow operable type (foot, knee or electronically operated) in work rooms, toilets and in the hand washing room before entering;

(ii) a suitable pressured hot and cold running potable water supply over a sink;

(iii) soap dispenser;

(iv) paper single use hand towels held in a dispenser and a sufficient number of receptacles for disposing of used towels;

(v) properly trapped waste pipes leading to drains;

(vi) signs advising persons to wash their hands on entering or reentering fish preparation or processing rooms shall be provided in a prominent position near food preparation or processing entrances.

(12) Where applicable boot disinfecting facilities or a suitable permanent bath, fitted with a drainage facility, for the washing of boots should be installed at the staff entrance in such a manner that persons entering the preparation/processing rooms cannot avoid passing through the bath and the use and control of footbaths shall be adequately designed, implemented and monitored.

(13) A room for cleaning and disinfecting work implements, utensils, recipients and small equipment, connected with a room for the storage of it shall be installed where required in the establishment, equipped with all necessary means for cleaning and disinfection, to include-

(a) hot and cold water points, with hoses where necessary;
(b) sinks with hot and cold water for the washing of the movable equipment and fish boxes;
(c) high-pressure cleaning and disinfecting systems;
(d) these facilities shall be constructed of corrosion resistant materials capable of being cleaned effectively;
(e) washing and disinfecting work implements, recipients, small equipment and utensils in stagnant water is forbidden.

(14) If sterilizing facilities are required, adequate provision for sterilizing work implements and equipment shall be provided and if the sterilizing medium used is not water, the

method of sterilizing shall be first approved by the Competent Authority and sterilizing facilities shall be-

(a) constructed of corrosion resistant materials;

(b) capable of being easily cleaned; and

(c) where necessary, fitted with a suitable means of supplying hot and cold water in sufficient quantities.

General conditions for chill storage rooms, cold storage rooms, blast and tunnel freezers and for chillers.

52. In chill storage rooms, in cold storage rooms, in blast and tunnel freezers and in chillers, the establishment shall have at least the following facilities-

(a) waterproof flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of the water as described in regulation 51 (1) and (2) of these Regulations and where under floor ventilation pipes are provided they shall be protected against pests;

(b) walls which have smooth surfaces and are easy to clean, durable and impermeable as described in regulation 51(4) of these regulations;

(c) ceilings which are easy to clean as described in regulation 51(5) of these Regulations;

(d) doors in durable materials which are easy to clean and plastic strip curtains or

similar shall be installed to assist in air retention and to minimise temperature fluctuations when cold storage room or freezer doors are open;

(e) other internal structures shall be constructed of smooth, impervious and corrosion resistant material;

(f) those parts which are exposed to impact damage shall be adequately protected;

(g) facilities designed to allow for adequate drainage of water away from the refrigeration unit;

(h) adequate artificial lighting as described in regulation 51(10) of these Regulations;

(i) where refrigeration equipment is installed in a processing or packing area sufficient space shall be allowed for cleaning around and between the equipment and no free space shall be allowed on top of the equipment.

Specific conditions for chill storage room.

53. In chill storage rooms for the storage of raw material the establishment shall have at least following facilities-

(a) adequate facilities, with sufficient capacity constructed to the same standard as the cold storage room for the storage of the fish at the temperature of melting ice-

(i) to store all the raw material arriving at the establishment and which is not processed immediately; and

(ii) to ensure adequate protection from contamination;

(b) tanks of stainless steel, glass fiber or plastic in which the fish can be mixed with ice in sufficient quantities to maintain the temperature at 0° C, in case of absence of the chilling facilities mentioned in this regulation;

(c) where necessary a sufficiently powerful refrigerated plant to keep products at temperatures prescribed in these Regulations, whatever the outside temperature may be;

(d) an accessible and easily readable thermometer read to and accurate to within 1° C, shall have its temperature taken and recorded at least once every four hours.

Specific conditions for cold storage rooms.

54. In cold storage rooms the establishment shall have at least the following facilities-

(a) adequate permanent cold storage facilities for the storage of finished products in all establishments producing frozen fish;

(b) different cold storage rooms or chambers designated in the premises utilized for its designed purpose e.g. the storage of frozen product only;

(c) freezing equipment sufficiently powerful and capable to keep products in cold storage rooms at an internal temperature below –18° C, whatever the ambient temperature may be and also during extreme operating conditions (during loading and unloading);

(d) doors to the cold store provided with plastic curtains in order to minimise the interchange of air during loading and unloading; and

(e) temperature recording device in a place where it can easily be read and the temperature sensor of the recorder shall be located in the area furthest away from the cold source, that is, where the temperature in the storage room is the highest and temperature charts shall be available for inspection by the supervisory authorities at least during the period in which the products are stored.

Specific conditions for freezers.

55. In freezers, establishment shall afford at least following facilities-

(a) a freezing facility appropriate to the type of the fishery products and its packaging and fish should never be frozen in a cold storage room;

(b) a freezing facility with sufficient capacity to freeze the fish to a temperature of at

least –18° C within eight hours of loading the freezer and for this reason, it is recommended that the freezing plant (motors, compressors, etc.) is rated at least 8 hp (7.5 kW)/1000lb of product to be frozen;

(c) in the design and operation of a freezing plant, regard shall be given to the relative capacity of the compressors and the maximum permissible load of any blast or tunnel freezer.

Specific conditions for brine freezing facilities.

56. In brine freezing rooms used solely for brine freezing whole tuna or other species, the establishment shall have at least the following facilities-

(a) general construction conditions are-

(i) walls, floors and ceilings complying with the requirements laid down for chill rooms;

(ii) areas-

(A) suitable clean;

(B) sealed against dust and pest;

(C) be maintained in such a manner that no microbiological, physical, chemical or other objectionable substances can contaminate the fishery

products or make the fishery products unfit for human consumption;

(iii) hand washing facilities that are readily available to processing staff;

(iv) hand washing and toilet facilities that are readily available to processing staff, changing rooms and a clean dry area for the storage of packing material if applicable when brine freezing rooms are not a part of an approved establishment;

(b) Specific brining conditions are -

(i) brining tanks, tank surfaces and coverings constructed in such a way that they are not a source of contamination for the fishery products;

(ii) brine checked at regular intervals and in such a way that the brine will not be a source of contamination for the fishery products;

(iii) freezing conditions, whereby the freezing temperature may be higher than –18° C, although not higher than –9° C, if intended for canning.

Specific conditions for ice plants and ice storage rooms.

57. In ice plants and ice storage rooms establishment shall have at least the following facilities-

(a) an ice making facility, able to produce ice in quantities adequate to satisfy all the needs of the process, including-

(i) transport of raw material from the port;

(ii) storage of raw material before processing; and

(iii) chilling of fish during processing;

(b) insulated ice storage rooms and storage facilities shall-

(i) comply with the requirements laid down for chill storage and cold storage rooms;

(ii) have facilities wherein ice can be stored and removed in an efficient, hygienic manner and can be protected from contamination at all times and it is prohibited to store ice on the floor where workers have to walk on to remove the ice;

(iii) have the capacity to store sufficient ice to satisfy the needs;

(c) it is recommended that-

(i) an ice making plant should be installed in each fish preparation or processing plant and the purchase of ice from external suppliers is permissible provided purchasers can verify the bacteriological quality of the ice;

(ii) the ice should be made in the form of flakes and if large blocks are produced they should be made in a hygienic way and be crushed by machine and manual crushing of bloc ice is prohibited.

Conditions for rooms where shellfish is shucked.

58. In rooms or parts of establishments where shellfish is shucked, the rooms in establishments shall-

(a) be satisfactorily clean;

(b) be maintained in such a manner that no microbiological, physical, chemical or other objectionable substances can contaminate the shellfish or make the shellfish unfit for human consumption;

(c) contain hand washing and toilet facilities that are readily available to processing staff;

(d) have a clean dry area for the storage of packing materials;

(e) have lighting in accordance with regulation 51(10) of these Regulations.

Conditions for rooms where packing material is stored.

59. Rooms designated for storage of packing material shall be-

(a) dust and pest proof;

(b) designed and maintained to prevent undesirable physical, microbiological or chemical contamination; and equipped with shelves, racks or pallets to store packing material, designed and

constructed in accordance with regulations 67 and 68 of these Regulations.

Conditions for rooms where non refrigerated fishery products are stored.

60. Rooms designated for storage of non-refrigerated fishery products shall be-

(a) of sound construction in accordance with the requirements concerning ceilings, walls, floors, doors, laid down in this regulation; and

(b) designed and maintained so as to prevent undesirable physical, microbial and chemical changes to processed fishery products and its packaging which could affect the wholesomeness of the processed fishery products.

Conditions for rooms where toxic chemicals and cleaning equipment are stored.

61. Rooms designated for storage of toxic chemicals and cleaning equipment shall be separate to the main storage area and all toxic chemicals used on-site should be clearly identified and stored, when not in use, in a locked facility.

Conditions for inspection rooms.

62. (1) The establishments shall have, if applicable, an Inspectorate room complying with and used under following conditions-

(a) if the volume of products treated requires regular or permanent presence of an official inspector or if fish is to be inspected by an inspector, a separate room-

(i) adequately equipped;

(ii) lockable;

(iii)adjacent to the processing area;

(iv) free from steam and fumes; and

(v) for the exclusive use of the Inspectorate;

(b) and shall be provided with-

(i) lighting intensity of at least 600 lux;

(ii) a clean bench or table for examination of the product;

(iii) a thaw tank or similar capable of defrosting the maximum number of samples for one batch;

(iv) running water for cleaning instruments.

Conditions for laboratories.

63. The establishments shall have, if applicable, laboratory rooms for microbiological and chemical examinations, which shall be separated from fishery product handling rooms.

General conditions for sanitary facilities.

64. (1)Establishments shall have adequate sanitary facilities for the personnel who handle fish as well as for those who handle materials and equipment which come into contact with the product and these social amenities consist of an adequate number of suitable and conveniently located changing rooms, flush toilets, showers, hand-washing facilities, and canteen if meals are taken on the site.

(2) The social amenities should be readily accessible to all persons who are likely to need them and there should be no direct access between the sanitary facilities such as changing room and toilets and any room in which fish, or materials or equipment which comes into contact with fish is handled and the hand washing facilities room should be the separator room between sanitary facilities and preparation or processing rooms.

(3) These hand washing facilities rooms shall not be used for the storage of any processing ingredients or food.

(4) The construction of the floors, walls, ceilings, doors and windows of the social amenities shall be of the same standard specified for the processing areas and the social amenities shall be well ventilated and illuminated.

Conditions for changing facilities, showers, toilets, hand washing facilities and canteen.

65. (1) Establishments shall have changing facilities containing-

(a) a section (room) for undressing city clothes and shoes this room should contain a locker or a hanger for each person to store or hang the city clothes and racks for the shoes the surfaces of the lockers or hangers and racks shall be smooth, non-absorbent and resistant to corrosion and the use of timber is not recommended for the construction of lockers, hangers and racks;

(b) a section (room) for dressing uniforms and boots this room should contain a locker or hanger for each person to store or hang the uniforms and racks for the boots and the surfaces of the lockers, hangers and racks shall be smooth, non-absorbent and resistant to corrosion and the use of timber is not recommended for the construction of lockers, hangers and racks;

(c) between the two sections, showers shall be available to be used after leaving the section for undressing city

clothes and before entering the section for dressing uniforms.

(2) Toilet and toilet areas shall be adjacent to but separate from changing rooms and shall be-

(a) completely separated from food handling areas and not open directly onto these areas;

(b) designed to ensure hygienic removal of waste matter;

(c) well lighted, ventilated and maintained in a clean and tidy condition;

(d) connected with the dirty city clothes or the clean changing room section uniforms;

(e) toilets shall have the same hygiene requirements as the processing room when connected with the clean changing room section;

(f) adequate numbers of sanitary facilities are considered to be as follows-

Number of employee	Number of toilets
1 to 9	2
10 to 24	3
25 to 49	4

50 to 99	6
for every additional 20	1 more;

(g) if personnel of both sexes are employed, separate sanitary facilities should be provided for each sex, in accordance with the above table and urinals may be substituted for water closets, up to 1/3 of the required number of WC's;

(h) all toilets and urinals shall be of the flushing variety and they should be constructed of materials which are easy to clean;

(i) to avoid airborne contamination from toilets into areas where food is exposed, preventive measures have to be taken to prevent contamination such as double doors, separate toilet room, and positive air flow system;

(j) doors of toilet cubicles where they are not in a separate toilet room shall be self-closing and full height.

(3) Hand washing facilities that is, hand-wash basins shall be provided near toilets in number equal to the sanitary facilities and they shall have a permanent provision of hot and

cold water and shall be provided with adequate quantities of liquid soap and taps shall be of the non-hand or elbow operable type.

(4) There shall be a provision of adequate quantities of single use paper towels, or the installation of hot-air hand dryers and other means of hand drying will not be accepted and if paper towels are used, a suitable waste bin shall be provided.

(5) A legible notice shall be prominently displayed instructing personnel to wash their hands after using the toilets.

(6) Hand washing facilities shall be installed before the entrance of the preparation or processing room.

(7) Persons coming or from the changing rooms, or from the canteen, or from the toilets shall be forced by a proper flow to pass through the hand washing facilities room before entering the processing room;

(8) The wash sinks shall have materials for cleaning and disinfecting the hands and disposable towels; the wash sink taps shall not be hand or elbow operable and provide running water at a suitable temperature hot and cold water to wash hands on an adequate way.

(9) Canteen should have the same hygiene requirements as the processing rooms when connected with the clean changing room section uniforms.

(10) A separate laundry facility should be provided, to include hot and cold water provision, exclusively for the washing of uniforms, unless this is done by external laundry contractors.

Minimum requirements for facilities and equipment.

66. The establishment shall afford in the working and storage rooms stipulated in regulation 50 of these Regulations, machinery, tools, utensils, equipment, instruments, product holding, handling and conveying systems complying with the requirements laid down in regulation 67.

General design and construction of facilities and equipment.

67. (1) All machinery, manufacturing systems including gravimetric, pneumatic, closed and automated systems, tools, utensils, equipment, instruments, product holding, handling and conveying systems in the establishments shall be designed, constructed and installed so as to-

(a) prevent the contamination and adulteration of the products with toxic materials, lubricants, fuel, metal fragments, contaminated water or other contaminants;

(b) avoid the accumulation of dirt which could contaminate the product and be the source of hygiene hazards;

(c) permit and enable-

(i) easy thorough cleaning and disinfection with hot water, detergent and disinfectant;

(ii) accessibility for inspection where necessary; and

(iii) maintenance in an appropriate sanitary condition.

(2) Seams or welds should be smooth to prevent build-up of contamination and facilitate cleaning.

(3) Above-mentioned working areas, instruments and working equipment shall be used only for work on fishery products.

(4) All product holding, handling and conveying systems, machinery, tools, utensils and equipment which come into contact with fishery products, shall be constructed of materials which are-

(a) smooth, non-absorbent and resistant to corrosion;
(b) free from pits, crevices and loose scale;
(c) made of materials which do not transmit odour, taste and are non-toxic;
(d) unaffected by food products;
(e) capable of withstanding repeated cleaning and disinfection, and easy to clean and disinfect.

(5) The use of wood and timber in general and other materials which cannot be adequately cleaned and disinfected is prohibited and this applies in particular to knife-handles, spades for ice handling and filleting or cutting boards.

(6) Timber that is used in doors, door jambs, windows in processing areas shall be sealed by a durable non-toxic surface coating such as, gloss enamel, epoxy or polyurethane paint.

(7) Clean and sound wooden pallets could be permitted-

(a) for the transport and the storage of processed food, packed in carton boxes, to

transport them in this areas where mastering is done and no unpacked products are handled and to store them in areas where only cardboard packed products are stored and unpacked products are absent;

(b) for the transport and export of fresh products, packed in foam boxes; but, in the rooms where packing in foam boxes is done, wooden pallets cannot be used and pallets made of plastic or other corrosion resistant materials shall be used in this case; and

(c) in container system units, transport vehicles and the like to transport carton and foam packed products.

(8) Racks and storage systems in cold storage rooms to store carton packed products can be made of clean and sound timber and corrosion resistant materials or timber sealed by a durable non-toxic coating is preferable.

(9) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

Machinery, equipment and overhead structures.

68. (1) All parts of machinery which come into contact with the fish shall be constructed of non- corrodible materials and the use of stainless steel and high density plastics is recommended.

(2) All the machinery shall be easy to clean, and its design shall permit it to be dismantled for cleaning purposes, if necessary.

(3) Equipment or fittings adjacent to wall or other equipment shall have any gaps sealed to prevent entry of moisture and dirt or have sufficient space to permit cleaning. Equipment standing directly on the floor shall be installed-

(a) by sealing directly to the floor to prevent the entry of moisture;

(b) on a raised socle coved at the junction of the floor and socle; or

(c) on legs with a minimum of 300 mm clearance between the underside of the equipment and the floor.

(4) Supporting framework for machinery, benches, sinks, work tables, foot stands, etc. shall be constructed of smooth, impervious materials free from openings, ledges or crevices in which pests or potential contaminants may accumulate.

(5) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimise accumulation of food particles, dirt, and organic matter and thus minimise the opportunity for growth of micro-organisms.

(6) All overhead structures, services and fittings including lighting shall be easy to clean and-

(a) installed so as to avoid contamination either directly or indirectly of food by condensation;

(b) installed as not to hamper cleaning, operations;

(c) insulated where appropriate and be designed and finished as to prevent the accumulation of dirt, minimise condensation, mould development and flaking.

(7) Requirements under subregulation (6) may be met by locating all pipes and machinery above the ceiling.

(8) Ducts, conduits and pipes may be recessed into the wall or mounted at least 25mm clear and long runs of exposed horizontal pipes should be avoided.

Product holding, handling and conveying.

69. A suitable system for the internal movement of fish within the plant shall be implemented and regard should be given to the need to maintain a regular flow of product by the following means-

(a) fish boxes, sufficient in number, shall be provided for the needs of the process shall only be used within the plant, not for external transport of fish;

(b) fish boxes, which are used to transport product to the plant, and for the movement of fish within the plant, shall be constructed of a high density plastic and be of a light colour and they shall have a smooth finish and their design shall avoid areas which could retain particles of product, grease and dirt and the boxes should be designed to permit drainage of any liquid;

(c) if trolleys, barrows, supports or bearers are used to carry large fish or to feed blast freezers or chillers, they shall be made of non-corrodible material and have a smooth finish;

(d) if conveyors are utilised they shall be constructed of non-corrodible impermeable materials such as, stainless steel or high density plastic;

(e) ice shovels should be made of a light coloured plastic, or of stainless steel and wood is not permitted in any part of the construction;

(f) chutes and other enclosed transport systems shall be-

(i) constructed with inspection and cleaning hatches;

(ii) easily dismantled for cleaning;

(iii) made of high density nylon, stainless steel or fibre glass free of crevices and have all internal junctions rounded out;

(g) where compressed air is used, the compressed air or other gases that come into direct contact with product or equipment surfaces or mechanically introduced into food or used to clean food-contact surfaces or equipment shall have a filtered air intake located in a clean place, contain no oil or substances hazardous to health or shall be treated or otherwise controlled in such a way that food is not contaminated with unlawful indirect food additives.

Work tables, foot stands, and small equipment.

70. (1) Work tables shall be constructed of materials which are non-corrodible, impermeable and non-toxic and stainless steel is preferable work tables shall be designed to

facilitate their cleaning and to avoid areas which could retain particles of the product, grease and dirt.

(2) If foot stands are used to raise personnel to the level of the work tables they should be constructed of stainless steel or other non-corrodible material and the use of wood in the construction of foot stands is not permitted.

(3) Racks for gloves and aprons shall be provided within the store for small equipment connected with the cleaning and disinfecting room.

(4) Hose points shall be provided together with hose racks made of rust resistant material.

Monitoring and measuring equipment.

71. (1) All equipment to be used for monitoring or measuring purposes where accuracy is important such as measuring, regulating or recording temperatures, pH, acidity, water activity or other conditions that control or prevent growth of undesirable microorganisms in fishery products shall-

(a) be checked to ensure their accuracy is sufficient for the task in hand;

(b) be adequate in number for their designated uses and adequately maintained;

(c) where appropriate be calibrated regularly;

(d) be checked on a regular way on their calibration status.

(2) Records shall be kept of the calibration and the calibration status.

General prerequisites for hygienic facilities.

72. Establishments shall afford also following facilities-

(a) hygienic waste water disposal system as described in regulations 209 to 218, Part XI of these Regulations;

(b) appropriate facilities for protection against pests such as insects, rodents, birds, as described in regulations 143 to 152 of Part XI of these Regulations;

(c) facilities to provide adequate supplies of drinking water as described in regulations 84 to 102 of Part XI of these Regulations;

(d) facilities for fishery products not intended for human consumption as described in regulations to 209 to 218 of Part XI of these Regulations.

Vehicles wash area.

73. (1) Establishments shall have adequate facilities for cleaning and disinfecting means of transport, however, such facilities are not compulsory if there is a requirement for the means of transport to be cleaned and disinfected at facilities officially authorised by the Competent Authority.

(2) Where vehicles and container system units used to carry fish are cleaned, a paved and drained area shall be used and the surface of the vehicle wash area shall-

(a) be durable and impervious;

(b) have a drainage gradient of at least 1:50 connected to the drainage system;

(c) have an adequate supply of pressured water for disinfection and cleaning operations.

Loading docks.

74. (1) Establishments shall have loading docks and the loading dock shall be-

(a) located in an area that is convenient to the stored products;

(b) enclosed or provided with a protective shelter to prevent fish from contamination during loading and unloading;

(c) the loading dock shall have an illumination of at least 250 lux.

(2) The area nominated for truck movement shall be finished with a well-drained surface which is impervious and durable.

(3) Unloading and loading equipment shall be constructed of a material that is easy to clean and disinfect.

BEST MAINTENANCE PRACTICES.

75. Buildings, vessels, equipment, utensils, refrigeration and all other physical aspects of an establishment including drains shall be kept in good repair, in a clean and orderly condition and operated in accordance with these Regulations.

Action plan and quality objectives.

76. An action plan to maintain the establishment has to be implemented.

Scheduling.

77. (1) Repairs shall be carried out as soon as possible without interference to handling and processing and may cause the facilities closure during certain repairs.

(2) Planned actions shall be scheduled in a timetable to demonstrate the commitment to the future actions.

(3) These schedules and timetables shall be approved by the Competent Authority and checked on its execution on a regular basis.

Responsibilities and authorities.

78. Responsibilities and authorities have to be established for the implementation, maintaining, monitoring and verification of the maintenance plan.

Procedures.

79. Procedures shall be established to ensure that maintenance will be done in such a way that the risk of contamination of the products is eliminated and a regular preventative maintenance programme shall be implemented, whereby equipment, utensils and premises are regularly reviewed for signs of wear and tear and whereby deficiencies are detected prior to a problem occurring.

Process control.

80. A fail safe control system shall be worked out to control the maintenance process and the measures taken shall be compared with the standards and verification has to be done to ensure that the corrective actions are done in the good way.

Instructions.

81. Work instructions and control instructions shall be documented and implemented to establish on a daily basis the principles designed in the procedures.

Documentation and records.

82. Checklists for controls, standards, recommendations and verification and records in case of fault shall be documented.

Training.

83. (1)Training on the spot and special training programmes shall be implemented to ensure that staff are continually reminded of the risks and their responsibilities within the food industry especially concerning the items of this chapter.

(2)Records of courses and training sessions attendances shall be kept for inspection and evaluation.

BEST POTABLE WATER PRACTICES.

84. (1) The objective of these Regulations 84 to 102 shall be to protect human health from the adverse effects of any contamination of potable clean water or clean seawater in contact with fishery products intended for human consumption.

(2) Establishments shall be required to provide a permanent supply of potable water or clean water within the meaning of these Regulations or alternatively of clean sea water and water may be treated by an appropriate system such as filtration and chlorination, UV sterilization if necessary to achieve the required standard and water shall be provided under pressure and in sufficient quantity.

(3) If the water used in the establishment receives additional treatment prior to use, this shall be done in accordance with the instructions of the manufacturer of any equipment or chemicals utilised and under supervision of the management of the establishment.

(4) However, by way of exception, a supply of non-potable water is permissible for the production of steam, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water

for other purposes and present no risk of contamination of the products and non-potable water pipes shall be clearly distinguished from those used for potable water or clean sea water.

Use.

85. (1) Only potable water shall be used by the management of any establishment-

(a) to come in contact with fish or fish-contact surfaces;

(b) to manufacture ice; and

(c) to clean and disinfect in the establishment.

(2) Without prejudice to the general requirement in regulations 84(1) and (2), clean water or clean seawater within the meaning of these Regulations may be used in contact with whole fishery products and for production of ice in contact with whole fishery products.

Water distribution system within the establishment.

86. (1) All pipe work in the water distribution system shall be impermeable, well-constructed and in good condition and iron pipes shall be painted externally in order to protect them from rusting.

(2)The provision of water to the sanitary facilities shall be isolated from the water system for the rest of the establishment and should be supplied from a separate circuit.

(3)There shall be provision to prevent backflow or cross contamination between potable and non-potable water within the establishment.

(4) The management of an establishment shall-

(a) account for the sources of water supply whether-

(i) municipal water (mains) with or without intermediary storage;

(ii) surface water, well water or bore-hole water with or without intermediary storage; and

(iii) desalinated sea water with or without intermediary storage or a combination of different sources;

(b) be responsible for ensuring that water used in the establishment is potable;

(c) be able to demonstrate the water distribution system within the establishment; and

(d) provide a water distribution or recirculation map whereon the pipes and outlets shall be identified by consecutive numbering enabling location on the establishment map and in the establishment.

Storage of water.

87. (1) The establishment shall possess adequate water storage tanks or cisterns with sufficient capacity to supply the requirements of the establishment when operating at maximum capacity and to allow in case of chlorination sufficient contact time between water and chlorine as stipulated in regulation 95.

(2) The tanks or cisterns shall be well constructed and the internal surfaces shall be smooth, impermeable and can be easily disinfected and cleaned.

(3) Each water tank or cistern shall be provided with an inspection hatch that permits entry for cleaning purposes and the design of the hatch shall protect against the entry of rainwater, ground water and any process water that may flow out of the establishment.

(4) Each water tank or cistern shall be protected against the entry of insects, rodents, other animals and dust.

(5) The area surrounding each water tank or cistern shall be maintained clean and free of accumulation of rubbish, dust, water and other materials that could contaminate the water.

(6) Each water tank or cistern shall have a floor with sufficient slope and drainage to enable proper cleaning.

(7) Water tanks shall be inspected at regular intervals with the objective of keeping them in good condition and a cleaning and disinfection plan shall be implemented as mentioned in regulation 120 of these Regulations.

Water circulation and recirculation.

88. (1) Water reused and circulated within a facility shall be treated and maintained in a condition so that no health hazard can result from its reuse and shall be potable if it comes into contact with food.

(2) Water recirculation and circulation systems shall be clearly identified and have-

(a) no cross connection between potable and non-potable water;

(b) non-return devices installed to prevent back flow into the systems;

(c) no dead ends;

(d) non-potable water outlets clearly identified.

(3) Water can only be used and reused or recirculated for cooling of a canned product if it is-

(a) potable;

(b) chlorinated to a level of not less than 0.5 ppm free residual chlorine at the end of the cooling cycle;

(c) filtered before re-use; and

(d) all storage tanks, cooling towers, pipelines or the like utilised in handling the water are constructed to facilitate inspection and cleaning.

Hot water and steam.

89. (1) The establishment shall possess hot and cold water in quantities and temperatures adequate for hand-washing by personnel and, for washing of equipment, machinery and the premises in general.

(2)The installation of either a steam system or pressurized hot water for cleaning of the establishment is recommended.

(3) Where steam or pressurized hot water is used, it shall be supplied in sufficient volume and pressure for the operation of the equipment and contain no hazardous substances.

Action plan and quality objectives.

90. Procedures and instructions shall be put in place by management to implement the chlorination system, to organise

the scheduling of the free residual chlorine checks, the microbiological checks and the physicochemical checks.

Scheduling.

91. (1) Planned actions shall be scheduled in a timetable to demonstrate the commitment to the future actions.

(2) These schedules and timetables shall be approved by the Competent Authority and checked on its execution on a regular basis.

Responsibilities and authorities of management and staff.

92. (1) The management of the establishment shall designate qualified staff to be responsible for the implementation, maintaining, monitoring and verification of the potable water control plan.

(2) The designated staff shall be authorised to take any necessary immediate action if conditions or results of test of the water indicate that such action is necessary for the purpose of ensuring food safety.

Monitoring.

93. (1) Documented procedures shall be installed to control and ensure the safety and the quality of water by-

(a) water analysis on residual chlorine content;
(b) microbiological;
(c) chemical;
(d) physio-chemical;
(e) biological tests for parasites, algae, other organisms such as animalcules (worms, larvae).

