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EXTRAORDINARY GAZETTE

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THE PURE FOOD (FISHERY PRODUCTS) REGULATIONS 2005

IN exercise of the powers conferred by Section 37 of the Pure Food Act 1996, I, the Minister of Health and Medical Services hereby make the following regulations,

Guiding Statements

The Pure Food (Fishery Products) Regulations 2005 shall reflect current best practice and be a product of an agreement between the Environmental Health Division of the Ministry of Health and Medical Services, Processors and International Standards and not the work of any one individual.

The use and design of its laws, standards and procedures must be fair to all processors and above all guarantee food safety.

The inspection system must ensure food safety, serve the exporter constructively, and be efficient, responsive and adapatable to change. It must also meet overseas import requirements.

This living document must be reviewed and changed to reflect the current needs of the Solomon Islands. Amendments must be clear, concise and understood by all users.

These Regulations will take effect over a twelve-month period. This period will be deemed a "transition period". During the transition period exporter must train staff in HACCP and hygiene principles, establish and implement a HACCP programme and upgrade good manufacturing practice provisions as prescribed in these Regulations.

These Regulations will come into effect on the Date of Issue and the 'transition period" will end no later than 1 February 2006.

Exemptions

Processors and exporters of traditonal cured products such as dried/smoked beche-de-mer, dried shark fin and similar specific low technology dried products destined for Asian markets are exempted from the application of these Regulations in recognition of the fact that the costs of upgrading facilities and processing would be unsustainable.

THE PURE FOOD (FISHERY) PROUCTS) REGULATIONS 2005

ARRANGEMENT OF REGULATIONS

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PART XIII
PRODUCT SAFETY ASSURANCE PLAN FOR PREPARATION AND PROCESSING OF FISHERY PRODUCTS HAZARD ANALYSIS CRITICAL CONTROL POINTS (HACCP)

Schedules

PART 1

PRELIMINARY

1. The regulations may be cited as the "Pure Food (Fishery Products) Regulations 2005" and shall come into force on such date as the Minister may appoint by notice published in the Gazette. *Short title and commencement*

2. In these Regulations unless the context otherwise requires: *Interpretation / definitions*

"approved" means approved by the Director of Environmental Division in writing;
"Authorised Inspector" An approved Health Inspector formally appointed by the Minister under Part IV the Pure Food Act (1996);
"aquaculture products" means all fishery products born and raised in controlled conditions until placed on the market as a food. However, seawater or fresh water fish or crustanceans caught in their natural environment when juvenile and kept until they reached the desired commercial size for human consumption are also considered to be aquaculture products. Fish and crustaceans of commercial size caught in their natural environment and kept alive to be sold at a later date are not considered to be aquaculature products if they are merely kept alive without any attempt being mae to increase their size or weight;
"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;
"CP" means Control Point, a processing step where the company may wish to address a quality concern not related to food safety;
"CCP" means Critical Control Point, and describes the application of a safety process at a specific location in order to prevent, reduce or eliminate a significant hazard;
"chiller or chill store" means a chamber or room used for reducing or maintaining the temperature of fish at or close to 0ºC;
"chilling" means the process of cooling fishery products to a temperature at or close to 0ºC;
"clean sea water" means seawater that is free from microbiological contamination, harmful substances and/or toxic marine plankton in such quantities as may affect the health quality of fishery products and which is used under the conditions laid down in these Regulations;
"colourings" means food additives which add or restore colour in a food
"Compeent Authority" means the Environmental Health Division within the Ministry of Health and the Medical Services of the Solomon Islands, which is responsible for carrying out food safety related health checks;
"consignment" means the quanity of fishery products bound for one or more customers in the country of destination and conveyed by one means of transport only;
"container" means the principle covering in which fish are packed;

"contaminant" means any biological or chemical agent, foreign matter, or other

substances not intentionally added to food that may compromise food safety or suitability.
"contamination" means the introduction or occurrence of a contaminant in food or food environment.
"control" (verb) means to take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.
"control" (noun) means the state wherein correct procedures are being followed and criteria are being met
"control measures" means any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
"currective action" means action taken when the results of monitoring at the CCP indicates a loss of control;
"critical limit" means a standard or criterion which separates acceptability from unacceptability;
"depuration" means purification of live bivalve molluscs by immersing them in clean water or seawater that has been cleaned by an approved method for the time necessary to remove microbiological contaminants;
"deviation" means failure to meet a critical limit;
"establishment" means any premises or facilities where fishery products are prepared, processed, chilled, frozen, packaged or stored. Auctions which only display and sale by wholesale take place are not deemed to be an establishment;
"fish" means all seawater or fresh water animals or parts thereof, including their roes, excluding aquatic mammals and turtles
"fish or fishery products" means any derivative of fish fresh prepared or processed, that are fit for human consumption;
"flow diagram" means a systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.
"food handler" means any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements
"food hygiene" means all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain
"food safety" means assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.
"foreign matter" means any organic or inorganic substance that is not permitted in these Export Standards, not indigenous to fish, detrimentally effects the quality of the fish or fitness for human consumption, and is included in or adheres to any part of the fish
"freezer" means a chamber used for the purpose of reducing fish temperature to - 18ºC or colder;
"fishing grounds" shall be interpreted as the name given by the fishing industry to the place where fish are harvested;

"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 - 18ºC or colder;
"frozen products" means products which have undergone a freezing process to reach a core temperature of - 18ºC or lower after temperature stabilization;
"fresh products" means any fishery product whether whole of prepared, including products packaged under vacuum in a modified atmosphere, which have not undergone any treatment to ensure preservation other than chilling;
"gully trap" means siphon system installed in the drainage system to cut off an open drain system from the outside air and avoid entrance of pests;
"Good Manufacturing Practice (GMP)" Compliance with the structural and operational requirements laid out in Parts IX, X and XI
"HACCP" is a system that identifies, evaluates, and controls hazards that are significant for food safety.
"HACCP Plan" is a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration.
"hazard" means a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.
"hazard analysis" means the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP Plan.
"Ice room" means a chamber used only for the storage of ice;
"importation" means the introduction in to the territory of fishery products from other countries
"ingredient" means any substance (including food additives) used in the processing of fish that ends up in the final product;
"Inspectorate" means the Inspection and Certification Unit of the Environmental Health Division in the Ministry of Health and Medical Services responsible for the organization of inspection of fishery products quality control and safety assurance systems;
"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 charges of an establishment;
"means of transport" means those parts set aside for good in automobile vehicles and aircraft, the holds of vessels, and containers for transsport by land, sea or air;
"Minister" means the Minister of Health and Medical Services;
"objectionable industry" means any industry neighbouring the fish preparation/processing plant that could cause contamination of the product either directly or indirectly. Includes a coal loading facility, cemetery, rubbish tip or sewerage treatment plant;

"officially laboratory" means the laboratory which is approved by the Competent Authority and is by that able to carry out official analyses;
"packaging" means the procedure of protecting fishery products by a wrapper, a container or any other suitable device;
"pest" means insect, rodent, birds, or other vermin
"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;
"potable water" means water that is fit for human consumption and is complying with the standard laid down in Division III of Part XI;
"prepared products" means any fishery product which has undergone an operation affecting its anatomical wholeness, such as gutting, heading, slicing, filleting, chopping, etc;
"preserve" means the process whereby products are packed in hermetically sealed containers and subjected to heat treatment to the extend that any micro-organisms that might proliferate are destroyed or inactivated, irrespective of the temperature at which the products is to be stored;
"presentation" means the form in which the fish is marketed, such as whole, gutted and headless;
"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 combination of these various processes;
"refrigerated brine" means brine cooled by a suitable refrigeration system;
"refrigerated seawater" means clean seawater cooled by a suitable method
"salt" means food grade Sodium Chloride;
"shall" or "must" denotes a mandatory requirement;
"should" or "may" denotes a recommended requirement
"sound" means free from disease, mould, decay or deterioration and is fit for human consumption;
"step" a point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption;
"sterile" means food that is free of micro-organisms which are capable of growth under the conditions it is likely to encounter during storage and transport
"sweeteners" means food additives which are used to impart a sweet taste to foodstuffs and/or table-top sweeteners;
"validation" means Obtaining evidence that the elements of the HACCP plan are effective.
"verification" means the application of methods, procedures and tests, in addition to those used in monitoring, to determine compliance with the HACCP plan and/or whether the HACCP plan needs modification;
"visible parasite" means a parasite or group of parasites which has a demension, colour or texture that is clearly distinguishable from fish tissues;
"visual inspection" means a non destructive examination of fish or fishing products without optical means of magnifying and under good light conditions for human vision, including if necessary, candling;
"wholesome" means the positive attributes (quality and safety) associated with a product

PART II

COMPETENT AUTHORITY

3. (1) In application of Section 2 of the Pure Food Act 1996, the Environmental Health Division of the Ministry of Health and Medical Services is empowered to enforce these Regulations

Ministry of Health / EHD

(2) The Organisation Chart for the Competent Authority is set forth in Schedule 1 to these Regulations.

Designation of the Competent Authority

(3) Responsibilities of the Competent Authority shall be in accordance
(a) with the tasks, duties and responsibilities given in the Act,
(b) with the responsibilities concerning Health Control laid down in Part VIII of these Regulations.

Responssibilities of the Competent Authority

4. In application of Section 8 of the Act, the Minister may appoint persons, who meet the qualifications.

Appointment of Health Inspectors

5. In application of Section 34 of the Act a "Pure Food Advisory Board" shall be installed and maintained to advise and assist the Minister and the Competent Authority as mentioned in Sub-section (3) of Section 34 of the Act.

Pure Food Advisory Board

PART III

ENFORCEMENT

6. (1) Enforcement Procedures concerning powers delegated to the Competent Authority are laid down in the Act.

Enforcement by the Act and Regulations

(2) Provisions in Regulation 3 of these Regulations empowers the Environmental Health Division of the Ministry of Health to enforce these Regulations.

PART IV

APPROVAL REQUIREMENTS

Approval of establishment

7. (1) In application of Section 10 and of Section 23(3) of the Act the following approval procedures for establishments must be implemented by the Competent Authority.

Approval of the ground Plan

(2) Before the management of an establishment start to build, rebuild or adapt an establishment, acting on their own initiative or on the initiative of the Competent Authority, an application for approval must be lodged with the Competent Authority to provide information about;

(a) activities carried out in the establishment; and

(b) the lay out (ground plan) and the product flow (established in a product flow chart on the ground plan).

(3) After receiving the application, the Competent Authority:

(a) must verify whether the proposal submitted has fulfilled the requirements laid down in Part XI (Division I) of these Regulations; and

(b) must, within 14 days, send an invitation to the management to discuss the application.

(4) Once the Competent Authority accepts the final proposal of the management, approval must be given to the plans and the specifications. This approval must be signified by the fixing of an official stamp of the Competent Authority over the signature of the Director to the plans and the specifications.

(5) On completion of the building, constructijon or renovation, extension or adoption, the management must request the Competent Authority in writing to conduct a formal regulatory inspection of the establishment.

(6) After the inspection, the Competent Authority:

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

(b) must within 14 days inform the management in writing whether or not the establishment has met those requirements and conditions.

(7) After approval, the plant will be issued with its national establishment approval number. *National Approval Number*

(8) The approval must be renewed if an establishment decides to carry out activities other than those for which it has received approval. *Renewal of approval*

8. (1) In application of Sections 2(4) and 10 of the Act an approval procedure has to be established by the Competent Authority for fishing vessels in accordance with Regulation 7 and resulting in registration and resulting in the provision of a registration number for these vessels complying with the provision of a registration number for these vessels and complying with the requirements for fishing vessels laid down in Part IX (Division I and II). *Approval of other facilities*

(2) In addition to sections 9 and 10 of the Act, an approval procedure has to 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. *Landing Sites*

(3) In addition to Sections 9 and 10 of the Act an approval procedure must be established by the Competent Authority for the approval of the sea port and airport facilities for offloading, transport and storage of fishery products resulting in registration and the provision of a registration number for these installation complying with the requirements: *Seaports and Airports*

(a) for unloaidng of fishery profucts laid down in Part X;
(b) for transport of fishery products laid down in Part XI (Division X); and
(c) for storage of fishery products laid down in Part XI (Division IX)

(4) The approval procedure laid down in Regulation 7 shall apply mutatis mutandis to the approval procedures described in Regulation 8.

(5) In application of Section 3(d), (k) and (m) of the Act, chemicals used; *Chemicals*

(a) for eradication of pests (insects, reptiles and rodents);
(b) for cleaning and disinfecting premises in the establishments and surroundings must be approved by the Com,petent Authority.

Official lists of approved establishments and facilities

9, (1) Competent Authority shall draw up an official list of:

(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 8(5):

(i) for eradication of pests

(ii) for cleaning and distinfecting purposes

(e) approved and registered seaport and airport facilities each of which shall have an official registration number.

Inspections

(2) The inspection of establishments, vessels, official and private landing sites and auctions, if applicable, shall be carried out regularly by the Competent Authority to verify whether the above-mentioned facilities still comply with the requirements and whether they are still allowed to keep their official registration number. If such inspection and monitoring reveals that the requirements are not being met anymore, the Competent Authority shall take appropriate action.

Updating

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

PART V

PLACING FISHERY PRODUCTS ON THE MARKET

Placing fishery products on the market

10. (1) Fishery products, caught in their natural environment and intended to be placed on the market must:

(a) in application of Section 2(4) of the Act:

(i) 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 Part IX (Division I and II)

(ii) have been handled, during and after landing, in accordance with Part X of these Regulations.

(b) in application of Section 3, 4 and 5 of the Act have been handled and, where appropriate packaged, prepared, processed, frozen, defrosted, or, stored hygienically in plants

approved in accordance with Regulation 7 of these Regulations in complilance with the requirements of Part XI (Division I) of these Regulations.

(c) in application of Section 5 of the Act have been appropriately packaged in accordance with the requirements laid down in Regulation 175 of these Regulations.

(d) in application of Section 6 of the Act havfe been given an identificaton mark in accordance with Regulation 176 of these Regulations.

(e) in application of Section 23(4) of the Act have been certified in accordance with the conditions laid down in Regulation 12 of these Regulations.

(f) in application of Section 4 of the Act havfe been stored and transported under satisfactory conditions of hygiene and temperature in accordance with Part XI (Division LX and X) of these Regulations.

(g) in application of Section 23(3) of the Act have been prepared and / or processed in accordance with the Quality Assurance programme established in Part XI and in accordance with the Safety Assurance Programme established in Part XIII of these Regulations.

(h) in application of Section 3(d) and (e) of the Act:

(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; and

(ii) not contain any substance in excess of any maxim quantity or proportion permitted by the provisions laid down in Part XII of these Regulations.

(i) in application of Section 15 of the Act 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 Part XI (Division IX and X) of these Regulations.

(2) Where gutting is possible from a technical, commercial and hygienic viewpoint,

(a) it must be carried out as quickly as possible after harvesting

(b) or otherwise it must be frozen on the vessel immediately

(3) The placing on the market of the following products shall be prohibited;

(a) Poisonous fish of the families Tetraodontidae, Molidae, Diadontidae, Balistidae, Murenidae and Canthigasteridae

(b) Fishery products containing bio-toxins such as ciguatera toxins or muscle paralyzing toxins.
(c) Fishery products containing other toxins, such as histamine, mercury in an amount higher than the levels established in VIII (Division I) of these Regulations.

Detailed requirements concerning the species concerned by this subject, concerning levels and methods of analysis are laid down in Part VIII (Division I) of these Regulations.

PART VI
IMPORTS

Imports

11. In applicatin of Section 22 of the Act, the following additional import conditions are established:

(1) 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, of Solomon Islands Products.

(2) Specific import conditions may be laid down:

(a) to protect the public health of the inhabitants of Solomon Islands without prejudice to the possibility that imported products may be exported; and

(b) 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.

PART VII
EXPORTS

Exports

12. In application of Section 23 and especially Sub-section (2) of the Act following additional export conditions are established:

(i) Provisions applied to exports of fishery products from Solomon Islands to other countries shall comply with the conditions laid down in these Regulations and with the requirements of the legislation of the country to which Solomon Islands exports.

(a) no person shall export, process for export or attempt to export or process for export, any fishery products 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.

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

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

PART VIII
HEALTH CONTROL

Scope

13. (1) In application of Sections 8, 9, 10, 12, 13 and 14 of the Act, fishery products caught in their natural environment must have undergone health control, checking and monitoring of the conditions for processing and placing on the market.

The Competent Authority shall establish a coherent and effective health control system and therefore must also indicate the frequency of control and inspection.

(2) The health control system shall be established on two levels:

(a) health control of "Environmental Conditions", named the "National Monitoring Programme"; and

(b) health control of "Production Condtions".

DIVISION 1
HEALTH CONTROL OF ENVIRONMENTAL CONDITIONS

The National Monitoring Programme

14. (1) The health control of Environmental Conditions named the "National Monitoring Programme" shall:

(a) be programmed on a yearly base;

(b) have a mid-term or long-term approach; and

(c) be implemented on directorate level

(2) The Competent Authority shall draw up a list of:

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

(b) chemicals (herbicides, pesticides, insecticides) used in the past and at present in Solomon Islands and neighbouring countries;

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

(d) potential microbiological contaminants of the fish surface

(3) The National Monitoring Programme shall monitor the sanitary soundness of the fishery products, which means the presence of parasites, toxins, microbes, viruses, accidental and intentional contaminants 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

Parasites

15. (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 published by the Competent Authority, based on scientific studies or research.

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

Fish toxins in general

16. 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 published by the Competent Authority, based on scientific studies or research.

Histamine

17. (1) Although histamine (or Scombrotoxin)

(a) is a toxin of enzymatic origin,

(b) occurring only by interruption of the cold chain,

(c) it has to be monitored on safety level as a part of an establishment's HACCP system; and

(d) has to be sampled and has to comply with the standards as laid down in Sub-section (2) of this Regulation,

the Competent Authority shall install a monitoring programme as a control system installed by the management of the establishment and to evaluate the risk for human health.

Sampling plan

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

(a) Nine samples must be taken from each batch, which must meet the followng requirements:

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

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

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

Species considered to be a hazard

(b) These limits apply only to fish species of the following families: scombridae, clupeidae, egraulidae and copyhaenidae. However, fish belonging to these families that have undergone enzyme-ripening treatment (fermentation) in brine may have higher histamine levels but not more than twic the above values.

Examination methods

(c) Examinations must be carried out in accordance with reliable, scientifically recognized methods, such as "High Performance Liquid Chromatography" (HPLC), or other recognised method.

Marine bio-toxins

18. (1) A monitoring programme shall be installed, if applicable, in order to establish whether the conditions for the production and the placing on market of live bivalvfe molluses are met.

Type PSP

(2) The following limits and methods shall be established:

(a) The total Paralytic Shellfish Poison (PSP) content in the edible parts of molluses (the whole body or any part edible separately) must not exceed 80 micrograms per 100 g of molluse flesh in accordance with the biological testing method in association, if necessary, with a chemical method for detection of Saxitoxin, or any other recognized method. If the results are challenged the reference method shall be the biological method.

(b) The customary biological testing methods must not give a positive result to the presence of Diarrhetic Shellfish Poison (DPS) in the edible parts of mollusscs (the whole body or any part edible separately).

Ichthyosarcotoxin type letrodotoxin

19. (3) A monitoring plan shall be installed by the Competent Authority to ensure that:

(a) no poisonous fish

(b) of the following families: Tetraodontidae, Modidae, Diodontidae, Canthigasteridae; and/or

(c) containing ichthyosarcotoxins, type tetrodotoxin is placed on the market.

Ichthyosareatoxin type ciguatoxin

20. A monitoring plan shall be installed by the Competent Authority, taking into account the requirements laid down in Regulation 16(1), to ensure that no fishery products containing bio-toxins such as ciguatera toxins or muscle paralyzing toxins are placed on the market.

Contaminants in aquatic environment

21. (1) A monitoring systme shall be established by the Competent Authority to check the level of contamination of fishery products by industrial chemicals, heavy metals, medicinal products, food additives, animal feed additives and pesticides. Without prejudice to the laws to be proclaimed concerning water protection and management, and in particular those concerning pollution of the aquatic environment, fishery products must not contain, in their edible parts:

(a) intentional contaminants present in the aquatic environment such as residuces of antibiotics and drugs; and

(b) accidental contaminants present the aquatic environment such as heavy metals, organo-chlorinate substancs and pesticides at such level that the calculated dietary intake exceeds the acceptable daily or weekly intake for humans.

Stanards for Chemical Contaminants

(2) Fishery products shall not contain following chemical contaminants on a level higher than as mentioned below:

(a) aldrin / dieldrin	0.3 ppm
(b) chlordane	0.3 ppm
(c) chlordecone	0.3 pmm
(d) DDT, TDE, DDE	5.0 ppm
(e) diquat	0.5 ppm
(f) fluridone	0.3 ppm
(g) heptachlor epoxide	0.3 ppm
(h) glyphosphate	0.25 ppm
(i) mirax	0.25 ppm
(f) PCB	2.0 ppm
(k) simazine	12.0 ppm
(l) 2,4-D	1.0 ppm

Mercury, Lead, Cadmium, Tin (inorganic)

Analysis method

Maximum limit

22. Monitoring mercury, Lead, Cadmium in fishery produces and inorganic Tin in canned fishery products shall be provided for as follows:

A monitoring plan to check the contamination of fishery products by mercury, Lead, Cadmium shall be put in place.

(1) Analysis methods, sampling plans and maximum limits for monitoring mercury, Lead, Cadmium in fishery products and inorganic tin in can products shall be established:

(a) the analysis method to be used in determining the total mercury content is the Atomic Absorption Sepectrometry (AAS); and

(b) the mean total mercury content, as determined by the analysis referred to in paragraph (i) hereof, of the edible parts of the fishery products must not exceed 0.5 ppm of fresh products (0.5 mg/kg of fresh weight). This average limit is however, increased to 1 ppm of fresh products (1 mg/kg of fresh weight) for the edible parts of the following species:

- Sharks (all species)
- Tuna (*Thunmus* app)
- Little tune (*Euthynnus* spp)
- Bonito (*Sarda* spp)
- Swondfish (*Xiphias gladias)*
- Sailfish (*Istiophorus platypterias* spp)
- Marlin (Makaira spp), and
- Rays (*Raja* spp)

(c) the mean total lead content, as determined by the analysis referred to in paragraph (1) (a) hereof, of the edible parts of the fishery products must not exceed 03ppm of fresh products (0.3m/kg of fresh weight).

