STATUTORY INSTRUMENT NO. 6 OF 2007

Published 19th April, 2007

THE PUBLIC HEALTH ACT, 1960
(ACT NO. 23 OF 1960)

THE FISHERY PRODUCTS REGULATIONS, 2007

Short title.

In exercise of the powers conferred on him by sections 107, 119 and 147 of the Public Health Act, 1960 the Minister of Health and Sanitation hereby makes the following Regulations:-

PART I–PRELIMINARY

Interpretation concepts, principles, etc..

1. (1) In these Regulations, unless the context otherwise requires –

"food" (or "foodstuff") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans;

"food law" means the rules, regulations and other enactments governing food in general, food quality and safety in particular, including any stage of production, processing and distribution of food, and also of feed produced for or fed to, food-producing animals;

"feed law" means the rules, regulations and other enactments governing food in general and feed safety in particular, including all stages of production, processing and distribution of feed and use of feed;

"equivalence" means the capability of different systems or measures to meet the same objectives;

"equivalent" means, in respect of different systems or measures, capable of meeting the same objectives;

"placing on the market" means the holding or displaying of fishery products for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves, excluding retail sales;

"primary production" includes the farming, fishing and collection of live fishery products with a view to their being placed on the market;

"associated operations" (to primary production) includes any of the following operations, if carried out on board fishing vessels:-

- the slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping;

- the transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within fish farms on land; and

- the transport of fishery products the nature of which has not been substantially altered, including live fishery products, from the place of production to the first establishment of destination;

(B) – BEST MAINTENANCE PRACTICES

(C) – BEST –POTABLE WATER PRACTICES

STATUTORY INSTRUMENT

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FISHERY PRODUCTS REGULATIONS, 2007
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- the transport of fishery products the nature of which has not been substantially altered, including live fishery products, from the place of production to the first establishment of destination;

"stages of production, processing and distribution" means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed for animal production;

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

"retail" means the handling or processing or both of fishery products and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;

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

"final consumer" means the ultimate consumer of a fishery product who will not use the food as part of any food business operation or activity;

"importation" means the release for free circulation of feed or food or the intention to release feed or food for free circulation into the territory of fishery products from other countries;

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

"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;

"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;

"fishing grounds" refers to the customary name given by the fishing industry to the place in which fishery products have been taken;

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

"salt" means food grade Sodium Chloride;

"shall" denotes a mandatory requirement;

"Food Unit" means the Food Unit within the Environmental Health Division of the Ministry responsible for health;

"Minister" means the Minister of Health and Sanitation;

"should" denotes a recommended requirement;

"Fisheries Act" means the Fisheries (Management and Development) Act, 1994;

Definitions in relation to fish business.

"fish business" means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of fishery products;

"fish business operator or management" means the natural or legal persons responsible for ensuring that the requirements of food law are met within the fish business under their control;

"establishment" (plant or factory) means any unit of a fish business;

Definitions in relation to water.

"potable water" means water that is fit and intended for human consumption and is complying with the standards laid down in Part XII;

"clean water" means clean seawater or fresh water of a similar quality;

"clean seawater" means natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food;

Definitions in relation to feed business.

"feed" (or "feeding-stuff)" means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

"feed business" means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;

"feed business operator" means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;

Definitions in relation to construction and equipment.

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

"gully trap" means a water sealed trap, designed to hold a liquid seal that prevents the passage of gas and air but will not affect the flow of a liquid, and installed in the drainage of premises, through which the premises drainage is connected to the external drain, so as to cut off an open drainage system from the outside air and avoid entrance of pests;

"bell syphon trap" means a water sealed trap, designed to hold a liquid seal that prevents the passage of gas and air but will not affect the flow of a liquid, installed to drain a floor, whereby the grid part is constructed at floor level and the liquid seal is under the floor level and connected to the external drain;

"syphon air trap" means a fitting or device, bent in the shape of a horizontal S-tube, installed under a sink and that is designed to hold a liquid seal that will prevent the passage of gas, but will not affect the flow of a liquid;

Definitions in relation to vessels.