(2) Sampling points shall be identified and selected so the water in the whole supply system of the establishment is tested over a period and the frequency of the sampling shall be justified

based on records of compliance and assessment of possible risks for contamination of the system.

Process control.

94. (1) A fail safe control system has to be worked out to control the safety and the quality of water and the results shall be compared with the standards and verification has to be done to ensure that the corrective actions are successful.

(2) Records shall be kept of tests showing that effective treatment was maintained or that the microbiological quality was suitable.

Instructions and standards for chlorination.

95.(1) Where an establishment uses a chlorination system it shall comply with the following-

(a) chlorine shall be added on-line by dosing or injection (gas or liquid) prior to intermediary storage to permit sufficient contact time with the water in order to allow the chlorine to react with the organic matter;

(b) the retention tank shall have the capacity to retain water together with the chlorine added for at least twenty to thirty minutes;

(c) the chlorine not combined after twenty to thirty minutes remains as free residual chlorine available in line to react with whatever contamination present in the piping system such as back syphonages and dead ends;

(d) the cleaning programme for the intermediary storage tanks shall be documented, monitored and demonstrated;

(e) the management of an establishment shall put in place measures to ensure the

functioning of the chlorination system, and the free residual chlorine shall be checked at intervals of not less than eight hours or at the start of each shift but at least once a day.

(2) An alarm system is recommended to be applied to ensure the functioning of the chlorination system.

(3) The residue of free chlorine at the time of use of the water in direct contact with products shall be no higher than the amount allowed in potable water in the municipal potable water supply of Guyana.

(4) The products fish, shrimp, molluscs, etc., shall not be washed, dipped, glazed, or treated with hyper-chlorinated water of concentration higher than that stipulated in subregulation 96(3).

Official control of potable water.

96. (1) For the purposes of the minimum requirements of these Regulations potable water in contact with fishery product shall be wholesome and clean if it-

(a) is free from any micro-organisms and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health; and

(b) meets the minimum requirements set out for microbiological and chemical parameter in Schedule Five, Part I, Chapter 1 and 2.

Schedule Five

(2) As regards the parameters set out in Schedule Five Part I, Chapter 3, the values apply for monitoring purposes and

for the fulfillment of the obligations imposed in case of remedial actions laid down in regulation 101 of these Regulations.

(3) The Competent Authority shall set values for additional parameters not included in Part I of Schedule Five where the risk for contamination of fishery products so requires and the values set should, as a minimum guarantee that the potable water is free from any micro-organism and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health.

Instructions for official monitoring.

97.(1)The Minister shall take all measures necessary to ensure that regular monitoring of the quality of intended for human consumption is carried out, in order to check that the water available to consumers meets the requirements of these Regulations and in particular the chemical parametric values.

(2) Samples should be taken so that they are representative of the quality of the water used throughout the year.

(3) The Minister shall take all measures necessary to ensure that, where disinfection and the use of certain substances or materials forming part of the preparation or distribution of water intended for human consumption, the efficiency of the disinfection treatment applied is verified, the use of the substances is governed and that any contamination from disinfection by-products is kept as low as possible without compromising the disinfection in order to avoid harmful effects on human health.

Schedule Five

(4) To meet the obligations imposed in subregulation (1), appropriate monitoring programmes shall be established by the competent authorities for potable water intended in fishery

product activities and these monitoring programmes shall meet the minimum requirements set out in, Schedule Five, Part II.

(5) The Competent Authority for potable water shall ensure that additional monitoring is carried out on a case-by-case basis of substances and micro-organisms for which no parametric value has been set in accordance with regulation 96 of these Regulations, if there is reason to suspect that they may be present in amounts or numbers which constitute a potential danger to human health.

(6) The Competent Authority shall verify by sampling and testing the water in the fishery establishments as an integrated part of the official control of the auto-control system as stipulated in regulation 30 of these Regulations.

Instructions for official sampling by Competent Authority for fishery products.

98. (1) Without prejudice to the requirements of sampling frequency set out in Table 2 of Part II, of Schedule Five.

Schedule Five

(a) the frequency of water sampling in general for the purpose of check monitoring in a fishery product establishment-

(i) in the case of water supplied from a public distribution network, without intermediary storage, shall be at least once per three months from various representative outlets within the plant as laid down in this subregulation (3);

(ii) in the case of water supplied from a public distribution network with intermediary

Schedule Five

storage, or from a town water source, shall be at least once per month from various representative outlets within the plant as laid down in this subregulation (3).

(b) the frequency of water sampling for the purpose of audit monitoring in a fishery product establishment shall be at least once per year.

(2) The sampling points shall be determined by the competent authorities and shall meet the relevant requirements set out in Part II and samples for check monitoring and audit monitoring laid down in Part II, Table 1 of Schedule Five are to be collected by an authorised officer of the Competent Authority and analysed in an official laboratory.

(3) The method of sampling of potable water and ice shall follow the procedure set out in Part IV to Schedule Five.

Specifications for the testing.
Schedule Five

99. (1) The specifications for the analyses of parameters set out in Part III of Schedule Five shall be complied with.

(2) Test methods other than those specified in Part III, Chapter 1 of Schedule Five, may be used, provided that it can be demonstrated that the results obtained are at least equivalent to those produced by the methods specified and the Competent Authority that has recourse to alternative methods shall provide all relevant information concerning such methods and their equivalence.

(3) For those parameters listed in Part III, Chapters 2 and 3 of Schedule Five, any method of analysis may be used provided that it meets the requirements set out therein.

Instructions for remedial action following official control of water in fish processing establishments.

100. (1) The Competent Authority for potable water shall ensure that any failure to meet the parametric values set in accordance with regulation 96 of these Regulations is immediately investigated in order to identify the cause and further sampling shall be carried out.

(2) Two consecutive samples should not be positive for coliform organisms and if the samples show the presence of E. coli or Enterococci, the water of the said source shall not be used until the contamination has been eliminated.

(3) If, despite the measures taken to meet the obligations imposed, water intended for human consumption does not meet the parametric values set in accordance with regulation 96 of these Regulations, the Competent Authority for potable water shall ensure that the necessary remedial action is taken as soon as possible to restore its quality and shall give priority to their enforcement action, having regard inter alia to the extent to which the relevant parametric value has been exceeded and to the potential danger to human health.

(4) Whether or not any failure to meet the parametric values has occurred, the competent authority for potable water shall ensure that any supply of water intended for human consumption which constitutes a potential danger to human health is prohibited or its use restricted or such other action is taken as is necessary to protect human health.

Schedule Five

(5) The Competent Authority for potable water shall decide what action under subregulation (4) should be taken, bearing in mind the risks to human health which would be caused by an interruption of the supply or a restriction in the use of water intended for human consumption and the Minister may establish guidelines to assist the Competent Authority for potable water to fulfil their obligations under this regulation.

(6) The Minister may establish guidelines to assist the Competent Authority for potable water to fulfil their obligations under subregulation (5).

(7) In the event of non-compliance with the parametric values or with the specifications set out in Part I, Chapter 3 of Schedule Five, the Competent Authority shall consider whether that non-compliance pose any risk to human health and they shall take remedial action to restore the quality of the water where that is necessary to protect human health.

(8) The Minister shall ensure that, where remedial action is taken, consumers are notified except where the Competent Authority considers the non-compliance with the parametric value to be trivial.

(9) Where results of official control of water and ice used in a fishery establishment as provided for in regulation 98(3) of these Regulations reveals results which are non-compliant with criteria in Part I and part II of Schedule Five the Competent Authority within the meaning of these Regulations shall request the establishment to take immediate action to ensure that such water is not used in contact with products.

Documentation and records of control of water.

101. (1) The establishment shall document the layout of the water supply system and the complete procedures, instructions

and criteria for the control and treatment of sea and potable water used in contact with fishery products.

(2)The establishment shall keep records of all sampling and results of testing, including corrective actions taken in case of failure to meet the required standards.

(3)The Competent Authority within the meaning of these Regulations shall keep records of all sampling and testing carried out for the purpose of official control of water used in contact with fishery products, including corrective action requests and other actions taken in case of failure to meet the required standards.

Training.

102. Training on the spot and special training programme shall be implemented to ensure that-

(a) staff are continually reminded of the risks and their responsibilities especially concerning the assurance of water quality and safety;

(b) records of courses and training sessions attendances are kept for inspection and evaluation.

BEST RAW MATERIAL PRACTICE.

103. The intake of fishery products shall be organised in accordance to the requirements with respect to the quality and safety of the products stipulated by customers but at least to the requirements imposed by these Regulations.

Action plan and quality objectives.

104. (1) A supplier, quality and safety assurance agreement has to be agreed between supplier and management of the establishment to work out principles concerning product control, quality standards raw materials, ingredients or additives known to be, or reasonably expected to be, contaminated with,

maintaining the cold chain, hygiene and food safety and traceability.

(2) Raw materials, ingredients or additives known to be, or reasonably expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or adulterated with foreign substances to such an extent that, even after hygienic and scientific processing into a final product would be unfit for human consumption, shall not be accepted and used by management of any establishment.

(3) Raw-materials shall be chilled as soon as possible after catching or harvesting and same shall be kept at temperature approaching that of melting ice throughout storage and transport.

Scheduling.

105. (1) Planned actions shall be scheduled in a timetable to demonstrate the commitment to the future actions.

(2) These schedules and timetables shall be approved by the Competent Authority and checked on its execution on a regular base.

Responsibilities and authority.

106. Responsibilities and authorities shall be established for the implementation, maintaining, monitoring and verification of the described best raw material practices.

Procedures.

107. (1) A procedure to implement supplier quality and safety assurance has to be worked out, applicable for all steps from aquaculture farm or fishing ground up to raw material storage at the factory to ensure that raw materials received are safe for food manufacturing use and comply with the required quality and safety level.

(2) A supplier of raw materials shall enter into a written agreement of guarantee, with management or management

representative of an establishment, in the nature of the matter hereunder specified-

(a) quality standards and product control-all raw material has to undergo arrival inspection at plant based on its specifications agreed in the supplier quality and safety assurance agreement and products that do not reach the quality and safety standards that are laid down in the raw material specifications, agreed between the supplier and the management of the establishment, will be rejected and returned to the supplier, or will be disposed of by agreement between the supplier and the management of the establishment;

(b) maintaining the cold chain- the raw material shall be handled in accordance with the temperature regimes laid down in the specifications mentioned in the supplier quality and safety assurance agreement and at least in accordance with the temperature regimes laid down in these Regulations;

(c) hygiene and food safety- the products shall be transported, stored and handled under conditions that will protect against contamination and minimise deterioration;

(d) raw material specifications as- ice or fish ratio, maximum core temperature allowed at arrival in the factory, maximum time

between catch and icing, maximum time between catch and intake at the establishment, maximum rejects allowed before the whole batch is refused, specifications about species related hazards, organoleptic specifications, chemical specifications concerning freshness determination, microbiological specifications, the way and the method of transport;

(e) traceability- each consignment of incoming raw-materials shall be appropriately labelled or accompanied with information that allow for traceability to the supplier and area of catch or farming and traceability codes will also be established, granted and approved by the Competent Authority in order to facilitate product recalls.

(3) The unloading of fishery products at the establishment's jetty, shall comply with the following requirements-

(a) unloading and landing equipment shall be constructed of material which is easy to clean and disinfect and shall be kept in a good state of repair and cleanliness; and

(b) during landing, loading and unloading, contamination of fishery products shall be avoided and it shall in particular be ensured that-

(i) unloading and landing operations proceed rapidly;

(ii) fishery products are placed without unnecessary delay in a protected environment at the temperature required on the basis of the nature of the product and, where necessary, in ice in transport, storage or market facilities, or in an establishment;

(iii) equipment and handling practices that cause unnecessary damage to the edible parts of the fishery products are not authorised;

(iv) personnel shall endeavour to protect the fishery products from physical damage during the unloading of the vehicle; they should not stand on the fish and should prevent it from falling on the floor;

(v) all the equipment used in the unloading of fish shall be washed and disinfected after each batch and this applies to fish boxes, shovels, flume systems, conveyors and other miscellaneous equipment;

(vi) during the unloading of the vehicle, the doors of the reception of the establishment shall be open for the minimum time possible;

(vii) the vehicle is unloaded immediately after the approval of the batch and fish

should never be stored in the vehicle whilst awaiting processing nor should fish be left outside the establishment.

(4) Raw material inspection, handling and storage of accepted raw material shall be worked out in instructions, and shall be documented by delivery records and product quality records, enabling also traceability of the products-

(a) before unloading, each vehicle arriving at the establishment with fish for processing, shall be inspected, to ensure that-

(i) the interior of the vehicle is clean;

(ii) the fish has not been exposed to detrimental climatic conditions;

(iii) other materials which could contaminate the fish are not carried together with the fishery products;

(iv) labelling and other information for traceability is available and within requirements;

(b) before unloading commences, a sample of fish shall be collected from the vehicle, and the internal temperature measured and the mean temperature should be 0° C, and no fish shall have a temperature of more than 5° C for fresh fishery products and the temperature of brine frozen fishery products shall not be higher than –9° C;

(c) before unloading commences a representative sample of each batch of fish shall be taken for sensory evaluation of smell and appearance of raw fish, as described in regulation 113 and 114 of these Regulations;

(d) the quality control manager shall indicate his approval of the batch, based on the results of the above tests and quality control manager shall sign an inspection form and assign a batch code to the fish before unloading of the vehicle commences.

(5) The initial stages of processing that is, washing of raw material, separation of extraneous material and gutting shall commence as soon as possible after unloading the vehicle.

(6) Fishery products which are not processed immediately upon arrival at the establishment shall be washed with clean water at 0° C (if necessary), and stored with ice in suitable reception tanks or put in fish-bins, iced and stored in a chill room.

(7) The storage of raw material shall comply with the following requirements-

(a) if more fish than can be processed immediately, should arrive at the establishment the excess shall be stored in suitable tanks with ice and water, or alternatively be held in a chill storage

room, in order that the temperature of the product is kept at 0° C;

(b) it is recommended that all product which is stored for more than one day before processing is eviscerated and the priority shall be to eviscerate the fish as soon as possible after arrival at the establishment (if not done previously) in order to maintain the intrinsic quality of the product;

(c) the evisceration of the fish should be done carefully in order to avoid the contamination of the fish flesh;

(d) only fish complying with the requirements laid down in regulation 112, 113 and 114 of these Regulations shall be stored and all products unfit for human consumption shall be removed and kept separately in the designated room;

(e) fish shall not be stored in heaps, and the depth of storage tanks should be kept to a minimum to prevent damage and tanks should contain water before filling with fish in order to prevent damage;

(f) the duration of storage of raw material shall be kept to a minimum;

(g) the water contained in the storage tanks should be changed at regular intervals during the storage period, and also between the storage of different batches of fish.

(8) Management of an establishment engaged in the processing or packing of aquaculture products for export market shall-

(a) obtain guarantee from the producer or supplier that the withdrawal time has been complied with;

(b) shall ascertain that aquaculture product brought into the establishment shall not contain-

(i) residue levels, which exceed maximum permitted limits;

(ii) any trace of prohibited substances or products.

Process control.

108. A fail safe control system shall be implemented whereby measurements and checks are compared with standards, followed by corrective actions if necessary.

Instructions.

109. Work instructions and control instructions shall be implemented in detail.

Raw material specifications.

110. (1) Raw material shall be specified by its freshness, physical soundness, sanitary soundness and temperature.

(2) The freshness shall be checked by organoleptic, physical and chemical parameters.

(3) The physical soundness shall be checked visually.

(4) The sanitary soundness comprises the parasite and toxin checks, the checks on contaminants, adulterants and microbiological checks.

(5) The temperature of fishery products shall be taken on the level of the bone and under the skin to control whether the fishery products are in the condition of warming up or cooling down.

Freshness.

111. (1) Organoleptic examination of freshness shall be carried out to verify that the raw materials are fit for human consumption.

Schedule Six

(2) The criteria that shall be used for the organoleptic examination are general appearance, colour, consistency, smell and eventually taste and flavor as established in Schedule Six.

(3) The organoleptic examination shall be repeated after the first sale of fishery products, if it is found that the requirements of this regulation have not been complied with or when considered necessary and after the first sale, fishery products shall at least comply with the minimum freshness requirements mentioned in this regulation.

(4) Based on the results of the organoleptic examination lot categories shall be established under the following conditions-

(a) each lot shall contain products of the same degree of freshness, if it is not, the lot shall be placed in the lowest freshness category represented herein;

(b) product categories shall be established under following conditions-

(i) fish, selachii, and cephalopods placed by lot in freshness category and extra shall be free

of pressure marks, injuries, blemishes and bad discoloration;

(ii) fish, selachii, and cephalopods placed by in freshness category A shall be free of blemishes and bad discoloration and very small proportion with slight pressure marks and superficial injuries shall be tolerated;

(iii) for fish, selachii and cephalopods placed by a lot in freshness category B, a small proportion with more serious pressure marks and superficial injuries shall be tolerated and fish shall be free of blemishes and bad discoloration and when products are being classified by freshness category, without prejudice to the health rules applicable, the presence of visible parasites and their possible effect on the quality of the product shall be taken into consideration with allowance being made for the type of product and its presentation.

(5) Physical, chemical or other checks to determine freshness and to prevent fishery products which are unfit for human consumption from being placed on the market, shall be established.

Schedule Seven

(6) If the organoleptic examination reveals any doubt as to the freshness of the fishery products, use may be made of additional physical, chemical or other checks considered as necessary or microbiological analysis-

(a) physical methods are-

(i) refractometric index of the eye-liquid (refractometer);

(ii) skin resistance for alternative current (fish tester);

(iii) pH of the fish meat;

(b) the chemical method is TVB-N (Total Volatile Basic Nitrogen).

(7) Unprocessed fishery products belonging to the species categories designed by the Competent Authority shall be regarded as unfit for human consumption where, organoleptic assessment having raised doubts as to their freshness, and where additional chemical checks reveal that the TVB-N limits set by the Competent Authority are exceeded-

(a) the reference method to be used for checking the TVB-N limit is the method involving distillation of an extract deproteinised by perchloric acid as set forth in Schedule Seven to these Regulations;

(b) distillation as referred to in paragraph (a) shall be performed using apparatus which complies with the principles of the diagram as set forth in Schedule Seven to these Regulations or can be performed by an equivalent automatic steam distillation apparatus;

(c) the routine methods which may be used to check the TVB-N limits are as follows-

(i) microdiffusion method described by Conway and Byrne (1933);

(ii) direct distillation method described by Antonacopoulos (1968);

(iii) distillation of an extract deproteinised by trichloracetic acid (Codex alimentarius Committee on Fish and Fishery Products (1968);

(iv) the sample shall consist of about one hundred grams (100g) of flesh, taken from at least three different points and mixed together by grinding.

(8) The Competent Authority shall recommend to official laboratories the use, as a matter of routine, of the reference method referred to in Schedule Seven to these Regulations and in case of doubt or in the event of dispute regarding the results of analysis performed by one of the routine methods only the reference method may be used to check the results.

Physical soundness.

112. Fish shall be free of-

(a) heavy injuries and scratches;

(b) bad discoloration;

(c) blemishes; and

(d) dirt.

Sanitary Soundness.

113. (1) The management of an establishment shall plan and implement controls with respect to sanitary soundness, the presence of parasites, toxins, microbes, viruses, environmental, accidental and intentional contaminants or adulterants which could endanger or render to injurious to human health.

(2) The Competent Authority shall provide the management of an establishment with all necessary information from the national monitoring and surveillance programs, as

required in regulation 18, to enable an efficient planning of controls mentioned in paragraph (1).

(3) Fishery products shall not contain parasites which could be harmful for human health and toxin checks to be established are-

(a) histamine (toxin of enzymatic origin)-

(i) following sampling plan has to be established-

Nine samples shall be taken from each batch and these shall fulfill 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.

(ii) these limits apply only to fish species of the following families: scombridae, clupeidae, engraulidae and coryphaenidae. However, fish belonging to these families which have undergone enzyme-ripening treatment in brine may have higher histamine levels but not more than twice the above values;

(iii) examinations shall be carried out in accordance with reliable, scientifically recognised methods, such as "high performance liquid chromatography" (HPLC);

(b) marine biotoxins: type DSP (Diarrhetic Shellfish Poison) and PSP (Paralytic shellfish poison)-

(i) the total Paralytic Shellfish Poison (PSP) content in the edible parts of molluscs (the whole body or any part edible separately) shall not exceed 80 micrograms per 100 g of mollusc flesh in accordance with the biological testing method – in association if necessary with a chemical method for detection of Saxitoxin – or any other method recognised by the EC Commission;

(ii) if the results are challenged the reference method shall be the biological method and the customary biological testing methods shall not give a positive result to the presence of Diarrethic Shellfish Poison (DSP) in the edible parts of molluscs (the whole body or any part edible separately).

(c) Ichthyosarcotoxins : type tetraodotoxin-

The placing on the market of poisonous fish of the following families: Tetraodontidae, Molidae, Diodontidae, Canthigasteridae shall be forbidden;

(d) Ichthyosarcotoxins : biotoxinetype ciguatoxin or other muscle-paralyzing toxins-

The placing on the market of fishery products containing biotoxins such as ciguatera toxins or muscle paralyzing toxins shall be forbidden.

(4) Microbiological criteria, for the microbiological checks, including sampling plans and methods of analysis, shall be laid down for raw-materials where necessary to protect public health.

Temperature control.

114. Temperature control after fishing, during transport in the fish-holds, during landing and offloading, during selling, during storage and transport, during processing shall be done to check if the temperature of the fishery products is complying with the requirements, laid down in these Regulations.

Seizure.

115. If the organoleptic examination, physical and chemical checks, checks on physical and sanitary soundness or temperature checks, reveal that the fishery products are not fit for human consumption, measures shall be taken to withdraw them from the market and denature in such a way that they cannot be re-used for human consumption and products proven to be adulterated shall be subject to seizures, testing and subsequent disposal when found to be unfit for human consumption.

Records and documentation.

116. (1) A "supplier quality assurance agreement" document, which is signed by both, the supplier and the customer shall be available and a register is used to record all information about the incoming material.

(2) The following shall be recorded: species, weight, origin, temperature, quality condition of product, accepted and rejected fish, reason of reject, etc.

(3) When there is no official inspection on the landing sites, the official inspectors will cross-check the control and the evaluation of the fish quality and the safety done by the quality managers at the reception of the establishments and recorded in the registers.

Training.

117.(1) A training program shall be in place whereby fishermen, transporters, off loaders and the inspection team in the reception shall be involved to ensure that staff are continually reminded of the risk and their responsibilities within the food industry especially concerning the provisions of this regulation.

(2) Records of courses and training sessions attendances shall be kept for inspection.

BEST CLEANING AND DISINFECTING PRACTICES.

118. (1) In dry processing, when food contact surfaces are used for manufacturing or holding low-moisture food, all food contact surfaces shall be in a dry, sanitary condition at the time of use.

(2) When the surfaces are wet-cleaned, they shall, when necessary, be cleaned and disinfected and thoroughly dried before subsequent use.

(3) In wet processing when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and disinfected before use

and after any interruption during which the food-contact surfaces may have become contaminated.

(4) In processing where equipment and utensils are used in a continuous production operation, the utensils and food contact surfaces of the equipment shall be cleaned and disinfected as necessary.

(5) Food contact surfaces such as-

(a) processing equipment and instruments used for working on fishery products in the preparation and processing areas;

(b) crates, bins, baskets, containers used in auctions, preparation- and processing facilities for transporting, carrying, salting, brining, shelling, or shucking crustaceans or molluscs shellfish;

(c) cutting boards, working tables and work surfaces where fishery products come in contact with;

(d) machinery that make contact with food during processing and machinery used for mechanical recovery of fish flesh;

(6) Non-food contact surfaces such as -

(a) the building and the fixtures;

(b) social amenities (changing facilities, toilets, canteens);

(c) floors, drains, walls, ceilings, additional structures;

(d) waste containers shall be kept in a good state of repair and shall be cleaned and be kept clean at all times and disinfected-

(i) with effective cleaning and disinfecting preparations;

(ii) either immediately after the end of each working day or at such times as may be appropriate to maintain hygienic conditions as worked out in the instructions-

(A) so that they do not constitute a source of contamination for the products; and

(B) in a manner that adequate precautions are taken to prevent food, food contact surfaces or food packaging materials from being contaminated during cleaning or disinfecting of rooms, equipment or utensils.

(7) Cleaned and disinfected portable equipment and utensils shall be stored in a location and manner that protects food-contact surfaces from contamination after cleaning and disinfection. Cleaned and disinfected and to be cleaned and

disinfected equipment and containers shall not be stored in processing rooms.

(8) Roadways, yards and other areas in the immediate vicinity of the establishment shall be kept clean

(9) Establishments shall afford adequate facilities for cleaning and disinfecting buildings, fixtures, utensils, food contact surfaces and means of transport.

(10) Detergents and disinfectants shall be selected and tested for effectiveness of its purpose, shall be approved by the Competent Authority after receiving following information: trade name, type of chemical compound, active ingredients and method of use and these products shall be used in such a way that they do not have adverse effects on the machinery, equipment, products and not impart any flavours, odours or leave toxic residues.

(11) Toxic cleaning compounds and disinfecting agents shall be identified, held and stored in a manner that protects against contamination of food, food-contact surfaces or food-packaging materials and all relevant regulations promulgated by other government agencies for the application, use or holding of these products shall be followed.

(12) Surfaces contacting food shall be adequately rinsed after the use of detergents and disinfectants prior to handling of the food.

(13) The Competent Authority shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this Part, such verification may include-

(a) reviewing the Sanitation SOP's;

(b) reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;

(c) direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and

(d) direct observation or testing to assess the sanitary conditions in the establishment in accordance with these Regulations.

Action plan and quality objectives.

119. A cleaning and disinfection procedure for food-contact surfaces, non-food contact surfaces and intermediary storage water tanks shall be documented and implemented-

(a) to ensure that the plant, after cleaning and disinfection is free from pathogens and that the Total Plate Count from food contact surfaces is below a level (cfu/cm2) approved by the Competent Authority;

(b) in order to prevent the buildup of dirt such as scales and maggots and other residues as well as resistant microbiological populations;

(c) to ensure that the inner surfaces of the tanks shall not be a source of contamination for the potable water.

Scheduling.

120. (1) Planned actions shall be scheduled in a timetable to demonstrate the commitment to the future actions.

(2) These schedules and timetables shall be approved by the Competent Authority and checked on its execution on a regular basis.

Responsibilities and authorities.

121. Responsibilities and authorities shall be established for the implementation, maintaining, monitoring and verification of the cleaning and disinfecting practices.

Procedures and process control.

122. (1) A procedure defined out to ensure that in all sections in the establishment an adequate work method for cleaning and disinfection and a failsafe control system will be used.

(2) The method of cleaning and disinfection shall at least consist in and the different steps shall be established in following order-

(i) preparatory work before cleaning;

(ii) documented visual checks before starting cleaning;

(iii) cleaning with detergents;

(iv) rinsing to remove that cleaning agent;

(v) documented visual checks to evaluate the cleaning before starting disinfecting;

(vi) disinfecting;

(vii) rinsing to remove the sterilizing agent after the appropriate contact time;

(viii) final phase-

(i) equipment is reassembled and allowed to dry;

(ii) documented checks to evaluate the cleaning and disinfecting activities by quick tests or checks or by hygienogram.

(3) Cleaning shall be carried out as frequently as necessary, cleaning and disinfection shall be carried out either immediately after the end of each working day, when there is a risk of contamination or at such times as may be appropriate to maintain hygienic conditions as documented, but not less than daily.

(4) The machinery used for mechanical recovery of fish flesh shall be cleaned at frequent intervals and at least every two hours.

Instructions.

123. (1) In operation instructions, a hygiene work plan shall be defined for the cleaning and disinfection of each area and room in the establishment.

(2) In control instructions, instructions documented to define, establish and illustrate how to carry out the quick tests or checks and the hygienograms to evaluate the cleaning and disinfecting activities described in this chapter.

Specifications.

124. Specifications, such as trade name, compound active ingredient, methods of use, titration instructions, instructions concerning concentration and dilution and safety instructions, concerning cleaning and disinfecting agents used in the establishment shall be provided.

Documentation and records.

125. (1) All procedures, instructions, specifications and control activities shall be thoroughly documented and recorded.

(2) A documented predetermined programme shall be in place at each establishment.

Training.

126. (1)Training on the spot and special training programmes shall be implemented to ensure that staff are continually reminded of the risks and their responsibilities within the food industry especially concerning the cleaning and disinfecting practices.

(2) All cleaning personnel shall be suitably trained in cleaning techniques.

(3) Records of courses and training sessions attendances shall be kept for inspection.

BEST HYGIENE PRACTICES.

127. (1) In order to avoid contamination of the product a high standard of hygiene of the personnel, premises and equipment shall be maintained.