(d) The man total cadmium content, as determined by the analysis referred to in paragraph (1) (a) hereof, of the edible parts of the fishery products must not exceed 0.05ppm of fresh products (0.05mg/kg of fresh weight). This average limit is however, increased to 0.3ppm of fresh products (0.3mg/kg of

fresh weight) for the muscle meat of swordfish (Xiphias gladius) and to 0.1ppm of fresh products (0.1 mg/kg of fresh weight) for the muscle meat of edible parts of the following species:

- anchovy (Engraulis species)
- bonito (Sarda sarda)
- common two-banded seabream (Diplodus vulgaris)
- eel (Anguilla anguilla)
- horse mackerel or scad (Trachurus species)
- louver or luvar (luvarus imperialis)
- sandine (Sandina pilchardus)
- sardinops (Sardinops species)
- tuna (Thunus species, Euthynnus species, Katsuwonus pelamis)
- wedge sole (Dicologoglossa cuneata)

(e) the man inorganic tin content, as determined by the analysis referred to in paragraph (1) (a) hereof, of the canned fishery products must not exceed 200ppm of products (200mg/kg)

Sampling plan

(f) Sampling plans shall be laid down for fresh and frozen fishery products by the Competent Authority. These shall take into account, on the one hand, the results obtained from national checks and, on the other hand, the following factors:

i) Product type:
Category (a) - species listed in paragraph (b) hereof;
Category (b) - other species

ii) The minimum number of samples to be taken per lot for each product category shall be:
Category (a) 10 samples taken from 10 different individuals
Category (b) 5 samples taken from 5 different individuals

The analysis shall be carried out on a finely homogenized mixture of the samples so as to obtain the mean value of the mercury, lead, cadmium in fishery products and inorganic tin content in canned products. The incremental 10 fish samples for heavy metal (mercury, lead, cadmium and tin) analysis shall be of similar weight. In the case of fish of the species listed in paragraph (a) hereof, that are of various sizes, the sample taken must represent the size composition of the fish batch. The weight of an incremental sample shall be at least 100 grams, resulting in an aggregate sample of at least about 1kg.

Records and date of the monitoring programme

23. Records and data of monitoring results of the National Monitoring Programme shall be available at any time.

DIVISION II
HEALTH CONTROL OF PRODUCTION CONDITIONS

Scope

24. (1) The health control of "Production Conditions" shall:
(a) be done on a daily or regular inspection basis
(b) have a short term approach and,
(c) be implemented at inspectorate level

Monitoring of the Production chain

(2) The health control of Production Conditions shall monitor 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 to dispatch as laid down in these Regulations.

Health check before first sale

25. (3) Arrangements for the organisation, implementation and maintenance of health checks must be made by the Competent Authority to establish:
(a) An inspection comprishing an organoleptic check carried out by sampling concerning the freshness of the products:
i) by the Competent Authority of each bach 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 receiption of fish in an establishment, cross checked at regular intervals by the official health inspector;
to check whether they are fit for human consumption, in accordance with the requirements laid down in Part XI (Division IV) of these Regulations.
(b) An inspection comprising physical, chemical or microbiological methods if the organoleptic examination reveals any doubt as to the freshness of the product in accordance with the requirements laid down in regulation 114 of these Regulations.
(c) An inspection of the physical soundness of the fishery products in accordance with the requirements laid down in Regulation 115 of these Regulations.
(d) An inspection of the sanitary soundness of the fishery products in accordance with the requirements laid down in Regulation 116 of those Regulations.

Vessels

26. (1) Arrangements for checking, controlling and monitoring the hygiene rules applicable to fishery products caught on board fishing vessels must be made by the inspection service in order to establish whether the fishery products 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 Part IX (Division I and II) of these Regulations.
(2) Such arrangements will include, in particular, a check on factory

vessels and / or 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 coherent and effective inspection, the Competent Authority shall:

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

(b) establish an approval procedure for factory vessels in accordance with the approved procedure for establishments as referred to in Regulation 7 of these Regulations;

(c) control the systems (quality assurance; good practices; safety assurance; HACCP) installed by the qualified person (quality manager) on board of the factory vessels;

(d) indicate the frequency of inspection; and

(e) make records of every inspection

Landings

27. Arrangements for checking, controlling and monitoring the hygiene rules and conditions for landing and first sale must be made by the inspection service 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 Part X of these Regulation

Transport

28. Arrangement for checking, controlling and monitoring the hygiene rules and conditions of landing and first sale must 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 hygiene rules and conditions established in Part XI of these Regulations.

Processing establishments

29. Arrangements for checking, controlling, inspection and monitoring at regular intervals of establishments must be made by the inspectorate, 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; and

(c) whether fishery products, prepared or processed from fish species which are estimated to be a potential hazard under Regulation 13 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;

in accordance with the qualify assurance programme established in Part IX and in accordance with the safety assurance programme

established in Part XIII and in accordance with the requirements for the use of sweeteners, food colouring and / or other food additives laid down in Part XII of these Regulations.

Approval requirements

30. Arrangements for controlling and monitoring the approval and registration conditions and requirements, laid down in Regulation 7 of these Regulations must be made by the Competent Authority in order to establish whether these conditions and requirements are still fulfilled.

Certificate

31. Arrangements for

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

(b) stipulation of reliable conditions for certification must be made by the inspectorate to ensure that errors or fraud can be excluded and that the declarations on the export certificates are truthful.

Airports and Seaports

32. Arrangements for checking, controlling and monitoring the hygiene, chilling storage conditions, and the frozen storage conditions at airports and seaports must be made by the inspectorate in orer to establish whether the fishery products have been handled, stored and dispatched in accordance with the hygienic rules and conditions established in Part XI (Division IX and X) of these Regulations.

Records

33. Records of controls, checks and inspection shall be made available at any time.

DIVISION III
LABORATORIES

Official Laboratories

34. (1) The Competent Authority shall, after auditing and on the basis of an 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 and shall also establish the audit level: GLP (good laboratory practice) or accreditation.

(3) To be approved, laboratories must:

(a) be able to carry out the following non-clinical tests:

i) microbiological tests (e.g. on food, contact surfaces, residues of antibiotics), and / or

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

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

bio-toxins);

iv) physical and chemical tests for freshness determination of fishery products (e.g. pH measurements, refractometric index of the eye liquid.

TVB-N (Total Volatile Base-Nitrogen)

(b) equipped to do analyses of:

i) organic and inorganic chemicals;

ii) marine and fish toxins;

iii) biological organisms; and

iv) microbiological organisms

as described in these Regulations

(c) able to work under "Good Laboratory Practices"

(4) These competences and facilities need not be present in one specific laboratory; different laboratories could be in charge and approved for different types of test or tests.

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

(6) The Competent Authority shall draw up a list of the approved laboratories and designate, on the basis of the audit report their testing speciality.

PART IX
STRUCTURAL REQUIREMENTS

DIVISION I
FISHING VESSLES

35. (1) The following shall apply concerning the construction of fishing vessels and the equipment installed on them:

(a) Holds or other parts of the vessel where fishery products are stored must:

(i) be covered and self draining

(ii) be well insulated

(iii) have provision for holding a acceptable quantity of ice or have alternative means of refrigeration

iv) not contain objects or products liable to damage or transmit harmful properties and abnormal characteristics to the food.

These structures must be designed for ease of cleaning

(b) Decks used for fish handling may be constructed of one or

more of the following materials, namely surface-coated aluminium, fibreglass, timber coated with an epoxy (or similar) finish. Where fish does not normally come into contact with the deck and the timber is clear, sound and well caulked, timber is allowed on exposed decks.

(c) Where opeations are carried out in daylight hours exposed handling areas shall be properly covered with a clean awning that is kept in good repair.

(d) Water used at any stage of handling / processing shall comply, with the parameters of potable water, laid down in Part XI (Division III) of these Regulations or of clean seawater. Seawater intakes for vessels shall be located forward of any toilet or bilge discharge.

(e) Sinks, processing tables, equipment used for gutting, heading and the removal of fins, and containers and equipment in contact with the fishery products must be made of or coated with a materail that is waterproof, resistant to decay, smooth and easy to clean and disinfect. When used they must be completely clean.

(2) The following conditions concerning use and maintenance shall apply:

(a) when used, the section of vessels or the containers reserved for the storage of fishery product must be completely cleaned and, in particular, must not be capable of being contaminated by fuel used for the propulation or bilge water.

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

(3) The following conditions concerning handling and storage of fishery products on board shall apply:

(a) as soon as they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source of heat. When they are washed, water used must be either potable water complying with the parameters set out in Part XI (Division III) of these Regulations or clean sea water, so as not to impair their quality or wholesomeness.

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

(c) fishery products other than those kept alive must undergo

chilling or freezing as soon as possible after landing;

(d) where fish are headed and/or gutted on board such operation must be carried out hygienically and products must be washed immediately and thoroughly with potable water or clean seawater. The viscera and parts, which may pose a threat to public health, must be removed and set apart from products intended for human consumption. Livers and roes intended for human consumption must be chilled or frozen. Staff assigned to handling fishery products shall maintain a high standard of cleanliness for themselves and all outer clothing.

Additional conditions

36. (1) Additional hygiene conditions are applicable to vessels designed and equipped to store fishery products for more than twenty-four hour, other than those equipped for keeping fish, shellfish and molluses alive without other means of conservation.

(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 35 of these Regulations are also applicable.

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

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

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

(c) Containers used for the storage of products must ensure their preservation under satisfactory conditions of hygiene and, in particular, allow drainage of water. When used they must be completely clean.

(d) In refrigerated holds, refrigeration capacity shall be sufficient to rapidly cool fish from ambient temperature to the temperature of melting ice and hold it at this temperature.

(e) Water proof and separate storage room shall be provided for the storage of cartons, ship to shore containers and the like.

(f) Hydraulic circuits shall be protected in such a way as to ensure no oil leakage can contaminate products.

(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:

The intensity of illumination shall be a minimum of:

220 lux in the processing area

540 lux where the product is being inspected

(h) Sanitary facilities including toilet and shower facilities shall be sufficient in number for the normal complement of crew. Any toilet must be equipped with a non-hand, non-elbow operated wash basins located in the toilet room or immediately outside the door. A berth shall be available for each member of the crew and when required for Health Inspectors.

(4) The following conditions concerning use and maintenance shall also apply:

(a) The working decks, the equipment and the holds, tanks and containers shall be cleaned and disinfected after each time they are used. Control and monitoring for the presence of pests shall carried out regularly.

(b) Cleaning products, disinfectants, insecticides and all potentially toxic substances shall be stored in a locked store or cupboard pysically separated from fish cartons and ship to shore containers. Their use must not present any risk of contaimination of fishery products.

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

(a) Ice for chilling of fishery products must be used in such a way and in such quantities, so that fishery products will attain the temperature of melting ice as quickly as possible.

(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 and process shall ensure that:

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

(ii) toilet facilities are not used unless they are self

contained; and

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

Provided always that (i), (ii) and (iii) shall not apply to vessels that use a self-contained water system and the water meets the requirements laid down in Part XI (Division III) of these Regulations.

(6) The following condition concerning personnel shall apply:

(a) Ship owners or their representatives shall take all the measures necessary to prevent persons liable to contaminate fishery products from working on board or handling such products until there is evidence that such persons can do so without risk.

Fishing vessels equipped for freezing

37. (1) General hygiene conditions applicable to fishery products on board fishing vessels laid down in Regulation 35 of these Regulations are applicable to fishing vessels equipped for freezing.

(2) Additional hygiene conditions apply to fishing vessels designed and equipped to preserve fishery products on board under satisfactory conditions for more than 24 hours and are laid down in regulation 36 of these Regulations.

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

(a) Fishing vessels must have freezing equipment sufficiently powerful to:

i) achieve rapid reduction in temperature to - 18ºC or less

ii) keep products in storage rooms at - 18ºC or less

iii) freeze whole fish in brine intended for canning at - 9ºC or less

(b) Products to be frozen must comply with the requirements of conditions for the fresh products laid down in Regulation 163 of the Regulations.

(c) Temperature recording devices in storage rooms must be located in a place where they can easily be read. The temperature sensor of the recorder must be located in the area furtheest away from the cold storage, where the temperature in the storage room is the highest.

(d) Freezing machinery shall be physically separated from the hold in which frozen product is stored;

(e) If the freezer is located within a 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, freezer holds, blast freezers, plate freezers and the like shall be capable of reducing the temperature of fish undergoing freezing to - 18ºC or colder.

(f) A waterproof, hygiene and separate storage room shall be provided for the storage of all packaging materials.

(g) On prawn trawlers, prawns can be packed and frozen whole, or headed when the hygiene conditions comply with the requirements in the general, the additional, and the specific hygiene conditions laid down in Regulations 35, 36 and 37 of these Regulations. When prawns are headed before packing and freezing special hygiene measures have to be taken to prevent contamination.

(h) When brine - freezing, the brine shall not be a source of contamination.

Fishing vessels equipped for chilling

38. (1) General hygiene conditions applicable to fishery products on board all fishing vessels laid down in regulation 35 of these Regulations are applicable to Chilled Seawater (CSW) and Refrigerated Seawater (RSW) equipped vessels.

(2) Additional hygiene conditions apply to fishing vessels designed and equipped to preserve fishery products on board under satisfactory conditions for more than 24 hours as laid down in regulation 36 of these Regulations.

(3) Fishing vessels equipped with CSW or RSW systems shall comply with the following requirements:

(a) Tanks must be equipped with adequate seawater filling and drainage installations and must incorprate devices for achieving uniform temperature throughout the tanks.

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

(c) The operation of the tank or container system must secure a chilling rate which ensures the mix of fish and seawater reaches 3ºC or less within six hours and 0ºC after sixteen hours;

(d) After each unloading the tank's circulation systems and containers must be completely emptied and thoroughly cleaned using potable or clean seawater and should only be re-filled with clean seawater; and,

(e) The date and reference number of the tank must be clearly indicated on the temperature records. These must be kept and made available to the inspectorate.

Fishing vessels equipped for handling shellfish etc

39. Fishing vessels equipped for keeping fish, shellfish and molluses alive without other means alive without other means of conservation on board, shall comply with the general hygiene conditions applicable fishery products on board all fishing vessels, as laid down in Regulation 35 of these Regulaltions.

Fishing vessels equipped for cooking on-board

40. (1) Fishing vessels equipped for cooking crustanceans and molluscs on board must comply with the general hygiene conditions applicable to fishery products on board all for fishing vessels, as laid down in Regulation 35 of these Regulations.

(2) Additional hygiene conditions apply to fishing vessels designed and equipped to preserve fishery products on board on under satisfactory conditions for more than 24 hours laid down in Regulation 36 of these Regulations also applicable.

(3) Any cooking must be followed by rapid cooling. Water and / or ice used for this purpose must be potable water or clean seawater. Cooling must continue until the temperature approaching that of melting ice is reached.

(4) Shelling or shucking must be carried out under lygienic conditions avoiding the contamination of the product. Where such operations are done by hand, workers must pay attention to the washing of their hands and that all working surfaces are cleaned thoroughly. If machines are used, they must be cleaned at frequent intervals and disinfected after each working day.

(5) After shelling or shucking, cooked products must immediately be frozen or kept chilled at a temperature that will preclude the growth of pathogens and be stored in appropriate conditions.

(6) Every manufacturer must carry out micro-biological checks on its production at regular intervals, complying with the following:

(a) The microbiological standards set forth in Schedule 3 to these Regulations shall be checked by the mlanufacturer during the manufacturing process and before crustacean and molluscan shellfish productss are cooked in the processing plant, and 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 hygiene control systems; 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 (2)

(c) An undertaking:

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

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

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

DIVISION II
FACTORY VESSELS

Factory vessel design and equipment

41. (1) The minimum requirements for the design and equipment for factory vessels are as follows:

(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 kept apart. The reception area and its movable parts must be easy to clean. It must 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. They must 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. If a waste processing unit operates on board, a separate hold must 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. If waste is stored and processed on board with a view to cleaning, separate areas must be allocated for that purpose;

(g) equipment providing a supply of potable water within the meaning of Part XI (Division III) of these Regulations relating to the quality of water intended for human consumption or clean seawater. The seawater intake must 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 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. The wash basins must be equipped with appliances for washing and drying the hands that comply with hygiene requirements; the wash basin taps must not be hand / elbow-operable.

(2) Areas used for the preparation and processing or freezing/quick freezing of fishery products must have:

(a) a non-slip floor that is also easy to clean and disinfect and equipped for easy drainage of water.

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

(c) the hydraulic circuits arranged or protected in such ways as to ensure that it is not possible for any leakage of oil or hydraulic fluid 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/elbow-operable and with single use towels.

(3) Equipment and tools such as cutting tables, containers, conveyors, gutting or filleting machines, etc, must be constructed of materials that are resistant to seawater corrosion, easy to clean and disinfect, and well maintained.

(4) Factory vessels that freeze fishery products must 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 holds at a temperature that complies with the specifications of these Regulations. The storage holds must be equipped with a temperature recording system placed so that the temperature can be easily monitored.

Handling and storage on factory vessels

42. (1) A qualified person on board the factory vessel must be responsible for applying best practices. That person shall have the authority to ensure that the provisions of this Division are applied and shall make available to inspectors the programme 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 as follows:

(a) Floor, walls and partitions, ceilings or roof linings, equipments and instruments used for working on fishery products must 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 must be systematically, controlled:

(c) rodenticides, insecticides, disinfectants and any other potentially toxic substance must be stored in store rooms or cupboards that can be locked; their use must not present any risk to the products:

(d) Only potable water, within the meaning of Division III of Part XI of these Regulations, or clean seawater; shall be used. However, if other sources of water are used for steam production, fire-fighting and cooling of refrigeration equipment, a separate clearly identified piping system must be installed that present no risk of contamination to the products.

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

(3) The general conditions of hygiene applicable to staff shall be as follows:

(a) The highest possible standard or cleanliness is required of staff. More specifically.

i) Staff must wear suitable clean working clothes and headgear that completely enclose hair. This applies particularly to those handling exposed fishery products.

ii) Staff assigned to the handling and preparation of fishery products must be required to wash their hands and at least each time work is resumed. Wounds to the hands must be covered by a waterproof dressing.

iii) Smoking, spitting, eating drinking in work and storage premises of fishery products must 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.

(c) When recruited, any person working on and handling fishery products shall be required to prove, by a medical certificate, that there is not impediment to such employment.

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

(a) Operations such as heading and gutting must be carried out hygienically. The products must be washed thoroughly with potable water or clean seawater immediately after such operations.

(b) Operations such as filleting and slicing must be carried out in such a way as to avoid the contamination or spoilage of fillets and slices, and in a place other than used for heading and gutting operations. Fillets and slices must not remain on work tables any longer than is necessary for their preparation and must be protected from contamination by appropriate packaging. Fillets and slices to be sold fresh must be chilled as quickly as possible after preparation.

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

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

(a) Fresh products to be frozen or quick-frozen must comply with the requirements for fresh products laid down in Regulation 163 of these Regulations.

(b) Store room must have temperature recording device in a place where it can easily be read. The temperature sensor of the recorder must be located in the area further away from the cold source, i.e where the temperature in the store room is the highest. Temperature charts must be available for inspection by the Competent Authority or inspectorate for at least the period in

which products are stored.

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

(a) The conditions of hygiene for frozen products as laid down in Regulation 163 of these Regulations.

(b) The conditions of hygiene for frozen products as laid down in Regulation 164 of these Regulations.

(c) The conditions of hygiene for thawing products as laid down in Regulation 165 of these Regulations.

(d) The conditions of hygiene for processed products as laid down in Regulation 167, 168, 169, 170, 171, 172, 173, of these Regulations.

(e) The conditions concerning parasites laid down in Regulation 174 of these Regulations.

(7) Fishery products must be wrapped and packaged under the following conditions of hygiene.

(a) Packaging must 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 must comply with all the rules of hygiene, and in particular:

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

ii) they must not be capable for transmitting to the fishery products substances harmful to human health;

they must be strong enough to protect the fishery products adequately.

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

(d) Packaging materials must be stored in premises away from the production area and be protected from dust and contamination.

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

(a) Fishery products must, during storagfe be kept at the temperature laid down in these Regulations and in particular:

i) fresh or thawed fishery products and cooked and chilled crustacean and mulluscan shellfish products must

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, must be kept at a temperature of -18ºC or less in all parts of the products, allowing for the possibility of brief upward fluctuations of not more than 3ºC;

iii) during transport processed product must be kept at the temperature specified by the manufacturer.

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

PART X

REQUIREMENTS FOR FISH LANDINGS

General conditions

43. (1) Unloading and landing equipment must be constructed of corrosive resistant material that is easy to clean, disinfect and kept in a good state of repair and cleanliness.

(2) During unloading and landing, contamination of fishery products must be avoided. It must 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 products;

(c) equipment and handling practices that damage fishery products are prohibited.

Fish landings and auction

44. (1) If fishery products are displayed for sale at fish landings or auctions they must:

(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 hand washing and single use hand towels;

(d) be well lit to facilitate the inspection of fishery products provided for in Regulation 25 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 must not be

admitted to markets; crates must, after each sale, be cleaned and rinsed inside and outside with potable water or clean sea water; where required, they must be disinfect. Undesirable animals must not be admitted;

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

(g) be closable and be kept closed when the Competent Authority considers if necessary;

(h) have facilities to provide adequate supplies of potable water within the meaning of Part XI (Division III) of these Regulations or alternatively of clean seawater or seawater treated by an appropriate system, under pressure and in sufficient quantity. However, by way of exception, a supply of non-potable 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. Non-potable water pipes must be clearly distinguished from those used for potable water or clean sea water;

(i) have special watertight receptacles made of corrosion-resist ant 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 and adequately-equipped lockable room, and the equipment necessary for carrying inspection.

(2) After landing or, where appropriate, after first sale, fishery products must be transported without delay, under the conditionss laid down in Part XI (Division X) of these Regulations to their place of destination.

(3) However, if the conditions laid down in subject 2 of this Regulation hereof 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 must have sufficiently large cold rooms which satisfy the following conditions. They must have:

(a) water proof flooring which is easy to clean and disinfect and laid have down in such a way as to facilities the damage of the water or provided with equipment or 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 of temperatures prescribed in these Regulations.

In such cases, fishery products must be stored at a temperature approaching that of melting ice.

Hygiene conditions for fish landings and auctions

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

(a) Floors, walls and partititons, ceiling or roof linings, equipment and, instruments used for working on fishery products must 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 must be systematically exterminated in the premises or on the equipment. Rodenticides, insecticides, disinfectants and any other potentially toxic substances must be kept locked away and their use must not present any risk of contamination of the products.

(c) Working areas, instruments and working equipment must be used only for work on fishery products. However, following authorization by the Competent Authority, they may be used at the same time or other times for work on other foodstuffs.

(d) Potable water, within the meaning of Part XI (Division III) of these Regulations must be available. However, non-potable water may be used for steam production, fire-fighting equipment 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 must 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 as follows:

(a) The highest possible standard of cleanliness is required of staff more specifically:

i) Staff must wear suitable clean working clothes

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

iii) Smoking, spitting, eating and drinking in work and storage premises of fishery products must 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.

(c) 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 AND PRODUCTION SYSTEMS

DIVISION 1
PHYSICAL AND STRUCTURAL REQUIREMENTS OF PROCESSING ESTABLISHMENTS

Location

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

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

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

(c) where there is:

i) good access to water, power and all weather roads;

ii) good evacuation facilities for waste water and waste solids

(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.

Surrounding areas

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

(a) suitable graded, grassed or landscaped, in which case:

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) or suitably paved or concreted, in which case:

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 place should be properly maintained, i.e.

- the grounds should be kept clean, tidy at all times and free of accumulated of water;
- equipment should be stored properly,
- litter, rubbish and waste should be regularly removed;

to prevent surrounding grounds constituting an attractant, breeding place or harbourage for pests, or becoming a source for dust or contaminants entering the food handling and storage areas where food is exposed.

(2) If guard dogs are present, they should not have access to any part of the establishment where fish is handled, including the loading and unloading areas.

(3) If the plants' grounds are bordered by property not under the operator's control and not maintained in the manner described in this section, extra care shall be taken to inspect, exterminate or other methods to exclude pests, dirt and filth that may be a source of food contaminations.