"freezer vessel" means any vessel on board which freezing of fishery products is carried out, and where appropriate, after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping or packaging;

"factory vessel" means any vessel on board which fishery products undergo one or more of the following operations, followed by wrapping or packaging, that is to say, filleting, slicing, skinning, shelling, shucking, mincing or processing;

Definitions in relation to production.

"fishery products" means all sea water or fresh water animals (except for live bivalve molluscs, live echinoderms, live tunicates, and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, and products of such animals;

"bivalve molluscs" means filter-feeding lamellibranch molluscs;

"aquaculture products" means all fishery products born and raised in controlled conditions until placed on the market as a foodstuff, and includes, seawater or fresh water fish or crustaceans caught in their natural environment when juvenile and kept until they reached the desired commercial size for human consumption , but excluding fish and crustaceans of commercial size caught in their natural environment and kept alive to be sold at a later date and which are not considered to be aquaculture products because they are merely kept alive without any attempt being made to increase their weight or size;

"fish product" means any derivative of fish;

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

"high risk product" means a product that has a higher likelihood to be contaminated during a part of the production process such as, cooked product;

Definitions in relation to bivalves.

"production area" means any sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or sites used for the cultivation of bivalve molluscs, and from which live bivalve molluscs are taken;

"gatherer" means any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market;

"conditioning" means the storage of live bivalve molluscs coming from class A production areas, purification centres or dispatch centres in tanks or any other installation containing clean seawater, or in natural sites, to remove sand, mud or slime, to preserve or to improve organoleptic qualities and to ensure that they are in a good state of vitality before wrapping or packaging;

"relaying" means the transfer of live bivalve molluscs to sea, lagoon or estuarine areas for the time necessary to reduce contamination to make them fit for human consumption, but does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening;

"relaying area" means any sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs;

"purification centre" means an establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption;

"dispatch centre" means any off-shore establishment for the reception, conditioning, washing, cleaning, grading wrapping and packaging of live bivalve molluscs fit for human consumption;

Definitions in relation to preparing and processing of fishery production.

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

"unprocessed products" means fishery products that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, cut, cleaned, trimmed, chilled, frozen, deep-frozen or thawed;

"prepared fishery products" means unprocessed fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting or chopping;

"mechanically separated fishery product" means any product obtained by removing flesh from fishery products using mechanical means resulting in the loss or modification of the flesh structure;

"processing" means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;

"processed products" means fishery products resulting from the processing of unprocessed products containing ingredients that are necessary for their manufacture or to give them specific characteristics;

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

"hermetically sealed container" means a container that is designed and intended to be secure against the entry of hazards;

"primary tar fraction" refers to the purified fraction of the water-insoluble high-density tar phase of condensed smoke and falls within the definition of "smoke flavourings";

Definitions in relation to smoking.

"primary smoke condensate" refers to the purified water-based part of condensed smoke and falls within the definition of "smoke flavourings";

"primary products" refers to primary smoke condensates and primary tar fractions;

"derived smoke flavourings" refers to flavourings produced as a result of the further processing of primary products and which are used or intended to be used in or on foods in order to impart smoke flavour to those foods;

"smoke flavouring" means a smoke extract used in traditional foodstuffs smoking processes;

"flavouring" means flavouring substances, flavouring preparations, processed flavourings, smoke flavourings or mixtures thereof;

Definitions in relation to food additives.

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

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

Definitions in relation to chilling.

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

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

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

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

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

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

Definitions in relation to freezing.

"freezing of fish" : means the continuous and quick process of reducing the thermal core temperature of fish or fishery products from an ambient temperature to –18° C or lower ;

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

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

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

"ice room" means a chamber or room used only for the manufacture or storage or both of ice;

Definitions in relation to wrapping and packaging

"wrapping" means the placing of fishery product in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself;

"container" means the principal covering in which fish are packed;

"packaging" means the placing of one or more wrapped fishery products in a second container, and the latter container itself;

Definitions in relation to safety assurance.