(2) The provision of this regulation applies to persons who-

(a) work in the unloading or reception of raw material, in the preparation or processing areas and in the packing areas;

(b) handle materials which come into contact with fishery products; and

(c) enter the establishments including management staff, cleaners, inspectors and visitors.

(3) The persons mentioned above shall maintain a high level of personal hygiene and shall take all the necessary precautions to prevent the contamination of the fishery products.

(4) The requirements contained in this regulation shall be displayed in visible notices inside the working and handling rooms.

Action plan and quality objectives.

128. Procedures and instructions shall be implemented and maintained to avoid the contamination of the products by personnel, equipment and premises, to ensure optimal personal hygiene in all production steps in all circumstances, to ensure optimal hygiene conditions during processing and to ensure optimal safety of the product.

Scheduling.

129. (1) Planned actions shall be scheduled in a timetable to demonstrate the commitment to the future actions.

(2) These schedules and timetables shall be approved by the Competent Authority and checked on its execution on a regular basis.

Responsibilities and authority.

130. (1) The management of an establishment shall allocate responsibility for ensuring personnel compliance with the requirements of this division, to competent supervisory personnel.

(2) It shall be the responsibility of the supervisor and of each member of staff to conduct him or herself in a responsible manner with respect to the products and equipment.

(3) All personnel shall understand and comply with the requirements of these Regulations.

(4) Responsibilities and authorities shall be established for the implementation, maintaining, monitoring and verification of the plan for Best Hygiene Practices.

Procedures concerning hygiene.

131. Procedures concerning the following shall be documented to ensure that measures to maintain the highest possible standard of cleanliness and hygiene are implemented-

(a) general conditions of hygiene applicable to the construction and operations; and

(b) general conditions of hygiene applicable to staff as protective clothing, personnel hygiene, hand hygiene, food borne diseases.

General conditions applicable to construction and operation.

132.(1) Floors, walls and partitions, ceilings or roof linings, equipment and instruments used for working on fishery products shall be kept in a satisfactory state of cleanliness and repair, so that they do not 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) Working areas, instruments and working equipment shall be used only for work on fishery products.

(4) Potable water, or clean sea water shall be used for all purposes.

(5) Detergents, disinfectants and similar substances shall be approved by the Competent Authority and used in such a way that they do not have adverse effects on the machinery, equipment and products.

General conditions applicable to staff.

133. (1) The highest possible standard of cleanliness is required of staff and procedures shall be put in place for-

(a) entering the plant (entrance for personnel, changing clothes, reception of uniforms and boots, storage of personal effects and clothing, showering);

(b) entering the processing room (handwashing, checks by a supervisor on personal hygiene);

(c) leaving the plant (changing clothes, cleaning and disinfecting uniforms and boots);

(d) use of toilets by entering and leaving the plant and during processing.

Protective clothing.

134. (1) All personnel and visitors entering the preparation or processing rooms shall at all times wear-

(a) suitable clean protective working clothing of a light colour, which covers the minimum outdoor clothing or replaces it;

(b) impermeable boots or footwear which are kept clean and in good condition;

(c) head-covering (headgear) which completely encloses all hair. If involved in medium or high risk product processing personnel shall wear a head

covering that encloses the scalp, hair, beard and moustache;

(d) in addition, an impermeable apron for personnel who handle fish and unpacked fish products.

(2) Protective clothing shall-

(a) be provided by the management of the establishment;

(b) not have outer pockets, be clean and lightly coloured, be either washable or disposable be maintained in a clean condition and in good repair;

(c) not be worn outside the preparation or processing areas;

(d) be changed and laundered daily or earlier when contaminated;

(e) be stored in a clean locker, or similar space or hung on a hanger in the clean changing room, away from contamination and the processing area.

(3) If the personnel who handle fish also wear gloves, these-

(a) shall be made of plastic or rubber;

(b) and either be of a disposable type or alternatively, be capable of being easily cleaned and disinfected;

(c) shall be in a sound, clean and sanitary condition.

(4) If the personnel wear disposable gloves or other disposable protective clothing, the disposable clothing shall be discarded after use and not be reused.

Personal hygiene.

135. (1) All staff while on duty in food handling areas shall maintain a high degree of personal cleanliness.

(2) The personnel who handle fish shall not wear-

(a) jewellery, including rings, necklaces, bracelets, brooches or earrings;
(b) nail varnish or fingernail polish and artificial eyelashes;
(c) watches; and
(d) other personal effects and clothing.

(3) Long hair shall be tied back and covered with a hair net, as well as protective head covering as mentioned in regulation 134 (1)(c).

(4) Any behaviour which could result in the contamination of fishery and fish products such as-

(a) smoking;

(b) use of tobacco;

(c) chewing;

(d) spitting;

(e) eating and drinking; and

(f) other unhygienic behavior,

shall be prohibited in fishery product handling areas, work and storage premises of fishery products.

(5) Clear legible notices and signs shall be prominently displayed to indicate and advise that these activities are prohibited.

Hand hygiene.

136. (1) All personnel shall wash their hands with hot water and soap frequently and in particular-

(a) on entering product processing areas;

(b) immediately after using the toilets;

(c) after handling dirty or contaminated materials;

(d) after chewing, eating, smoking or drinking;

(e) after cleaning procedures, handling detergents and similar clean up chemicals; and

(f) whenever contaminated.

(2) The wearing of clean gloves does not exempt the wearer from having thoroughly washed their hands.

(3) Workers shall maintain hand hygiene during production and have facilities to wash their hands during work.

(4) Gloves and outer garments that contact fish or contact surfaces shall be made of an impermeable material and shall be maintained in clean and sanitary conditions.

(5) If gloves are worn, they shall also be washed, disinfected and dried (outside and inside) at regular intervals and persons handling fishery products, ingredients and items used in

food handling, shall wash and disinfect their hands immediately after handling any material that might be capable of transmitting contamination.

(6) Any person with an injury, a cut, an open wound or a wound that is infected shall no continue to handle the food or food contact surfaces until the injury is covered with a clean waterproof impermeable dressing that is securely attached.

(7) The plant shall be provided with a first aid box, which should contain-

(a) a sufficient quantity of impermeable dressings of a bright colour;
(b) antiseptic cream;
(c) cotton wool and adhesive tape; and
(d) alcohol or other disinfectant lotion.

Foodborne diseases.

137. (1) When recruited, any person working on and handling fishery products shall be required to prove, by a medical certificate, that there is no impediment to such employment.

(2) If the management of an establishment engaged in direct handling of fish has reason to suspect that any person is likely to transmit a disease producing organism to the product, the manager shall ensure, the person does not enter the facility until that person produces a certificate from a medical practitioner indicating that they are free from infection and are non-infective.

(3) The employer shall take all the requisite measures to prevent persons liable to contaminate fishery products from working on and handling them, until there is evidence that such persons can do so without risk.

(4) No person shall prepare , pack or handle any material likely to be used in constructing the product, until-

(a) a current yearly medical certificate stating that they are free of any communicable disease is obtained;

(b) by medical examination or supervisory observation is shown not to-

(i) suffer from or to be a carrier of foodborne disease;

(ii) have or appears to have an illness, disease, open lesions or to suffer from a condition causing a discharge of pus or serum (e.g. weeping sore, infected cuts, boils) from any part of the head, neck, hands or arms or any other source of microbiological contamination by which there is a reasonable possibility that fish, fish-contact surfaces or fish-packaging materials will become contaminated.

(5) Workers who resume duty after sick-leave shall follow the measures laid down in the instructions defined in the quality manual of the establishment.

(6) Precautions shall be taken to prevent visitors to food handling areas from contaminating fishery products and this shall include the use of protective clothing and visitors shall comply with provisions of these Regulations.

(7) Operators in pathogen testing laboratories shall change their uniform prior to entering food handling areas.

Process control.

138.(1) A fail safe control system shall be implemented whereby the activities of the personnel are checked and controlled by the supervisors, on their compliance with the activities described in the procedures and the instructions.

(2) A supervisor shall be responsible to check all the steps described in the procedures and instructions.

Instructions.

139. (1) The instructions shall define the measures to assure the hygiene of the personnel, and to contribute to the safety (pathogens) and the shelf life (spoilage bacteria) of the fishery products.

(2) Instructions shall be given to personnel how to-

(a) enter the factory;
(b) clean and disinfect hands;
(c) clean and disinfect knifes, cutting boards, tables, gloves and hands;
(d) report after sick-leave; and
(e) leave the factory.

Specifications.

140. Specifications shall be in place for uniforms, boots, detergents and disinfectants.

Documentation and records.

141. All procedures, instructions, specifications, control and check-activities shall be thoroughly documented and recorded.

Hygiene training.

142. (1) The manager of an establishment shall arrange for adequate and continuous training of all food handlers in personal hygiene and hygienic handling of fishery products and of all personnel involved in cleaning and disinfection, so it is understood how to take the precautions necessary to prevent contamination of fishery products.

(2) Training shall include reference to relevant parts of this regulation.

BEST PEST CONTROL PRACTICES.

143. (1) The establishment-

(a) shall afford appropriate facilities against pests such as insects, rodents, birds, or other animals;

(b) shall take effective measures to exclude pests from the processing areas and to protect the products against the contamination by pests;

(c) animals, with exception of the live animals such as crustaceans and fish, kept to be placed on the market alive are not admitted and guard or guide dogs may be allowed in some areas of the property if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials;

(d) shall implement and maintain a pest control plan, containing an effective and continuous schedule for the detection, control and eradication of pests, to avoid contaminations of the products by pests on two levels-

(i) passive level, that means prevention, protection, proofing, construction measures;

(ii) active level, that means extermination by use of-

(A) mechanical methods : trapping (rodents);

(B) electrical methods : electrocuter (insects);

(C) chemical methods : poisons (rodenticides and insecticides).

(2) Prevention and extermination of pests shall be carried out in a manner that will not constitute a hazard to human health and product safety.

(3) The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces and food-packaging materials.

(4) Control measures involving treatment with chemicals shall only be undertaken by personnel who have a complete understanding of the health hazards these chemicals may pose to the product.

Action plan and quality objectives.

144. An action plan shall be defined-

(a) on a passive level in a manner that the establishment is proofed and appropriate facilities are implemented in such a way that no birds, insects, rodents and other vermin can enter in the establishment and that hiding

places for rodents, insects and pests are moved away;

(b) on an active level in a manner that pests are destroyed with mechanical, electrical or chemical methods.

Scheduling.

145. (1) A time schedule shall be defined to organise and to control the actions on active and passive levels.

(2) Appropriate periodic measures shall be taken to prevent the establishment of colonies of insects and rodent pests both within and around the plant.

(3) These schedules and timetables shall be approved by the Competent Authority and checked on its execution on a regular basis.

Responsibilities and authorities.

146. (1) Responsibilities and authorities shall be established for the implementation, maintaining, monitoring and verification of the Pest Control Practices.

(2) If pest control or a part of the plan is put on contract, the management remains responsible.

Procedures.

147. (1) A procedure shall be documented and implemented to assure a consistent pest control plan and a proper work method on the passive and active level.

(2) The method of working will at least consist of-

(a) for the passive level- the building shall be pest proof against vermin such as insects, rodents and birds by proper design and controlling openings such as-

(i) doors-

When door is closed it shall fit tightly so that no gap between door and frame is larger than 3mm across.

Doors to the outside shall be closed when not in use for transporting goods in or out of the premises or people passing through;

(ii) windows-

All windows that can be opened shall be covered with a tight fitting fly screen of mesh size less than or equal to 1mm. The frames with the flyscreen should be displaceable for cleaning purposes;

(iii)ventilation-

At some point on the way from where the ventilation duct opens to the outside of the premises to the point where it opens into the inside it shall be closed with a screen of mesh size no larger than 1 mm;

(iv)drains-

All drain openings shall be covered with grates of hole size not larger than 10 mm across. There shall be a water lock (gully traps) in the drain pipings somewhere on the way from the drain opening to the collecting well;

(v) harbourage-

Various trash and garbage inside or outside buildings that could be a harbourage for pests shall be removed;

(b) For the active level-

(i) rodents, insects and any other vermin shall be systematically exterminated in the premises or on the equipment;

(ii) there should be available a documented plan for extermination of pests and this plan shall include-

(A) list of numbered traps and a map showing their location or a bait map;

(B) routine checks to verify that food, water and shelter is inaccessible to pests at every location within premises and to check the presence of rodent infestation that is the presence of faecal droppings, runs and smears, holes and gnawing, damage to food, foot prints, gnawing and squeaking sounds and gnawing traces on baits;

(C) inspection of infestation in areas adjacent to premises;

(D) inspection of incoming material for pest infestation;

(E) there should be a responsible person within the firm knowledgeable about pest control and the pests likely to occur within the premises even if outside expertise on pest control is employed;

(F) storage areas should be organised so that they can be easily inspected for possible rodent infestation;

(iii) rodent traps shall be strategically placed, with the assistance of an external expert if necessary, to exterminate rodents that may get into the premises and traps may also be placed outside the premises to exterminate and monitor the presence of rodents;

(iv) at least one electric fly trap shall be installed at every entrance to rooms where processing takes place and where packaging material is store;

(A) fly killers shall not be placed over processing lines or in front of fans;

(B) distance of electric trap from floor shall be 2.5 to 3 m;

(C) the fly killer shall be on twenty-four hours a day;

(D) bulbs shall be replaced at least every year or according to manufacturer's specifications;

(E) the catch basin should be cleaned regularly;

(F) rodenticides, insecticides and any other potentially toxic substances shall be stored in premises or cupboards which can

be locked and their use shall not present any risk of contamination of the products.

Process control.

148. A fail safe control system shall be implemented to check whether the pest-control plan is in compliance with the requirements described in this regulation.

Instructions.

149. (1) Instructions shall be put in place to implement on a daily base the principles and work methods designed in the procedures.

(2) Instructions shall be defined by management together with personnel to deal with the active and passive pest control.

Specifications.

150. Specifications, such as trade name, compound active ingredient, methods of use, instructions concerning concentration or dilution and safety instructions concerning the pesticides shall be provided and available at all times.

Documentation and records.

151. All procedures, instructions, specifications, control and check activities shall be thoroughly documented and recorded and in particular the trap-map, bait map and the routine check records shall be available at all times for the Inspectorates.

Training.

152. (1) The manager of an establishment shall arrange for adequate and continuous training of the personnel involved in pest control. Training shall include reference to relevant parts of this regulation.

(2) Records of courses and training sessions attendances shall be kept for inspection and evaluation.

BEST MANUFACTURING PRACTICES.

153. (1) Preparation and processing practices shall be implemented and maintained with the purpose to process a safe and high quality finished product.

(2) The activities considered are the activities done in the preparation, processing and packing rooms as weighing, sorting, washing, preparation, chilling, freezing, thawing, processing, packing, expedition and control activities.

Action plan and quality objectives.

154. Good manufacturing practices shall be implemented with the purpose-

(a) to avoid as much as possible any cross-contamination of the product (fillet) with contaminants from the fish (skin) or from the work and factory environment;

(b) to build up a logic and practical flow of the products from raw material to finished product;

(c) to build up a logical and practical flow of-

(i) waste products that leave the processing line;

(ii) additives and packing materials that join the processing line;

(d) to organise a logical and practical flow of-

(i) dirty recipients and equipment that leave the processing line; and

(ii) clean recipients and equipment that join the processing line;

(e) to avoid temperature violence, exceeding the requirements specified for the process.

Scheduling.

155. (1) Planned actions shall be scheduled in a timetable to demonstrate the commitment to the future actions.

(2) These schedules and timetables shall be approved by the Competent Authority and checked on its execution on a regular basis.

Responsibilities and authorities.

156. Responsibilities and authorities shall be established for the implementation, maintaining, monitoring and verification of the described best manufacturing practices.

General conditions and procedures for the preparation and processing of fishery products.

157. (1) Fishery products shall be processed rapidly, without delay and shall always be treated in a hygienic manner.

(2) All necessary and reasonable actions and precautions shall be taken in order to minimise the contamination of the fish.

(3) Fish shall never be placed on the floor without the protection of appropriate fish boxes nor the fish boxes be placed directly on the floor but on a pallet.

(4) Fishery products from different harvests or from different fishing boats should, ideally, not be mixed together and keeping them separate will prevent contamination between lots and enable easier identification in case of subsequent rejection.

(5) During preparation or processing, the temperature of the fishery products shall be maintained at a temperature determined by management of the establishment and approved by the Competent Authority and the time-temperature combination shall be used as guideline.

(6) Should operation cease, the processing of fish which has already started should be finished or alternatively the fish should be transferred to a chiller or adequately iced.

(7) Deteriorated and damaged product and extraneous material shall be removed from the processing area immediately, in order to avoid contamination of the fish.

(8) Fishery products which have become spoilt, or which have been contaminated or which are no longer fit for human consumption shall not be admitted to the establishment and if identified during processing, such fish shall be isolated immediately and adequately disposed of without contaminating acceptable quality products.

Conditions for washing and decontamination of the fish skin.

158. (1) The fishery products shall be decontaminated as soon as they arrive in the preparation area and this shall include-

(a) the separation of extraneous material such as crabs, wood, detritus, mud;

(b) the washing of fishery products with adequate quantities of clean potable water where necessary and chilled to below 5° C.

(2) Fishery products shall be cleaned and washed always under running water and cleaning and washing shall not be done in stagnant water or with hyper-chlorinated processing water.

Procedures.

159. (1) Procedures shall be documented and implemented to ensure that in all stages of the process the necessary preventive measures on the level of quality control are taken to process a safe and high quality product.

(2) The procedures represent the flow of the products through the factory and during this flow, special attention is emphasized to avoid contamination, cross-contamination and rise of temperature of the products (time-temperature control).

Conditions and procedures for the preservation of fresh, chilled fishery products.

160. (1) The chilling of fishery products shall be carried out under the following conditions-

(a) the chilling of fishery products shall be performed with sufficient rapidity to prevent undesirable physical, chemical and microbiological deterioration;

(b) the temperature of fishery products that have been chilled shall reach at the end of the chilling cycle, the temperature of melting ice with a tolerance of ± -1° C.

(2) To control histamine formation, the internal temperature of the fishery products should be brought from ambient temperature to 10° C or below within six hours, and once chilled be maintained as close to the temperature of melting ice as possible.

(3) After chilling, during preparation or processing, the fishery products shall not be exposed to temperatures above 4°C for a cumulative period of more than two hours and chill storage rooms shall comply with following conditions-

(a) establishments preparing fresh fish as a final product shall have a chill room

for raw material and a chill storage room for finished fresh products;

(b) a chill storage room used to store chilled fish shall be operated at the temperature of melting ice;

(c) a chill storage room shall not be used for the purpose of the initial freezing of fish or fish product;

(d) chill storage rooms shall be kept clean and free from accumulation of ice and the floor and general structure of chill storage room shall be maintained in good condition.

(4) The chilling of unpackaged fishery products shall be carried out under following conditions-

(a) where chilled, unpackaged fishery products (raw material) are not dispatched, prepared or processed immediately after reaching the establishment, they shall be stored or displayed under ice in the establishment's chill storage room and re-icing shall be carried out as often as necessary;

(b) the ice used, with or without salt, shall be made from potable water or clean sea water and be stored under hygienic conditions in containers

provided for the purpose; such containers shall be kept clean and in a good state of repairs.

(5) Pre-packed fresh products shall be chilled with ice or mechanical refrigeration creating similar temperature conditions.

(6) The preparation of fishery products shall be carried out in compliance with following requirements-

(a) if they are not carried out on board, operations such as heading and gutting shall be carried out hygienically and the products shall be washed thoroughly with potable water or clean sea water immediately after such operations;

(b) the quantities of fish on the work tables at any one time should be kept to a minimum;

(c) fish which is held on the tables awaiting processing shall be protected by adequate quantities of ice and due to the fact that the tables provide a good heat transfer medium, the fish should rest on a layer of ice, as well as being covered with it;

(d) should operation cease the process fishery products should not be left on the work tables and processing of fish

already on the tables shall be completed before the workers leave their posts;

(e) the internal temperature of the fishery products should be maintained below a limit designated by management and approved by the Competent Authority during processing and handling on the worktables;

(f) 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 place other than that used for heading and gutting operations and fillets and slices shall not remain on worktables any longer than is necessary for their preparation. Fillets and slices to be sold fresh shall be chilled as quickly as possible after preparation;

(g) all equipment used for the filleting of fish should be washed and disinfected regularly during the process and this applies to knives, cutting boards, tables, etc;

(h) fillets should be rapidly rinsed immediately after filleting and prior to subsequent packing;

(i) all persons who fillet fish should wash their hands well and wear clean gloves before commencing their work;

(j) if the fillets are not immediately packed or frozen they shall be stored at 0° C with adequate quantities of ice, or in a chill storage room, different from the chill storage room for raw material;

(k) containers used for the dispatch or storage of fresh fishery products shall be designed in such a way as to ensure both their protection from contamination and their preservation under sufficiently hygienic conditions and, more particularly, they shall provide adequate drainage of melt water.

Conditions and procedures for freezing and for the storage of frozen products.

161. (1) Freezing of fishery products shall be carried out under the following conditions-

(a) establishments shall have freezing equipment in blast, contact, plate, tunnel or brine freezers sufficiently powerful to achieve a rapid reduction in the temperature so that the temperatures laid down in this regulation can be obtained as fast as possible in the core of the product;

(b) fresh products to be frozen or quick-frozen shall comply with the requirements, the conditions and procedures for fresh products laid down in regulation 160;

(c) the freezing process shall be carried out in a way that minimises undesirable, chemical and microbiological changes therefore-

(i) fish shall be frozen in a room or chamber specifically designed for this purpose, kept clean and free from accumulation of ice;

(ii) blocks of fish or fish products for freezing shall not have a maximum thickness greater than 80 mm;

(iii) if the fish is not to be packed and frozen immediately it shall be stored with sufficient ice to maintain its temperature at 0° C or in a chill store at that temperature;

(iv) any glaze water which is added to the fish shall first be chilled to 0° C and it is

recommended that a mixture of ice and potable water be used;

(v) during the unloading of the freezer the internal temperature of the fish shall not be permitted to rise above –18° C. Ideally freezers should be unloaded and the fish packed in a chamber held at 0° C or less;

(vi) the packing of master cartons shall be done rapidly to prevent the internal temperature of fish rising above - 18° C.

(2) When freezing fishery products, management shall take into account the freezing capabilities of the facilities-

(a) freezing chambers or other freezing equipment, when utilized for the initial freezing of unfrozen fish or fishery products should reduce the product temperature through the zone of maximum crystallization (in most products –1° C to –5° C) preferably within four hours but not exceeding six hours from the commencement of the refrigeration process;

(b) where the refrigeration process is continued in order to reduce the thermal core

temperature to –18° C or colder, the whole refrigeration process should be preferably completed within eight hours, but not exceeding twelve hours;

(c) longer freezing times damage the texture and quality of the fishery products, and indicate that the capacity of the freezing plant is inadequate;

(d) the process should not be regarded as completed unless and until the product temperature has reached –18° C at the thermal center after thermal stabilization. An exception is brine frozen fish to be used for canning, which may be frozen at higher temperature, although not exceeding –9° C.

(3) Any blast freezer should not be overloaded with quantities of fish in excess of the designed capacity and reference should be made to the specifications of the supplier of the refrigeration equipment,in order to determine the recommended capacity, but generally loading should not exceed 70 % of the internal volume.

(4) To keep fishery products in a frozen condition by proper storage of frozen fishery products, in cold storage rooms, the storage shall comply with the following requirements-

(a) plants must have freezing equipment sufficiently powerful to keep products in the storage rooms at a temperature not exceeding those laid down in these

Regulations, whatever the ambient temperature may be;

(b) the floor and general structure of the cold storage rooms shall be maintained in good condition;

(c) all cold storage rooms should be kept clean and free from accumulation of ice;

(d) the cold storage room shall be well organised, with separation of different products and batches;

(e) in order to permit the free circulation of air within the cold storage room, product shall not be stored in contact with the walls or floor. The use of a pallet and rack system is recommended;

(f) poultry, meat and other products which may contaminate the fishery products should not be stored in the cold storage room unless the product is packaged and physically separated from the seafood product;

(g) cardboard shall not be placed on the floor for the purposes of keeping it clean;

(h) whenever possible, any products which have been stored longest shall be the first to be distributed (first in, first out principle);

(i) effective measures shall be taken to keep temperature variations to a minimum after the freezing process and during handling and transport;

(j) cold storage rooms shall have a temperature-recording device in a place where it can easily be read and the temperature sensor of the recorder shall be located in the area furthest away from the cold source that is where the temperature in the storage room is the highest;

(k) temperature charts shall be available for inspection by the supervisory authorities at least during the period in which the products are stored.

Condition and procedures for thawing products.

162. (1) Establishments that carry out thawing operations shall comply with the following requirements-

(a) fishery products shall be thawed under hygienic and controlled time-temperature conditions; their contamination shall be avoided and there shall be adequate drainage for any melt water produced and during thawing, the temperature of the products shall not increase excessively and shall be monitored;

(b) fishery products shall be brought to its thawed state as quickly as possible

without causing undesirable physical, biochemical and microbial changes to the food;

(c) if water to thaw the fishery products is used, a control system shall be implemented;

(d) after thawing, fishery products shall be handled in accordance with requirements of this regulation and where they are prepared or processed, these operations shall be carried out without delay and if they are put directly onto the market, particulars as to the thawed state of the fish shall be clearly marked on the packaging.

Conditions and procedures for the mechanical recovery of fish flesh.

163. The mechanical recovery of fish flesh shall be carried out under the following conditions-

(a) mechanical recovery of gutted fish shall take place without undue delay after filleting, using raw materials free of guts and where whole fish are used, they shall be gutted and washed beforehand;

(b) the machinery shall be cleaned at frequent intervals at least every two hours;

(c) after recovery mechanically, recovered flesh shall be frozen as

quickly as possible or incorporated in a product intended for freezing or stabilizing treatment.

Conditions and procedures for processed fishery products.

164. (1) Fresh, frozen and thawed products used for processing shall comply with the requirements laid down for fresh, frozen and thawed products in this chapter.

(2) Where the processing treatment is carried out to inhibit the development of pathogenic micro-organisms, or if it is a significant factor in the preservation of the product, the treatment shall be scientifically recognised by the Inspectorate.

(3) Contamination, cross-contamination and deterioration of fishery products shall be prevented-

(a) by design -

(i) operating practices shall be designed to avoid contamination of product, product surfaces and packaging materials;

(ii) processes in which there is risk of contamination to the final product including-

(A) prawn heading, deveining and peeling;

(B) lobster heading, gutting and deveining;

(C) dismembering, gutting and scaling of fish,

shall take place in areas physically separated by location or partition from

where the product is further processed or packed;

(iii) pet food and fish meal preparation and packing shall take place in a building separated from that used for processing fishery products for human consumption.

(b) by operating practices-

(i) effective measures shall be taken to prevent raw material or semi processed material coming into contact with and contaminating the end product;

(ii) all steps in the production process including packaging shall be performed without unnecessary delay and under conditions which will minimise the possibility of contamination, deterioration and growth of micro-organisms;

(iii) for the preparation and processing of high risk products-

(A) contaminated protective clothing worn by a person handling raw materials or partially processed foods shall be discarded before the person comes in

contact with high risk processed food;

(B) if there is a likelihood of contamination, hands shall be washed thoroughly between handling processed food at different stages of processing;

(C) all equipment which has been in contact with raw materials or contaminated material shall be thoroughly cleaned and sanitised prior to being used in contact with processed food.

Conditions and procedures for smoking.

165. (1) Smoking shall be carried out in separate premises or a special place equipped, if necessary, with a ventilation system to prevent the smoke and heat from the combustion from affecting other premises or places where fishery products are prepared, processed or stored.

(2) Materials used 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 products.

(3) Materials used to produce smoke, that had been painted, varnished, glued, or has undergone preservation treatment or any other chemical treatment shall be prohibited.

(4) After smoking, products shall be cooled rapidly to the temperature required for their preservation before being packaged.

Conditions and procedures for salting.

166. (1) Salting operations shall take place in different premises and sufficiently removed from the premises where the other operations are carried out.

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

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

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

Conditions and procedures for cooking crustaceans and molluscan shellfish.

167. (1) Where processes are being heated in any way such as blanching, retorting, there shall be adequate control to ensure the correct temperature or time regime is used to ensure the product achieves the desired functionality and shelf life without jeopardising human health.

(2) Any cooking shall be followed by rapid cooling and water used for this purpose shall be drinking water or clean sea water and if no other method of preservation is used, cooling shall continue until the temperature approaching that of melting ice is reached.

Schedule Three

(3) Shelling or shucking, shall be carried out under hygienic conditions avoiding the contamination of the product and 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 and 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 will preclude the growth of pathogens, and be stored in appropriate premises.