(4) Operating systems for waste treatment and disposed 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.

48. (1) The conceptual design of a fish processing establishment must take full consideration of raw materials, processing methods, efficient and hygienic flow of the processing line, elimination of waste, ease of cleaning and allowing for full protection against contamination.

Design of a processing establishment

(2) The building must protect the processing line and products against contaminants (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.).

(3) The processing line (reception, processing, dispatch) should be directly connected with the side and complementing 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 must be available.

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

(a) There is separation by walls, locations, 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 operations which may cause cross contamination of food.

(b) There is a good lay-out and flow from raw materials through finished products and dispatched. The processing layout should be designed:

i) so that the distribution of equipment and processing activities facilitates the rapid processing of fish;

ii) in such a way that fish is not exposed to contamination by toxic materials or bacteria from the plant environment or by cross contamination during production between final products and raw products;

iii) in such a way that the intrinsic quality of the fish is maintained;

(c) All possible preventative measures and provisions must be taken already on constructioin level:

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

ii) to minimize the risk of food contamination by contact surfaces, packing materials, offals, drainage systems etc;

iii) to minimize maintenance;

iv) to facilitate cleaning and disinfection;

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

vi) to minmize airborne contamination;

vii) to guarantee safety and a healthy work environment

viii) 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 severage;

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

xii) to install an adequate electrical supply to maintain normal and efficient operation of all electrically power equipment and lighting.

xiii) to ensure that:

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

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

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

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

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

Requirements for working, handling and storage rooms

49. (1) The different working, handling and storage rooms in the establishments as described in Regulation 50 shall comply with the minimum conditions and requirements laid down in Regulations 52 to 67 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 68 to 76 of these Regulations.

General conditions for working rooms

50. (1) The establishment shall afford pending to its purpose, 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 shall be designed for work to be carried out in logical sequence and under satisfactory conditions;

(b) In general and pending the preparation and/or processing activities, the following completely separated working rooms

could be needed:

i) reception room;

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

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

iv) ice maker/storage room;

v) processing room or 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 and/or processing products;

viii) freezing facilities or rooms for freezing raw whole fish in brine at - 9ºC;

ix) dry room for packaging (mastering);

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 stores for finished fresh products both connected with the expedition room;

xv) storage room for storage of finished products at ambient temperature

xvi) expendition room;

xvii) social amenties with:

(A) changing room for city clothes and shoes

(B) showers

(C) changing room for uniforms and boots

(D) toilet block

(E) hand-washing room

(F) laundry and canteen

(2) The main processing area in which fish is handled should have only one entrance for personnel being independent and separate from any entrances and exits used for raw materials, finished products and other materials used during processing.

Conditions, preparation and processing rooms

51. In rooms where products are handled, prepared and processing, the establishment and shall afford at least the following facilities:

(1) Floors shall have:

(a) hard impact resistant surfaces, impermeable to grease and water, which permit easy cleaning and disinfaction and laid down in such a way as to facilitate the drainage of the water. Concrete floors shall have a high density, impermeable finish that is maintained in good condition.

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

(c) floor joints sealed with impervious materials, finished flush with the surface.

(d) junctions between floor and walls curved to facilitate cleaning.

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

(2) Effluent disposal systems and drains have to comply with the following requirements. The establishment shall have:

(a) an efficient and hygiene 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 which 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 conditioins but also to carry peak loads.

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

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

(B) to prevent the entry of rodents

An open drainage system vented through and gully traps are not allowed.

iii) have solid traps to prevent the passage of solid

materials to the external sewage system. Solid traps installed in conjuction with floor drains or/and 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. Where this occurs they shall be designed and maintained to ensure that flooding of the premises cannot occur due to backflow.

(b) 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 system 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.

(3) 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, not 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; and

vi) be easy to clean and disinfect;

(c) Angles between walls, between walls and floors and between walls and floors and between walls and ceilings, shall be sealed and covered to facililitate 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; and
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 4 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.

(4) Ceiling shall comply with following requirements:
(a) In buildings in which the roof frame is exposed, the installation of a suspended ceiling should be considered. Otherwise all parts of the structure must be smooth and painted a light colour. There should be easy access to all parts of the roof structure to facilitate cleaning.
(b) Ceiling 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 minimise accumulation of dust and dirt;
iv) be capable of being effectively cleaned;
v) have all overhead machinery and pipes located above ceiling; and
vi) minimize condensation, mould development and flaking.

(5) Doors shall comply with the following requirements:
(a) The doors of the reception room by which enters raw materials. and the doors of the expeditions room, by which leave the finished products, using suitable materials to protect them from impact damage. These doors should possess either plastic curtains or air curtains or a self-closing curtain or a self-closing device, in order to minimize 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; and

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 non-toxic, durable and of light colour; and

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 minimize movement of air into or between areas where food is exposed, processed or packed.

(6) Windows and external opening shall comply with following requirements:

(a) On construction level

i) Window frames shall be made of a smooth impermeable material; and

ii) Window sill 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 separatioin is required shall be constructed to render the opening pest proof.

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

(A) kept in good repair

(B) that is easy to remove 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, must be sealed against the

entry of pests and dust.

(7) Stairs, catwalks, platforms, stands to raise personnel's 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; and

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

(8) The ventilation system shall comply with the following requirements:

(a) Adequate and sufficient ventilation shall be provided to minimize the accumulation of odours, vapours, gases, dust and to prevent excessive build up of heat, steam, condensation, contaminated air and other undesirable 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 cleans, 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 minimizes the potential for contaminating food, packing materials and food-contact surfaces;

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

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.

(9) Illumination shall meet the following conditions:

(a) Adequate natural or artificial lighting shall be provided throughout the establishment and light produced shall not distort colourings 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; and

iii) 250 lux in other areas

(c) Light fittings shall be

i) equipped with a diffuser or other means so that breakage will not contaminate the product;

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

iii) readily accessible for cleaning purposes.

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

(10) Hand washing facilities:

(a) All areas in which fishery products are handled should be provided with hand washing facilities. The location of these hand washing facilities shall be arranged in a way that they are:

i) sufficient in member;

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

iii) also located adjacent to the social amenities and just before personnel enter the preparation or processing room.

(b) The hand washing facilities shall be provided with:

i) taps of the non-hand/elbow operable type (foot, knee or electrically 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 contained within a dispenser;

iv) single use paper hand towels held in a

dispenser and a sufficient number of receptables for disposing of used towels;

v) properly trapped waste pipes leading to drains; and

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

(11) 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 room cannot avoid passing through the bath.

(12) A room for cleaning and disinfecting work implements, utensils, recipients and small equipment, connected with a room for the storage of them 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; and

(c) high-pressure cleaning and disinfecting systems.

These facilities shall be constructed of corrosion resistant materials capable of being cleaned effectively.

(13) If sterilizing facilities are required, adequate provision for sterilizing work implements/equipment shall be provided:

(a) If the sterilizing medium used is not water, the method of sterilizing shall be first approved by the Competent Authority.

(b) Sterilising facilities shall be:

i) constructed of corrosion resistant materials;

ii) capable of being easily cleaned; and

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

Chill stores, cold stores, chillers and freezers

52. For chill stores, cold stores, chillers and freezers, the establishment shall afford at least the following facilities:

(a) Waterproof flooring that are 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. Where under floor ventilation pipes are provided they shall be pest-proofed.

(b) Walls that have smooth durable, impermeable surfaces that is easy to clean, as described in Regulation 51(3) of these Regulations.

(c) Ceilings that are easy to clean as described in Regulation 51(4) of these Regulations.

(d) Doors made from durable materials that are ease to clean. Plastic strip curtains or similar shall be installed to assist in air retention and to minimize temperature fluctuations when cold stores or freezer doors are open.

(e) Other internal structure constructed of smooth, impervious and corrosion resistant material.

(f) Those parties that are exposed to impact damage adequately protected.

(g) Facilities designed to allow for adequate drainage of water away from the refrigeration until.

(h) Adequate artificial lighting as described in Regulation 51(9) 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. No free space shall be allowed on top of the equipment.

Chill stores

53. In chill stores used for the storage of raw material the establishment shall afford at least following facilities:

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

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

ii) to ensure adequate protection from contamination

(b) Tanks of stainless steel, glass fibre or plastic in which the fish can be mixed with ice in sufficient quantities to maintain the temperature at 0ºC, in case of absence of the facilities mentioned in this Regulation at (a) above.

(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 themometer read to and

accurate to within 1ºC shall have its temperature taken and recorded at least once every 4 hours.

54. In cold stores, establishment shall afford at least the following facilities: *Cold stores*

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

(b) Different cold stores 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 of maintaining products in cold stores at an internal temperature below - 18ºC, whatever the ambient temperature may be, and also under extreme operating conditions (during loading and unloading).

(d) Doors to the cold store must be provided with plastic curtains (or similar item) in order to minimize the interchange of air during loading and unloading.

(e) A temperature recording device in a place where it can easily be read. The temperature sensor of the recorder must be located in the area furthest away from the cold source, i.e. where the temperature in the storage room is the highest. Temperature charts must be available for inspection by the Competent Authority or the inspectorate at least during the period in which the products are stored.

55. In freezers, establishment shall afford at least following facilities: *Freezers*

(a) A freezing facility appropriate to the presentation of the fishery products and its packaging. Fish should never be frozen in cold storage room.

(b) A freezing facility with sufficient capacity to freeze the fish to a temperature of a least - 18ºC with 8 hours of loading the freezer. For this reason, it is recommended that the freezing plant (motors, compressors, etc,) is rated at least 8 hp (7.5 KW) / 10001b of product to be frozen.

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

56. In brine freezing rooms reused solely for brine freezing whole tuna or other species, the establishment shall afford at least the following facilities: *Brine freezing*

(c) General construction conditions are:

i) Walls, floors and ceiling complying with the requirements laid down for chill rooms;

ii) Areas:

(A) suitably clean,

(B) sealed against dust and pests,

(C) 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 consumptions.

iii) Head 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.

(d) Specific brining conditions are:

i) Brining tanks, tanks surfaces and coverings constructed such a way that they are not a source of contamination for the fishery product.

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 - 18ºC, although not higher than -9º).

Ice plants / ice stores

57. In ice plants and ice storage room establishment shall afford 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

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

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

iii) with the capacity to store sufficient ice to satisfy needs.

(c) It is recommended that:

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

ii) the ice should be made in the form of flakes. If large blocks are produced they should be made in a hygienic way and be crushed by machine. Manual crushing of block ice is prohibited.

Live fish facilities

58. In rooms or parts of the establishment where animals such as crustaceans and fish are kept and packed alive, establishments shall, without prejudice to the description of facilities laid down in other Regulations in this Part:

(a) have appropriate fittings ensuring the best survival conditions provided with water of a quality such that no harmful organisms or substances are transferred to the animals;

(b) be satisfactorily clean;

(c) be maintained in such a manner that no microbiological, physical, chemical or other objectionable substances can contaminate the live fishery products or make them unfit for human consumption;

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

(e) have lighting in accordance with Regulation 51(9) of these Regulations.

Shellfish shucking

59. 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 ssubstances 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(9) of these Regulations.

Depuration

60. In areas, rooms or parts of establishments used solely for the depurations of shellfish, the establishment shall afford at least following facilities:

(a) Depuration tanks which are located, constructed and designed to:

i) prevent contamination of shellfish by other animals or pets;

ii) keep unpurified shellfish separate; and

iii) enable a hydraulic flow with minimum turbulence through the tank.

b) A purification system that shall be designed to provide sufficient water of adequate quality throughout the system in a manner that accomplishes effective purification.

Storage conditions for packing materials

61. In premises for storage of packing materials, the establishment shall afford rooms that shall be:

(a) dust and pest proof;

(b) designed and maintained to prevent undesirable physical, microbiological or chemical contamination;

(c) equipped with shelves, racks or pallets to store packing material designed and constructed in accordance with Regulation 69 of these Regulations.

Non-refrigerated products

62. If premises for storage of non-refrigerated fishery products, the establishment shall afford rooms which shall be:

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

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

Storage of toxic chemicals

63. In premises for storage of toxic chemicals and cleaning equipment, the establishment shall afford a room in which all toxic chemicals used on-site should be clearly identified and stored, when not in use, in a locked and signed facility separate to the main processing area.

Inspection rooms

64. The establishment shall afford, if applicable, an inspection service room complying with and used under following conditions:
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:

(a) adequately equipped;
(b) lockable;
(c) adjacent to the processing area;
(d) free from steam and fumes; and
(e) for the exclusive use of the inspection service

And, shall be provided with:

(f) lighting intensity of at least 600 lux;
(g) a clean bench or table for examination of the products;
(h) a thaw tank or similar capable of defrosting the maximum
(i) number of samples for one batch; and
(j) running water for cleaning instruments

65. The establishments shall afford, if applicable, laboratory rooms for microbiological or/and chemical examinations, which shall be separated from fishery products handing rooms. *Laboratries*

66. (1) Establishments shall afford adequate sanitary facilities in any social amenities for the personnel who handle fish as well as for those who handle materials and equipment that come into contact with the products. These social amenities comprise, in an adquate number, suitable and conveniently located changing rooms, flush toilets, showers, handwashing facilities and canteen (if meals are taken) in the establishment. *Social amenities*

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

(3) These facilities 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. The social amenities shall be well ventilated and illuminated.

67. (1) Establishments shall afford changing facilities containing: *Toilets, showers and hand washing facilities*

(a) an area for undressing out of day 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. The use of timber is prohibited for the construction of lockers, hangers and racks.

(c) showers that can be used before entering the work area.

(2) Toilet and toilet areas shall be adjacent 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; and

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

Toilets should be connected with the dirty (day clothes) or the clean (uniforms) changing room. Toilets shall have the same hygiene requirements as the processing room when connected with the clean changing room section.

Adequate numbers of sanitary facilities are considered to be as follows:

No of employees	No of WCs
1 to 9	2
10 to 24	3
25 to 49	4
50 to 99	6
for every additional 20	1 more

If personnel of both sexes are employed, separate sanitary facilities should be provided for each sex, in accordance with the above table. Urinals may be substituted for water closets, and may account for up to $^1/_3$ of the required number of WCs.

All toilets and urinals must be of the flushing variety. They should be constructed of materials that are easy to clean.

To avoid airborne contamination from toilets into areas where food is exposed preventative measures must be taken to protect against contamination (such as double doors, separate toilet room and positive airflow system).

(3) Hand washing facilities (i.e. hand-wash basins) shall be provided near toilets in a number equal to the sanitary facilities. They shall have a permanent provision of hot and cold water and shall be provided with adequate quantities of liquid soap. Taps

shall be of the non-hand/elbow operable type.

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

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

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

Persons coming out from the changing rooms, or from the canteen, or from the toilets must (by appropriate physical design) be forced to pass through the hand washing facilities room before entering the processing room;

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

(5) Any canteen should meet the same hygiene requirements as the processing rooms when connected with the clean changing room section (uniforms).

(6) 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

68. The establishment shall afford, in the working and storage rooms mentioned in Regulation 50 of these Regulations, machinery, tools, utensils, equipment, instruments, product holding, handling and conveying systems complying with the requirements laid down in following regulations.

Design and constructijon of facilities and equipment

69. (1) All machinery, manufacturing systems including gravimetric, pneumatic, and closed and automated systems, tools, utensils, equipment, instruments, product holding, handling and conveying system 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; and

(c) permit and enable:

i) easy and thorough cleaning and disinfection with hot

water, detergent and disinfectant;

ii) accessibility for inspection where necessary; and

iii) maintenance in appropriate sanitary conditions.

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

The above-mentioned working areas, instruments and working equipment must be used only for work on fishery products.

(2) All product holding, handling and conveying systems, machinery, tools, utensils and equipment which come into contact with fishery products, shall be constructed of materials that 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 or taste and are non-toxic;

(d) unaffected by food products; and,

(e) capable of withstanding repeated cleaning and disinfection, and easy to clean and disinfect;

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

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

Clean and sound wooden pallets are permitted:

(a) for the transport and the storage of processed food packed in carton boxes, to transport them in the area 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 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. Pallets made of plastice or of other corrosion resistant materials have to be used in this case.

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

Racks and storage systems in cold stores used to store packed products

can be made of clean and sound timber. Corrosion resistant materials or timber sealed by a durable non-toxic coating is preferable.

(4) 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

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

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

(3) Equipment or fittings adjacent to a 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 platform coved at the junction between it and the floor; 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.

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

(5) 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; and

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

Requirements under (a), (b) and (e), may be met by locating pipes and machinery above the ceiling. Ducts, conduits and pipes may be recessed into the wall or mounted at least 25mm clear. Long runs of exposed horizontal pipes should be avoided.

Product holding, handling and conveying

71. (1) A suitable system for the internal movement of fish within the plant shall be installed. Regard should be given to the need to maintain a regular flow of products by the following means:

(a) Fish boxes, sufficient in number, shall be provided for the needs of the process. They must 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. They shall have a smooth finish and their design shall avoid areas that could retain particles of product, grease and dirt. 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 utilized, they must be constructed of non-corrodible impermeable materials (e.g. stainless steel or high density plastic).

(e) Ice shovels should be made of a light coloured plastic, or of stainless steel. 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; and

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, etc

72. (1) Work tables shall be constructed of materials that are non-corrodible, impermeable and non-toxic. Stainless steel is preferable. Work tables shall be designed to facilitate their cleaning and to avoid areas that could retain particles of the product, grease, dirt.

(2) If food stands are used to raise personnel to the level of the

worktables, they should be constructed of stainless steel or other non-corrodible material. 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 meassuring equipment

73. (1) All equipment to be used for monitoring or measuring purposes where accuracy is important (i.e. measuring, regulating or recording temperatures, pH, acidity, water activity or other conditions that control or prevent growth of undesirable micro-organisms 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 caliberated regularly; and

(d) their calibration checked on a regular basis.

(2) Records shall be kept of the calibration status

Hygienic facilities

74. Establishments shall also afford the following facilities:

(a) Hygienic waste water disposal systems as described in Part XI (Division XI);

(b) Appropriate facilities for protection against pests such as insects, rodents, birds, as described in Part XI (Division VII);

(c) Facilities for fishery products not intended for human consumption as described in Part XI (Division XI).

Vehicle wash areas

75. (1) Establishment shall afford 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 systems units used to carry fish are cleaned, a paved and drained area shall be used.

(3) The surface of the vehicle wash area shall:

(a) be durable and impervicous;

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

(c) have an adequate supply of pressured water for disinfection and cleaning operations.

76. (1) Establishments shall afford loading docks. The loading dock

Loading docks

shall be:

(a) located in an area that is convenient to the stored products;

(b) enclosed or provided with a protective shelter to protect 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 that is impervious and durable.

(3) Unloading and loading equipment shall be constructed of a material that is easy to clean and disinfect.

DIVISION II
MAINTENANCE REQUIREMENTS

Scope

77. 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

78. An action plan to maintain the establishment must to be implemented.

Scheduling

79. (1) Repairs shall be carried out as soon as possible without interference to handling or processing and may cause the facilities closure during certain repairs.

(2) Planned actions shall be scheduled in a timetable to demonstrate the commitment to future actions.

(3) These schedules and timetables shall be approved by the Competent Authority and checked for execution on a regular basis.

Responsibilites

80. Responsibilities and authorities have to be established for implementing, maintaining, monitoring and verifying the maintenance plan.

Procedures

81. Procedures must be established to ensure that maintenance will be done in such a way that the risk of contamination of the products is eliminated. A regular preventative maintenance programme must be implemented, whereby equipment, utensils and premises are regularly reviewed for signs of wear and tear and where deficiencies are detected prior to a problem occuring.

Process Control

82. A fail safe control system has to be worked out to control the maintenance process. The measures taken must be compared with the

standards. Verification has to be done to ensure that the corrective actions are done in the good way.

Instructions

83. Work instructions and control instructions have to be developed to work out implementation procedures in detail and to monitor these on a regular and appropriate basis.

Documents and records

84. Records for controls, standards, recommendations and verification must be kept for review and inspection purposes.

Training

85. Training on the spot and special training programmes must be installed to ensure that staff are continually reminded of the risks and their responsibilities within the food industry especially concerning the items of this Part. Records of courses, training sessions and attendance must be kept for inspection.

DIVISION III
REQUIREMENTS FOR POTABLE WATER

Scope

86. (1) These Regulations concern standards of water intended for human consumption to be observed in fishery product activities.

(2) Facilities shall be required to provide a permanent supply of potable water within the meaning of this Division or alternatively of clean seawater or seawater treated by an appropriate system (filtration and chlorination, UV sterilization) under pressure and in sufficient quantity.

(3) If the water used in the establishment receive additional treatment prior to use, this must be done in accordance with the instructions of the manufacturer of any equipment or chemicals utilized 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. Non-potable water pipes must be clearly distinguished from those used for potable water or clean sea water.

Use

87. (1) For the purpose of this Division, water intended for human consumption shall mean all water used for that purpose, either in its original state or after treatment, regardless of origin:

(a) whether supplied for consumption; or

(b) whether:

i) used in a food production undertaking for the manufactures, processing preservation or marketing of products or substances intended for human consumption; and

ii) affecting the wholesomeness of the food stuff in its finished form.

(2) The management of the establishment shall only use potable water:

(a) that comes in contact with fish or fish-contact surfaces;

(b) that is used in the manufacture of ice; and

(c) that is used for cleaning and disinfecting in the establishment.

Application

88. Regulations 86 to 105 of this part shall not apply to:

(a) natural mineral waters; and

(b) medicine water

Distribution system

89. (1) All pipe-work in the water distribution system shall be impermeable, well constructed and in good condition. Iron pipes shall be painted externally in order to protect them against 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-contaminations 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/without intermediary storage

ii) surface water, well water or bore-hole water with/without intermediary storage

iii) desalinated seawater with/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/reticulation map whereon the outlets shall be identified by consecutive numbering so that they can be located in the establshment.

90, (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. *Water Storage*

(2) The tanks or cisterns shall be well constructed and the internal surfaces shall be smooth, impermeable, easily to clean and disinfect.

(3) Each water tank or cistern shall be provided with an inspection hatch that permits entry for cleaning purposes. 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 accumulations of rubbish, dust, water and other materials that could contaminate the water.

(6) Water tanks shall be inspected at regular intervals with the objective of keeping them in good conditions. A cleaning and disinfection plan has to be installed as mentioned in Regulation 122 of these Regulations.

91. (1) Water re-used and circulated within a facility shall be treated and maintained in a condition so that no health hazard can result from its re-use and shall be potable if it comes into contact with food. *Circulation and re-circulation*

(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) dead ends;

(d) non-potable water outlets clearly identified

(3) Water can only be used and reused or re-circulated for the cooling of canned products 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 similar, utilized in handling the water are constructed to facilitate inspection and cleaning.

Hot water and steam

92. (1) The establishment shall possess a means of heating water to a temperature of at least 80ºC in quantities adequate for hand-washing by personnel and, if required, for washing of equipment, machinery and the premises in general.

(2) The installation of either a steam system or pressurised hot water for cleaning the estalishment is recommended.

(3) Where steam or pressurised 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 quality objectives

93. Procedures and instructions shall be installed by management to implement an effective chlorination system, and to organize the schedule for monitoring free residual chlorine, microbiological analysis, and physiochemical analysis.

Scheduling

94. (1) Planned actions shall be scheduled in a timetable to demonstrate the commitment to the future actions.