"code of best practices" are those practices to be implemented under the responsibility of the fish business operator that ensure quality of the fishery products on structural and operational level, not directly related to food safety (in the areas of plant construction, maintenance, use of processing water, raw material acceptance, cleaning and disinfecting, hygiene, pest control, manufacturing, storage, transport, by products and waste disposal) and are the prerequisite measures and conditions necessary to control hazards by the safety assurance system (HACCP);

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

Definitions in relation to quality assurance.

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

"hazard" means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;

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

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

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

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

"verification"(relating to HACCP) means the application of methods, procedures and tests, in addition to those used in monitoring, to determine compliance with the HACCP plan or whether the HACCP plan needs modification or both;

"verification"(relating to inspection) means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled;

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

"risk analysis" means a process consisting of three interconnected components: risk assessment, risk management and risk communication;

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

"risk management" means the process, distinct from risk assessment of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;

"risk communication" means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;

Definitions in relation to parasites.

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

Definitions in relation to inspection and control.

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

"Competent Authority" means the central authority of a country competent to ensure compliance with the requirements of these Regulations and competent to carryout veterinary checks and to organize official controls or any other authority to which that central authority has delegated that competence, the Food Unit being designated as such Authority in Sierra Leone by regulation 2;

"control body" means an independent third party to which the Competent Authority has delegated certain control tasks;

"control plan" means a description established by the Competent Authority containing general information on the structure and organization of its official control systems;

"Inspectorate" means the Food Unit within the Environmental Health Division of the Ministry of Health and Sanitation, responsible for the organisation and the inspection of the quality control and safety assurance systems;

"approved" means approved by the Competent Authority in writing;

"auto-control"(own checks) means the quality and safety assurance systems implemented by the management of the establishment;

"documentary check" means the examination of commercial documents and where appropriate, of documents required under feed or food law that are accompanying the consignment;

"identity check" means a visual inspection to ensure that certificates or other documents accompanying the consignment tally with the labelling and the content of consignment;

"physical check" means a check on the feed or food itself, which may include checks on the means of transport, on the packaging, labelling and temperature, the sampling for analysis and laboratory testing and any other check necessary to verify compliance with feed or food law;

"verification" (relating to inspection) means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled;

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

"fail safe control system" means a system to ensure control and monitoring against a standard and by implementing corrective actions in case of any deviation from the standard;

"inspection" means the examination of establishments, of animals and food, and the processing thereof, of fish businesses, and their management and production systems, including documents, finished product testing and feeding practices, and of the origin and destination of production inputs and outputs, in order to verify compliance with the legal requirements in all cases;

"non compliance" means does not meet the requirements of the Act and these Regulations;

"audit" means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;

"monitoring" means conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed or food law;

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

"official control" means any form of control that the Competent Authority performs for the verification of compliance with food law;

"official fish inspector" means any of the Health Superintendents and Health Officers qualified in accordance with these Regulations, to act in such a capacity and appointed by the Competent Authority;

"approved fish inspector" means a fish inspector designated by the Competent Authority to carry out specific official controls on holdings on its behalf;

"official auxiliary" means a person qualified, in accordance with these Regulations, to act in such a capacity, appointed by the Competent Authority and working under the authority and responsibility of an official fish inspector ;

"official certification" means the procedure by which the Competent Authority or control bodies, authorised to act in such a capacity, provide written, electronic or equivalent assurance concerning compliance;

"official detention" means the procedure by which the Competent Authority ensures that feed or food is not moved or tampered with pending a decision on its destination; and includes storage by feed and food business operators in accordance with instructions from the Competent Authority;

"sampling for analysis" means taking feed or food or any other substance (including from the environment) relevant to the production, processing and distribution of feed or food or to the health of animals, in order to verify through analysis compliance with feed or food law or animal health rules;

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

"health mark" means a mark indicating that, when it was applied, official controls had been carried out in accordance with these Regulations;

"official analysis" means analysis carried out by an official laboratory; Definitions in relation to laboratories.

"official laboratory" means a laboratory which is approved by the Competent Authority and is by that able to carry out official analyses.