(5) Every manufacturer shall carry out microbiological checks on his production at regular intervals, complying with the standards set forth in Schedule Three of these Regulations.

Conditions and procedures for processing shrimps.

168. (1) All tanks or sinks used for the washing of shrimp shall be supplied with a constant flow of water, sufficient to replace the contents of the tank every half hour.

(2) Tanks used for the washing of shrimp should be emptied completely and washed and disinfected during every cessation in the process and between different batches of shrimp.

(3) All product which is stored for more than one day before processing should be beheaded and the priority should be to de-head the shrimp as soon as possible after arrival at the plant if not done previously.

(4) If shrimp intended for peeling and de-veining is not to be processed immediately, it should be stored with sufficient quantity of ice to maintain its temperature at 0° C.

(5) The shrimp should be peeled and de-veined rapidly in order to minimise the rise in temperature and if the peeled and de-

veined shrimp is not to be frozen immediately it should be stored at 0° C with adequate quantities of ice.

(6) Higher standards of hygiene and cleanliness should be maintained at the work tables on which shrimp is peeled and deveined, due to the higher risk of contamination of the shrimp flesh itself.

(7) If the final product is to be head-on shrimp, the processing of the raw material should commence as soon as possible after arrival at the plant the nature of the product demands rapid processing with rigorous temperature control.

(8) Chilled water shall be used for the washing of head-on shrimp, at all stages of the process.

(9) Any areas in which cooked or head-on shrimp is processed should be air-conditioned, in order to maintain an air temperature of less than 25° C.

Conditions and procedures for cooked shrimp.

169. (1) Cooked shrimp shall only be handled in an area separate to that in which the raw product is processed and there shall be no direct access for personnel between the two areas.

(2) All personnel who handle cooked shrimp, or who work in or enter the area in which it is processed, shall wear coats, boots, hats and aprons which are used exclusively by such personnel, and which are kept separate from the protective clothing used in the processing of raw shrimp and in order to avoid confusion it is recommended that the uniforms, boots, etc. should be of a different colour.

(3) All persons entering the cooked products area shall wash their hands and boots.

(4) No equipment or other articles including fish boxes, knives etc. shall be transferred from an area in which raw shrimp is handled to the cooked product area, without first receiving a thorough cleaning and disinfection.

(5) If the final product is to be head-on shrimp, this should be processed immediately, and without a period of storage.

Conditions and procedures for canning.

170. (1) A scheduled process for low acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low acid foods in hermetically sealed containers.

(2) A "Standard Operating Procedure" Manual shall be compiled specifying the-

(a) establishment of the thermal process with-

(i) heat penetration; and

(ii) heat distribution study;

(b) process control system with-

(i) equipment description;

(ii) monitoring system;

(iii) general operations in thermal process room;

(c) container integrity checks-

(i) incoming containers;

(ii) seaming machines;

(iii) evaluation of double seam integrity;

(iv) cooling water monitoring;

(v) cooling of containers;

(vi) post-process handling of containers;

(d) documentation and records-

(i) processing and production records;

(ii) management review of records;

(iii) process deviation records,

and shall be approved by the Competent Authority.

(3) Canning conditions shall comply with following requirements-

(a) the water used for the preparation of cans shall be potable water;

(b) the process used for the heat treatment shall be appropriate, having regard to such major criteria as the heating time, temperature, filling, size of containers, etc., a record of which shall be kept;

(c) the heat treatment shall be capable of destroying or inactivating pathogenic organisms and the spores of pathogenic micro-organisms;

(d) the heating equipment shall be fitted with devices for verifying whether the containers have in fact undergone appropriate heat treatment;

(e) potable water shall be used to cool containers after heat treatment, without prejudice to the presence of any chemical additives used in accordance with good technological practice to prevent corrosion of the equipment and container.

(4) The following checks shall be carried out to verify the canning process-

(a) further checks shall be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat treatment-

(i) incubation test: incubation shall be carried at 37° C for seven days or at 35° C for ten days, or at any other equivalent combination;

(ii) microbiological examination of the content of the containers in the establishment's laboratory or in another approved laboratory;

(b) samples shall be taken of production each day at predetermined intervals, to ensure the efficiency of sealing or of any other

method of hermetic closure. For that purpose, appropriate equipment shall be available for the examination of cross-sections of the can-seams;

(c) checks are carried out in order to ensure that containers are not damaged;

(d) all containers which have undergone that treatment under practically identical conditions during a same period of time shall be given a batch identification mark.

Conditions and procedures concerning parasites.

171. (1) The general conditions for the visual inspection shall be implemented as follows-

(a) during production, and before they are released for human consumption fish and fish products shall be subject to a visual inspection for the purpose of detecting and removing any parasites that are visible;

(b) visual inspection shall be performed on a representative number of samples;

(c) the persons in charge of on shore plants and qualified persons on board factory vessels shall determine the scale and frequency of the inspections required in paragraph (b) of this subregulation by reference to the nature of the fishery products, their geographical origin and their use;

(2) Visual inspection of eviscerated fish shall be carried out as follows-

(a) during production, the visual inspection of eviscerated fish shall be carried out by qualified persons on the abdominal cavity and livers and roes intended for human consumption and according to the system of gutting used, the visual inspection shall be carried out;

(i) in case of manual evisceration in a continuous manner by the operative at the time of evisceration and washing;

(ii) in the case of mechanical evisceration by sampling carried out on a representative number of samples being not less than ten fish per batch;

(b) the visual inspection of fish fillets or fish slices shall be carried out by qualified persons during trimming after filleting or slicing where an individual examination is not possible because of the size of the fillets or the filleting operations, a sampling plan shall be drawn up and kept available for the Competent Authority where candling of fillets is possible from

a technical viewpoint, it shall be included in the sampling plan.

(3) Measures to take before release for consumption are-

(a) fish or parts of fish which are obviously infested with parasites, and which are removed, shall not be placed on the market for human consumption;

(b) the fish and fish products referred to in paragraph (c) of this subregulation which are to be consumed as they are, shall, in addition be subjected to freezing at a temperature of not more than –20° C in all parts of the product for no less than twenty-four hours and products subjected to this freezing process shall be either raw or finished;

(c) fish and products subjected to the condition in paragraph (b) of this subregulation are-

(i) fish to be consumed raw or almost raw;

(ii) the following species if they are to undergo a cold smoking process at which the internal temperature of the fish is less than 60° C-

(A) herring;

(B) mackerel;

(C) sprat;

(D) (wild) Atlantic and Pacific salmon;

(iii) marinated or salted herring where this process is insufficient to destroy the larvae of the nematodes;

(d) manufacturers shall ensure that fish and fish products listed in paragraph 3 (c) of this subregulation or the raw materials for use in their manufacture are subject to the treatment described in paragraph (b) of this subregulation prior to their release for consumption;

(e) the fishery products listed in paragraph (c) of this subregulation shall, when they are placed on the market, be accompanied by a document from the manufacturer stating the type of process they have undergone.

Conditions and procedures concerning packaging.

172. (1) The time that elapses between processing and packaging shall not cause the food to suffer any undesirable physical, chemical or microbiological deterioration.

(2) Packaging shall be carried out under satisfactory conditions of hygiene, to preclude contamination of the fishery products-

(a) labels, tags and adhesives used in packaging shall not contaminate food;

(b) a container of food for export shall not contain any foreign objects except the food.

(3) 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; and

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

(i) the ink used to apply description markings, inks and colourants applied to food shall not contaminate the food and shall be non-toxic;

(ii) inks applied to food or packaging shall not contain any of the following substances;

(A) antimony;

(B) arsenic;

(C) cadmium;

(D) chromium;

(E) lead;

(F) mercury;

(G) other toxic metals;

(iii) fluorescent brighteners or carcinogens, mutagens and

teratogens shall not be used in inks applied to food or packaging;

(iv) a lacquer applied to the inner surface or part of the inner surface of covering shall-

(A) cover the inner surface in a continuous film;

(B) be uniform in thickness;

(C) leave no area of the surface uncoated;

(D) firmly adhere to the covering;

(E) be compatible and non-toxic with the food being packed;

(c) they shall be strong enough to protect the fishery products adequately-

(i) the first envelope, which is in direct contact with the food can be plastic food packing materials, a foam box or a can;

(ii) the second envelope, which is not in direct contact with the food is a cardboard box or a master carton;

(d) fishery products shall not be transported unless they are packed and covered in

such a way that will enable the goods to reach their destination in a satisfactory and wholesome condition;

(e) with the exception of certain containers made of impervious, smooth and corrosion-resistant materials which are easy to clean and disinfect, which may be re-used after cleaning and disinfecting, packaging materials may not be re-used;

(f) packaging materials used for fresh products held under ice shall provide adequate drainage for melt water;

(g) unused packaging materials shall be stored in premises connected with the production area and protected from dust and contamination in accordance with the requirements laid down in regulation 59 of these Regulations.

Labelling, traceability and identification mark.

173. (1) It shall be possible to trace for inspection purposes the plant of dispatch of consignments of fishery products, by means of labelling and by the accompanying documents and for that purpose, without prejudice of the provisions concerning labeling of food products laid down in other regulations, at least the following information shall appear on the packaging or, in the case of non-packaged products in the accompanying documents-

(a) country of dispatch which may be written out in full or shown as an abbreviation using capitals;

(b) identification of the establishment or factory vessel by its official approval number;

(c) identification of the freezer vessel, in case of marketing from a freezer vessel, by its official registration number;

(d) an internal lot or batch number which allows the establishment to trace back to the supplier of the raw-materials and other ingredients that may have been used in the product;

(e) the Competent Authority shall approve of all labels to be used or placed on the packaging of all species of fish including Siluriformes fish products before products may be placed on the market or be exported and labels shall contain a principal display panel and information panel with-

(i) name of product with descriptive designation;
(ii) net quantity statement;
(iii) country of origin;
(iv) handling statements;
(v) shipping ID mark link to health certificate;
(vi) nutritional facts panel;

(vii) ingredients statements;

(viii) address line for the address of the establishment and Competent Authority approval number.

(2) All the letters and figures shall be fully legible and grouped together on the packaging in a place where they are visible from the outside without any need to open the said packaging and the product name, inspection legend, handling statement, net weight statement, ingredients statements, address line, nutrition fact panel or safe handling instructions and the appropriate descriptive terms of the product shall also be used without confusing or misleading the consumers.

Process control.

174. (1) A failsafe pre-control system, as part of the autocontrol system, shall be implemented whereby measurements and checks are compared with standards, and followed by corrective actions.

(2) Cross contamination and adulteration shall be pre-controlled by implementing the other prerequisite programmes (best practices) and shall be controlled by sampling, chemical and microbiological analysis.

(3) Time-temperature abuse shall be pre-controlled by implementing the procedures and instructions laid down in this part, and shall be controlled by temperature measuring.

(4) Systems for management of raw materials, semi-manufacture and final products, throughout receiving, processing and storage, shall include adequate markings and labels which ensure that it for any product placed on the market is possible to

trace to the supplier of the raw material and the buyer of the final product.

(5) All measuring equipment, gauges and devices used in connection with food shall be graduated so as to be read easily and calibrated so as to be accurate.

(6) A calibration system shall be applied either in-house or by an external authority and results of the calibration kept for two years unless otherwise specified in these Regulations.

Instructions.

175. (1) The following instructions shall be documented and implemented in detail for every specific case-

(a) work instructions such as-

(i) chilling, freezing, thawing fishery products;

(ii) preparation of fishery products as rinsing, filleting, skinning, trimming, grading, packing, mechanical recovery of fish;

(iii) processing of fishery products as canning, smoking, salting and cooking;

(iv) to prevent cross contamination, temperature abuse;

(v) use of sweeteners, colours and food additives other than colours and sweeteners;

(b) control instructions such as-

(i) controlling time-temperature conditions;

(ii) candling;

(iii) visual checks.

Final product specifications.

176. (1) Product quality specifications as process description (nature of the packing – unit packing – volume or weight per unit packing) shelf life and storage conditions, transport conditions, distribution conditions, label information shall be in place if applicable.

(2) Product safety specifications shall be in place, if applicable for-

(a) potential chemical hazards as-

(i) environmental chemical and pesticides;

(ii) sweeteners, colours and food additives other than colours and sweeteners;

(iii) ichthyotoxins;

(iv) scombrotoxins;

(v) ciguatera;

(b) potential biological hazards as microbes and parasites; and

(c) potential physical hazards.

Documentation and records.

177. All procedures, instructions and specifications, control and monitoring activities shall be thoroughly documented and recorded.

Training.

178. (1) Training on the spot and special training programmes shall be implemented to ensure that staff are continually reminded of the risks and their responsibilities within the food industry especially concerning preparation and processing of fishery products.

(2) Records of courses and training sessions attendances shall be kept for inspection and evaluation.

BEST STORAGE PRACTICES.

179. (1) The storage of fishery products (raw materials and finished products), packing material, cleaned recipients, tubs, baskets and equipment and other products as ingredients, additives, chemicals, has to be organised in accordance to the requirements with respect to temperature, humidity, quality and safety of the products, imposed by customers but at least to the requirements stipulated by this regulation.

(2) Storage shall be under conditions that will protect materials against physical, chemical and microbiological contamination as well as against deterioration of the materials and the containers.

Action plan and quality objectives.

180. (1) Procedures and instructions shall be implemented and maintained-

(a) for storage of raw materials and finished products-

(i) to avoid decrease of shelf life of the products and deterioration;

(ii) to avoid decomposition of fishery products;

(iii) to eliminate or minimise possible occurrence of contamination and proliferation of micro-organisms.

(b) for storage of packing material to prohibit the chance of spoilage, damage or contamination on packing materials;

(c) for storage of chemicals-

(i) to identify hold, use and store toxic compounds in a manner that protects against contamination of food, contact surfaces of food-packaging materials;

(ii) to identify, hold and store toxic cleaning compounds, disinfecting agents and pesticide chemicals in a manner that protects against contamination of fish, fish-contact surfaces or fish-packing materials.

(2) only those toxic materials-

(a) required to maintain clean and sanitary conditions;

(b) necessary for use in laboratory testing procedures;

(c) necessary for plant and equipment maintenance and operation; and

(d) necessary for use in the plant's operations,

are allowed to be used and stored in the plant.

Scheduling.

181. (1) Planned actions shall be scheduled in a timetable to demonstrate the commitment to the future actions.

(2) These schedules and timetables shall be approved by the Competent Authority and checked on its execution on a regular base.

Responsibilities and authorities.

182. Responsibilities and authorities have to be established for the implementation, maintaining, monitoring and verification of the described best storage practices.

Procedures.

183. Procedures shall be defined to ensure that the hygienic requirements with respect to storage of fishery products, dry

ingredients, chemicals, packaging material and finished products are met.

Temperature conditions for fishery products during storage.

184. Fishery products shall, during storage, be kept at the temperatures set out in these Regulations, and in particular-

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

(i) fresh or thawed fishery products shall always be chilled with ice, whether or not completed with mechanical refrigeration;

(ii) prepacked fishery products may be chilled with ice or with mechanical refrigeration;

(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;

(c) to prevent Scombrotoxin formation of fish that has first been chilled and then frozen for a long time, fish should not be exposed to a temperature rise above 4.4 ° C from the time it is frozen for a cumulative period of more than twelve hours and an uninterrupted period of exposure should not exceed six hours;

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

Storage conditions for fresh fishery products.

185. (1) Fresh fishery products shall be-

(a) maintained under conditions that will prevent spoilage;

(b) protected against damage;

(c) protected against contamination;

(d) not processed or used unless inspected for contamination, decomposition and parasites and found to be in a sound condition and the nature and frequency of such inspections shall be set by the exporter and approved by the Competent Authority.

(2) Fishery products may not be stored with other products, which may contaminate them or affect their hygiene, unless they are packed in such a way as to provide satisfactory protection.

(3) No materials other than those used for immediate processing shall be stored in an area in use or in processing.

Storage conditions for frozen fishery products.

186. (1) The freezing of fish shall not be carried out in a cold store.

(2) Frozen fish shall be protected from dehydration and freezer burn by-

(a) the application of a glaze; or

(b) by enclosure in an impervious wrap.

(3) A record of cold store room temperatures shall be maintained.

(4) The air velocity in cold store rooms shall be moderate and no higher than necessary to achieve uniform temperatures within the rooms.

(5) Products should be stacked so that air circulation within the storage room is not impaired and except in jacketed rooms no direct contact with ceilings and floors shall be allowed.

(6) A system of controlled stock rotation shall be employed in cold stores and chill rooms.

Storage conditions for dry ingredients.

187. Dry ingredients shall be stored in a closed, good ventilated, pest proof and clean area with the required room temperature and humidity and the products shall be protected against spoilage, damage and contamination.

Storage conditions for packaging materials.

188. (1) Packaging materials shall be stored in a closed, good ventilated, pest proof, dust-free and clean area with the required room temperature and humidity.

(2) Packaging materials shall be protected by poly-sheets in a way that the inside of the boxes are protected against contamination.

(3) Empty cans shall not be exposed at ambient conditions without protection.

Storage conditions for hazardous substances.

189. (1) Pesticides, cleaning agents or other substances which could represent a hazard to health shall be suitably labelled with a warning about their toxicity and use and extreme care taken to avoid the chemicals contaminating food, food contact surfaces and ingredients.

(2) Hazardous substances shall be stored in rooms or cabinets used only for that purpose and handled only by authorised and properly trained persons.

(3) Except when necessary for hygienic or preparation purposes no substances which could contaminate food may be used or stored in food handling areas or be stored with any product, ingredients or product packaging material.

Process Control.

190. (1) A fail-safe control system shall be implemented-

(a) to control temperatures of chill rooms and cold rooms and cold rooms (storage rooms for frozen products) shall have a temperature recording device in place and temperature charts shall be available for inspection by the supervisory authorities at least during the period in which the products are stored;

(b) to control the compliance with the requirements for-

(i) chemicals;

(ii) packing materials;

(A) first envelope (polybags and foam boxes),

(B) second envelope (cartons),

laid down in the Supplier Quality Assurance Agreement for chemicals, ingredients and packing materials.

Instructions.

191. Control instructions shall be put in place-

(a) to implement the daily temperature control activities in the fish storage facilities for fresh and frozen fish; and

(b) to implement the control activities for the hygiene and storage organisation in the storage rooms.

Specifications.

192. Temperature standards and tolerances shall be implemented in every establishment.

Records.

193. The temperature conditions, the hygienic conditions and the piling practices in chill storage rooms, cold storage rooms and other storage facilities shall be recorded.

Training.

194. A training program shall be in place and shall include reference to relevant parts of this regulation.

BEST TRANSPORT PRACTICES.

195. (1) The transport of fishery products (raw materials and finished products) has to be organised in accordance to the requirements with respect to temperature, humidity, quality and safety of the products, imposed by customers but at least to the requirements imposed by this regulation.

(2) Transport shall be done under conditions that will protect materials against physical, chemical and microbiological contamination as well as against deterioration of the materials and containers.

(3) Transport from aquaculture facilities shall be carried out in compliance with the law relating to Aquaculture.

Quality objectives and action plan.

196. Procedures and instructions shall be implemented and maintained-

(a) for transport of raw materials and finished products-

(i) to avoid decrease of shelf life of the products;

(ii) to avoid decomposition of fishery products;

(iii) to eliminate possible occurrence of contamination;

(iv) in case of live fish, to ensure that the viability of the fish and food safety is not adversely affected.

(b) for transport of packing material, to prohibit the chance of spoilage, damage or contamination.

Scheduling.

197. (1) Planned actions shall be scheduled in a timetable to demonstrate the commitment to the future actions.

(2) These schedules and timetables shall be approved by the Competent Authority and updated whenever necessary.

Responsibilities and authority.

198. (1) Responsibilities and authorities have to be established for the implementation, maintaining, monitoring and verification of the described transport practices.

(2) It shall be the responsibility of the owner of the vehicle to comply with the provisions of this regulation but the management of the establishment shall supervise the unloading of vehicles and shall communicate to its owner the existence of any infractions.

Procedures.

199. Procedures shall be defined to ensure that the hygienic requirements for contamination prevention, temperature maintenance with respect to transport of raw materials, finished products and packaging materials are met.

Temperature conditions for fishery products during transport.

200. Fishery products shall, during transport, be kept at the temperature laid down in this regulation 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-

(i) fresh or thawed fishery products shall always be chilled with ice whether or not completed with mechanical refrigeration;

(ii) prepared fishery products may be chilled with ice or with mechanical refrigeration;

(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;

(c) when frozen fishery products are transported from a cold storage plant to an approved establishment to be thawed on arrival for the purposes of preparation or processing and where the distance to be covered is short, not exceeding 50 km or one hour's journey, the Competent Authority may grant a derogation from the conditions laid down in regulation 203 of this regulation;

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

Hygienic conditions required for vehicles transporting fishery products.

201. (1) The parts of the vehicle, in which chilled or frozen fish is transported shall-

(a) be clean and in good state of repair;

(b) be covered during transport of the product in order to prevent exposure to dust, birds, insects and sunlight;

(c) be of adequate size, shall have sections or containers designed specifically for storage of fishery products;

(d) be constructed and equipped in such a way that the temperature laid down in this regulation can be maintained throughout the period of transport;

(e) be equipped with internal surfaces of the cargo area constructed from smooth, corrosion resistant impervious materials, free from cracks and crevices, which are easy to clean and the use of wood is not permitted unless it is painted with gloss paint of a light colour and the fish are carried in fish boxes;

(f) have internal surface joints that are smooth or flush and sealed to prevent the entry of moisture and shall be finished in such a way that they do not adversely affect the fishery

products and shall be easy to clean and disinfect;

(g) have adequate drainage, if ice is used to chill the products, in order to ensure that water from melted ice does not stay in contact with the products;

(h) if lighting is supplied, have light sources covered by a shatterproof shield.

(2) The hygiene conditions on construction level for vessels transporting fishery products are laid down in regulation 37.

General transport conditions for fishery products.

202. (1) Means of transport used for fishery products may not be used for transporting other products likely to impair, transmit harmful properties or abnormal characteristics, or contaminate fishery products, except where the fishery products can be guaranteed uncontaminated as a result of such transport being thoroughly cleaned and disinfected.

(2) Mechanical cooling system shall not impair by smell or odour the fishery products.

(3) Animals shall never be carried in the cargo area.

(4) Ramps, if provided, shall not be stowed in the cargo area.

(5) Fishery products shall not be transported in a vehicle or container which is not clean or which should have been disinfected.

(6) Vehicles may transport only fishery products which are fit for human consumption and the transport of wastes and by-products in fish vehicles is prohibited.

(7) After each journey the vehicle and any fish boxes used should be washed with water and detergent, followed by disinfection.

Specific requirements for specific types of transport.

203. (1) The transport of raw fishery products fresh on ice by road shall be done-

(a) in closed insulated containers (whereby is agreed that the different layers of raw materials are completely covered with ice) in open means of transport; or

(b) in open not insulated containers in insulated means of transport, provided with mechanical refrigeration where the distance to be covered or the journey is so long that melting of ice cannot be avoided without mechanical refrigeration.

(2) Raw fresh frozen fishery products shall be transported in clean closed precooled containers, holds or other means of transport on the appropriate temperature laid down in this regulation, provided with a thermometer to be able to control temperature.

(3) Packed frozen finished products in cartons and packed fresh on ice finished products in polystyrene packing material are transported in clean closed pre-cooled containers or other means of transport, on the appropriate temperature, laid down in this regulation, provided with a thermometer to be able to control temperature.

(4) Fishery products which have been subjected to sterilisation in hermetically sealed containers shall be transported in clean closed containers or other means of transport on ambient

temperature in a way that cartons and the cans are not damaged during loading, transport and offloading.

(5) The shipment containers used to transport frozen products shall be made of easy to clean material, and are checked and pre-cooled before loading and after stuffing, the container is again cooled down to –18° C before leaving the establishment for the harbour.

Process control.

204. A fail safe control system shall be implemented whereby the transport activities of raw materials and finished products are checked and controlled on their compliance with the activities described in the procedures and the instructions.

Instructions.

205. Instructions shall be put in place for-

(a) measurement of temperature in chilled and frozen products;

(b) transporting fish by transport boats;

(c) offloading boats;

(d) loading carrier;

(e) transport by carrier; and

(f) cleaning and disinfecting means of transport.

Specifications.

206. Specifications shall be defined for all means of transport and their use.

Documentation.

207. All procedures, instructions, specifications, control and check activities shall be thoroughly documented and recorded.

Training.

208. (1) Management of an establishment shall arrange adequate and continuous training of all food handlers and transporters in hygienic handling of fishery products so it is understood how to take precautions necessary to prevent contamination and deterioration of fishery products.

(2) Training shall include reference to relevant parts of this regulation.

BEST WASTE DISPOSAL PRACTICES.

209. The establishment shall have appropriate facilities-

(a) to treat the byproducts on an appropriate way, in the case, by-products are products destined for human consumption;

(b) to separate guts, parts and other waste that may constitute a danger to public health and remove from the vicinity of product intended for human consumption;

(c) to drain the liquid waste water and treat the sewage.

Quality objectives and action plan.

210. Procedures and instructions shall be implemented and maintained-

(a) to treat the by-products, if applicable;

(b) to prevent the contamination of fishery products with bacteria from residues and wastes;

(c) to deal with waste water drainage and sewage treatment.

Scheduling.

211. (1) Planned actions shall be scheduled in a timetable to document the commitment to the future actions.

(2) The schedules and timetables shall be approved by the Competent Authority and checked on his execution on a regular base.

Responsibilities and authority.

212. Responsibilities and authorities shall be established for the implementation, maintaining, monitoring and verification of regulations described in Best Waste Disposal Practices.

Procedures.

213. (1) Procedures shall be defined to ensure that the hygienic requirements with respect to by-products, solid and liquid waste disposal are met.

(2) Waste containers and their use shall comply with following hygienic requirements.

(3) Unless special facilities are provided, for the continuous disposal of waste, the latter shall be placed in leak-proof, impermeable containers-

(a) which are provided with tight fitting lids to prevent the entry of insects, rodents and other animals;

(b) which are designed to facilitate cleaning and disinfection;

(c) which are clearly marked for that purpose only or be of a different colour to boxes used for fish for human consumption;

(d) which, when used for temporary storage of viscera and offal in the work room, should be kept below the level of the work tables to avoid splashing and contamination of the product;

(e) which shall be always thoroughly cleaned and disinfected after use.

(4) Disposal of waste shall comply with following hygienic requirements-

(a) waste shall not be allowed to accumulate in working areas but shall be removed either continuously or regularly, as soon as the containers are full, but at least at the end of each working day, from the main work room to the premises allocated for the storage of such containers;

(b) waste shall be removed from the vicinity of the establishment at regular intervals in order to ensure that the waste not constitute a source of contamination for the establishment or of pollution of its surroundings by the development of smells and the presence of insects and rodents;

(c) the room in which residues and wastes are stored shall-

(i) have a permanent water supply and adequate drainage;

(ii) be kept clean;

(iii) be regularly inspected to ensure that this requirement is met.

Process control.

214. A fail safe control system shall be installed to control the compliance with the requirements laid down in regulation 211, regulation 212 and regulation 214.

Instructions.

215. (1) Instructions shall be documented and implemented on how to-

(a) treat the by-products if applicable;

(b) dispose of guts, offal and waste;

(c) deal with waste water and sewage;

(d) store and remove waste; and

(e) organise the cleaning and disinfection of containers, waste storage rooms waste water drainage channels, solid mesh traps, gully traps and manholes.

Specifications.

216. Specifications shall be in place concerning identifications and the use of the waste containers.

Records and documentation.

217. All procedures and instructions, control and check activities shall be thoroughly documented and recorded.

Training.

218. (1) Management of an establishment shall arrange for adequate and continuous training of the concerning personnel in hygienic handling of by- or waste products, so it is understood how to take precautions necessary to prevent contamination of fishery products.

(2) Training shall include reference to relevant parts of this Division.

PART XII

CONDITIONS FOR THE USE OF FOOD ADDITIVES

Food additives in General.

219. (1) Fishery products, intended to be placed on the market shall not contain sweeteners, colours or food additives other than sweeteners and colours-

(a) not included in these Regulations; or

(b) in excess of any maximum quantity or proportion permitted by the regulations of Part XII.

(2) In the context of these Regulations, "quantum satis" means that no maximum level is specified but colouring matters shall be used according to best manufacturing practices at a level not higher than is necessary to achieve the intended purpose and provided that they do not mislead the consumer.

(3) Maximum levels indicated in these Regulations refer to fishery products as marketed unless otherwise stated.

Sweeteners.

220. (1) Sweeteners within the meaning of these Regulations are food additives which are used to impart a sweet taste to processed fishery products.

(2) Only the following sweeteners at the mentioned concentrations may be used in the manufacture of sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs -

E950 Acesulfame K at 200 mg/kg

E951 Aspartame at 300 mg/kg

E954 Saccharine and its Na, K and Ca salts at 160 mg/kg

E959 Neohesperidine DC at 30 mg/kg

Colours.