(2) These schedules and timetable shall be approved by the Competent Authority.

Responsibilities and authorities

95. Responsibilities and authorities have to be established for implementing, maintaining, monitoring and verifying the potable water control plan.

Procedures

96. Procedures shall be implemented to control and safeguard the safety and the quality of water by:

(a) water analysis on residual chlorine contents;

(b) microbiological tests; and

(c) physiochemical tests.

Process Control

97. A fail safe control system has to be worked out to control the safety and the quality of water. The results must be compared with the standards. Verification has to be done to ensure that the corrective actions are successful.

Instructions and standards for chlorination

98. (1) The chlorination system shall comply with the following;

(a) chlorine shall be added in-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 to retain water together with the chlorine added for 30 minutes;

(c) the cleaning programme for the intermediary storage tanks

shall be documented, monitored and demonstrated;

(d) 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 8 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 products (fish, shrimp, molluses etc) shall not be washed, dipped, glazed, or treated with chlorinated water. It is recommended to use, in the case of an in-plant chlorinating system, the same residual chlorine level as authorised by the legislation in the Solomon Islands for potable water intended for direct human consumpton.

Standards for microbiological examination

99. (1) The general quality and safety parameters and limits, the patterns and frequency of standards analysis, the reference methods of analysis for microbiological monitoring are set fourth in Table 1(a), 1(b) and 1(c) of Schedule 4 to these Regulations.

(2) Water intended for human consumption should not contain pathogenic organisms. If it is necessary to supplement the microbiological analysis of water intended for human consumption, the samples should be examined not only for the bacteria referred to in Table 1 but also for the pathogens including:

(a) Salmonella;

(b) Pathogenic staphylococci; and

(c) Entero-viruses

Nor should such water contain,

(d) Parasites;

(e) Algae: or

(f) Other organisms such as animalcules (worms / larvae).

(3) 100 ml sample should not be positive for coliform bacteria, Escherichia coli or enterococci. If two consecutive samples show the presence of coliform bacteria, *E. coli* or enterococci, the water from the said source(s) must not be used until the contamination has been eliminated

(4) If the results of the initial or monitoring tests are unsatisfactory, an immediate investigation and further sampling must be carried out. The sample must be examined immediately using parameters as laid down in Table 1a of Schedule 4 to these Regulations.

Quality and safety parameters

100. The general quality and safety parameters and limits, the patterns and frequency of standard analysis, the reference methods of analysis for biological monitoring are set forth in Tables 2(a), 2(b) and 2(c) and 2(d) of Schedule 4 to these Regulations.

Standards for biological examinations

101. The genenral quality and safety parameters and limits, the patterns and frequency of standard analysis, the reference methods of analysis for biological monitoring are set forth in Tables 3(a), 3(b) and 3(c) of Schedule 4 to these Regulations.

Sampling

102. (1) Water sample shall be collected in sterile bottle. The tap to be sampled shall be run for at least 2-3 minutes to flush out the pipe. Before a water sample is drawn from the tap, the end of the tap shall be sterilised with a flame, and water shall be allowed to flow for 5 minutes before the sample is collected.

In cases where the test is undertaken 3 hours or more after sampling the bottles must be stored in ice.

To neutralize the chlorine, Sodium thiosulphate (crystals or solution) is introduced into the water sampling bottle prior to sterilization.

(2) The samples shall be taken from various appropriately coded outlets within the plant. A rotation system should be organised to ensure that over a set period samples are taken from each outlet.

Ice shall also be regularly tested.

(3) The result of the examination shall have the identification of the outlet where the sample is collected.

Laboratories

103. (1) The yearly (3 months) full examination sample (organoleptic, Physicochemical, undesirable and toxic substances, microbiological parameters) is to be collected by an official person and analysed in an official laboratory.

(2) The routinely-taken, samples are to be collected by the management of the establishment and analysed in the in-plant laboratory or in an external private accredited laboratory approved by the Competent Authority. The examinations are to be carried out under the supervision of the official inspector.

Records

104. The complete procedure of the control and treatment of sea and potable water used shall be documented by the quality management including treatment and measurement results. Records shall be kept of tests showing that effective treatment was maintained or that the microbiological quality was suitable.

105. Training on the spot and special training programs must be established to ensure that staff are continually reminded of the risks and their responsibilities especially concerning the assurance of water quality and safety and records of courses and training sessions attendance are kept for inspection and evaluations. *Training*

DIVISION IV

REQUIREMENTS FOR HANDLING RAW MATERIALS

106. The intake of fishery products has to be organized in accordance to the requirements with respect to the quality and safety of the products imposed by customers but at least to the requirements imposed by this Regulation. *Scope*

107. A supplier quality and safety assurance agreement has to be entered into between supplier and management of the establishment to work out principles concerning product control. Quality standards, maintaining the cold chain, hygiene and food safety. *Action plan and quality objectives*

108. (1) Planning actions shall be scheduled in a timetable to demonstrate the commitment to the future actions. *Scheduling*

(2) These schedules and timetable shall be approved by the Competent Authority and checked for execution on a regular basis.

109. Responsibilities and authorities have to be established for implementing, and maintaining, monitoring and verifying the described procedures for handling raw materials. *Responsibilities and authority*

110. (1) A procedure to establish supplier quality and safety assurance has to be worked out, applicable for all steps from 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 levels. There must be a documented agreement which is signed by both the quality manager of the establishment and the supplier ensuring guarantee about: *Procedures*

(a) *quality standard and product control:* namely, all raw materials has to undergo inspection on arrival at the plant on specifications agreed in the supplier quality and safety assurance agreement. Products that do not meet the quality and safety standards that are laid down for 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: namely, the raw material must 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;* namely, the products must be transported, stored and handled under conditions that will protect against contamination and minimize deterioration.

(d) *raw material specifications:* namely, ice/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, organolopetic specifications, chemical specifications concerning freshness determination, microbiological specifications, the way and the method of transport.

(2) The unloading of fishery products at the establishment jetty, shall comply with the following requirements:

(a) Unloading and landing equipment must be constructed of material that is easy to clean and disinfect and must be kept in a good state of repair and cleanliness.

(b) During landing, loading and unloading, contamination of fishery, products must be avoided. It must 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 marker 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) staff shall endeavour to protect fishery products from physical damage during unloading of vehicles; they should not stand on fish and should prevent it from falling onto the floor;

v) all the equipment used in the unloading of fish shall be washed and disinfected after each use. 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. Fish should never be stored in the vehicle whilst awaiting processing nor should fish be left outside the establishment.

(3) Instructions for raw material inspection, handling and storage procedures must be documented. Records of delivery and product quality must be kept to enable 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; and

iii) other materials that could contaminate the fish are not carried together with the fishery products.

(b) Before unloading commences, a sample of fish shall be collected from the vehicle, and the internal temperature measured. The mean temperature should be 0ºC, and no fish shall have a temperature of more than 5ºC for fresh fishery products.

The temperature of brine frozen fishery products shall not be higher then -9ºC.

(c) Before unloading commences a representative sample of each batch of fish shall be taken for sensory evaluation of smell and appearance, as described in Regulations 114 and 115 of these Regulations.

(d) The quality control manager shall indicate his approval of the batch based on the results of the above test. He or she shall sign an inspection form and assign a batch code to the fish before the unloading of the vehicle commences.

(4) The initial stages of processing (washing of raw material, separation of extraneous material and gutting) shall commence as soon as possible after unloading the vehicle.

(5) Fishery products which are not processed immediately upon

arrival at the establishment shall be washed with clean water at 0ºC (if necessary), and stored with ice in suitable reception tanks or put in fish-bins iced and stored in a chill room.

(6) The storage of raw material must comply with the following requirements:

(a) If more fish should arrive at the establishment than can be processed immediately, 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 0ºC.

(b) It is recommended that no products are stored for more than one day before processing is eviscerated. 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 carefully in order to avoid the contamination of the fish flesh.

(d) Only fish complying with the requirements laid down in Regulations 114, 115 and 116 of these Regulations shall be stored. 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. 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.

Process **111.** A fail safe control system must be installed whereby measurements and checks are compared to standards, followed by corrective actions if required.

Instructions **122.** Work instructions and control instructions must be formulated to work out the implemented procedures in detail.

Raw materials **113.** (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, and checks on contaminants 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

114. (1) Organoleptic specifications concerning freshness must be established. Each batch of fishery products must be submitted for inspection and inspected by the Competent Authority at the time of landing or before first sale to check whether they are fit for human consumption. This inspection comprises an organoleptic check carried out individually or by sampling. The criteria that can be used for the organoleptic check are: general appearance, colour, consistency, smell and eventually taste and flavour.

The organoleptic examination must be repeated after the first sale of fishery products, if it is found that the requirements of these regulations have not been complied with or when considered necessary. After the first sale, fishery products must at least comply with the minimum freshness requirements mentioned in these Regulations. The following categories can be mentioned:

(a) Freshness categories shall be established under following conditions:

i) Fishery products must be marketed only if they meet the requirements of this standard for the freshness categories; and

ii) Common marketing standards are laid down for the following products:

(A) Saltwater fish (all bony species);

(B) Selachii (Cartilaginous fish);

(C) Cephalopods (cuttlefish, squids, octopus); and

(D) Crustaceans (shrimps, lobsters, crabs etc.)

iii) The freshness category of each lot shall be determined based on organoleptic criteria.

iv) Freshness shall be defined by reference to the special ratings for different types of products set out in the tables, set forth in Schedule 5 of these Regulations.

v) On the basis of ratings referred to in clause (iv), products specified in (ii) shall be classified by lot in one of the following freshness categries:

(A) Extra, A, B in the case of fish, *selachii, cephalopods;* and

(B) Extra, or A in the case of shrimps.

vi) The criteria for fish unfit for human consumption are set out in the "not admitted" category in tables set forth in Schedule 5 of these Regulations.

(b) Lot categories shall be established under following conditions: Each lot must contain products of the same degree of freshness, if not, the lot shall be placed in the lowest freshness category represented herein.

(c) Product categories shall be established under following conditions:

i) Fish, selachii, and cephalopods placed by lot in freshness category Extra must be free of pressure marks, injuries, blemishes and bad discoloration. A very small proportion with slight pressure marks and superficial injuries shall be tolerated.

ii) Fish, selachii, and cephalopods placed by lot in freshness category A must be free of blemishes and bad discoloration. A very small proporation with alight pressure marks and superfield 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. Fish must be free of blemishes and bad discolouration. 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.

(2) Physical, chemical or other checks to determine freshness and to prevent fishery products that are unfit for human consumption from being

placed on the market, shall be established.

If the organoleptic examination reveals any doubt as to the freshness of the fishery products, use may be made of physical, chemical or other checks considered necessary or microbiological analysis.

(a) Physical methods ae:

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 Base-Nitrogen). Unprocessed fishery products belonging to the species categories designated by the Competent Authority shall be regarded as unfit for human consumption where organoleptic assessment raises doubts as to their freshness and chemical checks reveal that the TVB-N limits set by the Competent Authority are exceeded:

i) 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 6 to these Regulations.

ii) Distillation as referred to in clause (i) must be performed using apparatus that complies with the principles of the diagram as set out in Schedule 6 to these Regulations, or can be performed by an equivalent automatic steam distillation apparatus.

iii) The routine methods which must be used to check the TVB-N limits are as follows:

(A) microdiffusion method described by Conway and Byrne (1933)

(B) direct distillations method described by Antonacopoulos (1968)

(C) distillation of an extract deproteinised by trichlororacetic acid (Codex alimentarius Committee on Fish and Fishery Products - 1968).

iv) The sample must consist of about one hundred grams of flesh, taken from at least three different points and mixed together by grinding.

The Competent Authority shall recommend to official laboratories the use, as a matter of routine, of the reference method referred to in Schedule 6 to these Regulations. 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

115. (3) Fish shall be free of:

(a) heavy injuries and scratches;

(b) bad discolouration; and

(c) blemishes and dirt.

Sanitary soundness

116. (1) In order to control sanitary soundness, the presence of parasites, toxins, micro-organisms, viruses, accidental and intentional contaminants that could endanger human health, shall be checked.

The sanitary soundness can be checked by systematic control, by random sampling or by implementing a national monitoring programme. The fisheries sector and industry shall check and control the sanitary soundness of the fishery products and the Competent Authority shall collect all necessary information from the monitoring programme to inform and assist the industry.

(2) Fishery products shall not contain parasites that could be harmful for human health.

(3) Toxin checks to be established are:

(a) Histamine

i) the following sampling plan has to be established:

Nine samples must be taken from each batch for analysis. These must meet the following requirements:

(A) the mean value must not exceed 100 ppm

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

ii) These limits apply only to fish species of the following families: *scombridae, chipeidae, engraulidae* and *coryphaenidae*. However, fish belonging to these families that have undergone enzyme-ripening treatment in brine may have higher histamine levels but not more than twice the above values.

iii) Examinations must be carried out in accordance with reliable, scientifically recognized methods, such as "high performance liquid chromatography" (HPLC).

(b) Monitoring mercury, lead, cadmium in fishery products and inorganic tin in canned products shall be done as follows: A monitoring plan to check the contamination of fishery products by heavy metals shall be put in place.

Analysis methods, sampling plans and maximum limits for monitoring mercury, lead, cadmium content and inorganic tin fishery products shall be established:

i) the analysis method to be used in determining the total mercury content is the Atomic Absorption Spectrometry (AAS); and,

ii) the mean total mercury content, as determined by the analysis referred to in clause (i) hereof of the edible parts of the fishery products must not exceed 0.5 ppm of fresh products (0.5 mg/kg of fresh weight). This average limit is, however, increased to 1 ppm of fresh products (1 mg/kg of fresh weight) for the edible parts of the following species.

- Sharks (all species)
- Tuna (*Thunnus spp)*
- Little tuna *(Euthynnus spp)*
- Bonito *(Sarda spp)*
- Sailfish *(Istiophorus Platyterias spp)*
- Marlin *(Makaira spp) and*
- Rays *(Raja spp)*

iii) The mean total lead content, as determined by analysis referred to in paragraph (3.b.i) hereof, of the edible parts of the fishery products must not exceed 0.3ppm of fresh products (0.3 mg/kg of fresh weight).

iv) the mean total cadmium content, as determined by the analysis referred to in paragraph (3.b.i) hereof, of the edible parts of the fishery products must not exceed 0.05ppm of fresh products (0.05mg/kg of fresh weight) for the muscle meat of Swordfish (Xiphias gladius) and 0.1ppm of fresh products (0.1mg/kg of fresh weight for the muscle meat of edible parts of the following species:

- anchovy (Engraulis species)
- bonito (Sarda sarda)
- common two-banded seabream (Diplodus vulgaris)
- eel (Anguilla anguilla)
- grey mullet (Mugil labrosus labrosus)
- horse mackerel or scad (Trachurus species)
- louver or luvar (luvarus imperialis)
- sandine (Sandina pilchardus)
- sardinops (Sardinops species)

- tuna (Thunus species, Euthynnus species, Katsuwonus pelamis)
- wedge sole (Dicologoglossa cuneata)

v) Sampling plans shall be laid down for fresh and frozen fishery products by the Competent Authority. These shall take into account, on the one hand, the results obtained from national checks and that the mini mum number of samples to be taken per lot of each product category is 10 samples taken from 10 different individuals.

vi) The analysis shall be carried out on a finely homogenized mixture of the samples so as to obtain the mean value of the mercury, lead, cadmium in fishery products. The incremental 10 fish samples for heavy metal (mercury, lead, cadmium and tin) analysis shall be of similar weight. In the case of fish that are of various sizes, the samples taken must represent the size composition of the fish batch. The weight of an incremental sample shall be at least 100 grams, resulting in an aggregate sample of at least about 1kg.

vii) The sampling plans referred to in (v) above and subsequent mofification thereof shall be notified to the Inspection Service.

(4) Microbiological criteria, for the microbiological checks, including sampling plans and methods of analysis, shall be laid down to protect public health.

Temperature control

117. Temperature control after fishing, during transport in the fish-holds, during landing and offloading, during selling, during storage and transport and during processing shall be done to check if the temperature of the fishery products complies with the requirements laid down in these Regulations.

Seizure

118. 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 must be taken to withdraw them from the market and denature in such a way that they cannot be re-used for human consumption.

Records and documentation

119. (1) A "supplier quality assurance agreement" document, which is signed by both the supplier and the customer shall be available. A register shall be used to record all information about the incoming material.

120. (1) A training programme shall be in place whereby fishermen, transporters, off loaders and the inspection team in the reception must be involved to ensure that staff are continually reminded of the risks and their responsibilities within the food industry especially concerning the provisions of this Part. *Training*

(2) Records of courses, training sessions, and attendances shall be kept for inspection.

DIVISION V
CLEANING AND DISINFECTING

121. (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. When the surfaces are wet-cleaned, they shall, when necessary, be cleaned and disinfected and thoroughly dried before subsequent use. *Scope*

(2) In wet processing when cleaning is necessary to product against the introduction of micro-organisms 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.

(3) 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.

(4) (a) Food contact surfaces such as:

i) processing equipment and instruments used for working on fishery products in the preparation and/or processing sector;

ii) Crates, bins, basket, containers used in auctions, preparation and processing facilities for transporting, carrying, salting, brining, shelling,

iii) or shucking crustaceans or molluscan shellfish;

iv) cutting boards, working tables and work surfaces which fishery products come in contact with;

v) machinery that come into contact food during processing and machinery used for mechanical recovery of fish flesh;

(b) and non-food contact surfaces such as:

i) the building and the fixtures;

ii) social amenities (changing facilities, toilets, canteens);

iii) floors, drains, walls, ceilings, additional structures;
iv) waste containers

must be kept in a good state of repair and must be cleaned and be kept clean at all times and sanitized as follows with effective cleaning and sanitizing preparations, 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:

i) so that they do not constitute a source of contamination for the products; and
ii) in a manner that ensures adequate precautions are taken to prevent food, food contact surfaces or food packing materials from being contaminated during the cleaning or disinfecting of rooms equipment or utensils.

(5) 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 equipment and containers shall not be stored in processing rooms.

(6) Roadways, yards and other areas in the immediate vicinity of the establishment shall be kept clean.

(7) Establishment shall afford adequate facilities for cleaning and disinfecting buildings' fixtures, utensils, food contact surfaces and means of transport.

(8) Detergent and disinfectants shall be selected and tested for effectiveness of their purpose and shall be approved by the Competent Authority after receiving the following information: trade name, type of chemical compound, active ingredients and method of use. These products shall be used in such a way that they do not have adverse effects on the machinery, equipment, products and do not impart any flavours or odours or leave toxic residues.

(9) 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. All relevant regulations promulgated by other government agencies for the application, use or holding of these products shall be followed.

(10) Surfaces contacting food must be adequately rinsed after the use of detergents and disinfectants prior to handling food.

122. A cleaning and disinfection procedures for food-contact surface, non-food contact surfaces and intermediary storage water tanks shall be worked out: *Action plan and quality objectives*

(a) to ensure that the plant, after cleaning and disinfection is free from pathogens and that the Total Plate Count from food contact surface is below a level (cfu/cm2) admitted by quality management and approved by Competent Authority;

(b) in order to prevent the build up of dirt, such as scales, and maggots and other residues as well as resistant microbiological populations;and

(c) to ensure that the inner surface of the tanks are not a source of contamination for the potable water.

Such cleaning and disinfection plan for the establishment, water tanks, cisterns and intermediary water tanks has to be established and documented.

123. (1) Planned actions shall be scheduled in a timetable to demonstrate the commitment to the future. *Scheduling*

(2) These schedules and timetables shall be approved by the Competent Authority and checked for execution on a regular basis.

124. Responsibilities and authorities have to be established for implementing maintaining, monitoring and verifying cleaning and disinfection and a fail safe control system shall be implemented. *Responsibilities*

125. (1) A procedure has to be worked out to ensure that, in all sections of the establishment, a proper work method for cleaning and disinfection and a fail safe control system will be used. *Procedures and process control*

(2) The method of working shall at least consist of, and the different steps shall be established in following order:

(a) preparatory work before cleaning;

(b) documented visual checks before starting cleaning;

(c) cleaning with detergents;

(d) rinsing to remove that cleaning agent;

(e) documented visual checks to evaluate the cleaning before starting disinfecting;

(f) disinfecting;

(g) rinsing to remove the disinfectant after the appropriate contact time;

(h) final phase;

i) equipment is reasssembled and allowed to dry

ii) monitoring to assess the cleaning and disinfecting activities.

(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 worked out in the instructions, but not less than daily.

Instructions **126.** (1) In operation instructions, a hygiene work plan shall be worked out for the cleaning and disinfection of each area and room in the establishment.

(2) control instructions shall be worked out to define, establish and illustrate how to carry out the rapid tests to evaluate the cleaning and disinfecting activities described in this Part.

Specifications **127.** 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.

Documents **128.** (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 **129.** (1) Training on the spot and special training programmes must be implemented to ensure that staff are continually reminded of the risks and their responsibilities within the food industry especially concerning cleaning and disinfecting practices. All cleaning personnel shall be suitably trained in cleaning techniques.

(2) Records of all training activities must be kept for inspection.

DIVISION VI
GOOD HYGIENE PRACTICES

Scope **130.** (1) In order to avoid contamination of the product a high standard of hygiene of the personnel, premises and equipment shall be maintained.

(2) Regulations 130 to 155 inclusive applies to persons who:

(a) work in the unloading or reception of raw material, in the preparation / processing areas and in the packing areas;

(b) handle materials which come into contact with fishery products,

(c) enter any establishment (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 necssary precautions to prevent the contamination of the fishery products.

(4) The requirements contained in this division shall be displayed in visible notices inside the working and handling rooms.

Action plan

131. (1) Procedures and instructions shall be installed and maintained to avoid the contamination of the products by personnel, equipment and premises and to ensure optimal personal hygiene in all production steps in all circumstancs and to ensure optimal hygiene conditions during processing and to ensure optimal safety of the product.

(2) These schedules and timetables shall be approved by the Competent Authority and checked for execution on a regular basis.

Scheduling

132. (1) Planned actions shall be scheduled in a timetable to demonstrate commitment to Future action.

(2) These schedules and timetables shall be approved by the Competent Authority and checked for execution on a regular base.

Responsibility

133. (1) The management of an establishment shall allocate responsibility for ensuring personnel compliance with the requirements of this division to a competent supervisor.

(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 products and equipment. All personnel shall understand and comply with the requirements of these Regulations.

(3) Responsibilities and authorities have to be established for implementing, maintaining, monitoring and verifying the plan for best hygiene practices.

Procedures

134. Procedures concerning:

(a) general conditions of hygiene applicable to construction and operations; and

(b) general conditions of hygiene applicable to staff, protective clothing, personnel hygiene, hand hygiene, food borne diseases must be worked out to ensure that measures to maintain the highest possible standard of cleanliness and hygiene are implemented.

General conditions for construction and operations

135. (1) Floors, walls and partitions, ceilings or roof linings, equipment and instruments used for working on fishery products must 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 other vermin must be systematically exterminated.

(3) Work areas, instruments and working equipment must be used only for processing fishery products.

(4) Potable water, or (when appropriate) clean sea water, must be used for all purposes.

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

General conditions for staff

136. (1) The highest possible standard of cleanliness is required of staff.

(2) 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 and showering);

(b) entering the processing room (hand washing and checks by a supervisor on personal hygiene);

(c) leaving the plant (changing clothes and cleaning and disinfecting uniforms and boots); and

(d) use of toilets on, entering and leaving the plant and during processing.