(2) The following concepts, principles and procedures for food law shall form a general framework for measures taken under these Regulations:–

(a) It is the general objective of these Regulations to pursue a high level of protection of human life and health and the protection of consumers' interests, wherever in the world, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare and the environment.

(b) These Regulations shall aim also to achieve the free movement in the world of fishery products and feed for aquaculture animals manufactured or marked according to the general principles and requirements thereof.

Precautionary principle.

(c) In order to achieve the general objective of a high level of protection of human health and life, these Regulations shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

(d) Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

(e) Risk management shall take into account the results of risk assessment, and in particular, factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in paragraph (f) are relevant, in order to achieve the general objective of these Regulations stated in paragraph (a).

Risk analysis.

(f) In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the European Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

(g) Measures adopted on the basis of paragraph (f) shall be proportionate and no more

restrictive of trade than is required to achieve the high level of health protection with regard to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration, and the measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

Protection of consumers's interest.

(h) These Regulations shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the fishery products they consume, and shall also aim at the prevention of -

(i) fraudulent or deceptive practices;
(ii) the adulteration of food; and
(iii) any other practices which may mislead the consumer.

Principles of transparency, public consultation.

(i) There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law except where the urgency of the matter does not allow it.

Public information.

(j) Without prejudice to applicable national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, the Competent Authority shall take appropriate steps to inform the general public of the

nature of the risk to health, identifying to the fullest extent possible the fishery product or feed, or type of fishery product or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

PART II – COMPETENT AUTHORITY

Designation of competent authority.

2. (1) In application of section 110 of the Act, the Food Unit within the Environmental Health Division of the Ministry of Health shall be the Competent Authority in Sierra Leone incorporating the inspection service for verifying and certifying compliance of fishery and aquaculture products with the requirements of these Regulations and is generally empowered to enforce these Regulations.

(2) Responsibilities of the Competent Authority shall be in accordance with –

(a) the relevant provisions of the Act, the Fisheries Act, 1994 and

(b) the responsibilities concerning health control laid down in Part VII.

(3) The Food Unit as the central Competent Authority shall designate the other authorities to be responsible for the purposes and official controls set out in these Regulations, whether at regional, district or other levels.

(4) (a) The Competent Authority shall ensure -

(i) the effectiveness and appropriateness of official controls on feed and food at all stages of production, processing and distribution, and the use of feed;

(ii) that staff carrying out official controls are free from any conflict of interest;

(iii) that other competent authorities have, or have access to, an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively;

(iv) that they have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively;

(v) that they have the legal powers to carry out official controls and to take the measures provided for in these Regulations;

(vi) that they have contingency plans in place, and are prepared to operate such plans in the event of an emergency;

(vii) that the feed and food business operators are obliged to allow any inspection carried out in accordance with these Regulations and to assist staff of the Competent Authority in the accomplishment of their tasks;

(b) when the competence to carry out official controls is conferred on an authority or authorities other than the central authority, in particular those at regional or local level, efficient and effective co-ordination shall be ensured between all the competent authorities involved, including where appropriate in the field of environmental and health protection;

(c) the Food Unit shall ensure the impartiality, quality and consistency of official controls at all levels. The criteria listed in paragraph (a) of sub-regulation (4) must be fully respected by every authority on which the competence to carry out official controls is conferred;

(d) when, within a delegated competent authority, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units;

(e) the Food Unit and any delegated competent authority shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of these Regulations and such audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.

General obligations with regard to official controls.

3. (1) The following general obligations with regard to the organisation of official controls shall be ensured:–

(a) the Food Unit shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of these Regulations taking account of–

(i) identified risks associated with animals; feed or food, feed or food businesses, the use of feed or food or any process, materials, substance, activity or operation that may influence feed or food safety, animal health or animal welfare;

(ii) feed or food business operators' past record as regards to compliance with feed or food law or with animal health and animal welfare rules;

(iii) the reliability of any own checks that have already been carried out; and

(iv) any information that may indicate non-compliance.