221. (1)"Colours" within the meaning of these Regulations are-

(a) substances which add or restore colour in a food, and include natural constituents of foodstuffs and natural sources which are normally not consumed as foodstuffs as such and not normally used as characteristic ingredients of food; and

(b) preparations obtained from foodstuffs and other natural source materials obtained by physical or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents.

(2) However, the following substances shall not be considered colours for the purposes of these Regulations-

(a) foodstuffs, whether dried or in concentrated form and flavourings incorporated during the manufacturing of compound foodstuffs, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect, such as paprika, turmeric and saffron; and

(b) colours used for the colouring of the inedible external parts of foodstuffs.

(3) The colour, E160 b Annatto, Bixin, Norbixin may be used at 10 mg/kg in smoked fishery products.

(4) In following processed fishery products-

(a) fish paste and crustacean paste;

(b) precooked crustaceans;

(c) salmon substitutes;

(d) surimi;

(e) fish roe;

(f) smoked fish.

(5) Under mentioned colours may be used at quantum satis-

E101	(i) Riboflavin
	(ii) Riboflavin-5'-phosphate
E140	Chlorophylls and chlorophyllins
E141	Copper complexes of chlorophylls and chlorophyllins
E150a	Plain caramel
E150b	Caustic sulphite caramel
E150c	Ammonia caramel
E150d	Sulphite ammonia caramel
E153	Vegetable carbon
E160a	Carotenes
E160c	Paprika extract, capsanthin, capsorubin
E162	Beetroot red, betanin
E163	Anthocyanins
E170	Calcium carbonate
E171	Titanium dioxide

E172 Iron oxides and hydroxides

(6) Following colours-

E100 Curcumin

E102 Tartrazine

E104 Quinoline Yellow

E110 Sunset Yellow FCF

Orange Yellow S

E120 Cochineal, Carminic acid, Carmines

E122 Azorubine, Carmoisine

E124 Ponceau 4R, Cochneal Red A

E129 Allura Red AC

E131 Patent Blue V

E132 Indigotine, Indigo carmine

E133 Brilliant Blue FCF

E142 Green S

E151 Brillant Black BN, Black PN

E155 Brown HT

E160d Lycopene

E160c Beta-apo-8'-carotenal (C30)

E160f Ethyl ester of Beta-apo-8'-carotenic acid (C30)

E161b Lutein

may be used single or in combination in-

(a) fish paste and crustacean paste up to the maximum level of 100 mg/kg;

(b) precooked crustaceans up to the maximum level of 250 mg/kg;

(c) salmon substitutes up to the maximum level of 500 mg/kg;

(d) surimi up to the maximum level of 500 mg/kg;

(e) fish roe up to the maximum level of 300 mg/kg;

(f) smoked fish up to the maximum level of 100 mg/kg.

Food additives other than colours and sweeteners.

222. (1) Food additives other than colours and sweeteners within the meaning of these Regulations are-

(a) "preservatives" are substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by micro-organisms;

(b) "antioxidants" are substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes;

(c) "carriers", including carrier solvents, are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive without altering its technological function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;

(d) "acids" are substances which increase the acidity of a foodstuff or impart a sour taste to it;

(e) "acidity regulators" are substances which alter or control the acidity or alkalinity of a foodstuff;

(f) "anti-caking agents" are substances which reduce the tendency of individual particles of a foodstuff to adhere to one another;

(g) "anti-foaming agents" are substances which prevent or reduce foaming;

(h) "bulking agents" are substances which contribute to the volume of a foodstuff without contributing significantly to its available energy value;

(i) "emulsifiers" are substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff;

(j) "emulsifying salts" are substances which convert proteins contained in cheese into a dispersed form and thereby bring about homogenous distribution of fat and other components;

(k) firming agents" are substances which make or keep tissues of fruit or vegetables firm or

crisps, or interact with gelling agents to produce or strengthen a gel;

(l) "flavour enhancers" are substances which enhance the existing taste and odour of a foodstuff;

(m) "foaming agents" are substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff;

(n) "gelling agents" are substances which give a foodstuff texture through formation of a gel;

(o) "glazing agents" (including lubricants) are substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating;

(p) "Humectants" are substances which prevent foodstuffs from drying out by counteracting the effect of an atmosphere having a low degree of humidity, or promote the dissolution of a powder in an aqueous medium;

(q) "Modified starches" are substances obtained by one or more chemical treatments of edible starches, which may have undergone a physical or enzymatic treatment, and may be acid or alkali thinned or bleached;

(r) "packaging gases" are gases other than air, introduced into a container before, during or

after the placing of a foodstuff in that container;

(s) "propellants" are gases other than air which expel a foodstuff from a container;

(t) "raising agents" are substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter;

(u) "sequestrants" are substances which form chemical complexes with metallic ions;

(v) "stabilizers" are substances which make it possible to maintain the physico-chemical state of a foodstuff; stabilizers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff and include also substances which stabilize, retain or intensify an existing colour of a foodstuff;

(w) "thickeners" are substances which increase the viscosity of a foodstuff.

(2) For the purpose of these Regulations the following are not considered as food additives-

(a) substances used for treatment of potable water;

(b) products containing pectin and derived from dried apple pomace or peel of citrus fruits, or from a mixture of both, by the action of dilute

acid followed by partial neutralisation with sodium or potassium salts ("liquid pectin");

(c) chewing gum bases;

(d) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolitic enzymes;

(e) ammonium chloride;

(f) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten;

(g) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts and having no additive function;

(h) caseinates and casein;

(i) inulin.

(3) In processed fishery products under mentioned food additives may be used at quantum satis-

E170	Calcium carbonates-
	(i) Calcium carbonates
	(ii) Calcium hydrogen carbonate
E260	Acetic acid
E261	Potassium acetate
E262	Sodium acetates-
	(i) Sodium acetate

	(ii) Sodium hydrogen acetate (diacetate)
E263	Calcium acetate
E270	Lactic acid
E290	Carbon dioxide
E296	Malic acid
E300	Ascorbic acid
E301	Sodium ascorbate
E302	Calcium ascorbate
E304	Fatty acid esters of ascorbic acid-
	(i) Ascorbyl palitate
	(ii) Ascorbyl stearate
E306	Tocopherol-rich extract
E307	Alpha-tocopherol
E308	Gamma-tocopherol
E309	Delta-tocopherol
E322	Lecithins
E325	Sodium lactate
E326	Potassium lactate
E327	Calcium lactate
E330	Citric acid
E331	Sodium citrates-
	(i) Monosodium citrate
	(ii) Disodium citrate

(iii) Trisodium citrate

E332 Potassium citrates-

(i) Monopotassium citrate

(ii) Tripotassium citrate

E333 Calcium citrates-

(i) Monocalcium citrate

(ii) Dicalcium citrate

(iii) Tricalcium citrate

E334 Tartaric acid (L(+)-)

E335 Sodium tartrates-

(i) Monosodium tartrate

(ii) Disodium tartrate

E336 Potassium tartrates-

(i) Monopotassium tartrate

(ii) Dipotassium tartrate

E337 Sodium malates-

(i) Sodium malate

(ii) Sodium hydrogen malate

E351 Potassium malate

E352 Calcium malate-

(i) Calcium malate

(ii) Calcium hydrogen malate

E354	Calcium tartrate
E380	Triammonium citrate
E400	Alginic acid
E3401	Sodium alginate
E402	Potassium alginate
E403	Ammonium alginate
E404	Calcium alginate
E406	Agar
E407	Carrageenan
E410	Locust bean gum
E412	Guar gum
E413	Tragacanth
E414	Acacia gum (gum arabic)
E415	Xanthan gum
E417	Tara gum
E418	Gellan gum
E422	Glycerol
E440	Pectins-
	(i) pectin
	(ii) amidated pectin
E460	Cellulose
	(i) microcrystalline cellulose
	(ii) powdered cellulose

E461	Methyl cellulose
E463	Hydroxpropyl cellulose
E464	Hydroxpropyl methyl cellulose
E466	Carboxy methyl cellulose Sodium carboxy methyl cellulose
E470a	Sodium, potassium and calcium salts of fatty acids
E470b	Magnesium salts of fatty acids
E471	Mono- and diglycerides of fatty acids
E472a	Acetic acid esters of mono- and diglycerides of fatty acids
E472b	Lactic acid esters of mono-and diglycerides of fatty acids
E472c	Citric acid esters of mono- and diglycerides of fatty acids
E472d	Tartaric acid esters of mono- and diglycerides of fatty acids
E472e	Mono- and diacetyl tartaric acid esters of mono- and diglycerids of fatty acids
E472f	Mixed acetic and tartaric acid esters of mono and diglycerides of fatty acids
E500	Sodium carbonates- (i) Sodium carbonate (ii) Sodium hydrogen carbonate (iii) Sodium sesquicarbonate

E501	Pottasium carbonates-	
	(i)	Potassium carbonate
	(ii)	Potassium hydrogen carbonate
E503	Ammonium carbonates-	
	(i)	Ammonium carbonate
	(ii)	Ammonium hydrogen carbonate
E504	Magnesium carbonates-	
	(i)	Magnesium carbonate
	(ii)	Magnesium hydroxide carbonate (syn. Magnesium hydrogen carbonate)
E507	Hydrochloric acid	
E508	Potassium chloride	
E509	Calcium chloride	
E511	Magnesium chloride	
E513	Sulphuric acid	
E514	Sodium sulphates-	
	(i)	Sodium sulphate
	(ii)	Sodium hydrogen sulphate
E515	Potassium sulphates-	

	(i) Potassium sulphate
	(ii) Potassium hydrogen sulphate
E516	Calcium sulphate
E524	Sodium hydroxide
E525	Potassium hydroxide
E526	Calcium hydroxide
E527	Ammonium hydroxide
E528	Magnesium hydroxide
E529	Calcium oxide
E530	Magnesium oxide
E570	Fatty acids
E574	Gluconic acid
E575	Glucono-delta-lactone
E576	Sodium gluconate
E577	Potassium gluconate
E578	Calcium gluconate
E640	Glycine and its sodium salt
E938	Argon*
E939	Helium*
E941	Nitrogen*
E942	Nitrous oxide*
E948	Oxygen*
E1200	Polydextrose

E1404	Oxidised starch
E1410	Monostarch phosphate
E1412	Distarch phosphate
E1413	Phosphated distarch phosphate
E1414	Acetylated distarch phosphate
E1420	Acetylated starch
E1422	Acetylated distarch adipate
E1440	Hydroxy propyl starch
E1442	Hydroxy propyl distarch phosphate
E1450	Starch sodium octenyl succinate
E420	Sorbitol-
	(i) Sorbitol
	(ii) Sorbitol syrup
E421	Mannitol
E953	Isomalt-
	(i) Maltitol
	(ii) Maltitol syrup
E966	Lactitol
E967	Xylitol

(4) In processed fishery products-

(a) under mentioned food additives-

E620	Glutamic acid;
E621	Monosodium glutamate
E622	Monopotassium glutamate

E623 Calcium diglutamate

E624 Monoammonium glutamate

E625 Magnesium diglutamate,

may be used individually or in combination up to the maximum level of 10 g/kg.

(b) undermentioned food additives-

E626 Guanylic acid;

E627 Disodium guanylate;

E628 Dipotassium guanylate;

E629 Calcium guanylate;

E630 Inosinic acid;

E631 Disodium inosinate;

E632 Dipotassium inosinate;

E633 Calcium mesinate;

E634 Calcium 5'-ribonucleotides;

E635 Disodium 5'-ribonucleotides,

may be used individually or in combination expressed as guanylic acid up to the maximum level of 500 mg/kg.

(5) In raw or prepared fishery products following food additives-

E290 Carbon dioxide

E938 Argon

E939 Helium

E941 Nitrogen

E948 Oxygen

E331 Sodium citrates

E332 Potassium citrates

E333 Calcium citrates

E420 Sorbitol-

(i) Sorbitol

(ii) Sorbitol syrup

E421 Mannitol

E953 Isomalt

E965 Maltiol-

(i) Maltiol

(ii) Maltiol syrup

E966 Lactitol

E967 Xylitol may be used at quantum satis.

(6) In frozen, raw, prepared or processed fish, crustaceans, molluscs and cephalopods undermentioned food additives may be used at quantum satis-

E420 Sorbitol-

(i) Sorbitol

(ii) Sorbitol syrup

E421 Mannitol

E953 Isomalt-

(i) Maltitol

(ii) Maltitol syrup

E966 Lactitol

E967 Xylitol.

Preservatives.

223. (1) The following groups of preservatives mentioned in this regulation can be used to prolong the shelf-life of fishery products-

(a) the following sorbates-

E200 Sorbic acid

E202 Potassium sorbate

E203 Calcium sorbate and

(b) the following benzoates-

E210 Benzoic acid

E211 Sodium benzoate

E212 Potassium benzoate

E213 Calcium benzoate,

may be used singly or in combination in-

(i) semi preserved fish products including fish roe products up to the maximum level of 2000 mg/kg or mg/l;

(ii) salted dried fish up to the maximum level of 200 mg/kg;

(iii) cooked shrimps up to the maximum level of 2000 mg/kg;

(iv) cooked Crangon crangon and Crangon vulgaris up to maximum level of 6000 mg/kg.

(2) Whereby the levels of all substances mentioned above are expressed as the free acid.

The following preservatives food additives described as suflur dioxide and sulphites-

E220 Sulphur dioxide;

E221 Sodium sulphite;

E222 Sodium hydrogen sulphite;

E223 Sodium metabisulphite;

E224 Potassium metabisulphite;

E226 Calcium sulphite;

E277 Calcium hydrogen sulphite;

E228 Potassium hydrogen sulphite,

may be used singly or in combination with-

(a) fresh and frozen crustaceans and cephalopods up to the maximum level of 150 mg/kg in the edible parts

(b) crustaceans, family of penaeidae, solenoceridae, aristeidae-

(i) up to 80 units, up to the maximum level of 150 mg/kg in the edible parts;

(ii) between 80 and 120 units, up to the maximum level of 200 mg/kg in the edible parts;

(iii) over 120 units, up to the maximum level of 300 mg/kg in the edible parts;

(iv) cooked, up to the maximum level of 50 mg/kg in the edible parts.

(c) whereby-

(i) maximum levels are expressed as SO_2 in mg/kg and relate to the total quantity, available from all sources;

(ii) an SO_2 content of not more than 10 mg/kg is not considered to be present.

(3) The food preservative food additives, E251 Sodiumnitrate and E252 Potassiumnitrate may be used at 200 mg/kg in pickled herring and sprat whereby residual amount, nitrite formed from nitrate included, is expressed as $NaNO_2$.

(4) The food preservative food additive E284 Boric acid and E285 Sodium tetraborate (borax) may be used at 4 g/kg, expressed a boric acid in Sturgeon's eggs (caviar).

Antioxidants.

224. (1) The antioxidants E315 Erythorbic acid and E316 Sodium erythorbate may be used at 1500 mg/kg, expressed as erythorbic acid, in-

(a) preserved and semi-preserved fish products;

(b) frozen fish with red skin.

(2) The antioxidant E385 Calcium disodium ethylene diamine tetra-acetate (Calcium disodium EDTA) may be used up to the maximum level of 75 mg/kg in-

(a) canned and bottled crustaceans and molluscs;

(b) canned and bottled fish.

Polyphosphates as Cryoprotectants.

225. The following polyphosphates (E452) especially-

(a) sodium polyphosphate;

(b) potasium polyphosphate;

(c) sodium calcium polyphosphate;

(d) calcium polyphosphates;

may be used in-

(a) surimi up to the maximum level of 1g/kg;

(b) fish and crustacean paste up to the maximum level of 5g/kg;

(c) frozen fillets of unprocessed fishery products up to the maximum level of 5g/kg;

(d) frozen crustacean products up to the maximum level of 5g/kg.

PART XIII

PRODUCT SAFETY ASSURANCE SYSTEM

FOR PREPARATION AND PROCESSING OF FISHERY PRODUCTS

(HAZARD ANALYSIS CRITICAL CONTROL POINTS) (HACCP)

Introduction.

226. (1) The implementation of a Product Safety Assurance System for the preparation and processing of fishery products means implementing all those actions aimed at ensuring and demonstrating that a fishery product satisfies the product safety requirements of this regulation.

(2) A Product Safety Assurance Program (HACCP – Hazard Analysis Critical Control Points) has to be implemented if the hazard analysis reveals that processors have food safety hazards that they might control.

(3) The implementation of the HACCP system is laid down in Part XIII of these Regulations.

(4) Hazard Analysis and Critical Control Point (HACCP) System requirements for Preparation and Processing Facilities approved for the fish and fishery products of the order siluriformes shall be validated, verified and reassessed before the issuance of export health certificate.

The seven principles.

227. (1) It is recommended that a model of a logical approach be followed of which the following principles form the essential components-

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

(b) identification of critical points;

(c) establishment of critical limits for each critical point;

(d) establishment of monitoring and checking procedures;

(e) establishment of corrective action to be taken when necessary;

(f) establishment of verification and review procedures; and

(g) establishment of documentation concerning all procedures and records.

(2) Such a model or the principles on which it is based should be issued with the flexibility appropriate to each situation.

Hazards.

228. (1) A hazard is a biological, chemical or physical property that may cause a food to be unsafe for consumption.

(2) To be considered as a real hazard, a hazard must be of a nature such that their elimination or reduction to acceptable levels is essential to the production of safe food.

(3) A direct hazard causes a problem by the consumption of the concerned fishery product

(4) An indirect hazard causes a problem by transferring pathogens or other hazards to products which are not cooked before consumption (cross contamination) in working areas or kitchen during handling and preparation.

(5) Hazards can be-

(a) biological hazards-

(i) pathogenic microorganisms (e.g. bacteria, viruses);

(ii) parasites;

(b) chemical hazards-

(i) natural toxins;

(ii) chemicals;

(iii) pesticides;

(iv) drug residues;

(v) unapproved food and colour additives;

(vi) decomposition (safety only, e.g. histamine);

(c) physical hazards: metal, glass, etc.

(6) Hazards can be-

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

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

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

(7) Species related hazards are potential hazards that are associated with specific species of fishery products and species related hazards are-

(a) chemical contamination;

(b) mercury;

(c) natural toxins-

(i) paralytic Shellfish Poisoning (PSP);

(ii) neurotoxic Shellfish Poisoning (NSP);

(iii) diarrheic Shellfish Poisoning (DSP);

(iv) amnesic Shellfish Poisoning (ASP);

(v) ciguatera Food Poisoning (CFP°);

(vi) clupeotoxin;

(vii) chondrichthytoxin;

(viii) tetrodotoxin (Puffer fish);

(ix) gempylotoxin (escolar);

(d) histamine;

(e) food and colour additives;

(f) parasites (safety hazard);

(g) aquaculture drugs;

(h) pathogens.

(8) Process related hazards are potential hazards that are associated with inadequate food handling, preparation or processing and process related hazards are-

(a) inadequate drying, pathogen growth, toxin formation as a result of inadequate salt, sugar or nitrite concentration;

(b) pathogen survival through cooking;

(c) cross-contamination;

(d) temperature abuse during processing of cooked products and raw molluscan shellfish;

(e)temperature abuse during processing of non-cooked products;

(f) microbiological growth in batter;

(g) pathogen survival through pasteurization recontamination after pasteurization;

(h) temperature abuse during final cooling;

(i) temperature abuse during finished product storage;

(j) temperature abuse during distribution;

(k) food and colour additive.

The seven preliminary steps.

229. (1) Preliminary steps shall be included to consolidate the implementation of the HACCP plan.

(2) Preliminary step 1-define the terms of reference or scope of the plan and to know the scope of the plan the following questions have to be answered-

(a) will the study cover a whole process or one specific part and the study should highlight -

(i) slaughter—all farm species;
(ii) raw product—ground;
(iii) raw product—not ground;
(iv) thermally processed—commercially sterile;
(v) not heat treated—shelf stable;
(vi) heat treated—shelf stable;
(vii) fully cooked—not shelf stable;
(viii) heat treated but not fully cooked—not shelf stable;
(ix) product with secondary inhibitors—not shelf stable in cases of the siluriformes;

(b) will the study cover one product or a group of products;

(c) will all types of hazard categories initially (i.e. microbiological, chemical and physical) be covered;

(d) should the HACCP study stop at the end of the production line or continue through distribution, retail and consumer handling.

(3) Preliminary step 2 - Select and assemble a multidisciplinary team-

(a) the team which involves all parts of the enterprise concerned with the product, needs to include the whole range of specific knowledge and expertises appropriate to the product under consideration, its production (manufacture, storage and distribution), its consumption and the associated potential hazards;

(b) where necessary, the team will be assisted by specialists who will help it to solve its difficulties as regards assessment control of critical points.

(c) the team may consist of-

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

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

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

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

(4) Preliminary step 3- Describe the food, distribution and storage and the end of the product shall be described in terms of-

(a) composition (e.g. raw material ingredients, additives, etc.);

(b) structure and physico-chemical characteristics (e.g. solid, liquid, gel emulsion, pH, Aw, etc.);

(c) processing (e.g. heating, freezing, drying, salting, smoking, etc., and to what extent);

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

(e) storage and distribution conditions;

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

(g) instruction for use; and

(h) any microbiological or chemical criteria applicable.

(5) Preliminary step 4- Identify the intended use of the product and the multidisciplinary team shall define the normal or expected use of the product by the customer.

(6) Preliminary step 5- Identify the intended consumer. The multidisciplinary team shall define the normal or expected consumer target groups for which the product is intended. In specific cases, the suitability of the product for particular groups of consumers such as institutional caterers, travellers, etc., and for vulnerable groups of the population may have to be considered.

(7) Preliminary step 6- Develop and construct a flow diagram (description of a manufacturing process)-

(a) 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, packaging, storage and distribution shall be studied in sequence in a detailed flow diagram with sufficient technical data;

(b) types of data may include but are not limited to-

(i) plan of working premises and adjacent or adjoining premises;

(ii) equipment layout and characteristics sequence of all process steps (including the incorporation of raw materials, ingredients or additives and delays during or between steps);

(iii) technical parameters of operations (in particular time and temperature including delays);

(iv) flow of products (including potential cross-contamination);

(v) segregation of clean and dirty areas (or high/low risk areas); and

(vi) personnel routes.

(8) Preliminary step 7- Verify and confirm the flow diagram on-site. After the flow diagram has been drawn up, the multidisciplinary team should confirm it on site during operating hours and any observed deviation must result in an amendment of the original flow diagram to make it accurate.

The seven hazard analysis steps. Schedule Eight

230. (1) Hazard analysis step 1: Set up a hazard analysis worksheet set forth in Schedule Eight (column 1 – column 6) and record each processing step in column 1-

(a) Column 1: processing step;
(b) Column 2: potential hazard at this step;
(c) Column 3: significance of the potential food safety hazard (risk assessment);
(d) Column 4: justification of this decision;
(e) Column 5: preventive (control) measures;
(f) Column 6: is this step a critical control point (Yes or No).

(2) Hazard analysis step 2: Identify the potential species related hazards and record in column 2.

List all potential species related biological, chemical or physical hazards that may be reasonably expected to occur (including

acquisition and storage of raw materials and ingredients and delay during manufacture).

(3) Hazard analysis step 3: Identify the potential process related hazards and record in column 3.

Using the confirmed flow diagram as a guide, the team should list all potential process related hazards that may be reasonably expected to occur at each process step (including acquisition and storage of raw materials and ingredients and delay) during manufacture.

(4) Hazard analysis step 4: Understand the potential hazards. Hazard analysis requires two essential ingredients-

The first is an appreciation of the hazard (e.g. pathogenic organism or any disease agent that could harm the consumer.

The second is a detailed understanding of how these hazards could arise.

Thus the hazard analysis requires thorough microbiological, toxicological knowledge in combination with epidemiological and technical information.

(5) Hazard analysis step 5: Determine of the potential. Hazard is significant (risk assessment) and record in column 3 and 4 and a hazard is significant if the hazard is-

(a) reasonably likely to occur and if not properly controlled, it is likely to result as an unacceptable health risk to consumers and hazard analysis step 6: Identify preventive measures and record in column 5. Consider and

describe what preventive measures, if any, exist which can be applied for each hazard;

(b) preventive measures are those actions and activities that can be used to prevent hazards, eliminate them or reduce their impact or occurrence to acceptable levels;

(c) more than one preventive measure may be required to control an identified hazard and more than one hazard may be controlled by one control measure. For instance, pasteurization or controlled heat treatment may provide sufficient assurance of reduction of the level of both Salmonella and Listeria;

(d) preventive measures need to be supported by detailed procedures and specifications to ensure their effective implementation. For instance, precise heat treatment specifications, maximum concentrations of preservatives used in compliance with the applicable legislation on additives.

(6) Hazard analysis step 6: Identify preventive measures and record in column 5-

Consider and describe what preventive measures, if any, exist which can be applied for each hazard.

(a) preventive measures are those actions and activities that can be used to prevent hazards, eliminate them or reduce their impact or occurrence to acceptable levels;

(b) more than one preventive measure may be required to control an identified hazard and more than one hazard may be controlled by one control measure and for instance, pasteurization or controlled heat treatment may provide sufficient assurance of reduction of the level of both Salmonella and Listeria;

Schedule Nine

(c) preventive measures need to be supported by detailed procedures and specifications to ensure their effective implementation and or instance, precise heat treatment specifications, maximum concentrations of preservatives used in compliance with the applicable legislation on additives.

(7) Hazard analysis step 7: (= principle 2) Identify the critical control point (CCP) and record in column 6-

(a) a CCP may be a location, a point, a procedure or processing step in the process flow where by taking preventive measures, effective control can be installed and a food safety hazard can be prevented, eliminated or reduced to an acceptable level;

(b) the identification of a critical point for the control of a hazard requires a logical approach and such approach can be facilitated by the use of the decision tree set forth in Schedule Nine to these Regulations (other methods can be used by the team, according to their knowledge and experience);

(c) for the application of the decision tree, each process step identified in the flow diagram should be considered in sequence and 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;

(d) application of the decision tree should be flexible and requires common sense, having consideration for the whole manufacturing process in order to avoid, whenever possible, unnecessary critical points;

(e) examples of CCP's are: a specific heat process, chilling, specific sanitation procedures, adjustment of food to a given pH or salt content.

Actions to be taken after hazard analysis.

231. (1) If no CCP's are detected or identified in Hazard Analysis Step 7, the HACCP analysis is finished and there is no need to implement a HACCP Plan.

(2) The identification of critical control points has two consequences for the multidisciplinary team, which should-

(a) ensure that appropriate preventive 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 later stage, to include a control measure: If the hazard analysis reveals that processors have food safety hazards that they might control a

safety assurance plan (HACCP Plan has to be implemented);

(b) establish and implement an appropriate monitoring and checking system at each critical point to ensure effective control thereof and proceed to the activities specified in the HACCP Plan steps.

The seven HACCP plan form steps.

232. (1) HACCP plan step 1: Set up the HACCP plan form. The HACCP plan form has 10 columns-

(a) Critical point (CCP) = Processing step (column 1);
(b) Significant hazards (column 2);
(c) Parameter and Critical Limits for each preventive measure (column 3);
(d) What (column 4);
(e) How (column 5);
(f) Frequency : When (column 6);
(g) Who (column 7);
(h) Corrective actions (column 8);
(i) Records (column 9);
(j) Verification (column 10).

Schedule Ten

The HACCP plan form is set forth in Schedule Ten to these Regulations.

(2) HACCP plan step 2: Start the implementation of HACCP plan form (column 1).

(a) find the processing steps which we have identified as CCP in column 6 of the Hazard Analysis Worksheet. Record the names of

these processing steps in column 1 of the HACCP plan form;

(b) enter the significant hazards for which these processing steps were identified as CCP's in column 2 of the HACCP plan form. This information can be found in column 2 of the Hazard Analysis Worksheet;

(c) enter the preventive measures in column 3 of the HACCP plan form.

(3) HACCP plan step 3: Set up the critical factors (parameters) and critical limits for each preventive measure associated with each CCP (principle 3)-

(a) each control measure associated with critical control points should give rise to the specification of critical limits;

(b) those critical limits correspond to the extreme values acceptable with regard to product safety and they separate acceptability from unacceptability and they are set for observable or measurable parameters that can readily demonstrate that the critical point is under control; they should be based on substantiated evidence that chosen values will result in process control;

(c) examples of such parameters include temperature, time, pH, moisture level,

additive, preservative or salt level, sensory parameters such as visual appearance or texture, etc;

(d) in some cases, to reduce the risk of exceeding a critical limit due to process variations, it may be necessary to specify more stringent levels (i.e. target levels) to assure that critical limits are observed;

(e) critical limits may be derived from a variety of sources and when not taken from regulatory standards (e.g. frozen storage temperature) or from existing and validated guides of best practices, the team should ascertain their validity relative to the control of identified hazard and critical points.