Protective clothing

137. (1) All personal and visitors entering the preparation/processing rooms staff 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 that completely encloses all hair. If involved in medium or high risk processing personnel shall wear a head covering that enclose the scalp, hair, beard and moustache; and

(d) a water impermeable apron for personnel who handle fish and unpacked fish products.

(2) If personnel who handle fish also wear gloves, such gloves:

(a) shall be made of plastic or rubber;

(b) and be either a disposable type or, alternatively, be capable

of being easily cleaned and disinfected; and

(c) shall be in a sound, clean and sanitary condition.``

(3) If personnel wear disposable gloves or other disposable protective clothing, the disposable clothing shall be discarded after use and not be reused.

Personal hygiene

138. (1) All staff while on duty in food handling areas shall maintain a high degree of personal cleanliness.

(2) Personnel who handle fish shall not wear:

(a) jewellery, including rings, necklaces, bracelets, brooches or earings;

(b) nail varnish or fingernail polish and artificial eyelashes;

(c) watches; or

(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 Regulation 137 (1) (c) above.

(4) Any behaviour which could result in the contamination of fishery and fish products such as:

(a) Smoking;

(b) use of tobacco or betel nut;

(c) chewing;

(d) spitting;

(e) eating and drinking; and

(f) other unhygienic behaviour

Shall be prohibited in fishery products handling areas, work and storage premises of fishery products.

Hand hygiene

139. (1) All personnel shall wash their hands with water and soap frequently and in particular:

(a) on entering product processing areas;

(b) immediately after using the toilet;

(c) after handling dirty or contaminated materials;

(d) after chewing, eating, smoking or drinking;

(e) after cleaning procedures, handling dtergents and similar clean up chemicals; and

(f) whenever contaimated

The wearing of clean gloves does not exempt the wearer from having thoroughly washed their hands.

(2) Workers shall maintain hand hygiene during production and have facilities to wash their hands during work. Gloves and outer garments that contact fish or contact surfaces shall be made of an impermeable material and shall be maintained in a clean and sanitary condition. If

gloves are worn, they shall also be washed, disinfected and dried (outside and inside) at regular intervals.

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 transmsitting contaminants.

(3) Any person with an injury, a cut, an open wound or a wound that is infected shall not continue to handle the food or food contact surfaces until the injury is covered with a clean waterproof impermeable dressing that is securely attached.

(4) 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) cotton wool and adhesive tape; and

(c) alcohol or other disinfectant lotion

Food-borne diseases

140. (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 the 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 that the person does not enter the facility until he/she produces a certificate from a medical practitioner indicating that they are free from infection and are non-infections;

(3) The employer shall take all the required 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 persons who:

(a) is without a current (yearly medical certificate stating that they are free from any communicable disease; or

(b) by medical examination or supervisory observation is shown to:

i) suffer from or to be a carrier of food borne disease

ii) have or appear 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 from which there is a reasonable possibility that fish,

fish-contact surfaces or fish-packing materials will become contaminated.

shall prepare, pack or handle any material likely to be used in constructing the product, until the conditions is corrected. If workers come back after sick-leave, to work again, they have to follow the measures laid down in the instructions worked out in the instructions worked out in the quality manual of the establishment.

(5) Precautions shall be taken to prevent visitors to food handling areas from contaminating fishery products. This shall include the use of protective clothing. Visitors shall comply with provisions of these Regulations.

(6) Operators in pathogen testing laboratories shall change their uniform prior to entering food handling areas.

Process control

141. (1) A fail safe control system had to be installed by which the activities of the personnel are checked and controlled by the supervisors, in respect of their compliance with the activities described in the procedures and the instructions.

(2) A supervisor shall be responsible for checking all of the steps desribed in the procedures and instructions.

Instructions

142. (1) The instructions shall describe and work out the measures to assure the hygiene of the personnel, and to contribute to the safety (pathogens) and the shelf-life (spoilage bacteria) of fishery products.

(2) Instructions shall be given to personnel on how to:

(a) enter the factory;

(b) clean and disinfect hands;

(c) clean and disinfect knives, cutting boards, tables, gloves and hands;

(d) report after sick-leave; and

(e) leave the factory

Specofocatopms

143. Specifications shall be in place for uniforms, boots, detergents and disinfectants.

Documents

144. All procedures, instructions, specifications, control and check-activities shall be thoroughly documented and recorded.

Hygiene training

145. (1) The manager of an establishment shall arrange for adequate and continuous training of all food handlers in personal hygiene and involved in cleaning and disinfection, so that it is understood how to take the precautions necessary to prevent contamination of fishery products.

(2) Training shall include reference to relevant parts of these Regulations.

DIVISION VII
PEST CONTROL REQUIREMENTS

Scope

146. (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 and animals from the processing areas and to protect products against contamination by pests and animals, with exception of live animals such as crustaceans and fish to be placed on the market alive or not admitted. 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, and

(c) shall implement and maintain a pest control plan, containing an effective and continuous schedule for the detection, control and eradication of pests, to avoid contamination of the products by pests on two levels.

i) on a passive level that means prevention, protection, proofing, construction measures;

ii) on an active level that means extermination by use of:

- mechanical methods; trapping (rodents)
- electrical methods: electrocuter (insects)
- chemical methodss: poisons (rodenticides & insecticides).

(2) Prevention and extermination of pests will 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 chemical 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

147. (1) An action plan has to be worked out:

(a) on a passive level in a manner that the establishment is proofed and appropriate facilities are installed 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; and

(b) on an active level in a manner that pests are destroyed by mechanical, electrical or chemical methods.

Schedule

148. (1) A time schedule has to be worked out in an establishment to organise and to control the actions on both active and passive levels.

(2) Appropriate period measures shall be taken to prevent the establishment of colonies of insect and rodent pests both within and around the plant.

(3) These schedule and timetables shall be approved by the Competent Authority and checked for execution on a regular basis.

Responsibilities

149. (1) Responsibilities and authorities have to be established for implementing, maintaining, monitoring and verifying the Pest Control Programme.

(2) If pest control or a part of the plan is put out to contract, the management remains responsible for implementation of the plan.

Procedure

150. (1) A procedures has to be worked out to assure a consistent pest control plan with proper implementation of the passive and active levels.

(2) The method of working will at least consist of:

(a) For the passive level;

The building must be pest proof against vermin such as insects, rodents and birds by proper design and controls of openings such as:

i) Doors: When a door is closed, it shall fit so that there is no gap between the door and the frame more than 3 mm. Doors to the outside must be kept closed at all times when not in use.

ii) Windows: All windows that can be opened must be covered with a tight fitting fly screen of mesh size no larger than 1 mm. The fly-screened frames shall be removable for ease of cleaning.

iii) Ventilation: Outlets must be screened with a screen whose mesh size is no larger than 1mm.

iv) Drains: All drain openings must be covered with grating with hole sizes no larger than 10 mm across.

v) Harbourage: Various trash containers inside or

outside buildings that could harbour pests must be removed.

(b) For the active level:

i) Rodents, insects and any other vermin must be systematically exterminated from the establishment.

ii) A documented plan shall be available for extermination of pests. This plan shall include:

(A) the location and reference number of all traps (baited or otherwise).

(B) a routine check to verify that food, water and shelter is inaccessible to pests at every location within premises and to check for the presence of rodent infestation, i.e.the presence of faecal droppings, runs and smears, holes, damage to food, foot prints,gnawing and squeaking sounds and gnawing traces on baits.

(C) Inspection of infestation in areas adjacent to the establishment;

(D) Inspection of incoming material for pest infestation

(E) There shall be a responsible person within the establishment who is knowledgeable about pest control

(F) Storage areas should be organised so that they can be easily inspected for possible rodent infestation.

iii) Rodent traps must be strategically placed to exterminate rodents inside the establishment . Traps must also be placed outside to catch rodents before they can enter the establishment.

iv) At least one electric fly trap shall be installed at every entrance to rooms where processing takes place and where packaging materials are stored. The following conditions shall also apply

(A) electric fly traps must not be placed over processing lines or in front of fans.:

(B) electric fly traps must be suspended between 2.5 m and 3 m above the floor.

(C) electric fly traps must be left on 24 hours a day

(D) UV bulbs must be replaced at least every year or according to manufacturers specifications.

(E) catch trays for dead flies shall be regularly cleaned.

(3) Rodenticides, insecticides and any other potentially toxic substances must be stored in rooms or cupboards that can be locked when not in use. Their use must not present any risk of contamination to products. Toxic substances must not be placed where there is danger of contamination of the products. Toxic substances must be approved for their use and must not be handled during processing. The person assigned to handling toxic substance must be properly trained.

Process control

151. A fail safe control system has to be implemented to check whether the pest-control plan is in compliance with the requirements of these Regulations.

Instructions

152. (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 worked out by management together with personnel to deal with both active and passive pest control.

Specification

153 (1) Specifications, such as trade name, compound active ingredients, methods of use, instructions concerning concentration or dilution and safety instructions concerning the pesticide shall be provided and available at all times.

Documents

154. All procedures, instructions, specifications, control and check activities shall be thoroughly documented and recorded. In particular, the trap-map, bait map and the routine check records shall be available at all times for the inspection services.

Training

155. (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 these Regulations.

(2) Records of courses and training sessions attended must be kept for inspection and evaluation.

DIVISION VIII
MANUFACTURING REQUIREMENTS

Scope

156. (1) Handling and processing practices shall be implemented with the purpose of processing high quality and safe finished products.

(2) Handling and processing activities include handling, processing and packing rooms such as grading, weighing, sorting, washing,

preparing, chilling, freezing; thawing, processing, packing, distribution and all safety control activities.

Action plan and quality objectives

157. Procedures and instructions shall be introduced and maintained to implement good manufacturing practices with the purpose of:

(a) avoiding so far as possible any cross-contamination of products;

(b) drawing up and validating a product flow of the products raw material to finished product;

(c) drawing up a practical flow for:

i) waste products that leave the processing line; and

ii) additives and packing materials that join the processing-line;

(d) organizing a logical and practical flow for:

i) dirty receptacles and equipment that leave the processing line;
and;

ii) clean receptacles and equipment that join the processing line;

(c) avoid temperature violation, exceeding the requirements or recommendations specified for handling, processing and storage;

Schedules

158. (1) Planned actions shall be written in a schedule to ensure they are implemented as designed.

(2) The schedule shall be approved by the Competent Authority and checked for execution on a regular base.

Responsibility

159. Responsibilities and authorities must be established for implementing, maintaining, monitoring and verifying all described good manufacturing practices.

General procedures

160. (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 minimize contamination.

(3) Fish and fishery products must never be placed on the floor;

(4) Lots of fishery products from different harvests or from different fishing boats shall not be mixed together. Maintaining fish in lots will help prevent contamination between lots and enable easier identification in the event of subsequent rejection.

(5) During handling and processing the temperature of fishery

products shall be maintained within temperature tolerances prescribed in these Regulations.

(6) During stoppages, the processing of fish that has already started should be finished or alternatively the fish should be transferred to a chiller or adequately iced.

(7) Deteriorated and damaged products and extraneous materials 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 estalishment. If identified during processing, such fish shall be isolated immediately and adequately disposed of without contaminating acceptable quality products.

Washing fish product at receiving

161. (1) Fishery products shall be thoroughly washed as soon as they arrive at the processing establishment. This shall include:

(a) the separation of extraneous material such as crabs, wood, detritus and mud; and

(b) the washing of fishery products with adequate quantities of clean chilled potable water followed by icing or chill storage until ready for processing

(2) Fishery products shall always be cleaned and washed under running chilled water.

Procedures

162. (1) Procedures must be developed to ensure that in all stages of the process all necessary preventative measures on the level of quality control and food safety must be taken.

(2) The documented procedures must show the flow of products through the factory. During the process flow, special attention must be given to avoid contamination, cross-contamination, processing delays and rise of temperature of products.

Chilled products

163. (1) The chilling of fishery products shall be carried out as follows:

(a) performed with sufficient rapidity to prevent undesirable physical, chemical and microbiological deterioration;

(b) the temperature shall reach at the end of the chilling cycle the temperature of melting ice with a tolerance of ±2ºC; and

(c) to control histamine formation, the internal temperature of the fishery products shall be brought from ambient temperatures to 10ºC or below within 6 hours, and once chilled be maintained as close as possible to the temperature of melting ice. After

chilling, fishery products shall not be exposed to temperatures above 4ºC for a cumulative period of more than 2 hours.

(2) Chill stores shall comply with following conditions:

(a) Establishments processing fresh chilled fish products shall have separate chill stores for raw materials and finished chilled products;

(b) Chill stores used to store chilled fish shall be operated at the temperature of melting ice;

(c) Chill stores shall not be used for the purpose of initial freezing of fish or fish product; and,

(d) Chill stores shall be kept clean and free of accumulated ice. The floor and general structure of chill stores shall be maintained in good condition at all times.

(3) The chilling of unpackaged fishery products shall be carried out under the following conditions:

(a) Where chilled, unpackaged fishery products (raw material) are not dispatched, prepared or processed immediately after reaching the establishment, they must be stored or kept under ice in a chill store. Re-icing must be carried out as often as necssary; and

(b) Ice used, with or without salt, must be made from potable water or clean seawater and be stored under hygienic conditions in containers provided for the purpose, such containers must be kept clean and in a good state of repair.

(4) Pre-packed fresh products must be chilled with ice or kept in a chill store.

(5) The preparation of fishery products shall be carried out in compliance with following requirements:

(a) If not carried out on board vessels, operations such as heading and gutting shall be carried out quickly and hygienically. Products must be washed thoroughly with potable water or clean seawater immediately after such operations;

(b) The quantities of fish on work tables at any one time should be kept to a minimum;

(c) Fish held on tables waiting to be processed shall be protected by adequate quantities of ice;

(d) During work breaks, products shall not be left on the worktables. Processing of fish already on the tables shall be completed before line workers leave their posts;

(e) The internal temperature of fishery products shall be maintained below a limit designed 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 quickly and in such a way as to avoid contamination or spoilage, and in a place other than that used for heading and gutting operations. Fillets and slices must not remain on worktables any longer than is necessary for their preparation. Fillets and slices to be sold fresh must be chilled as quickly as possible after preparation;

(g) All equipment used for filleting of fish should be washed and disinfected regularly during processing. 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/or wear clean gloves before commencing their work;

(j) If fillets are not immediately packed or frozen they shall be stored at 0ºC with adequate quantities of ice, or in a chill store; and

(k) Containers used for the dispatch or storage of fresh fishery products must be designed in such a way as to ensure their protection from contamination and their preservation under sufficiently hygienic conditions and, more particularly, they must provide adequate drainage of melt water.

(6) To keep fishery products in a frozen conditions by proper storage of frozen fishery products, cold stores shall comply with the following requirements:

(a) The floor and general structure of the cold stores shall be maintained in good conditions;

(b) All cold stores shall be kept clean and free from accumulaltion of ice;

(c) Cold stores shall be well organised, with separation of different products and batches; and

(d) In order to permit the free circulation of air within the cold stores, products shall not be stored in contact with the walls or floor.

(e) Poultry, meat and other products that may contaminate the fishery products should not be stored in the cold stores unless the product is packaged and physically separated from seafood products.

(f) Cardboard shall not be placed on the floor for the purposes of keeping it clean.

(g) Whenever possible any products that have been stored

longest shall be the first to be distributed (first in, first out principle).

(h) Effective measure shall be to keep temperature variations to a minimum after the freezing process and during handling and transport.

(i) Cold stores must have temperature recording devices installed where they can easily be read. The temperature sensor of the recorder must be located in the area further away from the cold source, i.e. where the temperature in the storage room is the highest.

(j) Temperature records must be made available for inspection by the Competent Authorities.

Frozen products

164. (1) Freezing of fishery products shall be carried out under the following conditions:

(a) Establishments must have freezing equipment (blast- / contact-/ plate- / tunne or brine freezers) sufficiently powerful to achieve a rapid reduction in temperature so that the temperatures laid down to in this Regulation can be obtained as fast as possible to the centre of the product;

(b) Fresh products to be frozen must comply with the requirements, conditions and procedures for fresh products laid down in Regulation 163 of these Regulations; and

(c) The freezing process shall be carried out in a way that minimizes 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 of accumulated ice.

ii) blocks of fish for freezing shall not be thicker than 8 cm to ensure rapid freezing to the centre of the back.

iii) fish is not packed and frozen immediately shall be either stored with sufficient ice to maintain its temperature at 0ºC, or held covered in ice in a chill store.

iv) glaze water used on frozen fish shall first be chilled to 8ºC. A mixture of ice and potable water should be used.

v) During unloading of freezers, the internal temperature of the fish shall not be permitted to rise above - 18ºC.

vi) The packing of master cartons shall be done rapidly

to prevent the internal temperature of frozen product to rise above.- 18ºC.

(2) When freezing fishery products, management shall take into account the freezing capabilities of the facilities:

(a) Freezing equipment, when utilized for the initial freezing of unfrozen fish or fishery products should reduce the product temperature through the zone of maximum water crystallization (usually between - 1ºC to -5ºC) preferably within 4 hours, but not exceeding 6 hours, from the commencement of the refrigeration process.

(b) Where the refrigeration process is continued in order to reduce the thermal core temperature to - 18ºC or colder, the whole refrigeration process should preferably be completed with in 8 hours, but not exceeding 12 hours.

Longer freezing times damage the texture and quality of fishery products, and indicate that the capacity of the freezing plants is inadequate.

(c) The process shall not be regarded as complete until the temperature of the product has reached - 18ºC at the thermal centre after thermal stabilization. An excepton is brine frozen fish to be used for canning, which may be frozen at higher temperature, although not exceeding - 9ºC.

(d) Blast freezers shall not be loaded with fish in excess of the design capacity of the equipment. Reference should be made to 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.

Thawing

165. Eastablishments that carry out thawing operations shall comply with the following requirements:

(a) Fishery products must be thawed under hygienic and controlled time / temperature conditions. During thawing, the temperature of products must not increase excessively and must be monitored;

(b) Fishery products shall be brought to their thawed state as quickly as possible without causing undesirable physical, biochemical and microbial changes to the food;

(c) If water is used to thaw frozen products, a control system shall be installed; and

(d) After thawing, fishery products must be handled in accordance with the requirements of chilled products stated in these Regulations. When they are prepared or processed, these operations must be carried out without delay. If they are put directly onto the market, the thawed state of the fish must be clearly marked on the package.

Mechanical recovery of fish flesh

166. The mechanical recovery of fish shall be carried out under the following conditions:

(a) Mechanical recovery of gutted fish must take place without undue delay after filleting, using raw materials free of guts. Where whole fish are used, they must be gutted and washed beforehand;

(b) The machinery must be cleaned at frequent intervals, at least every two hours; and

(c) Mechanically recovered flesh must be frozen as quickly as possible or incorporated into a product intended for freezing or stabilizing treatment.

General procedures

167. (1) Fresh, frozen and thawed products used for processing must comply with the requirements laid down for fresh, frozen and thawed products in these Regulations.

(2) Where the processing treatment is carried out to inhibit the development of pathogenic micro-organisms, or if is a significant factor in the preservation of the product, the treatment must be scientifically recognized by the inspection service.

(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 products, product surfaces and packing materials;

ii) Processing in which there is risk of contamination to the final product including:

(A) prawn heading, de-veining and peeling;

(B) lobster heading, gutting and de-veining; and

(C) dismembering, gutting and scaling of fish;

iii) shall take place in physically separated locations or partitions away from where the product is further processed or packed.

iv) Pet food and fish meal preparation and packaging 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 any finished product.

ii) All steps in the production process including packaging shall be performed without unnecessary delay and under conditions that will minimize the

possibility of contamination, deterioration and growth of micro-organisms.

iii) For the preparation and/or 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 of processed food at different stages of processing; and

(C) all equipment that has been in contact with raw materials or contaminated material shall be thoroughly cleaned and sanitized prior to being used in contact with processed food.

Fish smoking

168. (1) Smoking must be carried out in separate premises or a special place equipped with a ventilation system to prevent the smoke and heat from affecting other premises or places where fishery products are prepared, processed or stored.

(2) Materials used for the smoking of fish must be stored away from the place of smoking and must be used in such a way that they do not contaminate products.

(3) Wood that has been painted, varnished, glued or undergone any chemical preservation treatment must not be used for fish smoking.

(4) After smoking products must be cooled rapidly to the temperature required for their preservation before being packaged.

Salting

169. (1) Salting operations must take place in different premises sufficiently far away from premises where other processing operations are carried out.

(2) Salt used in the treatment of fishery products must be clean and stored in such a way as to preclude contamination. It must not be re-used.

(3) Any container used for salting or brining must 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 must be cleaned before use.

Cooking crustaceans and shellfish

170. (1) Where products are being heated in any way, such as blanching or retorting, there shall be adequate control to ensure that the correct temperature / time regime is used to achieve the desired functionality and shelf-life without jeopardizing consumer health.

(2) Any cooking must be followed by rapid cooling. Water used for this purpose must be potable water or clean seawater. If no other method of preservation is used, cooling must continue until the temperature approaches that of melting ice.

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

(4) After shelling or shucking, cooked products must immediately be frozen or kept chilled at a temperature that will preclude the growth of pathogens, and be stored in appropriate premises.

(5) Every manufacturer must carry out microbiological checks on its production at regular intervals, complying with the standards set forth in Schedule 3 to these Regulations.

Processing shrimps

171. (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 30 minutes.

(2) Tanks used for washing shrimp shall be emptied and cleaned between different batches of shrimp.

(3) All products stored for more than one day before processing should be beheaded. The priority should be to behead 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 a sufficient quantity of ice to maintain a temperature of 0ºC.

(5) Shrimp should be peeled and de-veined rapidly in order to minimize the rise in temperature.

(6) Peeled and de-veined shrimp not frozen immediately should be stored at 0ºC with adequate quantities of ice.

(7) Higher standards of hygiene and cleanliness should be maintained at the work tables on which shrimp is peeled and de-veined, due to the higher risk of contamination of the shrimp flesh itself.

(8) 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 contol

(9) Chilled water shall be used for the washing of head-on shrimp at all stages of the process.

(10) 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 25ºC.

Cooked Shrimp

172. (1) Cooked shrimp shall only be handled in an area separated from areas where raw product is processed. There shall be no direct access for workers between the two areas.

(2) All personnel who handle cooked shrimps, or who work in or enter the area in which it is being processed shall wear coats, boots, hats and aprons that are used exclusively by such personnel, and are kept separate from the protective clothing used in the processing of raw shrimp. 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 article (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 disinfecting.

(5) If the final product is to be head-on shrimp, this should be processed immediately and without a period of storage.

Canning

173. (1) A scheduled process for low acid canned foods shall be established by qualified persons having expert knowledge of thermal processing requirement for low acid foods packed in hermetically sealed containers. A "Standard Operating Procedure" Manual shall be compiled specifying the following:

(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 The Standard Operating Procedures Manual shall be based on the requirements laid down in Title 21 Food and Drugs, Code of Federal Regulations, Chapter 1, Food and Drug Administration, Department of Health and Human Services, Part 113, Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers (21 CFR p.113).