(b) official controls shall be carried out without prior warning, except in cases such as, audits where prior notification of the feed or food business operators is necessary; and may also be carried out on an ad hoc basis;

(c) official controls shall be carried out during any of the stages of production, processing and distribution of feed or food; and shall include controls on feed and food businesses, on the use of feed and food, on the storage of feed and food, on any process, material, substance, activity or operation including transport applied to feed or food and on live animals, required to achieve the objectives of these Regulations;

(d) official controls shall be applied, with the same care, to exports outside the country as they are with the placing on the market within the country;

(e) the Minister shall take all necessary measures to ensure that products intended for dispatch to another country are controlled with the same care as those intended to be placed on the market in their own territory;

(f) the Competent Authority of the country of destination may check compliance of feed and food with feed and food law by means of non-discriminatory checks;

(g) if, during a check out at a place of destination or during storage or transport, the country establishes non-compliance, it shall take the appropriate measures, which may include re-dispatch to the country of origin.

(2) The Food Unit may delegate specific tasks related to official controls to one or more control bodies in accordance with paragraphs (a) to (c), and may also establish a list of tasks that may or may not be delegated; but activities in relation to enforcement procedures as actions in case of non-compliance and sanctions shall not be the subject of such a delegation:

(a) the Food Unit may delegate specific tasks to a particular control body only if–

(i) there is an accurate description of the tasks that the control body may carry out and of the condition under which they may be carried out;

(ii) there is proof that the control body–

(A) has the expertise, equipment and infrastructure required to carry out the tasks delegated to it;

(B) has a sufficient number of suitably qualified and experieced staff; and

(C) is impartial and free from any conflict of interest as regards to the exercise of the tasks delegated to it;

(iii) the control body works and is accredited in accordance with Standard EN 45004 “General criteria for the operation of various types of bodies performing inspection and/or another standard if more relevant to the delegated tasks in question”;

(iv) laboratories operate in accordance with international standards ISO 17025 and Good Laboratory Practices;

(v) the control body can communicate the results of the controls carried out to the Food Unit on a regular basis and whenever the Food Unit so requests. (If the results of the controls indicate non-compliance or point to the likelihood of non-compliance, the control body shall immediately inform the Food Unit);

(vi) there is efficient and effective co-ordination between the delegating Food Unit and the control body.

(b) the Food Unit after delegating specific tasks to control bodies shall organise audits or inspections of control bodies as necessary. If, as a result of an audit or an inspection, it appears that such bodies are failing to carry out properly the tasks delegated to them, the delegating Food Unit may withdraw the delegation, and shall withdraw it without delay if the control body fails to take appropriate and timely remedial action;

(c) where the Food Unit wishes to delegate a specific control task to a control body it shall notify the Minister with a detailed description of–

(i) the Food Unit to delegate the task;

(ii) the task that it would delegate; and

(iii) the control body to which it would delegate the task.

Staff performing official controls.

4. The Food Unit or a delegated authority shall ensure that all of its staff performing official controls -

(a) receive, for the area of competence appropriate training enabling it to undertake its duties competently and to carry out official controls in a consistent manner, and such training shall cover as appropriate the following areas:-

(i) legislation, that is to say,

(A) the study of the texts and interpretation of the Act and these Regulations;

(B) assessment of non-compliance with legislation;

(ii) inspection and controls: Inspection Manual and Codes of Best Inspection Practices, including:–

(A) Inspection and Controls in general:

* Control procedures

* Different control techni ques such as, auditing, sampling and inspection

* Legal proceedings and implications of official controls

* Contingency arrange ments for emergencies, including communication between the country and overseas authorities

* Any other area, includding animal health and animal welfare necessary to ensure that official controls are carried out in accordance with these Regulations;

(B) * Official controls Implementation of Inspections and Controls

* The different stages of production, processing and distribution, and the possible risks for human health and where appro priate for the health of animals and plants and for the environment;

* Quality assurance: Management systems that feed and food businesses operate and their assessment in so far as these are relevant for feed or food law requirements.

* Product Safety Assurance

* Hazards in animal feed and food production and the evaluation of the application of HACCP procedures.