(4) HACCP plan step 4: Establish a monitoring procedure (principle 4)-

(a) an essential part of own-checks is a program of observations or measurements performed at each critical point to ensure compliance with specified critical limits and the program should describe the methods, the frequency of observations or measurements and the recording procedure;

(b) observations or measurements must be able to detect loss of control at critical points and provide information in time for corrective action to be taken;

(c) observations or measurements can be made continuously or discontinuously and when observations or measurements are not continuous, it is necessary to establish a frequency of observations or measurements, which provides reliable information;

(d) the programme of observations or measurements should properly identify for each critical point-

(i) what will be monitored (column 4);

(ii) how monitoring and checking is performed (column 5);

(iii) when monitoring and checking is performed, and (column 6);

(iv) who is to perform monitoring and checking (column 7).

(5) HACCP plan step 5: Establish a corrective action plan (principle 5)- Establish corrective actions in case a deviation from a critical limit occurs-

(a) observations or measurements may indicate-

(i) that the parameter monitored tends to deviate its specified critical limits, indicating a trend toward loss of control and appropriate corrective action to maintain control must be taken before the occurrence of hazard; and

(ii) that the parameter monitored has deviated from its specified critical limits, indicating a loss of control and it is necessary to take appropriate corrective action to regain control;

(b) corrective action has to be planned in advance by the multidisciplinary team, for each critical point so that it can be taken without hesitation when a deviation is observed;

(c) such corrective action should include-

(i) proper identification of the person responsible for the implementation of the corrective action;

(ii) description of means and action required to correct the observed deviation;

(iii) action to be taken with regard to products that have been manufactured during the period when the process was out of control; and

(iv) written record of measures taken;

(d) corrective actions shall be entered in column 8 of the HACCP plan form.

(6) HACCP plan step 6: Establish record keeping (principle 6)-

(a) the approved HACCP plan and associated documentation and records shall be in file and available for inspection by regulatory agencies- Who is responsible for keeping the records should be clear at all times;

(b) four kinds of records are kept as part of the HACCP system- HACCP plan support documentation used in developing the plan-

(i) records of CCP monitoring;
(ii) records of corrective actions; and
(iii)records of verification activities.

(c) type of records shall be entered in column 9 of the HACCP plan form.

(7) HACCP plan step 7: Verification procedures (principle 7)- HACCP own checks system verification is necessary to ensure that the system is working effectively and the multidisciplinary team shall specify the methods and procedures to be use-

(a) usable methods may include in particular random sampling and analysis, reinforced analysis or tests at selected critical points, intensified analysis of intermediate or final products, surveys on actual conditions during storage, distribution and sale and on actual use of the product;

(b) verification procedures may include: inspection of operations, validation of critical limits, review of deviations, corrective action and measures taken with regard to the product, audits of the HACCP own checks system and its records;

(c) verification should provide for confirmation of the suitability of the own check system established and ensure, afterwards, with an

appropriate frequency, that the provisions laid down are still being properly applied;

(d) any change to the HACCP auto control system arising should be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is available;

(e) where criteria are specified in regulations, such criteria are to be used as reference values for the verification process;

(f) verification shall enter in column 10 of the HACCP plan form.

Review of the HACCP own checks system.

233. (1) A review of the HACCP plan is necessary to determine whether the plan is still appropriate and valid in case of change and is additional to the process of verification.

(2) When necessary such a review must result in the amendment of the provision stipulated.

(3) A HACCP review is undertaken in at least the following situations of change-

(a) factory lay-out and environment;

(b) change in raw material or finished product;

(c) processing system and conditions (packaging, storage or distribution conditions, etc.);

(d) process equipment;

(e) cleaning and disinfection program;

(f) health or spoilage risk associated with the product;

(g) new information on hazard, risks or intended use and consumers.

(4) Every version of the HACCP plan shall be dated and signed by the responsible person, highest in degree in the establishment and once the HACCP plan is signed management committed itself to implement the plan and take the consequences of the implementation.

Documentation and records.

234. (1) All procedures, instructions, specifications control and check activities shall be thoroughly documented.

(2) The person responsible for the establishment shall take all necessary measures to comply with these Regulations and to this end the following must be done-

(a) the person responsible for an establishment shall keep records of each lot of fish processed and shall keep a register of the processing carried out;

(b) the person responsible shall keep a written record or a record registered in a n indelible fashion concerning the auto control systems, laid down in Part VIII of these Regulations and concerning the checks (HACCP) laid down in Part XIII of these Regulations, with a view to submitting them to the Competent Authority;

(c) records shall show processing details including records of quantities, and

depending on the type of process employed, processing temperatures and time, salt content, pH, water content, details of sampling and other records relevant to show that fishery products have been processed in accordance with this regulation;

(d) records of the different checks and tests must be kept at least for the expected storage life of the products and for a period of two years be available to the Inspectorate.

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

Training.

235. The manager of an establishment shall arrange adequate and continuous training of all workers and training shall include reference to the relevant parts of this Part.

Recall Procedures.

236. (1) The establishment shall have in place 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 found unfit for human consumption and for that reason withdrawn from the market.

(2) The established procedures shall be tested in a mock recall which shall be documented.

(3) The establishment shall inform the Competent Authority immediately if it find reason to recall a batch of products from the market.

(4) The establishment shall provide any necessary information and carry out any necessary activity required by the Competent Authority in case recall of a batch from the market is considered necessary by the establishment or the Competent Authority.

(5) Recalled products shall be disposed in ways that do not compromise safety of other food products or the consumer in general.

(6) The method of disposal shall be approved by the Competent Authority.

Offences.

237. (1) A person who commits an offence under these Regulations shall be liable on summary conviction to a fine of five hundred thousand dollars.

Revocation.
Reg. 7 of 2003.

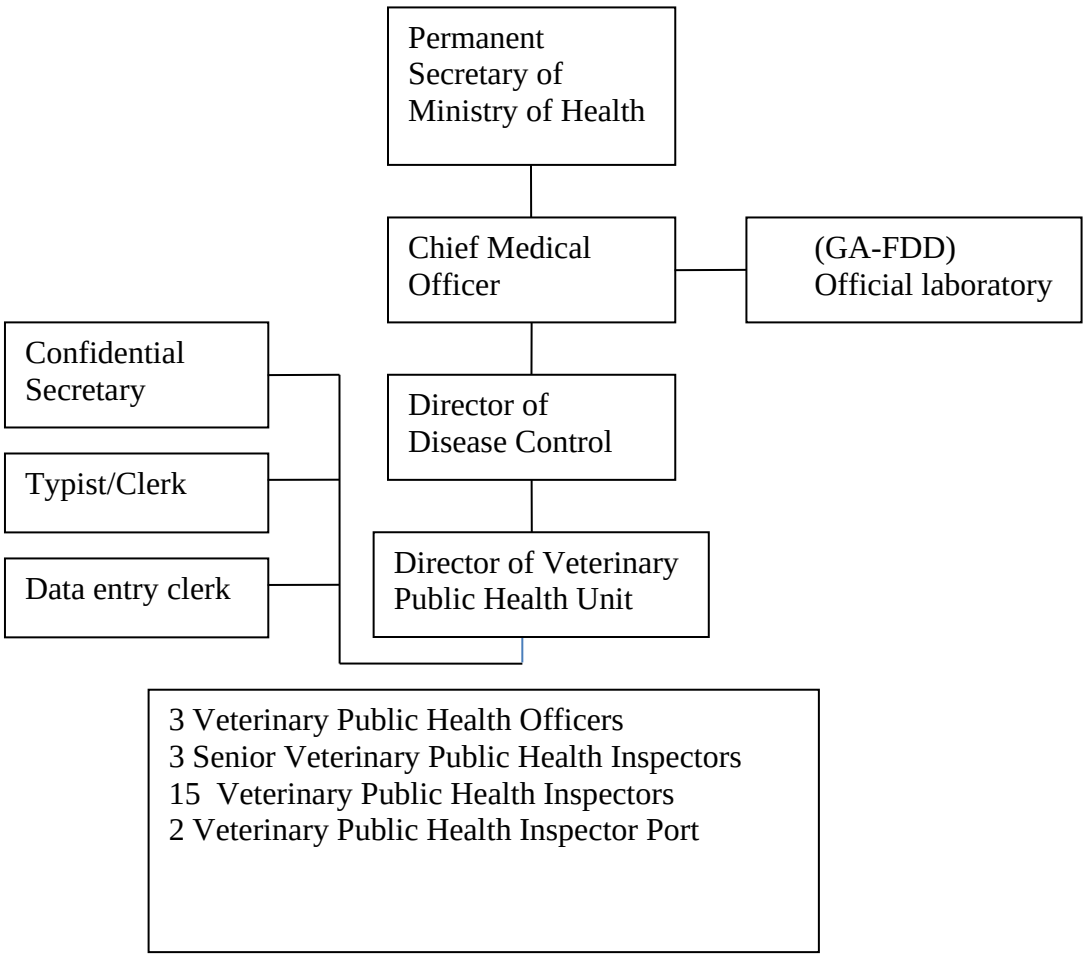
238. The Fishery Products Regulations are hereby revoked.

SCHEDULE ONE **Reg. 3**

Veterinary Public Health Unit

Organigram

This schedule lays down the organizational chart of the Veterinary Public Health Unit within the Ministry of Health as provided for in regulation 3 of these regulations.



SCHEDULE TWO **Reg. 15**

Export Health Certificates

The Competent Authority shall issue Export Health Certificates as required by exporters or importing markets or Guyana law. The Competent Authority shall ensure that the version of a certificate used is always the latest legal version required by the market.

SCHEDULE THREE Reg. 167

This Schedule lays down the microbiological standards applicable to fishery products placed on the market or intended to be placed on the market. Products that do not comply with the listed criteria shall be deemed unfit for human consumption.

Type of bacteria	Standard
Salmonella - cooked crustaceans and molluscan shellfish - Live bivalve mollusks and live echinoderms and gastropods	Absent in 25g n=5 c=0
E. coli - Live bivalve mollusks and live echinoderms and gastropods - Shelled and shucked products of cooked crustaceans and molluscan shellfish	230 MPN/100 g of flesh and intra-valvular liquid m = 1 cfu/g M = 10 cfu/g n = 5 c = 2
Coagulase positive Staphylococci - Shelled and shucked products of cooked crustaceans and molluscan shellfish	m=100 cfu/g M=1000 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

1. 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 positive staphylococci EN/ISO 6888-1 or 2

SCHEDULE FOUR **Reg. 17, 22 and 23**

This Schedule lays down Maximum residue limits (MRL´s), methods of sampling, sample preparations and criteria for methods of analysis for official control of the levels of environmental and other contaminants, including lead, cadmium mercury, dioxins and dioxin like PCB's and benzo(a)pyrene in fishery and aquaculture products, provided for in regulation 17, 22 and 23 of these Regulations.

PART I

Maximum Residue Limits (MRL`s)

Batches or production lot of fishery and aquaculture products in which the levels of environmental contaminants exceed the maximum limits indicated in Table 1 and Table 2 shall be regarded as unfit for human consumption and not placed or withdrawn from the market.

Table 1: Heavy Metals

Product	**Maximum Limit (ppm) For export to EU, USA and trade other markets**		
	Lead	**Cadmium**	**Mercury**
Muscle meat of all fish except where otherwise indicated below:	0.3	0.05	0.5
Little tuna (*Euthynnus* spp.) Marlin (*Makaira* spp.) Plain Bonito *(Orcynopsis unicolor)* Rays (*Raja* species) Tunas (*Thunnus* spp, and *Katsuwonus pelamis*.)		0.1	1.0
Kingfish Mullets (*Mullus* sp) Sail fish (*Istiophorus platypterus*) Shark and dogfish (all species) Snake mackerel (butterfish) *Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens)*			1.0
Bullet tuna *(Auxis species)*		0.2	
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

Product	**Maximum Limit (ppb) For export to US, EU and other trade markets**			
	Arsenic	**Lead**	**Cadmium**	**Mercury**
Muscle meat of all fish, crustaceans and molluscs.	200	25	10	200

Table 2: Other Environmental Contaminants

Dioxins and dioxin like PCBs(1) and (3)		
	Sum of dioxins (WHOPCDD/ F-TEQ)	Sum of dioxins and dioxin-like PCBs (WHOPCDD/ F-PCB-TEQ)
Muscle meat of fish and fishery products and products thereof, excluding eel. The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (*Nephropidae* and *Palinuridae*)	4,0 pg/g wet weight	8,0 pg/g wet weight
Muscle meat of eel (*Anguilla anguilla*)	4,0 pg/g wet weight	12,0 pg/g wet weight

Benzo(a)pyrene (2)	
Product	*Maximum levels (µg/kg wet weight)*
Muscle meat of smoked fish and smoked fishery products excluding bivalve molluscs. The maximum level applies to smoked crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (*Nephropidae* and *Palinuridae*)	5,0
Muscle meat of fish, other than smoked fish	2,0
Crustaceans, cephalopods, other than smoked. The maximum level applies to crustaceans, excluding the brown meat of crab and	5,0

excluding head and thorax meat of lobster and similar large crustaceans (*Nephropidae* and *Palinuridae*)	

(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). 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).

(2) Benzo(a)pyrene, for which maximum levels are listed, is used as a marker for the occurrence and effect of carcinogenic polycyclic aromatic hydrocarbons.

(3) Calculation of *Sum of dioxins (WHOPCDD/F-TEQ)* and *Sum of dioxins and dioxin-like PCBs (WHOPCDD/F-PCB-TEQ).*

Congener	TEF VALUE	Congener	TEF VALUE
Dibenzo-p-dioxins (PCDDs)		**Dioxin-like' PCBs Non-ortho PCBs + Mono-ortho PCBs**	
2,3,7,8-TCDD	1	*Non-ortho PCBs*	
1,2,3,7,8-PeCDD	1	PCB 77	0,0001
1,2,3,4,7,8-HxCDD	0,1	PCB 81	0,0001
1,2,3,6,7,8-HxCDD	0,1	PCB 126	0,1
1,2,3,7,8,9-HxCDD	0,1	PCB 169	0,01
1,2,3,4,6,7,8-HpCDD 0,01	0,01	*Mono-ortho PCBs*	
OCDD	0,0001	PCB 105	0,0001
Dibenzofurans (PCDFs)		PCB 114	0,0005
2,3,7,8-TCDF	0,1	PCB 118	0,0001
1,2,3,7,8-PeCDF	0,05	PCB 123	0,0001
2,3,4,7,8-PeCDF	0,5	PCB 156	0,0005
1,2,3,4,7,8-HxCDF	0,1	PCB 157	0,0005
1,2,3,6,7,8-HxCDF	0,1	PCB 167	0,00001
1,2,3,7,8,9-HxCDF	0,1	PCB 189	0,0001
2,3,4,6,7,8-HxCDF	0,1		
1,2,3,4,6,7,8-HpCDF	0,01		
1,2,3,4,7,8,9-HpCDF	0,01		
OCDF	0,0001		
Abbreviations used: 'T' = tetra; 'Pe' = penta; 'Hx' = hexa; 'Hp' = hepta; 'O' = octa; 'CDD' = chlorodibenzodioxin; 'CDF' = chlorodibenzofuran; 'CB' = chlorobiphenyl.			

PART II

DEFINITIONS

(1) A number of the most commonly used definitions in describing methods of sampling are given below:

(a)	Lot:	an identifiable quantity of food delivered at one time and determined by an official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings. In the case of fish, also the size of fish shall be comparable.
(b)	Sublot:	designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separated and identifiable.
(c)	Incremental sample:	a quantity of material taken from a single place in the lot or sublot.
(d)	Aggregate sample:	the combined total of all the incremental samples taken from the lot or sublot.
(e)	Laboratory sample:	sample intended for the laboratory

(2) A number of the most commonly used definitions that the laboratory will be required to use in establishing performance criteria for methods of analysis are given below:

(a)	r	repeatability, the value below which the absolute difference between two single test results obtained under repeatability conditions (i.e., same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95%) and hence $r = 2,8 \times S_r$.

(b)	S_r	**standard deviation, calculated from results generated under repeatability conditions.**
(c)	RSD_r	relative standard deviation, calculated from results generated under repeatability conditions [$(S_r / \bar{x}) \times 100$], where $\bar{x}$ is the average of results over all laboratories and samples.
(d)	R	reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardized test method), may be expected to lie within a certain probability (typically 95 %); $R = 2,8 \times S_R$.
(e)	S_R	standard deviation, calculated from results under reproducibility conditions.
(f)	RSD_R	relative standard deviation calculated from results generated under reproducibility conditions [$(S_R / \bar{x}) \times 100$]
(g)	$HORRAT_r$	the observed RSD_r divided by the RSD_r value estimated from the Horwitz equation using the assumption r = 0,66R
(h)	$HORRAT_R$	the observed RSD_R value divided by the RSD_R value calculated from the Horwitz equation ([a]).
(i)	LOD	Limit of Detection, smallest measured content from which it is possible to deduce the presence of the analyte with reasonable statistical certainty. The limit of detection is numerically equal to three times the standard deviation of the mean of blank determinations (n >20)
(j)	LOQ	Limit of Quantification, lowest content of the analyte which can be measured with reasonable statistical certainty. If both accuracy and precision are constant over a concentration range around the limit of detection, then the limit of quantification is numerically equal to six or ten times the standard deviation of the mean of blank determinations (n >20).
(k)	ų	Standard measurement uncertainty
(l)	U	The *expanded measurement uncertainty*, using a coverage factor of 2 which gives a level of confidence of approximately 95% (U= ų)
(m)	Uf	Maximum standard measurement uncertainty
(n)	Parametric values	The maximum or minimum level set for each individual parameter to be monitored.

PART III

METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE ENVIRONMTAL AND OTHER CONTAMINANTS IN FISHERY AND AQUACULTURE PRODUCTS

CHAPTER 1

GENERAL PROVISIONS FOR SAMPLING

1. Personnel

The Government of Guyana shall take all measures necessary to ensure that the sampling for the official control of the levels of lead, cadmium and mercury in fishery and aquaculture products is carried out in accordance with the methods described in this part of the Regulations.

2. Material to be sampled

Each lot or sublot that is to be examined must be sampled separately.

3. Precautions to be taken

In the course of sampling and preparation of laboratory samples, precautions must be taken to avoid any changes that would affect the content of the analyte adversely, affect the analytical determination or make the aggregate samples unrepresentative.

4. Incremental samples

As far as possible incremental samples shall be taken at various places distributed throughout the lot or sublot. The incremental samples shall be of similar weight and at least 100g. Departure from this procedure must be recorded in the record provided for under Chapter 1, Part III of this schedule.

5. Preparation of the aggregate sample

The aggregate sample is made up by uniting all incremental samples. The aggregate sample shall be at least 1 kg unless not practical,e.g. when a single package has been sampled.

6. Subdivision of aggregate sample into laboratory samples for enforcement, defence and referee purposes

The laboratory samples for enforcement, defence and referee purposes shall be taken from the homogenised aggregate sample. The size of the laboratory samples for enforcement shall be sufficient to allow at least for duplicate analyses.

7. Packaging and transport of aggregate and laboratory samples

Each aggregate and laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage in transit. All necessary precautions shall be taken to avoid change of composition of the aggregate and laboratory samples that might arise during transportation or storage.

8. Sealing and labelling of aggregate and laboratory samples

Each sample taken for official use shall be sealed at the place of sampling and identified following the national instructions. A record shall be kept of each sampling permitting each lot or sublot to be identified unambiguously (reference to the lot number shall be given) and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

CHAPTER 2

SAMPLING PLANS

1. Place of sampling

Sampling should ideally take place at the point where the commodity enters the food chain and a discrete lot becomes identifiable. The sampling method applied shall ensure that the aggregate sample is representative for the lot that is to be controlled.

2. Number of incremental samples

(1) (1) Large lots shall be divided into sublots on condition that the sublot may be separated physically. For products traded in bulk consignments (e.g. feed table 1 shall apply. For other products Table 2 shall apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20%.

(2) The minimum number of incremental samples to be taken from the lot shall be as given in Table 3. The incremental samples shall be of similar weight. Departure from this procedure must be recorded in the record provided for under Chapter 1, Point 8 of this Part.

Table 1: Subdivision of lots into sublots for products traded in bulk consignments

Weight of lot (tonnes)	**Weight or number of sublots**
≥ 1500	500 tonnes
>300 and <1500	3 sublots
≥100 and ≥300	100 tonnes
< 100	-

Table 2: Subdivision of lots into sublots for other products

Weight of lot (tonnes)	**Weight or number of sublots**
≥ 15	15-30 tonnes
<15	-

Table 3: Minimum number of incremental samples to be taken from the lot or sublot.

Weight of lot/sublot (kg)	Minimum number of incremental samples to be taken
< 50	3
≥50 and ≤500	5
> 500	10

(3) If the lot consists of individual packages, then the number of packages that shall be taken to form the aggregate sample is given in Table 4.

Table 4: Number of packages (incremental samples) which shall be taken to form the aggregate sample if the lot consists of individual packages.

Number of packages or units in the lot/sublot	Number of packages or units to be taken
1 to 25	1 package or unit
26 to 100	About 5 %, at least 2 packages or units
> 100	About 5 %, at maximum 10 packages or units

8. Specific sampling requirements for sampling of fish of different sizes

In case the lot to be sampled contains *small fishes* (individual fishes weighing < about 1 kg), the whole fish is taken as incremental sample to form the aggregate sample. In case the resulting aggregate sample weighs more than 3 kg, the incremental samples may consist of the *middle part,* weighing each at least 100 grams, of the fishes forming the aggregate sample. The whole part to which the maximum level is applicable is used for homogenization of the sample.

The middle part of the fish is where the centre of gravity is. This is located in most cases at the dorsal fin (in case the fish has a dorsal fin) or halfway between the gill opening and the anus.

In case the lot to be sampled contains larger fishes (individual fishes weighing more than about 1 kg), the incremental sample consists of the *middle part of the fish*. Each incremental sample weighs at least 100 grams.

For fishes *of intermediate size (about 1 to 6 kg)* the incremental sample is taken as a slice of the fish from backbone to belly in the middle part of the fish.

For *very large fishes (e.g. > about 6 kg),* the incremental part is taken from the right side (frontal view) dorsolateral muscle meat in the middle part of the fish. In case the taking of such a piece of the middle part of the fish would result in a significant economic damage, taking of three incremental samples of at least 350 grams each may be considered as being sufficient, independently of the size of the lot or alternatively an equal part of

the muscled meat close to the tail part and the muscle meat close to the head part of one fish may be taken to form the incremental sample being representative for the level of dioxins in the whole fish.

- If in a lot no particular size or weight class/category predominates, then the following sample procedure may be followed In case the size or weight of the fishes present in the batch differs more than 50 % but less than 100 %: Two separate representative samples are taken from each size or weight class/category within a batch.
- In case the size or weight of the fishes present in the batch differ more than 100%: Three separate representative samples are taken from each size or weight class/category within a batch

- In case the size or weight of the fishes

PART IV

SAMPLE PREPARATION AND PERFORMANCE CRITERIA FOR METHODS OF ANALYSIS USED IN OFFICIAL CONTROL OF THE LEVELS OF ENVIRONMENTAL AND OTHER CONTAMINANTS IN FISHERY AND AQUACULTURE PRODUCTS.

General requirements

The Government of Guyana shall take all measures necessary for sample preparation and methods of analyses used for the official control of the levels of lead, cadmium and mercury in fishery and aquaculture products to comply with the criteria described in this part of this Schedule.

CHAPTER 1

SPECIFIC SAMPLE PREPARATION PROCEDURES

1. Sample preparation procedures

There are many satisfactory specific sample preparation procedures which may be used for the products under consideration. Those described in the draft CEN Standard 'Foodstuffs — Determination of trace elements — Performance criteria and general consideration' have been found to be satisfactory but others may be equally valid.

The part of the animal selected for analysis shall always conform with the specification set in the criteria in Part I of this Schedule, i.e. muscle meat meaning muscle excl. skin and viscera.

All of the sample material received by the laboratory shall be used for the preparation of the laboratory sample. The complete aggregate sample shall be finely ground and thoroughly mixed using a process that has been demonstrated to achieve complete homogenization.

The analyst shall ensure that samples do not become contaminated during sample preparation. Wherever possible apparatus and equipment coming into contact with the samples shall not include any substances that may interfere

with the sample. This means specifically that

- for analysis of heavy metals, samples shall be in contact only with inert materials such as polypropylene, polytetrafluoroethylene etc., which are acid cleaned to minimize the risk of contamination. Metals of same type as to be analyzed shall be avoided.
- for analysis of benzo(a)pyrene, samples shall be in contact only inert materials such as aluminum, glass or polished stainless steel. Plastics shall be avoided. Containers shall be rinsed with high purity acetone or hexane before use to minimize the risk for contamination
- for analysis of dioxin and dioxin like PCB's, samples shall be stored and transported in glass, aluminum, polypropylene or polyethylene containers. Traces of paper dust shall not be present and the containers shall be rinsed with solvents certified free from dioxins or previously controlled for presence of dioxins.

CHAPTER 2

METHOD OF ANALYSIS AND ANALYTICAL PERFORMANCE CRITERIA FOR ANALYSIS OF HEAVY METALS AND BENZO(a)PYRENE

1. General requirements

Methods of analysis used for food control purposes must be in accordance with reliable, scientifically recognized methods.

2. Performance Criteria for the analytical test methods

Laboratories shall use a validated method that fulfils the performance criteria indicated in Table 5 or Table 6:

Table 5: Performance criteria for methods for lead, cadmium and mercury analysis.

Parameter	Value/comment
1) Applicability	*Fishery and aquaculture products.*
Limit of Detection	**For inorganic tin less than 5mg/kg** **Less than one tenth of the value of the criteria in Part I of this schedule, except if the value of the specification for lead is less than 0,1 mg/kg. For the latter, less than one fifth of the value of the specification.**

Limit of Quantification	For inorganic tin less than 10mg/kg Less than one fifth of the value of the criteria in Part I of this schedule except if the value of the specification for lead is less than 0,1 mg/kg. For the latter, no more than two fifths of the value of the specification.
Precision	$HORRAT_r$ or $HORRAT_R$ values of less than 2
Recovery	80-120 % (as indicated in the collaborative trial).
Specificity	Free from matrix or spectral interferences.

Table 6: Performance criteria for methods for benz(a)pyrene.

Parameter	**Value/comment**
2) Applicability	*Fishery and aquaculture products.*
Limit of Detection	**Less than 0,3µg/kg.**
Limit of Quantification	**Less than 0,9µg/kg.**
Precision	$HORRAT_r$ or $HORRAT_R$ values of less than 2
Recovery	50-120 % (as indicated in the collaborative trial).
Specificity	Free from matrix or spectral interferences. Verification of positive detection

3. Estimation of the analytical trueness and recovery calculations

Wherever possible the trueness of the analysis shall be estimated by including suitable certified reference materials in the analytical run.

The 'Harmonized Guidelines for the Use of Recovery Information in Analytical Measurement' developed under the auspices of IUPAC/ISO/AOAC shall be taken into account.
The analytical result shall be reported as x +/- U, whereby x is the mean of the analytical result and U is the expanded measurement uncertainty as defined in PART II of this schedule. The recovery shall also be reported for each analytical parameter.

4. Laboratory quality standards

In accordance with the provisions of regulation 35 of these Regulations, laboratories shall be accredited by a recognized body operating in accordance with ISO Guide 58 to ensure that they are applying analytical quality assurance. Laboratories shall be accredited following the EN ISO/IEC 17025 standard.

5. Expression of results

The results shall be expressed in the same units as the maximum levels laid down in Part I of this Schedule.

CHAPTER 3

METHOD OF ANALYSIS AND ANALYTICAL PERFORMANCE CRITERIA FOR ANALYSIS OF DIOXIN AND DIOXIN LIKE PCB'S

Monitoring for the presence of dioxins in foodstuffs may be performed by a strategy involving a screening method in order to select those samples with levels of dioxins and dioxin-like PCBs that are less than 25 % below or exceed the maximum level. The concentration of dioxins and sum of dioxins and dioxin-like PCBs in those samples with significant levels needs to be determined or confirmed by a confirmatory method.

Screening methods are methods that are used to detect the presence of dioxins and dioxin-like PCBs at the level of interest. These methods shall have a capacity for a high sample throughput and are used to sift large numbers of samples for potential positives. They shall be specifically designed to avoid false negatives.

Confirmatory methods are methods that provide full or complementary information enabling the dioxins and dioxin-like PCBs to be identified and quantified unequivocally at the level of interest.

Laboratories shall demonstrate the performance of a method in the range of the level of interest, e.g. 0,5x, 1xand 2x the level of interest with an acceptable coefficient of variation for repeated analysis. For details of acceptance criteria, see Table 7.

Limit of quantification for a confirmatory method shall be in the range of about one fifth of the level of interest.