(2) Canning conditions shall comply with following requirements:

(a) The water used for the preparation of cans must be potable water,

(b) The process used for the heat treatment must be appropriate, having regard to such major criteria as the heating time, temperature, filling, size of containers, etc, a record of which must be kept;

(c) The heat treatment must be capable of destroying or inactivating pathogenic organisms and the spores of pathogenic micro-organisms;

(d) The heating equipment must be fitted with devices for verifying whether the containers have in fact under gone appropriate heat treatment; and

(e) Potable water must 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 containers.

(3) The following checks must be carried out to verify the canning process:

(a) Checks must be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat treatment.

i) incubation test: incubation must be carried at 37ºC for seven days or at 35ºC 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 must 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 must be available for the examination of cross-seams.

(c) Checks are carried out in order to ensure that containers are not damaged.

(d) All containers that have undergone that treatment under practically identical conditions during the same period of time must be given a batch identification mark.

174. (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 products must 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 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 must be carried out, by qualified persons; on the abdominal cavity and livers and roes intended for human consumption. According to the system of gutting used, the visual inspection must be carried out as follows:,

i) in case of manual evisceration in a continuous manner by the operative at the time of evisceration and washing.

ii) in case of mechanical evisceration by sampling carried out on a representative number of samples being less than 10 fish per batch.

(b) The visual inspection of fish fillets or fish slices must 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 must be drawn up and kept available for the Competent Authority. Where candling of fillets is possible from a technical view point, it must 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, must not be placed on the market for human consumption.

(b) The fish and fish products referred to in paragraph (c) that are to be consumed as they are must, in addition, be subjected to freezing at a temperature of not more than - 20ºC in all parts of the product for not less than 24 hours. Products subjected to this freezing process must be either raw or finished.

(c) Fish and products subjected to the condition in paragraph (b) are:

i) fish to be consumed raw or almost raw, e.g. raw herring "maatje".

ii) the following species if they are to undergo a cold smoking process at which the internal temperature of the fish is less than 60ºC.

- herring
- mackerel
- sprat
- (wild) Atlantic and Pacific salmon.

iii) marinated and/or salted herring where this process is insufficient to destroy the larvae of the nematodes.

(d) Manufacturers must ensure that fish and fish products listed in paragraph (c) or the raw materials for use in their manufacture are subject to the treatment described in paragraph (b) prior to their release for consumption. The fishery products listed in paragraph (c) must, when they are placed on the market, be accompanied by a document from the manufacturer stating the type of process they have undergone.

Packaging **175.** (1) The time that elapses between processing and packaging shall not cause the food to suffer any undesirable physial, chemical or microbiological deterioration.

(2) Packaging must 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; and

(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 must comply with all the rules of hygiene and in particular:

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

(b) they must not be capable of transmitting to the fishery products substances harmful to human health, and:

i) the ink used to apply description markings, inks and colours 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 of carcinogens, mutagens and teratogens shall not be used in inks applied to food or packaging;

iv) lacquer applied to the inner surface or part of the inner surface of covering shall:

(A) cover the inner surface in 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 must be strong enough to protect the fishery products adequately and;

i) The first envelope, which is in direct contact with food, can be plastic food packing materials, a foam box or a can.

ii) The second envelope, with is not in direct contact with the food can be 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 that 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 must provide adequate drainage of melt water.

(g) Unused packaging materials must be stored in premises connected with the production area and protected from dust and contamination in accordance with the requirements laid down in Regulation 61 of these Regulations.

Traceability and identification marks

176. (1) It must be possible to trace, for inspection purposes, the plant of dispatch of consignments of fishery products, by means of labelling and by accompanying documents. For that purposes, without prejudice of the provisions concerning labelling of food products laid down in other regulations, at least the following information must appear on the packaging or, in the case of non-packaged products, in the accompanying documents:

(a) Country of dispatch that may be written out in full or shown as an abbreviation using capitals.

(b) Identification of the establishment or factory vessel by its official approved number.

(2) All the letters and figures must 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.

Process control

177 (1) A fail-safe control system, as part of the food safety control system must be installed enabling monitoring and verification to be carried out against planned control activities, followed by corrective actions if required.

(2) Cross contamination shall be controlled by proper installing the other prerequisite programmes (good practices) and shall be controlled by sampling and microbiological analysis.

(3) Time-temperature abuse shall be controlled by the proper installation of procedures and instruction laid down in this Part, and shall be controlled by temperature measuring.

(4) 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. A calibration system shall be applied either in-house or by an external authority and results of the calibration kept for 2 years unless otherwise specified in these Regulations.

178. (1) Following instructions have to be made to work out the implemented procedures in detail for every specific case. *Instruction*

(a) Work instruction for e.g.

i) chilling, freezing, thawing fishery products

ii) preparation of fishery products such as rinsing, filleting, skinning, trimming, grading, packing, mechanical recovery of fish.

iii) processing of fishery products such as canning, smoking, salting and cooking

iv) to prevent cross contamination and temperature abuse

v) use of sweeteners, colours and food additives other than colours and sweeteners.

(b) Control instructions for e.g.

- controlling time-temperature conditions
- candling
- visual checks

179. (1) Product quality specifications such as process description (nature of the packing-unit packing-volume/weight per unit packing), self-life and storage conditions, transport conditions, distribution conditions and label information shall be in place when applicable. *Final product specifications*

(2) Product safety specifications for:

(a) potential chemical hazards such as:

i) environmental chemical and pesticides;

ii) sweeteners, colours and food additives other than colours and sweeteners;

iii) ichthyotoxin;

iv) scombrotoxin; and

v) ciguatera

(b) potential biological hazards as microbes and parasites; and

(c) potential physical hazards shall be in place when applicable

180. All precedures, instructions and specifications, control and monitoring activities shall be thoroughly documented and recorded. *Documents*

Training

181. (1) On the spot training 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 preparation and processing of fishery products.

(2) Records of courses and training session attendance must be kept for inspection and evaluation.

DIVISION IX
STORAGE REQUIREMENTS

Scope

182. (1) The storage of fishery products (raw materials and finished products), packing material, cleaned receptacles, tubs, baskets and equipment and other products such as ingredients, additives, chemicals, have to be organised in accordance with requirements as to temperature, humidity, quality and the safety of the products imposed by consumers and as a minimum standard to the requirements imposed by this Part.

(2) Storage shall be under conditions that will protect materials against physical, chemical and microbiological contamination, as well as again deterioration of the materials and the containers.

Quality objectives and action plan

183. (1) Procedures and instructions shall be implemented and maintained:

(a) For the storage of raw materials and finished products:

i) to avoid the decrease of shelf-life of the products and deterioration.

ii) to avoid decomposition of fishery products,

iii) to eliminate or minimize possible occurrence of contamination and the proliferation of micro-organisms,

(b) For the storage of packing materials to minimize the risk of spoilage, damage or contamination of packing materials; and

(c) For the storage of chemicals:

i) to identify hold, used and store toxic compounds in a manner that protects against food-packaging materials.

ii) to identify; hold and store toxic cleaning compounds, disinfecting agents and pesticide chemicals in a manner that protects against contaminatioin of fish, food-contact surface 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 the maintenance and operation of plant and equipment, and

(d) necessary for use in the plant's operations are allowed to be used and stored in the plant.

Scheduling

184. (1) Planned actions shall be scheduled in timetable to demonstrate the commitment to the future actions.

(2) These schedules and timetables shall be approved by the Competent Authority and checked for execution on a regular basis.

185. Responsibilities and authorities have to be established for implementing, maintaining, monitoring and verifying of the described storage practices.

186. Procedures shall be worked out to ensure that the hygiene requirements in respect of the storage of fishery products, dry ingredients, chemicals, packaging materials and finished products are met.

187. Fishery products must, during storage, be kept at the temperatues laid down in these Regulations, and, in particular:

(a) Fresh or thawed fishery products and cooked and chilled crustaceans and molluscan shellfish products must 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) pre-packed fishery products may be chilled with ice or with mechanical refrigeration.

(b) Living molluscan shellfish shall be kept at temperatures lower than 10ºC.

(c) Frozen fishery products, with the exception frozen fish in brine, intended for the manufacture of canned foods must be kept at an even temperature of - 18ºC or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than 3ºC. 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 4.4ºC from the time it is frozen for a cumulative period of more than 12 hours. An uninterrupted period of exposure should not exceed 6 hours.

(d) Processed products must be kept at the temperature specified by the manufacturer.

188. (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; and decomposition and parasites and found to be in a sound condition. The nature and frequency of such inspection shall be set by the exporter and approved by the Competent Authority.

(2) Fishery products may not be stored with any other products that 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 of frozen products

189. (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 temperature shall be maintained

(4) The air velocity in cold store rooms shall be moderate and no higher than necessary to achieve uniform temperature within the rooms.

(5) Products should be stacked so that air circulation within the storage room is not impaired. Except in jacketed rooms, no direct contact with ceiling and floors shall be allowed.

(6) A system of controlled stock rotation shall be employed in cold stores and chill rooms.

Non-refrigerated products

190. Premises used as a non-refrigerated store for processed fishery products shall be of sound construction and designed and maintained so as to prevent undesirable physical, chemical or microbiological contamination or changes to fishery products and their packaging that could affect the soundness of the fishery products.

Storage of dry ingredients

191. Dry ingredients shall be stored in a closed, good ventilated, pest proof and clean area with the required room temperature and humidity. The products shall be protected against spoilage, damage and contamination.

Storage of packaging materials

192. (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 of hazardous substances

193. (1) Pesticides, cleaning agents or other substances that 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 purposes 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

194. A fail safe Control system shall be installed:

(a) To control temperature of chill rooms and cold rooms. Cold rooms (storage rooms for frozen products) shall have a temperature recording device in place and have a temperature chart available for inspection by the supervisor at least during the period in which the products are stored.

(b) To ensure compliance with the requirements for

i) chemicals

ii) packing materials

(A) first envelope (plastic bags and foam boxes)

(B) second envelope (cartons)

laid down in the Supplier Quality Assurance Agreement for chemicals, ingredients and packing materials.

Instructions

195. Control instructions shall be put in place:

(a) to implement the daily temperature control acitvities in the fish storage facilities for fresh and frozen fish; and

(b) to implement that control activities for hygiene and storage organisation in the storage rooms.

Specifications

196. Temperature standards and tolerances shall be implemented in every establishment.

Records

197. Temperature conditions, hygiene conditions and inventory management practices in chill stores and cold stores shall be monitored and records maintained.

Training

198. A training programme shall be in place and shall include reference to the Regulations in this Part.

DIVISION X
TRANSPORT REQUIREMENTS

Scope

199. (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 Division.

(2) Transport shall be done under conditions that will protect materials against physical, chemical and microbiological materials and containers,.

Quality objectives and action plan

200. (1) Procedures and instructions shall be installed and maintained

(a) for the transport of raw materials and finished products in order:

i) to avoid decrease of shelf-life of the products;

ii) to avoid decomposition of fishery products; and

iii) to eliminate possible occurrence of contamination

(b) for the transport of packing material, to prohibit the chance of spoilage, damage or contamination.

Schedulling

201. (1) Planned actions and to be planned actions shall be scheduled in a timetable to demonstrate commitment to the future actions.

(2) These schedules and timetables shall be approved by the Competent Authority and checked for execution on a regular base.

Responsibility

202. (1) Responsibilities and authorities have to be established for the implementation, maintaining, monitoring and verification of the described trnasport practices.

(2) It shall be the responsibility of the owner of any vehicle to comply with the relevant provisions of this Part. However, the management of the establishment shall supervise the unloading of vehicles and shall communicate to its owner the existence of any infractions.

Procedures

203. Procedures shall be worked out to ensure that the hygienic requirements for contamination preventions, temperature maintenance with respect to transport of raw materials, finished products and packaging materials are met.

204. (1) Fishery products must, during transport, be kept at the temperature laid down in this Part and, in particular: *Temperature during transport*

(a) Fresh or thawed fishery products and cooked and chilled crustacean and molluscan shellfish products must 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) Living mollusc shellfish shall be kept at temperature lower than 10ºC.

(c) Frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned foods, must be kept at an even temperature of - 18ºC or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than 3ºC. 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 and/or processing and where the distance to be covered is short, that is to say not exceeding 50 km or one hour's journey, the Competent Authority may grant a derogation from the conditions laid down in this Regulation.

(d) Processed products must be kept at the temperature specified by the manufacturer.

205. (1) The parts of the vehicles, in which chilled or frozen fish is transported shall: *Hygiene conditions*

(a) be clean and in good state of repair;

(b) be covered during the transporting of the product in order to prevent exposure to dust, birds, insects and sunlight;

(c) be of adequate size and have sections or containers designed specifically for the storage of fishery products;

(d) be constructed and equipped in such a way that the temperature requirements laid down in these Regulations 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. 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 be finished in such a way that they do not adversely affect the fishery products and 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; and

(h) if lighting is supplied, have light sources covered by a shatterproof shield.

(2) The hygienic conditions on construction level for vessels transporting fishery products are laid down in Regulation 36 of these Regulations.

Live products

206. (1) Vehicles used for the transport of live fishery products shall

(a) be clean and capable of being cleaned and drained.

(b) be constructed so as to maintain the fish in a healthy condition and ensure a high survival rate;

(c) be capable of protecting the fish from the environment and temperature extremes;

(d) have any possible food contact surfaces constructed from smooth corrosion resistant, impervious materials free from cracks and crevices.

General conditions

207. (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 not to be contaminated 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 must 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 that are fit for human consumption. The transport of wastes and by products in fish vehicles is prohibited.

(7) The transport condition of fishery products to be placed on the market alive must not adversely affect the products.

(8) After each journey, the vehicle and any fish boxes used should be washed with water and detergent, followed by disinfection.

208. (1) The transport of raw fishery products fresh on ice by road shall be undertaken. *Specific conditions*

(a) in closed insulated containers (so as to guarantee that the different layers of raw materials are completely covered with ice) in non-insulated open means of transport; or,

(b) in open non-insulated containers in an insulated means of transport, provided with mechanical refrigeration, where the distance to be covered or the journey is of such a length that the melting of ice cannot be avoided without mechanical refrigeration.

(2) Raw fresh frozen fishery products shall be transported in clean closed pre-cooled containers, holds or other means of transport at the appropriate temperature laid down in these Regulations, and be provided with a thermometer to be able to control temperature.

(3) Packed frozen finished products in master cartons and packed fresh on ice finished products in polystyrene packing materials shall be transported in clean closed pre-cooled containers or other means of transport, at the appropriate temperature, laid down in these Regulations, and be provided with a thermometer to be able to control temperature.

(4) Fishery products that have been subjected to sterilization in hermetically sealed containers shall be transported in clean closed containers or other means of transport at an ambient temperature in a way that master cartons and 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 be checked and pre-cooled before loading. After loading, the container shall be cooled down to - 18ºC before leaving the establishment for the harbour.

209. A fail safe control system shall be installed whereby the transport activities of raw materials and finished products are checked and controlled for compliance with the activities described in the procedures and the instructions. *Process control*

210. Instructions shall be put in place for: *Instructions*

(a) the measurement of temperature of chilled and frozen products;

(b) transporting fish by boat;

(c) offloading boats;

(d) loading carriers;

(e) transport by carriers; and

(f) cleaning and disinfecting means of transport.

Specifications **211.** Specifications shall be put in place for all means of transport and their use.

Documents **212.** All procedures, instructions, specifications, control and checking activities shall be thoroughly documented and recorded.

Training **213.** (1) The management of an establishment shall arrange for the adequate and continous training of all food handlers and transporters in the hygienic handling of fishery products so that it is understood how to take the precautions necessary to prevent contamination and the deterioration of fishery products.

(2) Training shall include reference to the relevant Parts of these Regulations.

DIVISION XI
WASTE DISOSAL REQUIREMENTS

Scope **214.** The establishment shall afford appropriate facilities designed:

(a) to treat by-products in an appropriate way in the event that by-products are destined for human consumption;

(b) to separate and remove guts and other waste that may constitute a danger to public health from the vicinity of products intended for human consumption; and

(c) to drain liquid waste water and treat sewage.

Quality objectives and action plan **215.** Procedures and instructions shall be implementedd and maintained:

(a) to treat the by-products, if applicable;

(b) to prevent the contamination of fishery products with bacteria from residues and wastes; and

(c) to deal with waste water drainage and sewage treatment.

Scheduling **216.** (1) Planned actions shall be scheduled in a timetable to document commitment to future actions.

(2) Such schedules and timetables shall be approved by the Competent Authority and checked for execution on a regular basis.

Responsibility **217.** Responsibilities and authorities must be established for implementing, maintaining, monitoring and verifying waste disposal practices.

Procedures **218.** (1) Procedures shall be implemented so as to ensure that hygienic requirements in respect of by-products and solid and liquid waste disposal are met.

(2) Waste containers and their use shall comply with the following

requirements as to hygiene, and unless special facilities are provided for the continuous disposal of waste, waste must be placed in leak proof, impermeable containers:

(a) that are provided with tight fitting lids to prevent the entry of insects, rodents and other animals;

(b) that are designed to facilitate cleaning and disinfection;

(c) that are clearly marked for that purpose only or be of a different colour to boxes used for fish for human consumption;

(d) that, 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 fishery products; and

(e) that must be always thoroughly cleaned and disinfected after use.

(3) Disposal of waste shall comply with following hygienic requirements:

(a) waste must 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 does not constitute a source of contamination of 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 residue and waste are stored shall

- have a permanent water supply and adequate drainage
- be kept clean
- be regularly inspected to ensure that this requirement is met.

Process control

219. A fail safe control system shall be installed to control compliance with the requirements laid down in Regulations 214, 215 and 218 oif these Regulations.

Instructions

220. Instructions shall be put in place on how to:

(a) treat the by-products, if applicable;

(b) dispose of guts, offals and waste;

(c) deal with waste water and sewage;

(d) store and remove solid 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

221. Specifications shall be put in place concerning identifications and the use of the waste containers.

Records and documentation

222. All procedures and instructions, control and check activities shall be thoroughly documented and recorded.

Training

223. (1) The management of an establishment shall arrange for the adequate and continuous training of personnel in the hygienic handling of by-and/or waste products, so that it is understood how to take necessary precautions to prevent contamination of fishery products.

(2) Training shall include reference to the relevant parts of these Regulations.

PART XII
CONDITIONS FOR THE USE OF FOOD ADDITIVES

General

224. (1) In application of section 3 (d) and (e) of the Act, fishery products, intended to be placed on the market, must 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 these Regulations.

(2) In the context of these Regulations, *"quantum satis"* means that no maximum level is specified. However, 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 (E950, E951, E954, E959)

225. (1) Sweeteners within the meaning of these Regulations are food additives that are used to impart a sweet taste to processed fishery products.

(2) Only the following sweeteners at the mentioned concentration 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 General and specific cases

226. (1) "Colours" within the meaning of these Regulations are:

(a) that add or restore colour in a food, and include natural sources that are normally not consumed as food stuffs as such and not normally used as characteristic ingredients of food.

(b) preparations obtained from foodstuffs and other natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents.

(2) 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.

(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 the following processed fishery products:

(a) fish paste and crustacean paste;
(b) pre-cooked crustaceans;
(c) salmon substitutes;
(d) surimi;
(e) fish-roe; and
(f) smoked fish

the 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

(5) The 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, Cochineal Red A
E129 Allura Red AC
E131 Patent Blue V
E133 Brilliant Blue FCF
E142 Green S
E151 Brilliant Black BN, Black PN
E155 Brown HT
E160d Lycopene
E160c Beta-apo-8'-carotenal (C30)
E160f Ethyl ester of Beta-apo-8'-corotenic 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) salon 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 tothe maximum level of 300 mg/kg; and

(f) smoked fish up to the maximum level of 100 mg/kg.

Other food additives **227.** (1) Food additives other than colours and sweeteners within the meaning of these Regulations are:

(a) "preservatives" - namely, substances which prolong the self-life of foodstuffs by protecting them against deterioration caused by micro-organisms;

(b) "antioxidants" - namely, substances which prolong the self-life of foodstuffs by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes;
(c) "carrier", including carrier solvents - namely, substances used to dissolve, dilute, disperse or otherwise physically modify a food additive without altering its technological function (and without exerting any technical effect themselves) in order to facilitate its handling, application or use;
(d) "acids" - namely, substances which increase the acidity of a foodstuff and/or impart a sour taste to it;
(e) "acidity regulators" - namely, substances which alter or control the acidity or alkalinity of a foodstuff;
(f) "anti-foaming agents" - namely, substances which prevent or reduce foaming;
(g) "bulking agents" -namely, substances which contribute significantly to its available energy value;
(h) "emulsifiers" - namely, 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;
(i) "emulsifying salts" are substances which convert proteins contained in cheese into a dispersed form and thereby bring about the homogenous distribution of fat and other components;
(j) "firming agents" - namely, substances that make or keep tissues of fruit or vegetables firm or crisp, or interact with gelling agents to produce or strengthen a gel;
(k) "flavour enhancers" - namely, substances which enhance the existing taste and/or odour of a foodstuff;
(l) "foaming agents" - namely, substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff;
(m) "gelling agents" - namely, substances which give a foodstuff texture through the formation of a gel;
(n) "glazing agents" (including lubricants) - namely, substances which, when applied to the external surface of foodstuffs, impart a shiny appearance or provide a protective coating;

(o) " humectants" - namely, 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;
(p) "Modified starches" - namely, 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 bleach;

(q) "packaging gases" - namely, gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container;

(r) "propellants" - namely, gases other than air which expel a foodstuffs from a container;

(s) "raising agents" - namely, substances or combinations of substances which liberate gas and thereby increase the volume of dough or batter;

(t) "sequestrants" - namely, substances which form chemical complexes with metalic ions;

(u) "stabilizers" - namely, substances which make it possible to maintain the physiochemical state of a foodstuff; stabilizers include substances which enable the maintenance of a homoge nous dispersion of two or more immiscible substances in foodstuff and include also substances which stabilize, retain or intensify the existing colour of a foodstuff;

(v) "thickeners" - namely, substances that increase the viscosity of a foodstuff;

(2) For the purpose of the these Regulations the following are not considered as food additives:

(a) substances used for treatment of potable water;

(b) products containing pectin derived from the peel of citrus fruits, or from a mixture of both, by the action of dilute acid followed by partial neutralization 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 amylase enzymes;

(e) ammonium chloride;

(f) blood plasms, edible gelatine, protein hydrolysates and their salts, milk protein and gluten;

(g) amino acids and their salts other than glutamic acid, glycine, cysteine and their salts and having no additive function;

(h) caseinates and casein;

(i) inculin;

(3) In processed fishery products under mentioned food additives may be used at *quanium 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) Discodium 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 Arbic)
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 di-glycerides of fatty acids

E472a Acetic acid esters of mono-and di-glycerides of fatty acids
E472b Lactic acid esters of mono-and di-glycerides of fatty acids
E472c Citric acid esters of mono-and di-glycerides of fatty acids
E472d Tartaric acid esters of mon-and di-glycerides of fatty acids
E472e Mono-and diacetyl tartaric acid esters of mono-and di-glycerides of fatty acids
E472f Mixed acetic and tartaric acid esters of mono-and di-glycerides of fatty acids
E500 Sodium carbonates
(i) Sodium carbonate
(ii) Sodium hydrogen carbonate
(iii) Sodium sesquicarbonate
E501 Potassium 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)
(iii) 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 sulphates
E616 Calcium sulphate
E524 Sodium sulphate
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*
E842 Nitrons 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
Ssorbitol
Sorbitol syrup
E421 Mannitol
E953 Isomalt
Maltitol
Maltitol syrup
E966 Lactitol
E967 Xylitol

(4) In processed fishery products:

(a) under-mentioned food additives

E620 Glutamic acid
E621 Monosodium glutamate

E622 Mono-potassium glutamate
E623 Calcium di-glutamate
E624 Mono-ammonium glutamate
E625 Magnesium di-glutamate

may be used individually or in combination up to the maximum level of 10 g/kg.

(b) under-mentioned food additives

E626 Cuanylic acid
E627 Di-sodium guanylate
E628 Di-potassium guanylate
E629 Calcium guanylate
E630 Inosinic acid
E631 Di-sodium inosinate
E632 Di-potassium 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 the following food additives may be used at *quantum satis:*

E420 Sorbitol
(i) Sorbitol
(ii) Sorbital syrup
E421 Mannitol
E953 Isomalt
(i) Maltitol
(ii) Maltitol syrup
E966 Lactitol
E967 Xylitol

228. (1) The following groups of preservatives mentioned in this regulation can be used to prolong the shelf-life of fishery products.

(2) Sorbates

E200 Sorbic acid
E202 Potassium sorbate
E203 Calcium sorbate and benzoates:
E210 Benzoic acid
E211 Sodium benzoate
E211 Potassium benzoate
E213 Calcium benzoate

These may be used singly or in combination in

(a) semi preserved fish products including fish roe products up to the maximum level of 2000 mg/kg or mg/l;

(b) salted dried fish up to the maximum level of 2000 mg/kg;

(c) cooked shrimps up to the maximum level of 2000 mg/kg; and

(d) *cooked Crungon crungon and Crungon vulgaris* up to maximum level of 6000 mg/kg;

whereby the levels of all substances mentioned above are expressed as the free acid.

(3) The following preservatives and food additives described as sulphur dioxide and sulphites:

E220 Sulphur dioxide
E221 Sodium sulphite
E222 Sodium hydrogen sulphite
E223 Sodium metabisulphite

E224 Potassium metabisulphite
E226 Calcium sulphite
E227 Calcium hydrogen sulphite
E228 Potassium hydrogen sulphite
may be used singly or in combination in:
(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; and
iv) cooked, up to the maximum level of 50 mg/kg in the edible parts.
whereby
i) maximum levels are expressed as S02 in mg/kg and relate to the total quantity, available from all sources.
ii) a sulphur dioxide content of not more than 10 mg/kg is not considered to be present.

(4) The food preservative / food additives, E251, sodium nitrate, and E252, potassium nitrate, may be used at 200 mg/kg in pickled herring and sprat whereby residual amount, nitrite formed from nitrate is expressd as $NaNO_2$

(5) 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

229. (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; and
(b) frozen fish with red skin.

(2) The antioxidant E385 Calcium di-sodium ethylene di-amine tetraacetate (Calcium di-sodium EDTA) may be used up to the maximum level of 75 mg/kg in:

(a) canned and bottled crustaceans and molluscs; and
(b) canned and bottled fish.

Polyphosphates

230. The following polyphosphates (E452) especially

(a) Sodium polyphosphate
(b) Potassium polyphosphate
(c) Sodium calcium polyphosphate
(d) Calcium polyphosphates

may be used in

(a) Surimi up to the maximum level of 1g/kg;
(f) Fish and crustacean paste up to the maximum level of 5g/kg;
(g) Frozen fillets of unprocessed fishery products up to the maximum level of 5g/kg; and
(h) Frozen crustacean products up to the maximum level of 5g/kg.

PART XIII

PRODUCT SAFETY ASSURANCE PLAN FOR PREPARATION AND PROCESSING OF FISHERY PRODUCTS

HAZARD ANALYSIS CRITICAL CONTROL POINTS (HACCP)

Introduction

231. (1) The implementation of a Product Safety Assurance Plan for the preparation and processing of fishery products means implementing all activities aimed at ensuring and providing that a fishery product satisfies the product safety requirements of these Regulations.

(2) A Product Safety Assurance Plan based on the Hazard Analysis Critical Control Points (HACCP) system shall be implemented if product/process specific hazard analysis reveals that processors have significant food safety hazards that they must control.

(3) The way to implement the HACCP system is laid down in this Part of these Regulations.

The seven principles of HACCP

232. (1) It is a requirement that a logical approach for food safety be followed based on the seven principles of HACCP. These principles are:

(a) identification of hazards, analysis of risks and determination of measures necessary to control them;
(b) identification of Critical Control Points;
(c) establishment of Critical Limits for each Critical Control Point;
(d) establishment of Monitoring procedures;
(e) establishment of Corrective Action to be taken when

Monitoring indicates that there is a deviation in control parameters;

(f) establishment of Verification and review procedures

(g) establishment of Documentation concerning all procedures and records.

(2) The HACCP-based food safety plan shall be developed for each product manufactured by the establishment.

Hazards

233. (1) A hazard is a biological, chemical or physical attribute that can cause food to be unsafe to consumers.

(2) Hazards can be:

(a) Biological hazards, such as:

i) Pathogenic micro-organisms (e.g. harmful bacteria, viruses)

ii) Parasites

(b) Chemical hazards, such as:

i) natural toxins

ii) pesticides

iii) veterinary drug residues

iv) unapproved food and colour additives

(c) Physical hazards, such as metal, glass, etc...

(3) 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 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.

(4) Species related hazards that are potential hazards associated with specific species of fishery products. 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 (esolar)

(d) histarnine
(e) food and colour additives
(f) parasites (safety hazard)
(g) veterinary / aquaculture drugs
(h) pathogenic micro-organisms

(5) Process related hazards are potential hazards that are associated with food handling, preparation or processing. Examples of process related hazards are:

(a) Inadequate drying, pathogen growth, toxin formation as a result of inadequate salt, sugar; and or nitrite concentration;
(b) Pathogen survival through cooking;
(c) Cross-contamination;
(d) Temperature abuse during processing of cooked products;
(e) Temperature abuse during processing of chilled products;
(f) Microbiological growth in batters;
(g) Pathogen survival through pasteurization;
(h) Recontamination after pasteurization;
(i) Temperature abuse during final cooling;
(j) Temperature abuse during finished product storage;
(k) Temperature abuse during distribution;
(l) Excessive mounts of food and colour additive; and
(m) Important physical hazards.

Preliminary steps

234. The following steps shall be followed for developing a HACCP plan;

(1) Preliminary Step 1 is to define the scope of the HACCP plan. To help define the scope the following questions have to be answered:

(a) Will the study cover a whole process or one specific part?
(b) Will the study cover one product or a group of product?
(c) Will all type of hazard categories initially (i.e. microbiological, chemical and physical) be covered?
(d) Should the HACCP study start at receiving of material at the establishment or earlier at some other point between harvesting, landing and transporting?; and,
(e) stop at the end of the production line or continue through to distribution, retail and consumer handling?

(2) Preliminary Step 2 is to select and assemble a multidisciplinary HACCP team:

(a) The HACCP team must include expertise from all parts of the establishment who have particular knowledge about the specific product and process. The team shall include a full range of skills and experience appropriate to the product under consideration, its production (manufacture, storage and distribution), its consumption and the associated potential hazards.

(b) Where necessary, the HACCP team will be assisted by specialists who will help to solve any difficulties in regards assessment and control of hazards.

(c) The HACCP team can include:

i) a quality control specialist who understands the potential biological, chemical or physical hazards associates with a particular product type.

ii) a production specialist who has responsbility for, or is closely involved with, the tehcnical 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.

v) engineers who are familiar with all processing and associated equipment and machinery.

(d) Select a leader of the HACCP Team (this role should be given to the person most qualified and experienced in HACCP and food safety control measures).

(3) Preliminary Step 3 is to describe the food, distribution and storage. The end product shall be described in terms of:

(a) composition (e.g. raw material ingredients, additives, etc);

(b) structure and physiochemical 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 atmosplhere, etc.);

(e) storage and distribution conditions;

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

(g) instruction to the consumer for its intended use; and

(h) any microbiological or chemical criteria applicable.

(4) Preliminary Step 4 is to identify the intended use of the product. The HACCP team shall define the normal or expected use of the product

by the customer.

(5) Preliminary step 5 is to identify the intended consumer. The HACCP 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.

(6) Preliminary Step 6 is to develop a detailed product 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

iii) sequence of all process steps (including the incorporation of raw materials, ingredients or additives and delays during or between steps)

iv) technical parameters of operations (in particular time amd temperature including delays)

v) flow of products (including potential cross-contaminations)

vi) segregation of clean and dirty areas (high/low risk areas), and

vii) personnel routes

(7) Preliminary Step 7 is to validate the developed flow diagram on-site by walking through the plant to ensure that all processing steps are in fact included. Any observed omission or inaccuracy shall be corrected.

Hazard analysis **235.** (1) Hazard analysis step 1: Conduct a hazard analysis using the Hazard Analysis worksheet. The hazard analysis procedures shall be carried out by the full HACCP team. Columns 1 to 6 of the hazard analysis sheet are completed:

(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: preventative (control) measures

(f) Column 6: is this step a Critical Control Point (Yes or No)

The hazard analysis worksheet is set fourth in Schedule 7 to these Regulations.

(2) Hazard analysis step 2: Identify and 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 hazard 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 reasonable to occur at each processing step (including acquisition and storage of raw materials and ingredients and delay).

(4) Hazard analysis step 4: Understand the potential hazard. Hazard analysis requires two essential ingredients:

(a) The first is an appreciation of the hazard (e.g. pathogenic organism or any disease agent that could harm the consumer); and

(b) 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 if the potential hazard is significant (risk assessment) and record in column 3 and 4. A hazard is significant if the hazard is:

(a) reasonably likely to occur; and

(b) if not properly controlled, it is likely to result as an unacceptable health risk to consumers.

(6) Hazard analysis step 6: Identify preventative measures and record in column 5.

It is necessary to consider and describe what preventive measures, if any, exist that can be applied for each hazard, and:

(a) Preventative measures are those actions and activities that can be applied to prevent a hazard, eliminate a hazard, or reduce it to an acceptable level.

(b) More than one control measure may be required to control

an identified hazard and more than one hazard may be controlled by one control measure. For instance, pasteurizatin or controlled heat treatment may provide sufficient assurance of reduction of the level of both *Salmonella and Listeria*.

(c) Preventative measures need to be supported by detailed procedures and specifications to ensure that they will be effective. For instance, precise heat treatment specification, maximum concentrations of preservatives used in compliance with the applicable legislation on additives, etc.

(7) Hazard analysis step 7: Identify the Critical Control Point (CCP) and record in column 6.

(a) A CCP may be a location, a point, a procedure of processing step in the process flow where by taking preventative measures, effective control can be installed and a food safety hazard can be prevented, eliminate or reduced to an acceptable level.

(b) The identification of a critical point for the control of a hazard requires a logical approach. Such an approach can be facilitated by using the decision free set forth in Schedule 8 to these Regulations (other methods can be used by the teams, 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. 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) Example of CCPs 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 step 7.

236. (1) If the hazard analysis reveals that processors have significant food safety hazards that can be controled, a HACCP Plan has to be implemented however, if no CCPs are identified during hazard analysis, then a HACCP Plan is not required.

(2) The identification of CCPs has two consequences for the multidisciplinary team, since they should then:

(a) ensure that appropriate preventative measures are effective

and properly implemented for the identified hazard. If, however, a hazard has been identified at a step where control is necessary for product safety but no control measure exists at that step or at any other step, then product or process shall be modified.

(b) Establish and implement an appropriate Monitoring and Verification system at each critical point to ensure effective control thereof and proceed to the activities specified in the HACCP Plan steps.

HACCP plan form

237. (1) HACCP Plan step 1: Set up the HACCP plan form. The HACCP plan form has 10 columns:

(a) The processing step where a Critical Control Point has been identified by hazard analysis (column 1)

(b) The identified significant hazards (column 2)

(c) Critical Limit parameter for each CCP (column 3)

(d) Monitoring activities for each CCP:

i) What (column 4)

ii) How (column 5)

iii) Frequency: When (column 6)

iv) Who (column 7)

(e) Corrective actions (column 8)

(f) Verification (column 9)

(g) Records (column 10)

The HACCP plan form is set forth in Schedule 9 to these Regulations.

(2) HACCP plan step 2: Complete the HACCP plan form (column 1):

(a) State the processing steps where CCPs were identified during Hazard Analysis. Record the processing steps in column 1 of the HACCP plan form.

(b) Enter the significant hazard(s) against each CCP in column 2 of the HACCP plan form. This information is found in column 2 of the completed Hazard Analysis worksheet.

(3) HACCP plan step 3: Set up the Critical Limits for each control measure for each CCP (Principle 3).

(a) Each control measure associated with each CCP should be allocated a specific set of Critical Limit parameters.

(b) These parameters correspond to precise delineation that separates safe from unsafe (or acceptable from unacceptable). They are set for observable or measurable parameters that can readily demonstrate through Monitoring activities that process control are working or not.

(c) Examples of such parameters include a temperature, a time,

pH, moisture level, weight (of additive, preservative or salt level), sensory parameters such as visual appearance or texture, etc.

(d) In most cases, to reduce the risk of exceeding a Critical Limit due to process variations, it is necessary to specify more stringent levels (i.e. target levels) to assure that Critical Limits are observed. These limits are called operating limits.

(e) Critical limits must be precisely established by conferring with various scientific and technical resources or established regulatory standards. When not taken from regulatory standards (e.g frozen storage temperature) the HACCP team must validate these parameters in scientific / technical literature, research institutes, experts, research or other means. Reference documents confirming the validity of established Critical Limits must be kept for reference and inspection purposes.

(4) HACCP plan step 4: Establish Monitoring procedure (Principle 4).

(a) An essential part of a Monitoring programme is to conduct real-time observations or measurements against Critical Limits that establish whether hazards are being controlled. The programme shall describe what will be monitored, how Monitoring will be conducted, how frequent Monitoring will take place, and who will be responsible for carrying out Monitoring activities.

(b) Observations or measurements must be able to detect loss of control at a CCP instantaneously so that Corrective Actions to be taken as soon as possible.

(c) Observations or managements can be made continuously (automated measurements) or intermittently (manual measurements). When observations of measurements are carried out manually it is necessary to establish a frequency of observations or measurements that provides reliable feedback on the status of the control measure.

(d) The programme of observations or measurements should be identified for each critical point:

i) what will be monitored (column 4);
ii) how Monitoring will be performed (column 5);
iii) when Monitoring will be performed (column 6); and
iv) who will perform Monitoring (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) Monitoring may indicate/:

i) that Operating Limit parameter have been transgressed and there is a deviation trend towards the Critical Limit parameters. Appropriate action must be quickly taken to bring the system back within Operating Limits. Under such circumstance if action is taken soon enough no unsafe product is produced, and

ii) that Critical Limit parameter monitored has deviated from its specified Critical Limits, indicating a loss of control, i.e. potentially unsafe product is being produced.. It is now necessary to take specific, predefined Corrective Action to regain control.

(b) Corrective Action shall be planned in advance by the HACCP team for each CCP so that appropriate action can be taken quckly, without hesitation when Moinitoring has indicated that a Critical limit deviation has occurred.

(c) Scheduled Corrective Action should include:

i) proper allocation of responsibility to a trained person implementing Corrective Action activities

ii) description of means and action required to correct the observed deviation;

iii) action to be taken with affected products that were being manufactured during the period when the process was out of control (i.e. potentially unsafe product); and

iv) written records of measures taken.

(d) detailed Corrective Actions shall be entered in column 8 of the HACCP plan form.

(6) HACCP plan step 6: Verification procedures (Principle 6). HACCP Verification is necessary to ensure that the system is working effectively. The team shall specify the methods and procedures to be used:

(a) Methods may include random sampling and analysis, reinforced analysis, reinforced analysis or tests at select 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 shall include: inspection of

operations, validation of Critical Limits, review of all records, review of deviations, Corrective Action and measures taken with regard to the product, instrument calibration, internal audits of the HACCP system and its records.

(c) Verification activities shall be established to confirm the effectiveness of the HACCP plan implementation. All verification activities shall be described and a schedule drawn up showing appropriate frequencies, procedures and responsibilities.

(d) Any change to the HACCP Plan should be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is maintained.

(e) Where criteria are specific in regulations, such criteria are to be used for reference values for the Verification process.

(f) Verification activities against each CCP shall be entered in column 9 of the HACCP plan form.

(7) HACCP plan step 7: Establish Record Keeping (Principle 7).

(a) The approved HACCP plan and associated documentation and records shall be kept in files and made available for inspection by regulatory agencies. The person responsible for keeping the records should be clear at all times.

(b) Four kinds of records are kept as part of the HACCP system:

i) HACCP plan support documentation used in developing the plan.

ii) Records of CCP Monitoring

iii) Records of Corrective Actions

iv) Records of Verification activities

(c) Type of records shall be entered in column 10 of the HACCP plan form.

Review of the HACCP system

238. (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 laid down.

(3) A HACCP review shall be undertaken at least every twelve months. More frequent review shall be undertaken when any changes are made to the following:

(a) factory lay-out and environment;

(b) raw material or finished product;

(c) processing system and conditions (packaging, storage or

distribution conditions);

(d) process equipment;

(e) cleaning and disinfection programme;

(f) health or spoilage risk associated with the product; and/or

(g) new information on hazard/risks/intended use and/or consumer

(4) Every version of the HACCP plan shall be dated and signed by the establishment's highest ranked person. When the HACCP plan is signed it represents management's acceptance and commitment implementing the plan.

Documents and records

239. (1) All procedures, instructions, specifications control and Verificatioin activities shall be thoroughly documented.

(2) 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. Records shall show processing details including records of quantities, and depending on the type of process employed, processing temperature and times, 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. Records shall be kept at least for the expected storage life of the products and be available to the Competent Authority.

(3) For products that 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.

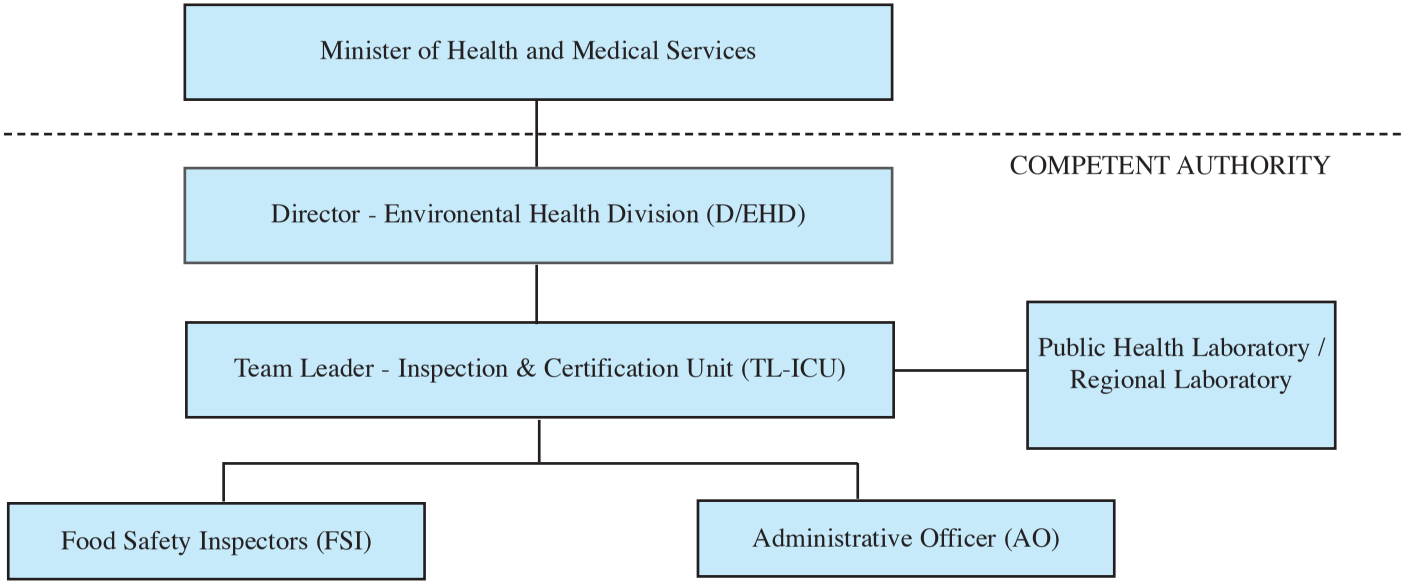
Training

240. The manager of an establishment shall arrange for adequate and continuous training of all workers. Training shall include reference to the relevant parts of this Part.

SCHEDULES

SCHEDULE No. 1
Organisation Chart of the Competent Authority within the Environmental Health Division

The Environmental Health Division will manage the system for administering the Directives and requirements of the Pure Food (Fishery Products) Regulation 2005 via the following organisationala chart.



SCHEDULE NO. 2
(Regulation 12)

This Schedule lays down the model for the Health Certificate, provided for in Regulation 12 of these Regulations.

Government of the Solomon Islands

Environmental Health Division
Ministry of Health and Medical Service

Pure Food Act 1996
Pure Food (Fishery Products) Regulations 2005

CERTIFICATE OF FITNESS FOR THE EXPORT OF FISHERY PRODUCTS

Number: _____

Name and Address Disptaching Producer and Country: _____

_____

Name and Address the Competent Authority: _____

_____

Reference Number of Health Certificate: _____

1.) Identification of the products

Product wild or farmed (delete where not applicable)

Species (scientific name):_____

Type of packaging: _____

Number of packages: _____

Net weight:_____

Temperature required during storage and transport:_____

Reference number of analysis report (if necessary):_____

H.) Origin of the fishery products

Address(es) and number(s) of the preparation or processing establishment(s) authorized for export by EHD: _____

_____

_____

III.) Destination of the fishery products

The fishery products are to be dispatched:

from (place of dispatch):_____

to (country and place of destination):_____

by the following means of transport:_____

(registration number of containers, flight number or name of ship)

Name and address of the consignor:_____

_____

Name and address of the consignee and address of the place of destination:_____

_____

iv. Health Attestation

The undersigned official inspector hereby certifies that:

i) The fishery products above have been handled, prepared or processed, identified, stored and transported under conditions at least equivalent to those laid down in Council Directive 91/493/EEC of 22 July 1991 laying down health conditions for the production and placing on the market of fishery products;

Dated at: _____ on _____
(place) (date)

Official Seal
(different colour to
document print)

_____
Signature EHD Authorised Officer

_____
Name, title and designation of the signature (capitals)

Dated this _____ day of _____ 20 ____

DIRECTOR
ENVIRONMENT HEALTH DIVISION

SCHEDULE No. 3
(Regulation 40, 170)

This Schedule lays down the microbiological standards applicable to the production of cooked crustaceans and molluscan shellfish provided for in Regulation 40 Item 6, and Regulation 170 Item 5, of these Regulations.

1. Pathogens

Type of pathoglen	Standard
Salmonella spp.	Absent in 25 g n -= 5 c = 0

In addition, pathogens and toxins thereof that are to be sought according to the risk evaluation must not be present in quantities such as to affect the health of consumers.