Regular blank controls and spiking experiments or analysis of control samples (preferably, if available, certified reference material) shall be performed as internal quality control measures.

Laboratory proficiency shall be proved by the continuous successful participation in inter laboratory studies for the determination of dioxins and dioxin-like PCBs in the relevant feed/food matrices.

In accordance with the provisions of regulation 35, laboratories shall be accredited by a recognised body operating in accordance with ISO Guide 58 to ensure that they are applying analytical quality assurance.

Laboratories shall be accredited following the EN ISO/IEC 17025 standard.

Screening methods may comprise bioassays via Gas chromatography, Atomic Absorption Spectrometry; confirmatory methods are high-resolution gas chromatography or high resolution mass spectrometry or any other appropriate methods.

Table 6 Performance Criteria for analytical methods for dioxin and dioxin like substances on total TEQ value

	Screening methods	Confirmatory Methods
False negative rate	< 1 %	
Trueness		– 20 % to + 20 %
Precision ($RSD_{R)}$	< 30 %	< 15 %

PART V

CHAPTER 1

COMPLIANCE OF THE LOT OR SUBLOT WITH THE CRITERIA FOR HEAVY METALS AND BENZO(a)PYRENE

3. Laboratory sample for enforcement

The control laboratory shall analyze the laboratory sample for enforcement at least in two independent analyses,

and calculate the mean and uncertainty of the results.

4. Accepted and rejected lot

The lot is accepted if the mean does not exceed the respective maximum level as laid down in Part I of this Schedule, taking into the account the expanded measurement uncertainty and recovery factor as defined in PART II of this schedule.

The lot is rejected if the mean exceeds the respective maximum level taking into account the expanded measurement uncertainty and recovery factor as defined in PART II of this schedule.

CHAPTER 2

COMPLIANCE OF THE LOT OR SUBLOT WITH THE CRITERIA FOR DIOXIN AND DIOXIN LIKE SUBSTANCES

The concentrations of the individual substances in a given sample shall be multiplied by their respective Toxic Equivalency Factor (TEF), as established by the World Health Organization and listed in Part I of this Schedule, and subsequently summed to give the total concentration of dioxin-like compounds expressed as Toxic Equivalents (TEQs).

The lot is accepted if the analytical result of a single analysis does not exceed the respective maximum level of dioxins and the sum of dioxins and dioxin-like PCBs as laid down in Part I of this Schedule taking into account the expanded uncertainty (U) as defined in Part II of this Schedule.

A lot or sublot is non-compliant if the measured value minus the expanded uncertainty (U) is above the established permitted level.

In case of a separate determination of dioxins and dioxin-like-PCBs the sum of the estimated expanded uncertainty of the separate analytical results of dioxins and dioxin-like PCBs has to be used for the sum of dioxins and dioxin-like PCBs.

SCHEDULE FIVE **Regs, 2,30,96, 98,99,100**

This Schedule lays down the microbiological, chemical, organoleptic, physio – chemical and biological quality and safety parameters with values and limits, monitoring procedures, minimum frequency of sampling and analyses, specifications for analysis and sampling methods for potable water, provided for in regulations 96 to 100 of these Regulations.

PART I

PARAMETERS AND PARAMETRIC VALUES

Chapter 1

Microbiological Parameters

Parameter	**Parametric value (number/100 ml)**
Escherichia coli (E. coli)	0
Enterococci	0

Chapter 2

Chemical Parameters

Parameter	**Parametric value**	**Unit**	**Notes**
Acrylamide	0,10	*µg*/1	Note 1
Antimony	5,0	*µg*/1	
Arsenic	10	*µg*/1	
Benzene	1,0	*µg*/1	
Benzo(a)pyrene	0,010	*µg*/1	
Boron	1,0	mg/1	
Bromate	10	*µg*/1	Note 2
Cadmium	5,0	*µg*/1	

Chromium	50	*µg*/1	
Copper	2,0	mg/1	Note 3
Cyanide	50	*µg*/1	
1,2-dichloroethane	3,0	*µg*/1	
Epichlorohydrin	0,10	*µg*/1	Note 1
Fluoride	1,5	mg/1	
Lead	10	*µg*/1	Note 3 and 4
Mercury	1,0	*µg*/1	
Nickel	20	*µg*/1	Note 3
Nitrate	50	mg/1	Note 5
Nitrite	0,50	mg/1	Note 5
Pesticides	0,10	*µg*/1	Note 6 and 7
Pesticides – Total	0,50	*µg*/1	Note 6 and 8
Polycyclic aromatic hydrocarbons	0,10	*µg*/1	Sum of concentrations of specified compounds; Note 9
Selenium	10	*µg*/1	Sum of concentrations of specified parameters
Tetrachloroethene and Trichloroethene	10	*µg*/1	Sum of concentrations of specified compounds; Note 10
Trihalomethanes – Total	100	*µg*/1	
Vinyl chloride	0,50	*µg*/1	Note 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, The Government of Guyana should strive for a lower value.

Note 3: The value applies to a sample of water intended for fishery product activities obtained by an adequate sampling method at the tap and taken so as to be representative of a weekly average value. Where appropriate the sampling and monitoring methods must be applied in a harmonised

fashion. The Government of Guyana must take into account the occurrence of peak levels that may cause adverse effects on human health.

Note 4: The Government of Guyana must ensure that all appropriate measures are taken to reduce the concentration of lead in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value.

When implementing the measures to achieve compliance with that parametric value, The Government of Guyana must progressively give priority where lead concentrations in water intended for human consumption are highest.

Note 5: The Government of Guyana must ensure that the condition that [nitrate]/50 + [nitrite]/3 ≤ 1, the square brackets signifying the concentrations in mg/1 for nitrate (NO_3) and nitrite (NO_2), is complied with and that the value of 0,10 mg/1 for nitrites is complied with ex water treatment works.

Note 6: '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 that are likely to be present in a given water supply need to be monitored.

Note 7: The parametric value applies to each individual pesticide. In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide the parameter value is 0,030 μg/1.

Note 8: 'Pesticides – Total' means the sum of all individual pesticides detected and quantified in the monitoring procedure.

Note 9: The specified compounds are:

- benzo(b)fluoranthene,
- benzo(k)fluoranthene
- benzo(ghi)perylene
- indeno(1,2,3-cd)pyrene

Note 10: Where possible, without compromising disinfection, The Government of Guyana should strive for a lower value.

The specified compounds are:

chloroform, bromoform, dibromochloromethane, bromodichloromethane.

The Government of Guyana must ensure that all appropriate measures are taken to reduce the concentration of THMs (Trihalomethanes) in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value.

When implementing the measures to achieve this value, The Government of Guyana must progressively give priority to those areas where THM (Trihalomethane) compounds in water intended for human consumption are highest.

Chapter 3

Indicator Parameters

Parameter	**Parametric value**	**Unit**	**Notes**
Aluminium	200	µg/1	
Ammonium	0,50	mg/1	
Chloride	250	mg/1	Note 1
Clostridium perfringens (including spores)	0	number/100 ml	Note 2
Colour	Acceptable to consumers and no abnormal change		
Conductivity	2 500	µS cm $^{-1}$ at 20^{o} C	Note 1
Hydrogen ion concentration	≥ 6,5 and ≤ 9,5		Notes 1 and 3
Iron	200	µg/1	
Manganese	50	µg/1	

Odour	Acceptable to consumers and no abnormal change		
Oxidisability	5,0	mg/1 O_2	Note 4
Sulphate	250	mg/1	Note 1
Sodium	200	mg/1	
Taste	Acceptable to consumers and no abnormal change		
Colony count 22°	No abnormal change		
Coliform bacteria	0	number/100 ml	Note 5
Total organic carbon (TOC)	No abnormal change		Note 6
Turbidity	Acceptable to consumers and no abnormal change		Note 7

RADIOACTIVITY

Parameter	Parametric value	Unit	Notes
Tritium	100	Bq/1	Notes 8 and 10
Total indicative dose	0,10	mSv/year	Notes 9 and 10

Note 1: The water should not be aggressive.

Note 2: This parameter need not be measured unless the water originates from or is influenced by surface water. In the event of non-compliance with this parametric value, The Government of Guyana must investigate the supply to ensure that there is no potential danger to human health arising from the presence of pathogenic micro-organisms, e.g. cryptosporidium.

Note 3: For still water put into bottles or containers, the minimum value may be reduced to 4,5 pH units.

For water put into bottles or containers which is naturally rich in or artificially enriched with carbon dioxide, the minimum value may be lower.

Note 4: This parameter need not be measured if the parameter TOC is analysed.

Note 5: For water put into bottles or containers the unit is number/250 ml.

Note 6: This parameter need not be measured for supplies of less than 10 000 m^3 a day.

Note 7: In the case of surface water treatment, The Government of Guyana should strive for a parametric value not exceeding 1,0 NTU (nephelometric turbidity units) in the water ex treatment works.

Note 8: Monitoring frequencies to be set later in Annex II.

Note 9: Excluding tritium, potassium –40, radon and radon decay products; monitoring frequencies, monitoring methods and the most relevant locations for monitoring points to be set later in Annex II.

Note 10: The Government of Guyana is not required to monitor drinking water for tritium or radioactivity to establish total indicative dose where it is satisfied that, on the basis of other monitoring carried out, the levels of tritium of the calculated total indicative dose are well below the parametric value.

PART II

MONITORING

TABLE 1

Parameters to be analysed

1. Check monitoring

The purpose of check monitoring is regularly to provide information on the organoleptic and microbiological quality of the water supplied for human consumption as well as information on the effectiveness of drinking-water treatment (particularly of disinfection) where it is used, in order to determine whether or not water intended for human consumption complies with the relevant parametric values laid down in this Schedule.

The following parameters must be subject to check monitoring. The Competent Authority may add other parameters to this list if they deem it appropriate.

Aluminium (Note 1)

Ammonium

Clostridium perfringens (including spores) (Note 2)

Colour

Conductivity

Escherichia coli (E. coli)

Hydrogen ion concentration

Iron (Note 1)

Nitrite (Note 3)

Odour

Pseudomonas aeruginosa (Note 4)

Taste

Colony count 22 ºC and 37 ºC (Note 4)

Coliform bacteria

Turbidity

Note 1: Necessary only when used as flocculant (*).

Note 2: Necessary only if the water originates from or is influenced by surface water (*).

Note 3: Necessary only when chloramination is used as a disinfectant (*).

Note 4: Necessary only in the case of water offered for sale in bottles or containers.

(*) In all cases, the parameters are in the list for audit monitoring.

2. Audit monitoring

The purpose of audit monitoring is to provide the information necessary to determine whether or not all the parametric values laid down in this Schedule are being complied with. All parameters set in accordance with regulation 97, (1) and (3) must be subject to audit monitoring unless it can be established by the Competent Authority, for a period of time to be determined, that a parameter is not likely to be present in a given supply in concentrations which could lead to the risk of a breach of the relevant parametric value. This paragraph does not apply to the parameters for radioactivity, which, subject to Notes 8, 9 and 10 in Part I Chapter 3 of this Schedule will be monitored in accordance with monitoring requirements adopted laid down later.

TABLE 2

Minimum frequency of sampling and analyses for water intended for human consumption supplied from a distribution network or from a tanker or used in a food-production undertaking.

The Government of Guyana must take samples at the points of compliance as defined in regulation 97 (5) to ensure that water intended for human consumption meets the requirements of these Regulations. However, in the case of a distribution network, the authority may take samples within the supply zone or at the treatment works for particular parameters if it can be demonstrated that there would be no adverse change to the measured value of the parameters concerned.

Volume of water distributed or produced each day within a supply zone. **(Notes 1 and 2)** **m^3**	**Check monitoring number of samples per year.** **(Notes 3, 4 and 5)**	**Audit monitoring number of samples per year.** **(Notes 3 and 5)**
≤ 100	(Note 6)	(Note 6)
> 100 ≤ 1 000	4	1
> 1 000 ≤ 10 000	4 + 3 for each 1 000 m^3/d and part thereof of the total volume	1 + 1 for each 3 300 m^3/d and part thereof of the total volume
> 10 000 ≤ 100 000		3 + 1 for each 10 000 m^3/d and part thereof of the total volume
> 100 000		10 + 1 for each 25 000 m^3/d and part thereof of the total volume

Note 1: A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and within which water quality may be considered as being approximately uniform.

Note 2: The volumes are calculated as average taken over a calendar year. The Government of Guyana may use the number of inhabitants in a supply zone instead of the volume of water to determine the minimum frequency, assuming a water consumption of 200 l/day/capita.

Note 3: In the event of intermittent short-term supply the monitoring frequency of water distributed by tankers is to be decided by The Government of Guyana.

Note 4: For the different parameters in Part I, The Government of Guyana may reduce the number of samples specified in the table if:

(a) the values of the results obtained from samples taken during a period of at least two successive years are constant and significantly better than the limits laid down in Annex I, and

(b) no factor is likely to cause a deterioration of the quality of the water.

The lowest frequency applied must not be less than 50% of the number of samples specified in the table except in the particular case of Note 6.

Note 5: As far as possible, the number of samples should be distributed equally in time and location.

Note 6: The frequency is to be decided by Government of Guyana.

PART III

SPECIFICATIONS FOR THE ANALYSIS OF PARAMETERS

The Government of Guyana must ensure that any laboratory at which samples are analysed has a system of analytical quality control that is subject from time to time to checking by a person who is not under the control of the laboratory and who is approved by the Competent Authority for that purpose.

Chapter 1

1. Parameters for which methods of analysis are specified

The following principles for methods of microbiological parameters are given either for reference whenever a CEN/ISO method is given or for guidance of further CEN/ISO international methods for these parameters. The Government of Guyana may use alternative methods, providing the provisions of regulation 100 are met.

Coliform bacteria and *Escherichia coli (E. coli)* (ISO 9308-1)

Enterococci (ISO 7899-2)

Pseudomonas aeruginosa (prEN ISO 12780)

Enumeration of culturable micro-organisms – Colony count 22 ºC

(prEN ISO 6222)

Enumeration of culturable micro-organisms – Colony count 37 °C

(prEN ISO 6222)

Clostridium perfringens (including spores)

Membrane filtration followed by anaerobic incubation of the membrane on m-CP agar (Note 1) at 44 ± 1 °C for 21 ± 3 hours. Count opaque yellow colonies that run pink or red after exposure to ammonium hydroxide vapours for 20 to 30 seconds.

Note 1: The composition of m-CP agar is:

Basal medium

Tryptose	30g
Yeast extract	20g
Sucrose	5g
L-cysteine hydrochloride	1g
$MgSO_4 \cdot 7H_2O$	0,1g
Bromocresol purple	40g
Agar	1.5g
Water	1 000g

Dissolve the ingredients of the basal medium, adjust pH to 7,6 and autoclave at 121 °C for 15 minutes. Allow the medium to cool and add the following supplements after being sterilised through membrane filter of pores diameter of 0.20 μm:

D-cycloserine	400mg
Polymyxine-B sulphate	25mg
Indoxyl-β-D-glucose	60mg

to be dissolved in 8 ml sterile water before addition

Filter – sterilised 0,5% phenolphthalein diphosphate solution	20ml
Filter – sterilised 4,5 % $FeCl_3 \cdot 6H_2O1$	2ml

Chapter 2

2. Parameters for which performance characteristics are specified

2.1 For the following parameters, the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness, precision and limit of detection specified. Whatever the sensitivity of the method of analysis used, the result must be expressed using at least the same number of decimals as for the parametric value considered in Annex I, Parts B and C.

Parameters	Trueness % of parametric value (Note 1)	Precision % of parametric value (Note 2)	Limit of detection % of parametric value (Note 3)	Conditions	Notes
Acrylamide				To be controlled by-product specification	
Aluminium	10	10	10		
Ammonium	10	10	10		
Antimony	25	25	25		
Arsenic	10	10	10		
Benzo(a)pyrene	25	25	25		
Benzene	25	25	25		
Boron	10	10	10		
Bromate	25	25	25		
Cadmium	10	10	10		
Chloride	10	10	10		
Chromium	10	10	10		
Conductivity	10	10	10		
Copper	10	10	10		
Cyanide	10	10	10		Note 4

1,2-dichloroethane	25	25	10		
Epichlorohydrin				To be controlled by-product specification	
Fluoride	10	10	10		
Iron	10	10	10		
Lead	10	10	10		
Manganese	10	10	10		
Mercury	20	10	20		
Nickel	10	10	10		
Nitrate	10	10	10		
Nitrite	10	10	10		
Oxidisability	25	25	10		Note 5
Pesticides	25	25	25		Note 6
Polycyclic aromatic hydrocarbons	25	25	25		Note 7
Selenium	10	10	10		
Sodium	10	10	10		
Sulphate	10	10	10		
Tetrachloroethene	25	25	10		Note 8
Trichloroethene	25	25	10		Note 8
Trihalomethanes – Total	25	25	10		Note 7
Vinyl chloride				To be controlled by-product specification	

2.2 For hydrogen ion concentration the specified performance characteristics are that the method of analysis used must be capable of measuring concentrations equal to the parametric value with a trueness of 0,2 pH unit and a precision of 0,2 pH unit.

Note 1 (*): Trueness is the systematic error and is the difference between the mean value of the large number of repeated measurements and the true value.

Note 2 (*): Precision is the random error and is usually expressed as the standard deviation (within and between batch) of the spread of results about the mean. Acceptable precision is twice the relative standard deviation.

(*) These terms are further defined in ISO 5725

Note 3: Limit of detection is either:

- three times the relative within batch standard deviation of a natural sample containing a low concentration of the parameter,
  or
- five times the relative within batch standard deviation of a blank sample.

Note 4: The method should determine total cyanide in all forms.

Note 5: Oxidation should be carried out for 10 minutes at 100 °C under acid conditions using permanganate.

Note 6: The performance characteristics apply to the individual pesticide and will depend on the pesticide concerned. The limit of detection may not be achievable for all pesticides at present, but the Government of Guyana should strive to achieve this standard.

Note 7: The performance characteristics apply to the individual substances specified at 2.5% of the parametric value in Annex I.

Note 8: The performance characteristics apply to the individual substances specified at 50% of the parametric value in Annex I.

Chapter 3

3. Parameters for which no method of analysis is specified

Colour

Odour

Taste

Total organic carbon

Turbidity (Note 1)

Note 1: For turbidity monitoring in treated surface water the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness of 2.5%, precision of 2.5% and a 2.5% limit of detection.

PART II

MONITORING

TABLE 1

Parameters to be analysed

3. Check monitoring

The purpose of check monitoring is regularly to provide information on the organoleptic and microbiological quality of the water supplied for human consumption as well as information on the effectiveness of drinking-water treatment (particularly of disinfection) where it is used, in order to determine whether or not water intended for human consumption complies with the relevant parametric values laid down in this Schedule.

The following parameters must be subject to check monitoring. The Competent Authority may add other parameters to this list if they deem it appropriate.

Aluminium (Note 1)

Ammonium

Clostridium perfringens (including spores) (Note 2)

Colour

Conductivity

Escherichia coli (E. coli)

Hydrogen ion concentration

Iron (Note 1)

Nitrite (Note 3)

Odour

Pseudomonas aeruginosa (Note 4)

Taste

Colony count 22 ºC and 37 ºC (Note 4)

Coliform bacteria

Turbidity

Note 1: Necessary only when used as flocculant (*).

Note 2: Necessary only if the water originates from or is influenced by surface water (*).

Note 3: Necessary only when chloramination is used as a disinfectant (*).

Note 4: Necessary only in the case of water offered for sale in bottles or containers.

(*) In all cases, the parameters are in the list for audit monitoring.

4. Audit monitoring

The purpose of audit monitoring is to provide the information necessary to determine whether or not all the parametric values laid down in this Schedule are being complied with. All parameters set in accordance with regulation 97 (1) and (3) must be subject to audit monitoring unless it can be established by the Competent Authority, for a period of time to be determined, that a parameter is not likely to be present in a given supply in concentrations which could lead to the risk of a breach of the relevant parametric value. This paragraph does not apply to the parameters for radioactivity, which, subject to Notes 8, 9 and 10 in Part I Chapter 3 of this Schedule will be monitored in accordance with monitoring requirements adopted laid down later.

TABLE 2

Minimum frequency of sampling and analyses for water intended for human consumption supplied from a distribution network or from a tanker or used in a food-production undertaking.

The Government of Guyana must take samples at the points of compliance as defined in regulation 97(5) to ensure that water intended for human consumption meets the requirements of these Regulations. However, in the case of a distribution network, the authority may take samples within the supply zone or at the treatment works for particular parameters if it can be demonstrated that there would be no adverse change to the measured value of the parameters concerned.

Volume of water distributed or produced each day within a supply zone. **(Notes 1 and 2)** **m^3**	**Check monitoring number of samples per year.** **(Notes 3, 4 and 5)**	**Audit monitoring number of samples per year.** **(Notes 3 and 5)**

≤ 100	(Note 6)	(Note 6)
> 100 ≤ 1 000	4	1
> 1 000 ≤ 10 000	4 + 3 for each 1 000 m^3/d and part thereof of the total volume	1 + 1 for each 3 300 m^3/d and part thereof of the total volume
> 10 000 ≤ 100 000		3 + 1 for each 10 000 m^3/d and part thereof of the total volume
> 100 000		10 + 1 for each 25 000 m^3/d and part thereof of the total volume

Note 1: A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and within which water quality may be considered as being approximately uniform.

Note 2: The volumes are calculated as average taken over a calendar year. The Government of Guyana may use the number of inhabitants in a supply zone instead of the volume of water to determine the minimum frequency, assuming a water consumption of 200 l/day/capita.

Note 3: In the event of intermittent short-term supply the monitoring frequency of water distributed by tankers is to be decided by The Government of Guyana.

Note 4: For the different parameters in Part I, The Government of Guyana may reduce the number of samples specified in the table if:

(c) the values of the results obtained from samples taken during a period of at least two successive years are constant and significantly better than the limits laid down in Annex I, and

(d) no factor is likely to cause a deterioration of the quality of the water.

The lowest frequency applied must not be less than 50% of the number of samples specified in the table except in the particular case of Note 6.

Note 5: As far as possible, the number of samples should be distributed equally in time and location.

Note 6: The frequency is to be decided by Government of Guyana.

PART III

SPECIFICATIONS FOR THE ANALYSIS OF PARAMETERS

The Government of Guyana must ensure that any laboratory at which samples are analysed has a system of analytical quality control that is subject from time to time to checking by a person who is not under the control of the laboratory and who is approved by the Competent Authority for that purpose.

Chapter 1

4. Parameters for which methods of analysis are specified

The following principles for methods of microbiological parameters are given either for reference whenever a CEN/ISO method is given or for guidance of further CEN/ISO international methods for these parameters. The Government of Guyana may use alternative methods, providing the provisions of regulation 100 are met.

Coliform bacteria and *Escherichia coli (E. coli)* (ISO 9308-1)

Enterococci (ISO 7899-2)

Pseudomonas aeruginosa (prEN ISO 12780)

Enumeration of culturable micro-organisms – Colony count 22 ºC

(prEN ISO 6222)

Enumeration of culturable micro-organisms – Colony count 37 ºC

(prEN ISO 6222)

Clostridium perfringens (including spores)

Membrane filtration followed by anaerobic incubation of the membrane on m-CP agar (Note 1) at 44 ± 1 ºC for 21 ± 3 hours. Count opaque yellow colonies that run pink or red after exposure to ammonium hydroxide vapours for 20 to 30 seconds.

Note 1: The composition of m-CP agar is:

Basal medium

Tryptose	30g
Yeast extract	20g
Sucrose	5g
L-cysteine hydrochloride	1g
$MgSO_4 \cdot 7H_2O$	0,1g
Bromocresol purple	40g
Agar	1.5g
Water	1 000g

Dissolve the ingredients of the basal medium, adjust pH to 7,6 and autoclave at 121 °C for 15 minutes. Allow the medium to cool and add the following supplements after being sterilised through membrane filter of pores diameter of 0.20 μm:

D-cycloserine	400mg
Polymyxine-B sulphate	25mg
Indoxyl-β-D-glucose	60mg
to be dissolved in 8 ml sterile water before addition	
Filter – sterilised 0,5% phenolphthalein diphosphate solution	20ml
Filter – sterilised 4,5 % $FeCl_3 \cdot 6H_2O1$	2ml

Chapter 2

5. Parameters for which performance characteristics are specified

5.1 For the following parameters, the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with trueness, precision and limit of detection specified. Whatever the sensitivity of the method of analysis used, the result must be expressed using at least the same number of decimals as for the parametric value considered in Annex I, Parts B and C.

Parameters	Trueness % of parametric value (Note 1)	Precision % of parametric value (Note 2)	Limit of detection % of parametric value (Note 3)	Conditions	Notes
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Aluminium	10	10	10		
Ammonium	10	10	10		
Antimony	25	25	25		
Arsenic	10	10	10		
Benzo(a)pyrene	25	25	25		
Benzene	25	25	25		
Boron	10	10	10		
Bromate	25	25	25		
Cadmium	10	10	10		
Chloride	10	10	10		
Chromium	10	10	10		
Conductivity	10	10	10		
Copper	10	10	10		
Cyanide	10	10	10		Note 4
1,2-dichloroethane	25	25	10		
Epichlorohydrin				To be controlled by-product specification	
Fluoride	10	10	10		
Iron	10	10	10		
Lead	10	10	10		
Manganese	10	10	10		
Mercury	20	10	20		

Nickel	10	10	10		
Nitrate	10	10	10		
Nitrite	10	10	10		
Oxidisability	25	25	10		Note 5
Pesticides	25	25	25		Note 6
Polycyclic aromatic hydrocarbons	25	25	25		Note 7
Selenium	10	10	10		
Sodium	10	10	10		
Sulphate	10	10	10		
Tetrachloroethene	25	25	10		Note 8
Trichloroethene	25	25	10		Note 8
Trihalomethanes – Total	25	25	10		Note 7
Vinyl chloride				To be controlled by-product specification	

5.2 For hydrogen ion concentration the specified performance characteristics are that the method of analysis used must be capable of measuring concentrations equal to the parametric value with a trueness of 0,2 pH unit and a precision of 0,2 pH unit.

Note 1 (*): Trueness is the systematic error and is the difference between the mean value of the large number of repeated measurements and the true value.

Note 2 (*): Precision is the random error and is usually expressed as the standard deviation (within and between batch) of the spread of results about the mean. Acceptable precision is twice the relative standard deviation.

(*) These terms are further defined in ISO 5725

Note 3: Limit of detection is either:

- three times the relative within batch standard deviation of a natural sample containing a low concentration of the parameter,

or

- five times the relative within batch standard deviation of a blank sample.

Note 4: The method should determine total cyanide in all forms.

Note 5: Oxidation should be carried out for 10 minutes at 100 ºC under acid conditions using permanganate.

Note 6: The performance characteristics apply to the individual pesticide and will depend on the pesticide concerned. The limit of detection may not be achievable for all pesticides at present, but the Government of Guyana should strive to achieve this standard.

Note 7: The performance characteristics apply to the individual substances specified at 2.5% of the parametric value in Annex I.

Note 8: The performance characteristics apply to the individual substances specified at 50% of the parametric value in Annex I.

Chapter 3

6. Parameters for which no method of analysis is specified

Colour

Odour

Taste

Total organic carbon

Turbidity (Note 1)

Note 1: For turbidity monitoring in treated surface water the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness of 2.5%, precision of 2.5% and a 2.5% limit of detection.

PART IV

Method of Sampling of Water

(a) The sample shall be collected in asterile bottle.
The tap to be sampled shall be run for long enough to completely flush the pipe supplying the tap, and in any case for 2 – 3 minutes.

Before a water sample is drawn from the tap, the tip of the tap shall be flamed using spirit and water shall be allowed to flow for 5 minutes before collection.

In cases where the laboratory test is undertaken 3 hours or more after sampling, the bottles must be kept in ice.

If a sample is to be taken from a chlorinated water supply, any trace of chlorine shall be neutralised immediately after collection. A crystal of sodium thiosulphate or 0,1ml of 2% solution of sodium thiosulphate introduced into the sampling bottle prior to sterilisation serves to neutralise the chlorine.

(b) The samples shall be taken from various outlets identified on the reticulation map. A rotation is organised between the identified outlets from which the water is in contact with the product.
Ice shall also be regularly tested.

(c) The result of the examination shall have the identification of the outlet where the sample is collected.

SCHEDULE SIX **Reg. 111**

This Schedule lays down Freshness Rating Tables for White Bony Fish, Bluefish, Selachii, Cephalopods, and Crustaceans provided for in regulation 111.