2. Organisms indicating poor hygiene (shelled or shucked product).

Type of pathoglen	Standard (per g)
Staphylococus aureus	m = 100 M = 1000 n = 5 c = 2
either: Thermotolerant coliform (44ºC solid medium)	m = 10 M = 1000 n = 5 c = 2
Or: *Escherichia coli* (on solid medium)	m = 10 M = 100 n = 5 c = 1

Where parameters n, m, M and c are defined as follows:
n = number of units comprising the sample
m = limit below which all results are considered satisfactory
M = acceptability limit beyond which the results are considered satisfactory
C = number of sampling units giving bacterial counts between m and M

SCHEDULE NO. 4
(Regulation 99, 100, 101)

This Schedule lays down the quality and safety parameters with limits, the patterns and frequency of standard analysis, the reference methods of analysis for microbiological, organoleptic, physiochemical and biological monitoring of water, provided for in regulation 99 of these regulations.

Table 1 (a) - Microbiological Parameters and Limits.

Parameter	Volume of the sample in ml	Guide Level (GL)	Maximum Admissible Concentration (MAC)
Coliform Bacteria	100	0	0 (number/100ml)
Escherichia coli	100	0	0 (number/100ml)
Enterococii	100	0	0 (number/100ml)
Clostridium perfringens (including spores)	100	0	0 (number/100ml)

1 This parameter need not be measured unless the water originates from or is influenced by surface water

Table 1(b) - Patterns and Frequency of Standards Analysis for Microbiological Monitoring of Water

Initial Monitoring	**Periodic Monitoring**	**Current Monitoring**
In the official laboratory	In the official laboratory	In the private laboratory, or, establishment's laboratory
Parameters (No. table 1a) No. 1 Coliform bacteria No. 2 *Escherichia coli* No. 3 Enterococci No. 4 *Clostridium perfringens*	Parameters (No. table 1a) No. 1 Coliform bacteria No. 2 *Escherichia coli* No. 3 Enterococci No. 4 *Clostridium perfringens*	Parameters (No. table 1a) No. 1 Coliform bacteria No. 2 *Escherichia coli* No. 4 *Clostridium perfringens*
Initial analysis should be carried out before the source is utilized	**Frequency**	**Frequency**
Volume of water distributed for produced each day within a supply zone (notes 2 and 3) m3	Periodic monitoring number of samples per year (Notes 4 and 6)	Current monitoring number of samples per year (notes 4, 5, and 6)
≤100	Note 7	Note 7
<100 ≥1000	1	4
>1000 ≤10,000	1 + 1 for each 3 300 m3/d and	4 +3 for each 1,000 m3/d and part thereof of the total volume
>10,000 ≤100,000	3 + 1 for each 10,000 m3/d and	
>100,000	+ 1 for each 25,000 m3/d and	

1. This parameter need not be measured unless the water originates from or is influence by surface water.
2. A supply zone is geograpohically 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.
3. The volumes are calculated as averages taken over a calendar year. A Member State 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 2001/day/capita.
4. In the event of intermittent short-tem supply the monitoring frequency of water distributed by tankers is to be decided by the Competent Authority.
5. For the different parameters the Competent Authority 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 1, 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 7.
6 As far as possible, the number of samples should be distributed equally in time and location.
7. The frequency is to be decided by the Competent Authority.

Table 1(c) - The Reference Methods of Analysis for Microbiological Monitoring of Water

Coliform bacteria *Escherichia coli*	AOAC Official Method 991.15 Total Coliforms and Escherichia coli Defined Substrate Technology (Colilert) Method.
Enterococci	ISO 7899-2
Clostridium perfrigens	*A spore count after heating samples to 80ºC* by:
	- Seeding in a medium with glucose, sulphite and iron. Count the black-halo colonies. - Membrane filtration, deposition of the inverted filter on a medium with glucose, sulphite and iron covered agar. Count the black colonies. - Distribution in tubes of different reinforced clostridial medium (DRCM), sub-culturing of the black tubes in a medium of limerus-treated milk. Count according to MPN.

(Note: references to be added as an amendment)

Additional Tests

Salmonella	Concentration by membrane filtration. Inoculation on a pre-enriched medium. Enrichment sub-culturing on isolating agar. Identification.
Pathogenic *Staphlococci*	Membrane filtration and culture on a specific medium (e.g. Chapman's hypersaline medium. Test for pathogenic characteristics.
Enteroviruses	Concentration by filtration, flocculation or centrifugation. Identification.

Table 2 (a) Organoleptic and Physiochemical Parameters

Parameters		Expression of the Results	Guide Level (GL)	Maximum Admissible Concentration (MAC)	Coments
Organoleptic	Odour	Dilution number	0 at 12°C 0 at 25°C	Acceptable to consumers, no abnormal change.	To be related to the taste test.
	Taste	Dilution number	0 at 12°C	Acceptable to consumers, no abnormal change.	To be related to the odour test.
	Turbidity	NTU	≤1	Acceptable to consumers, no abnormal change.	
Physiochemical	Temperature	°C	12	25	
	Hydrogen ion Concentration	pH unit	6.6 ≤pH ≤8.5	6.5 ≤pH9.5	The water should not be aggressive.
	Conductivity	uscm at 20°C	400	2500	The water should not be aggressive.
	Chloride	mg/l		250	The water should not be aggressive.
Undesirable Parameters	Nitrates	No mg/l		0.5	
	Amonium	MH4 mg/l		0.5	

Table 2(b) - Chemical Paratmeters for periodic monitoring

Parameter	Parametric value	Unit	Notes
Acrylamide	0,10	ug/1	Note 1
Antimony	5,0	ug/1	
Arsenic	10	ug/1	
Benzene	1,0	ug/1	
Benzo(a)pyrene	0,010	ug/1	
Boron	1,0	mg/1	
Bromate	25/10	ug/1	Note 2
Cadmium	5,0	ug/1	
Chromium	50	ug/1	
Copper	2,0	mg/1	Note 3
Cyanide	50	ug/1	
1,2-dichloroethane	3,0	ug/1	
Epichlorohydrin	0,10	ug/1	Note 1
Fluoride	1,5	mg/1	
Lead	25/10	ug/1	Notes 3 and 4
Mercury	1,0	ug/1	
Nickel	20	ug/1	Note 3
Nitrate	50	mg/1	Note 5
Nitrite	0,50	mg/1	Note 5
Pestricides	0,10	ug/1	Notes 6 and 7
Pestricides - Total	0,50	ug/1	Notes 6 and 8
Polycyclic aromatic hydrocarbons	0,10	ug/1	Sum of concentrations of specified compounds; Note 9
Selenium	10	ug/1	
Tetrachloroethene and Trichloroethene	10	ug/1	Sum of concentration of specified parameters
Trihalmomethanes - total	150/100	ug/1	Sum of concentrations of specified compounds; Note 10
Vinyl chloride	0,50	ug/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 correspon ding polymer in contact with the water.

Note 2: Where possible, without copromising disinfection, a lower value should be striven. The parametric value for bromate from 2 years after the entry into force of this regulation is lowered to 10 ug/1.

Note 3: The value applies to a sample of water intended for human consumption obtained by an adequate sampling method at the tap and taken so as to be representative of a weekly average value ingested by consumers.

Note 4: The parametric value for lead from 5 years entry into force of this regulation is lowered to 10 ug/1. 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.

Note 5: It should be ensured that the condition that [nitrite]/3≤1, the square brackets signify ing the concentrations in mg/1 for nitrate (NO), and nitrite (NO), is complied with and that the value of 0,10mg/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 which are likely to be present in a given supply need be monitored.

Note 7: The parametric value appliess to each individual pestricide. In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide the parametric value is 0,030 ug/1.

Note 8: 'Pestricides - 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, lower value should be striven. The specified compounds are:chloroform, bromoform,dibromochloromethane, bromodichloromethane. The parametric value for total THMs is lowered to 100 ug/1 from two years after the entry into force of this regulation.

Table 2(c) - Patterns and Frequency of Standard Analysis for Organoleptic, Physiochemical and Chemical Monitoring of Water

Standard Analysis Parameters to be Considered	Initial Monitoring	Occassional Monitoring in special situation or in case of accidents	Periodic Monitoring	Current Monitoring
Organoleptic Parameters	- odour - taste -turbidity (appearance)	The Competent Authority will determine the parameters according to circumstances, taking into account all factors that might have an adverse effect on the quality of drinking water supplied	- odour - taste - turbidity	- odour - taste - turbidity
			current monitoring analysis +other parameters as footnote	-Temperature - pH - Conductivity - chloride - Nitrite - Ammonium
Undesirable Parameters		as above	- Nitrites - Ammonium	- Nitrites - Ammonium
Chemical Parameters		as above	See Table 2b	Not applicable
Frequency	Initial analysis should be carried out before a source is exploited.	Occassional	See table 1b and note 7	See table 1b and note 8

1. Qualitative assessment
2. Except for water supplied in containers
3. Or other disinfectants and only in case of treatment
4. These parameters will be determined by the Competent Authority, taking into account of all factors which might affect the quality of the drinking water supplied to users and which could enable the ionic balance of the constituents to be assessed.
5. The Competent Authority may use parameters other than those mentioned in table 1 and 2 to this regulation.
6. An initial analysis to be carried out before a source is exploited, should be added. The parameters to be considered would be the current monitoring analysis plus inter alia various toxic or undesirable substance presumed present. The list will be drawn up by the Competent Authority.
7. For water drawn from public supplies, it shall be sufficient to show that the required examination has been carried out.
8. On routine checks, examinations carried out, in particular on chemical parameters, must concentrate on those that proved to be critical, aiming to eliminate sources of contamination. Some physical checks such pH, turbidity, organic matter should be checked even far more frequently than once a year in case of chlorination. Records of results of all examinations shall be retained for at least two years.

Table 2(d) - The Reference Methods of Analysis for Organoleptic and Physiochemical Monitoring

Parameters	Method	
Organoleptic	Odour	Successive dilutions tested at 12°C or 25°C
	Taste	Successive dilutions tested at 12°C or 25°C
	Turbidity	Nephelometry
Physiochemical	Temperature	Thermometry
	Hydrogen Ion Concentration	Electrometry
	Conductivity	Electrometry
	Residual Chlorine	Titrimetry Absorption spectrophotometry
Undesirable Parameters	Nitrites	Absorption spectrophotometry
	Nitrites	Absorption spectrophotometry
	Ammonia	Absorption spectrophotometry

Table 3(a): Biological Parameters and Units

Biological monitoring should be added when initial and periodic monitoring are done

Table 3(b): - The Reference Methods of Analysis for Biological Monitoring

Parameter	MAC
Parasites Protozoa Animalcules Algae	Absent Absent Absent

Table 3(c): - The Reference Methods of Analysis for Biological Monitoring

	Method
Protozoa Animalcules (worms / larvae)	Concentration by filtration on a membrane, microscopic examination. Test for pathogenicity. Concentration by filtration on a membrane, microscopic examination. Test for pathogenicity.

SCHEDULE NO. 5
Organoleptic Assessments - Regulation 114)

This Schedule lays down Freshness Rating Tables for White Bony Fish, Blue Fish, Selachii, Cephalopods and Crustaceans provided for in Regulation 114.

Freshness Rating Table for: (1) White Bony Fish

Criteria	Freshness Category			
	Extra	A	B	Not Permitted
Skin	Bright, iridescent pigmen (except for redfish) or opalescent. No dis-colouration	Pigmentation bright but not lustrous	Pigmentration in the process of becoming dis-coloured and dull	Dull pigmentation
Skin mucous	Acqueous transparent	Slightly cloudy	Milky	Yellowish grey, opaque
Eyes	Convex (bulging), black, bright pupil, slightly opalescent cornea	Convex slightly sunken, black dull pupil, slightly opalescent cornea	Flat, opalescent cornea, opaque pupil	Concave in the centre, grey pupil, milky cornea
Gills	Bright colour, no mucous	Less coloured, transparent mucous	Brown/grey, becoming discoloured thick opaque mucous	Yellowish milky mucous
Peritoneum (gutted fish)	Smooth, bright, difficult to detect from flesh	Slightly dull, can be detached from flesh	Speckled, comes away easily from the flesh	Do not stick
Smell of gills and abdominal cavity	Seaweedy	Not smell of seaweed	Fermented, slightly sour	Sour
Flesh	Firm and elastic, smooth surface	Less elastic	Slightly soft (flaccid), less elastic waxy (velverty) and dull surface	Soft (flaccid) scales easily detached from skin, surface rather wrinkled

1. Unfit for human consumption
2. or in a more advance state of decay
3. Fresh fish prior to onset of rigor mortis will not be firm and elastic,

Freshness Rating Table For: (2) Blue fish, Albacore or Longfinned Tuna, Bigeye Tuna, Mackerel.

Criteria	Freshness Category			
	Extra	A	B	Not Permitted
Skin	Bright pigmentation, bright shining iridescent colours, Clear distinction between dorsal and central surfaces	Loss of lustre and shine, duller colours, less difference between surface	Dull, lustreless, insipid colours, skin creased when fish curved	Very dull pigmentation
Skin mucous	Aqueous transparent	Slightly cloudy	Milky	Yellowish grey, opaque
Consistency of flesh	Very firm, right	Fairly rigid, firm	Slightly soft	Soft (flaccid)
Gills covers	Silvery	Silvery, slightly red or brown	Brownish and extensive seepage of blood from vessels	Yellowish
Eyes	Convex (bulging), blue, black bright pupil, transparent eye lid	Convex slightly sunken, dark pupil, slightly opalescent cornea	Flat, blurred pupil blood seepage around the eye.	Concave in the centre, grey pupil, milky cornea.
Smell of gills and abdominal cavity	Fresh seaweedy, pungent, iodine	Not smell of sea weed, neutral smell	Slightly sulphurous fatty smell, rancid bacon cuttings, or rotten fruit.	Rotten sour

1. Unfit for human consumption
2. Or in a more advanced state of decay

Freshness Rating Table for: (3) Selachii.

Criteria	Freshness Category			
	Extra	A	B	Not permitted [1]
Eyes	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 quality of clear mucous present on skin	Beyond rigor stage, no mucous on skin especially in mouth and gill openings	Some mucous in mouth and on gill openings, slightly flattened jaw.	Large quantity of mucous 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

Freshness Rating Table for: (4) Cephalopods

Criteria	Freshness category		
	Extra	A	B
Skin	Bright pigment-ation, 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 yellowlish
Tentacles	Resistant to removal	Resistant to removal	More easily removed
Smell	Fresh, Seaweed smell	Slightly or no smell	Ink smell

Freshness Rating Table for: (5) Shrimps

Criteria	Freshness category	
	Extra	A
Minimum requirements	Surface of the shell: moist and shiny, flesh must be free from any foreign odour, shimp must be free from sand, mucous 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

Freshness Rating Table for: (6) Lobster

Criteria	Freshness category		
	Extra	A	B
Minimum requirements	Bright pigmentation, no discoloration, Cephalothorax holds on the body	Dull pigmentation	Discoloured, Cephalothorax easily detached from tail
Flesh	Translucent	No longer translucent but not discoloured	Opaque and dull in appearance
Eye and gills	Shiny black eyes, pink gills	Eyes dull and grey/ black, gills greyish	Gill dark grey
Eye and gills	Characteristics mild shellfish smell	Loss of characterists smell. No ammonia smell	Slightly sour

SCHEDULE NO.6
(Regulation 114)

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 114.

DETERMINATION OF THE CONCENTRATION OF VOLATILE NITROGENOUS BASE (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 (TVB-N) in fish and fishery products. This procedure is applicable to TVB-N concentrations from 5 mg/100g at least 100mg/100g.

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/100g.

3. Brief description

The volatile nitrogenous bases are extracted from a sample by a solution of 0.6M perchloric acid. After alkalization, 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 either be distilled or demineralise 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 = 6g/100ml
4.2 sodium hydroxide solution = 20g/100ml
4.3 hydrochloric acid standard solution 0.05 mol/1 (0.05 N)

> **Note:** when using an automatic distillation apparatus, titration should take place with hydrochloic acid standard solution 0.01 mol/1 (0.01 N)

4.4 Boric acid solution = 3g/100ml
4.5 Silicone anti-foaming agent
4.6 Phenolphthalein solution = 1 g/100ml 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 sufficiently homogenous fish mince.
5.2 High speed blender with revolutions between 8,000 - 45,000 revolutions per minute
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. It must ensure that during the addition of alkalising substances the resulting free bases cannot escape.

6. Method

Warning: when working with perchloric acid, which is strongly corrosive, necessary caution and preventive measure must be taken.

The samples should, if at all possible, be prepared according to paragraph 6.1 as soon as possible after arrival.

6.1 Preparation of the sample.

The sample to be analysed should be grounded carefully in the meat grinder as described in section 5.1. Exactly 10g +0.1g of the ground sample is weighed in a suitable container, mixed with 90.0 ml perchloric acid (6 g/100ml) solution, homogenised for two minutes with a blender as described in section 5.2 and then filtered.

The extract thereby obtained can be kept for at least seven days at a tem perature between approximately 2ºC and 6ºC.

6.2 Steam distillation

50.0 ml of the extract obtained under section 6.1 are put in a apparatus for steam distillation as described in section 5.5. For a later check on sufficient alkalinisation of the extract, several drops of phenolphthalein halein prepared according to section 4.6 are added. After adding a few dropssilicone anti-foaming agent, and 6.5 ml of sodium hydroxide solution as specified in section 4.2, are added to the extract, and steam distillation begins immediately.

The steam distillation is regulated so that around 100 ml of distillate is produced within 10 minutes. The distillation outflow tube is submerged in a receiver with boric acid solution as specified in section 4.4, to which three to five drops of the indicator solution as described in 4.7 has 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 nitrogenous base contained in the receiver solution are determined by titration with standard hydrochloric solution as specified in section 4.3.

The pH of the end point should be 5.0+0.1.

6.3 Titration

Duplicate analysis are required. The applied method is correct if the difference of the duplicates is not greater than 2mg/100g.

6.4 Blank

A blind test carried out as described in section 6.2. Instead of the extract, 50.0 ml perchloric acid solution as specified in section 4.1. is used.

7. Calculation of TVB-N

By titration of the receiver solution with hydrochlric acid as in 4.3, the TVB-N concentration is calculated according to the following equation.

$$\text{TVB-N (expressed in mg/100g sample)} = \frac{(VI-VO) \times 0.14 \times 2 \times 100}{M}$$

where:
VI = volume of 0.01 M hydrochloric acid solution in ml for sample
VO = volume of 0.01 M hydrochloric acid solution in ml for blank
M = weight sample in g.

Remarks:

1. Duplicate analysis are required. The applied method is correct if the differece between duplicate is not higher than 2 mg/100g.
2. Check the equipment by distilling solutions of NH CI equivalent to 50 mg TVB-N/100g.
3. Standard deviation of reproducibility Sr = 1.20mg/100g.
   Standard deviation of comparability SR = 2.50 mg/100g

SCHEDULE NO.7
(Regulation 235)

Hazard Analysis Worksheet

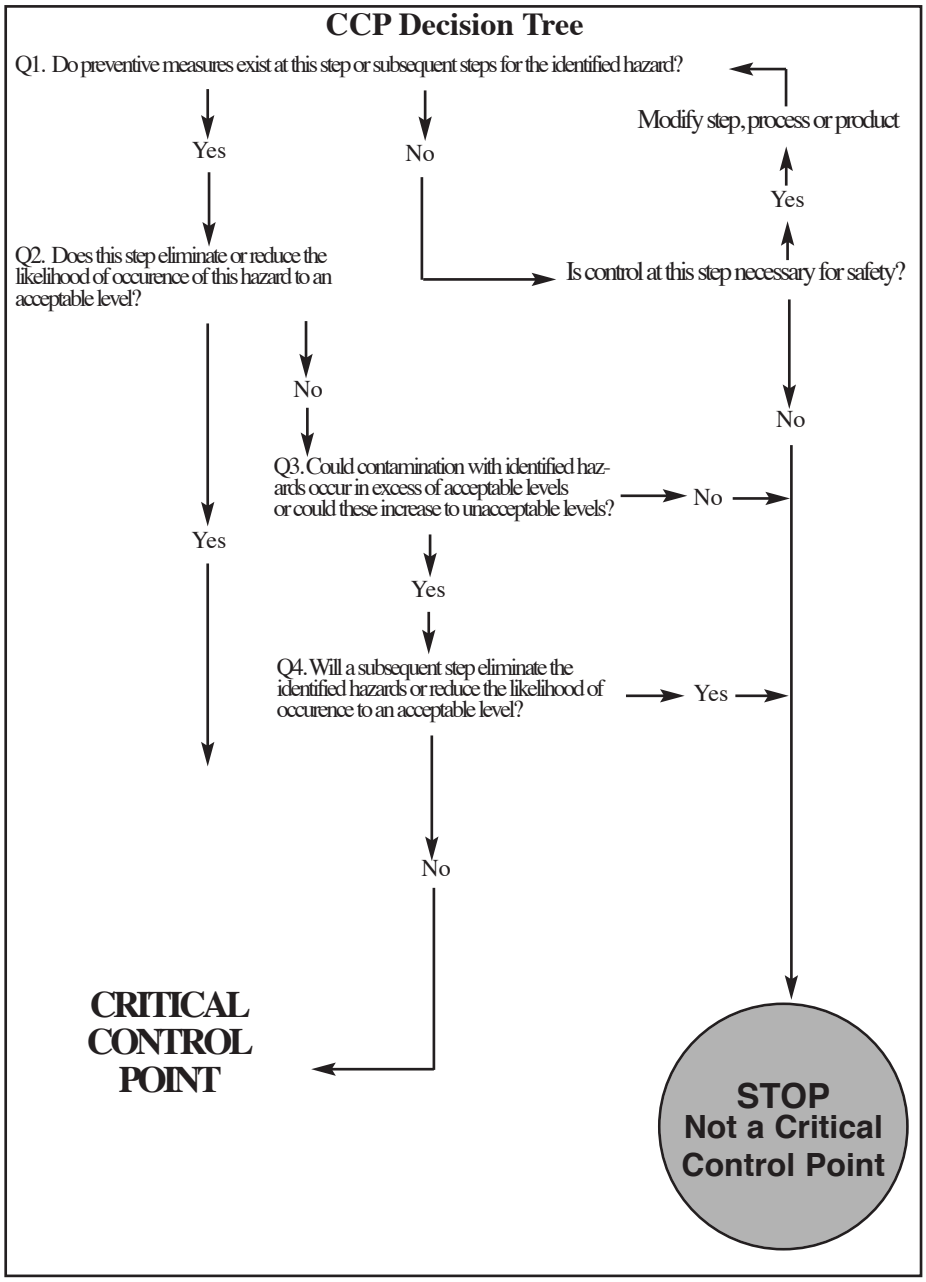
Name of Company:	Product Description:
Address:	Method of storage and distribution:
	Intended use/consumer:

(1) Ingredient/ processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards significant? (Yes/No)	(4) Justify your decision for column 3	(5) What pre-ventative measure(s) can be applied to prevent the Significant hazard	(6) Is this step a critical control point? (Yes/No)
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				

SCHEDULE NO. 8

This Schedule lays down the CCP Decision Tree - a tool used to help identify CCPs when conducting Hazard Analysis (see Regulation 235(7) of these Regulations).

Answer each question in turn for each identified significant hazard.



SCHEDULE NO.9
(Regulation 235)

HACCP Plan Form

Name of Company:	Product Description
Address:	Method of storage and distribution:
	Intended use / consumer:

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each preventative Measure	(4)	(5)	(6)	(7)	(8) Corrective Action	(9) Verification	(10) Records
			Monitoring						
			What	How	Frequency	Who			

Signature of Company Official:

Date:_____

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