Freshness Rating Tables for:

(1) White Bony Fish

	Freshness category			
Criteria	**Extra**	**A**	**B**	**Not permitted[1]**
Skin	Bright, iridescent pigment (save for redfish) or opalescent. No discoloration	Pigmentation bright but not lustrous	Pigmentation in the process of becoming discoloured and dull	Dull pigmentation
Skin mucus	Aqueous transparent	Slightly cloudy	Milky	Yellowish grey, opaque
Eye	Convex (bulging), black, bright pupil, transparent cornea	Convex and slightly sunken, black dull pupil, slightly opalescent cornea	Flat, opalescent cornea, opaque pupil	Concave in the center, grey pupil, milky cornea (2)
Gills	Bright colour, no mucus	Less coloured, transparent mucus	Brow/grey, be-coming discoloured thick opaque mucus	Yellowish, milky mucus[2]
Peritoneum (gutted fish)	Smooth, bright, difficult to detach from flesh	Slightly dull, can be detached from flesh	Speckled, comes away easily from flesh	Does not stick[2]
Smell of gills	Seaweedy	Not smell of seaweed	Fermented, slightly sour	Sour[2]

and abdominal cavity				
Flesh	Firm and elastic, smooth surface[3]	Less elastic	Slightly soft (flaccid), less elastic waxy (velvety) and dull surface	Soft (flaccid) 2, scales easily de-tached from skin, surface rather wrinkled

(2) Bluefish, Albacore or Longfinned tuna, Bigeye tuna, Mackerel

	Freshness category			
Criteria	**Extra**	**A**	**B**	**Not permitted[1]**
Skin	Bright pigmentation, bright shining irridescent colours, Clear distinction between dorsal and central surfaces	Loss of lustre and shine, duller colours, less difference between surface	Dull, lustreless, inspided colours, skin creased when fish curved	Very dull pigmentation
Skin mucus	Aqueous transparent	Slightly cloudy	Milky	Yellowish grey, opaque[5]
Consistency of flesh	Very firm, rigid	Fairly rigid, firm	Slightly soft	Soft (flaccid)[5]
Gills covers	Silvery	Silvery, slightly red or brown	Brownish and extensive seepage of blood from vessels	Yellowish[5]
Eye	Convex (bulging), blue, black, bright pupil	Convex and slightly sunken, dark pupil, slightly	Flat, blurred pupil, blood seepage around the eye	Concave in the center, grey pupil, milky cornea[5]

	transparent "eyelid"	opalescent cornea		
Smell of gills and abdominal cavity	Fresh seaweedy, pungent, iodine	Not smell of seaweed, neutral smell	Slightly sulphurous fatty smell, rancid bacon cuttings, or rotten fruit	Rotten sour[5]

a. Unfit for human consumption
b. Or in a more advanced state of decay
c. Fresh fish prior to the onset of rigor mortis will not be firm and elastic but will still be graded in category Extra
d. Unfit for human consumption
e. Or in a more advanced state of decay

(3) Selachii

	Freshness category			
Criteria	**Extra**	**A**	**B**	**Not permitted[1]**
Eye	Convex, and iridescent, small pupils	Convex and slightly sunken, loss of brightness and iridescent oval pupils	Flat, dull	Concave yellowish
Appearance	In rigor mortis or partially in rigor, small quantity of clear mucus present on skin	Beyond rigor stage, no mucus on skin and especially in mouth and gill openings	Some mucus in mouth and on gill openings, slightly flattened jaw	Large quantity of mucus in mouth and gill openings (2)
Smell	Seaweed smell	No smell or very slight stale but not ammonia smell	Slight ammonia, sour	Pungent ammonia smell (2)

[1] Unfit for human consumption [2] Or in a more advanced state of decay

(4) Cephalopods

	Freshness category		
Criteria	**Extra**	**A**	**B**
Skin	Bright pigmentation skin sticks to flesh	Dull pigmentation, skin sticks to flesh	Discoloured, easily detached from flesh
Flesh	Very firm, pearly White	Firm, chalky white	Slightly soft, pinkie white or slightly yellowish
Tentacles	Resistant to Removal	Resistant to removal	More easily removed
Smell	Fresh, seaweed	Slightly or no smell	Ink smell

(5) Crustaceans

(a) shrimps

	Freshness category	
Criteria	**Extra**	**A**
Minimum requirements	Surface of the shell: moist and shiny, flesh must be free from any foreign odour, shrimp must be free from sand, mucus or other foreign matter. Cephalothorax must stay attached to the body	The same as for extra
Shell	No melanosis, no red legs, Hepatopancreas intact	Red legs, hepatopancreas opened
Smell	Fresh seaweed, slightly sweet smell	No smell of seaweed, acidulous

(b) Lobster

	Freshness category		
Criteria	**Extra**	**A**	**B**
Shell	Bright pigmentation, no discoloration, Cephalothorax holds on the body	Dull pigmentation	Discoloured, Cephalothorax easily detached from tail
Flesh	Translucide	No longer trans-lucent but not discoloured	Opaque and dull in appearance
Eye and gills	Shiny black eyes, pink gills	Eyes dull and grey/ black, gills grayish	Gill dark grey
Smell	Characteristic mild shellfish smell	Loss of characteristic smell fish smell. No ammonia smell	Slightly sour

SCHEDULE SEVEN **Reg. 111**

This Schedule lays down the reference procedure for the determination of the concentration of volatile nitrogenous bases (TVB-N) in fish and fishery products provided for in regulation 111.

DETERMINATION OF THE CONCENTRATION OF VOLATILE NITROGENOUS BASES (TVB-N) IN FISH AND FISHERY PRODUCTS : A REFERENCE PROCEDURE

1. Purpose and area of application

This method describes a reference procedure for identifying the nitrogen concentration of volatile nitrogenous bases (Total – Volatile – Base N: TVB-N) in fish and fish products. This procedure is applicable to TVB-N concentrations from 5 mg/100 g at least 100 mg/100 g.

2. Definition

The TVB-N concentration is here understood to mean the nitrogen content of volatile nitrogenous bases determined by the procedure described. The concentration is stated in terms of mg/100 g.

3. Brief description

The volatile nitrogenous bases are extracted from a sample by a solution of 0.6 M perchloric acid. After alkalinsation the extract is submitted to steam distillation, and the volatile base components are absorbed by an acid receiver. The TVB-N concentration is determined by titration of the absorbed bases.

4. Chemicals

Unless otherwise indicated, reagent-grade chemicals should be used. The water used must be either distilled or demineralised and of at least the same purity. Unless indicated otherwise, a "solution" is to be understood as an aqueous solution.

4.1. Perchloric acid solution = 6 g/100 ml

4.2 Sodium hydroxide solution = 20 g/100 ml

4.3. Hydrochloric acid standard solution 0.05 mol/1 (0.05N)

Note : when using an automatic distillation apparatus, titration should take place with a hydrochloric acid standard solution 0.01 mol/0 (0.01 N)

4.4. Boric acid solution = 3 g/100 ml

4.5. Silicone anti-foaming agent

4.6. Phenolphtalein solution = 1 g/100 ml 95 % ethanol

4.7. Indicator solution (Tashiro Mixed Indicator)

2 g Methyl – red and 1 g Methylene – blue are dissolved in 1,000 ml 95 % ethanol

5. Instruments and accessories

5.1. A meat grinder to produce a sufficiently homogenous fish mince

5.2. High-speed blender with revolutions between 8,000 min –1 and 45,000 min –1

5.3. Fluted filter, diameter 150 mm, quick filtering

5.4. Burette, 5 ml, graduated to 0.01 ml

5.5. Apparatus for steam distillation

The apparatus must be able to regulate various amounts of steam and produce a constant amount of steam over a given period of time. It must ensure that during the addition of alkalising substances the resulting free bases cannot escape.

6. Execution

Warning: When working with perchloric acid, which is strongly corrosive, necessary caution and preventive measures should be taken.

The samples should; if at all possible, be prepared according to paragraph 6.1 as soon as possible after their arrival.

6.1. Preparation of the sample

The sample to be analyzed should be ground carefully by a meat grinder as described in paragraph 5.1 Exactly 10 g +-0.1 g of the ground sample are weighed in a suitable container, mixed with 90.0 ml perchloric acid solution as stated in paragraph 4.1, homogenized for two minutes with a blender as described in paragraph 5.2 and then filtered.

The extract thereby obtained can be kept for at least seven days at a temperature between approximately 2 deg. C and 6 deg. C.

6.2. Steam distillation

50.0 ml of the extract obtained according to paragraph 6.1 are put in an apparatus for steam distillation as described in paragraph 5.5. For a later check on sufficient alkalinization of the extract, several drops of phenolphthalein as specified in paragraph 4.6 are added. After adding a few drops silicone anti foaming agent 6.5 ml of sodium hydroxide solution as specified in paragraph 4.2 are added to extract, and steam distillation begins immediately.

The steam distillation is regulated so that around 100 ml of distillate are produced within 10 minutes. The distillation outflow tube is submerged in a receiver with 100 ml boric acid solution as specified in paragraph 4.4, to which three to five drops of the indicator solution as described in 4.7 have been added. After exactly 10 minutes, the distillation is ended. The distillation outflow tube is removed from the receiver and washed out with water. The volatile bases contained in the receiver solution are determined by titration with standard hydrochloric solution as specified in paragraph 4.3.

The pH of the endpoint should be 5.0+/-0.1.

6.3. Titration

Duplicate analyses are required. The applied method is correct if the difference of the duplicates is not higher than 2 mg/100g.

6.4. Blank

A blind test carried out as described in paragraph 6.2

Instead of the extract, 50.0 ml perchloric acid solution as specified in paragraph 4.1 are used.

7. Calculation of TVB-N

By titration of the receiver solution with hydrochloric acid as in 4.3, the TVB-N concentration is calculated with the following equation :

$$\text{TVB-N (expressed in mg/100 sample)} = \frac{(V1 - V0) \times 0.14 \times 2 \times 100}{M}$$

V1 = volume of 0.01 M hydrochloric acid solution in ml for sample

V0 = volume of 0.01 M hydrochloric acid solution in ml for blank

M = weight of sample in g.

Remarks :

1. Duplicate analyses are required. The applied method is correct if the difference between duplicates is not higher than 2 mg/100.
2. Check the equipment by distilling solutions of NH4Cl equivalent to 50 mg TVB-/100 g
3. Standard deviation of reproducibility SR = 1.20 mg/100 g
   Standard deviation of comparability SR = 2.50 mg/100 g

SCHEDULE EIGHT Reg. 230

This schedule lays down the Hazard Analysis Worksheet, provided for in regulation 230 to these Regulations.

Hazard Analysis Worksheet

Firm Name : _____ Product Description : _____
Firm Address : _____ Method of Storage and Distribution : _____
Intended Use and Consumer : _____

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/processing steps	Identify potential hazards Introduced, controlled or enhanced at this step (1)	Are any potential food-safety hazards significant? (Yes/No)	Justify your decisions for column 3	What preventative measures can be applied to prevent the significant hazards ?	Is this step a critical control point ? (Yes/No)
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				

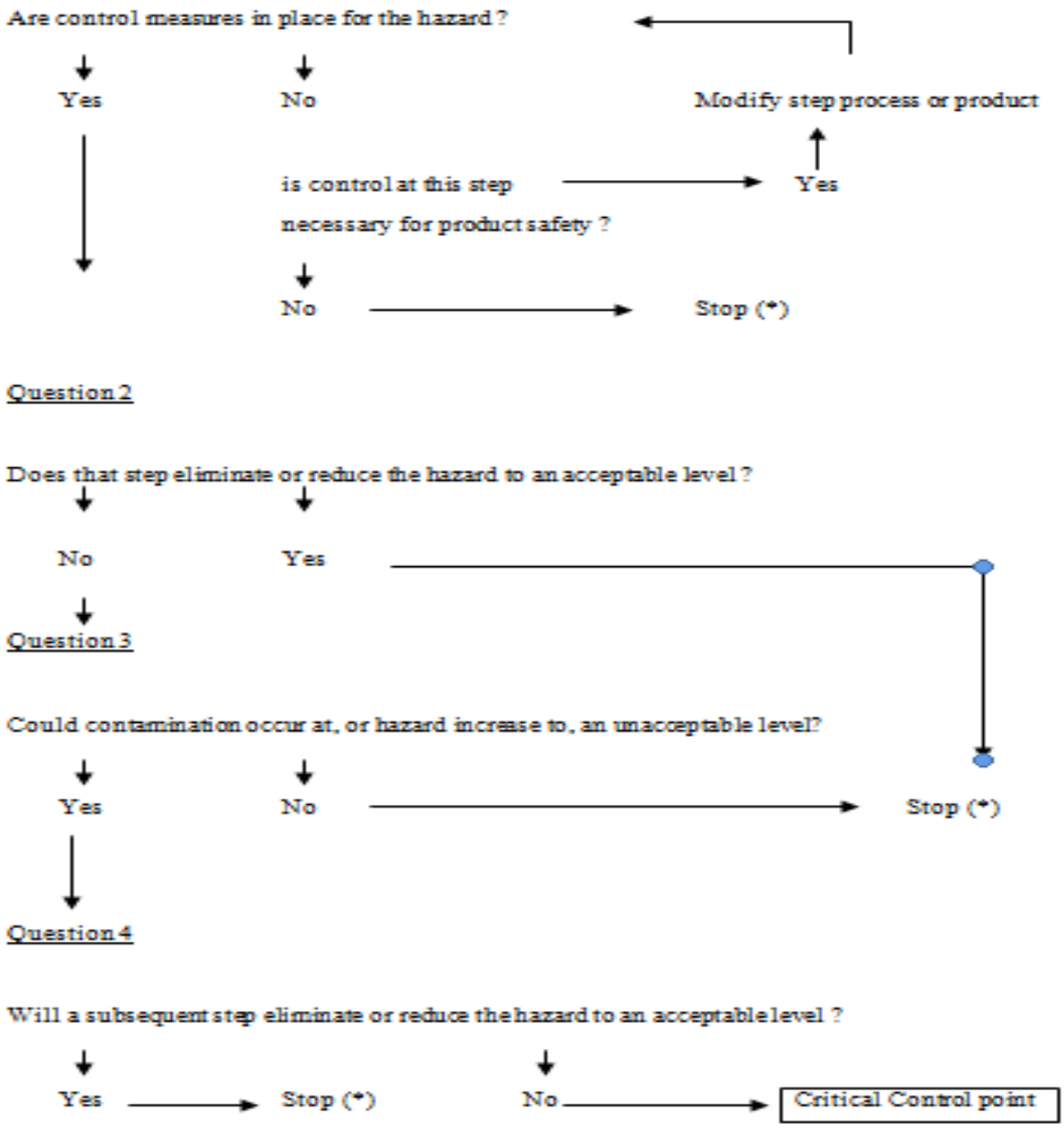
Signature of Company Official: _____ Date: _____

SCHEDULE NINE Reg. 230

This Schedule lays down the decision tree for the identification of critical points, provided for in regulation 230 (7) to these Regulations.

Decision tree for the identification of critical points

Answer each question in sequence, at each step and for identification of each hazard



(*) The step is not a critical control point. Proceed to next step.

SCHEDULE TEN **Reg. 232**

This schedule lays down the HACCP Plan Form, provided for in regulation 232 (1) to these Regulations.

HACCP Plan Form

Firm Name : _____
Firm Address : _____

Product Description :
_____
Method of Storage and distribution :
_____
Intended Use and Consumer :
_____

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	10
Critical Control Point (CCP)	Significant Hazards(s)	Critical Limits for each Preventive measure	Monitoring				Corrective action(s)	Records	Verification
			What	How	Frequency	Who			

Signature of Company Official: _____ Date: _____

SCHEDULE ELEVEN regs. 22 and 23

Official Control of residues of veterinary medical products and environmental contaminants in aquaculture animal products and marine species.

1. Random checks in the distribution chain

1. The Competent Authority in collaboration with the Veterinary Authority and the Authority as stipulated in the law relating to Aquaculture shall be responsible for implementing official controls to ensure compliance with these regulations.
2. The Competent Authority may ensure the undertaking of official random checks-
    a) at any point in the aquaculture animal feeding-stuffs production and distribution chain;
    b) throughout the production chain of aquaculture animal products covered by these Regulations.
3. The checks provided for in paragraph 1 must be conducted with a view to:
    a) detecting the application of an illegal treatment;
    b) detecting the residues of an authorised substance in excess of the limits established in Table 2 of this Schedule;
    c) detecting the levels of environmental contaminants listed in Schedule Four of this Regulation.
4. The checks provided for in chapter 1(2)(a) of this schedule in relation with fish feeding-stuffs imported into or produced in Guyana shall also include checks on compliance with any relevant standards for contaminants in feeds.
5. Samples taken by the Competent Authority for official controls must be-
    a) taken in accordance with chapter 5 of this Schedule;
    b) examined in an official laboratory.

2. National Residue Monitoring Plan and Report

The Competent Authority shall establish and implement a written annual residue monitoring plan for marine caught, aquaculture products and aquaculture feeds for the purpose of detecting the presence of residues and substances listed in Table 1, 2 and 3.

The Competent Authority shall prepare an annual report regarding the results obtained from the implementation of the plan referred to in this regulation.

The programme provided for in paragraph 1 shall be amended in the light of the results obtained.

3. Sampling levels and frequencies of the monitoring programme

The residue programme described in chapter 2 of this schedule shall comply with the sampling requirements laid down in chapter 5 of this Schedule.

The Competent Authority may adjust the minimum sampling levels and frequencies laid down in chapter 5 of this schedule provided that it is clearly established that such adjustments increase the overall effectiveness of the plan and do not reduce its ability to identify residues of, or cases of illegal treatment with substances listed in Table 1 of this schedule.

4.Design of the residue monitoring plan

1. The residue monitoring plan shall be made annually and shall take into account the specific situation of the aquaculture and marine caught seafood industry and specify in particular:

    a) evidence regarding the application to aquaculture products of the substances listed in Table 1 and 2

    b) current knowledge about the possible environmental contamination

    c) the infrastructure of the relevant departments involved in implementing the plans in particular, giving details of the technical resources to be employed

    d) a list of approved laboratories with details of their capacity for analysis of samples, including detection limits

    e) tolerances for authorised substances and MRLs, as laid down in Table 2 of these Regulations.

    f) a list of the substances to be detected, methods of analysis, standards for interpreting the findings and, in the case of the substances listed in Table 1, the number of samples to be taken, giving reasons for this number.

    g) the number of official samples to be taken in relation to the annual production.

    h) details of the rules governing the collection of official samples, and in particular the rules concerning the particulars to appear on such official samples.

    i) the type of measures laid down by the competent authorities with regard to aquaculture products in which residues have been detected.

5. Sampling requirements for Official Controls and the Residue Monitoring Programme

5.1 Objectives of sampling

For substances listed in Table 1, sampling should be aimed at detecting the illegal treatment. The emphasis of such sampling must be concentrated during the stage of production most likely to detect the illegal treatment, including feeds.

For substances listed in Table 2, surveillance should be aimed particularly at controlling the compliance with the MRLs indicated in the table in Table 2 and the monitoring of the concentration of environmental contaminants indicated in Table 3. To this end samples should be taken of aquaculture products at the point of harvest or which are placed on the market.

The compounds sought and the samples selected for analysis should be selected according to the likely use of these substances.

The samples must be targeted taking account of the following minimum criteria: sex, age, species, rearing system, all available background information, and all evidence of misuse or abuse of substances of this group.

5.2 Numbers of samples

For teleost aquaculture products the minimum number of samples to be collected each year must be *at least* 1 per 100 tonnes of annual production of each species of fish.

A sample is one or more fish, according to the size of the fish in question and of the requirements of the analytical method.

Each sample can be analysed for detecting the presence of one or more substances.

If production of a species is low, the further requirements in subchapter 5.1 and 5.3 of this Schedule shall still apply, i.e. the proportion may be less than 1 sample/100 tonnes.

5.3 Sampling for the Residue monitoring programme

One third of the total samples should be taken for the analysis of Table 1 substances. Samples must be taken at farm level, on fish at all stages of production, including aquaculture and marine products, which are ready to be placed on the market for consumption.

Two thirds of the total samples should be taken for the analysis of Table 2 and Table 3 substances. The sampling should be carried out-

a) preferably at the farm, on fish ready to be placed on the market for consumption;

b) either at the processing plant, or at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin, in the event of positive results, can be done.

5.4 Follow up to non-compliant results

If results of the monitoring program indicate that illegal treatment or not correct treatment has taken place in a farm, the Competent Authority shall immediately inform the Authority as stipulated in the law relating to aquaculture. The Authority shall ensure that a non-compliance notice prohibiting the moving of any animal or feed or other possible evidence from the farm is issued with immediate effect as stipulated in the law relating to aquaculture.

The Competent Authority and the Authority shall agree and plan adequate follow up activities to investigate further the nature and extent of the suspected case, and to take actions as deemed necessary to prevent further cases. The follow up activities shall include, but not necessarily be limited to further sampling, document reviews, visual inspection and interviews and guidance to the aquaculture production operator is issued for the aquaculture animals in the farm as stipulated in the law relating to aquaculture.

5.5 Annual Report

The Competent Authority shall prepare an Annual Report including

- the number and types of samples planned to be tested
- the number and types of samples actually tested
- the number of non-compliant results found.
- an overview of the number and nature of follow up actions, if any, taken in regard to cases of non-compliance.
- considerations and recommendations for next year's plan

6. Testing and reference laboratories

The Competent Authority shall designate the laboratories which are approved for the conducting of analyses for official controls in accordance with subregulation 35 of this Regulation.

Laboratories designated under paragraph shall use methods of analysis that comply with the related performance criteria specified by the Competent Authority.

The Competent Authority shall designate one of the designated testing laboratories as a national reference laboratory for each residue or residue group to be tested.

Reference laboratories shall be responsible for:

- assisting the Competent Authority in organizing the plan for monitoring residues.
- periodically organizing comparative tests for each residue or residue group assigned to them.

- disseminating information supplied by reference laboratories outside Guyana.

7. Costs of investigations/checks and analyses

1. The costs of the monitoring programmes performed in accordance with chapter 1 shall be borne by the Competent Authority.

   a) Except in the cases defined in chapter 7(1)(b) of this schedule, the costs of the official controls performed in accordance with chapter 1 and 2 of this schedule shall be borne by the Competent Authority.

   b) Where an official control identifies that aquaculture products have been subject to an illegal treatment, and the Competent Authority needs to perform additional controls to ascertain the nature and extent of the illegal treatment, then the cost of the additional controls shall be sustained by the aquaculture production operator.

8. Aquaculture animal products deemed unfit for human consumption

Aquaculture products which have been subject to an illegal treatment shall be considered to be unfit for human consumption.

Aquaculture products which have residues of authorised substances in excess of the maximum limits set in Table 2 of this Regulation shall be considered to be unfit for human consumption.

Without prejudice to criminal or administrative penalties the Authority may direct the owner of aquaculture products which are considered to be unfit for human consumption to undertake any action considered necessary to protect human health, including restrictions in movement or destruction, as stipulated in the law relating to Aquaculture.

Table 1: List of pharmacological active substances prohibited to use in aquaculture animals in any form

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Pharmacologically active substance	**MRL**	**MRPL*)**
Aristolochia spp. and preparations thereof	Not established	Not established
Chloramphenicol	Not established	0,3µg/kg
Chloroform	Not established	Not established
Chlorpromazine	Not established	Not established
Colchicine	Not established	Not established
Dapsone	Not established	Not established
Dimetridazole	Not established	As low possible, certainly no greater than 5µg/kg
Metronidazole	Not established	As low possible, certainly no greater than 5µg/kg
Nitrofurans (including furazolidone)	Not established	1µg/kg
Ronidazole	Not established	Not established
Sum of malachite green and leucomalachite green	Not established	2µg/kg

*) Because the substance is prohibited the MRL shall in reality be "0", however the definition of "0" will depend of the detection limit for the analytical method. To address this issue, the MRPL (Maximum Residue Performance Limit) has been established. This is the level which the analytical method at least shall be able to detect. If the analytical test method used can detect a lower level any level found (even if lower than the MRPL) shall be considered a positive finding.

Table 2: List of pharmacological active substances that may be allowed to use in aquaculture animals subject to prescription and compliance with the stipulated MRL´s in the aquaculture animals placed on the market.

Pharmacologically active substance	**Maximum Residue Limit MRL**	**Marker substance**
Ampecilin	50µg/kg - in muscle and skin in natural proportion	Ampecillin
Amoxicilin	50µg/kg - in muscle and skin in natural proportion	Amoxicilin
Bronopol	No MRL. For finfish only	
Chlortetracycline	100µg/kg - in muscle and skin in natural proportion	Sum of parent drug and its 4-epimer
Colistin	150µg/kg - in muscle and skin in natural proportion	Colistin
Cloxacillin	300µg/kg - in muscle and skin in natural proportion	Cloxacillin
Deltamethrin	10µg/kg - in muscle and skin in natural proportion Allowed for fin fish only	Deltamethrin
Difloxacin	300µg/kg - in muscle and skin in natural proportion	Difloxacin
Dicloxacillin	300µg/kg - in muscle and skin in natural proportion	Dicloxacillin
Danofloxacin	100µg/kg - in muscle and skin in natural proportion	Danofloxacin
Enrofloxacin	100µg/kg - in muscle and skin in natural proportion	Sum of enrofloxacin and ciprofloxacin
Erythromycin A	200µg/kg - in muscle and skin in natural proportion	Erythromycin A
Emamectin Benzoate	100µg/kg - in muscle and skin in natural proportion Allowed for fin fish only	Emamectin B1a
Flumequine	600µg/kg - in muscle and skin in natural proportion	Flumequine
Florfenicol	1000 µg/kg - in muscle and skin in natural proportion	total content of florfenicol and metabolites expressed in florfenicolamine
Lincomycin	100µg/kg - in muscle and skin in natural proportion	Lincomycin
Neomycin	500µg/kg - in muscle and skin in natural proportion	Neomycin B
Oxacillin	300µg/kg - in muscle and skin in natural proportion	Oxacillin
Oxolinic acid	100µg/kg - in muscle and skin in natural proportion	Oxolinic acid
Oxytetracycline	100µg/kg - in muscle and skin in natural proportion	Sum of parent drug and its 4-epimer

Pharmacologically active substance	**Maximum Residue Limit MRL**	**Marker substance**
Sulfonamides	100µg/kg - in muscle and skin in natural proportion	The actual parent substance
Tetracycline	100µg/kg - in muscle and skin in natural proportion	Sum of parent drug and its 4-epimer
Trimethoprim	50 µg/kg - muscle and skin in natural proportion	Trimethoprim
Tosylchloramidesodium	No MRL For fin fish only and for water-borne use only	Not applicable

Table 3: Substances with hormonal or thyrostatic action and of beta-agonists that are prohibited and allowed for certain purposes in aquaculture animals

*Prohibited:*All substances with thyrostatic, oestrogenic or gestagenic actions or which are beta-agonists shall be prohibited to be used in aquaculture animals. Substances with androgenic actions shall be prohibited for any other purpose than mentioned below. *Allowed:*Substances with androgenic actions shall be allowed for the purpose of sex inversion only in fish up to 3 months old from time of hatching.

3: Environmental contaminants to be monitored in aquaculture products

The National Residue Monitoring Plan and Report shall include monitoring for the substances mentioned below and the MRL´s stipulated in Schedule Four to this Regulation shall apply. Substances of agrochemicals (pesticides) for which there is no MRL established, but for which the Competent Authority suspect that illegal or inappropriate use may lead to unacceptable high level in the aquaculture product, shall be included in the plan on the basis stipulated in Regulation 17 and Schedule Four of this Regulation.

a) Organochlorine compounds including PCBs and dioxin like PCBs

b) Organophosphorus compounds

c) Chemical elements including mercury, lead and cadmium

d) Mycotoxins

e) Dyes

SCHEDULE TWELVE reg. 4

SUBJECT MATTER FOR THE TRAINING OF STAFF PERFORMING OFFICIAL CONTROLS

1. Different control techniques, such as auditing, sampling and inspection.
2. Standard Operational Procedures for implementing Official control.
3. The content of these Regulations and relevant parts of related to the laws of Guyana.
4. The content of relevant foreign markets regulations and the implication for export of fisheries product from Guyana to these markets.
5. The different stages of production, processing and distribution, and the possible risks for human health, and where appropriate for the health of animals and plants and for the environment.
6. Assessment of non-compliance with these Regulations.
7. Hazards in animal feed and food production.
8. The evaluation of the application of HACCP procedures.
9. Management systems such as quality assurance programmes that food businesses operate and their assessment in so far as these are relevant for the implementation of requirements in these Regulations.
10. Official certification systems.
11. Contingency arrangements for emergencies, including communication with other government institutions and foreign markets.
12. Legal proceedings and implications of official controls.
13. Examination of written, documentary material and other records, including those related to proficiency testing, accreditation and risk assessment, which may be relevant to the assessment of compliance with these Regulations; this may include financial and commercial aspects.
14. Any other area, including animal health and animal welfare, necessary to ensure that official controls are carried out in accordance with these Regulations.
15. Address the issue of species identification and associated risks.

Made this the _____ day of_____, 2023.

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Hon. Zulfikar Mustapha, M.P.
Minister of Agriculture