(iii) Laboratories:
Examination of written, documentary material and other records, including those related to proficiency testing, accreditation and risk assessment, which may be relevant to the assessment of compliance with feed or food law; including commercial and financial aspects.

(b) keep up-to-date in their area of competence and receive regular additional training as necessary;

(c) possess the aptitude for multi-disciplinary co-operation.

Transparency and confidentiality.

5. The Food Unit shall ensure that they carry out their activities with a high level of transparency. For that purpose, relevant information held by it shall be made available to the public as soon as possible; and in general, the public shall have access to -

(a) information on the control activities of the delegated authorities and their effectiveness;

(b) information to the general public (when there are reasonable grounds to suspect that `fishery products may present a risk for human health, then, depending on the nature, seriousness and extent of that risk)-

(i) of the nature of the risks to health;

(ii) the risk that it may present; and

(iii) the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

(2) The Food Unit shall take steps to ensure that members of its staff are required not to disclose information acquired when undertaking their official control duties which by its nature is covered by professional secrecy in duly justified cases, but the protection of professional secrecy shall not prevent the dissemination by the competent authorities of information referred to in sub-regulation (1) (b).

(3) Information covered by professional secrecy in particular–

(i) the confidentiality of preliminary investigation procedures or of current legal proceedings;

(ii) personal data;

(iii) information protected by national legislation concerning in particular professional secrecy, the confidentiality of deliberations, international relations and national defense, shall not be disclosed.

Control and verification procedures.

6. (1) The Food Unit or a delegated authority shall carry out official controls in accordance with documented procedures which shall contain information and instructions for staff performing official controls, including, *inter alia*–

(a) a statement on the objectives to be achieved;

(b) the organisation of the Food Unit and the relationship between the unit and the delegated authority;

(c) the relationship between the Food Unit and control bodies to which it has delegated tasks related to official controls;

(d) co-operation with other services or departments that may have relevant responsibilities;

(e) mutual assistance in the event that official controls require more than one member state to take action;

(f) monitoring and surveillance programmes;

(g) tasks, responsibilities and duties of staff;

(h) sampling procedures, control methods and techniques, interpretation of results and consequent decisions;

(i) verification of the appropriateness of methods of sampling, methods of analysis and detection tests;

(j) action to be taken following official controls;

(k) any other activity or information required for the effective functioning of the official controls.

(2) The Minister shall ensure that legal procedures provided by the Act as, for instance, section 121 of the Act are applied to ensure that staff of the competent authorities have access to premises and documentation kept by fish business operators so as to be able to accomplish their tasks properly.

(3) The Food Unit or a delegated authority shall from time to time -

(a) verify the effectiveness of official controls that they carry out; and

(b) ensure that corrective action is taken when needed and that the documentation referred to in sub regulation (i) is updated as appropriate.

(4) The documented procedures referred to in sub-regulation (1) shall include the Inspection Manual or Codes of Best Inspection Practices.

General plan and contengency plan for crisis management.

7. (1) The Government shall draw-up, in close co-operation with the Food Unit a general plan for crisis management in the field of the safety of fishery products (hereinafter referred to as "the general plan").

(2) The general plan shall specify the types of situation involving direct or indirect risks to human health deriving from fishery products which are not likely to be prevented, eliminated, or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by emergency measures such as -

(i) suspension of the placing on the market or use of the food in question;

(ii) suspension of exports of the fishery products in question from all or part of the country;

(iii) laying down special conditions for the fishery products in question;

(iv) any other appropriate interim measures, and as soon as possible, and at most within 10 working days the measures taken shall be confirmed, amended, revoked or extended and the reasons for a decision shall be made public without delay.

(3) The general plan shall also specify the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy.

(4) For the implementation of the general plan for crisis management referred to in sub regulations (1), (2) and (3), the Government shall draw up operational contingency plans setting out measures to be implemented without delay when fishery products are found to pose a serious risk to humans or animals either directly or through the environment.

(5) The contingency plans shall specify–

(i) the administrative authorities to be engaged;

(ii) the powers and responsibilities;

(iii) the channels and procedures for sharing information between relevant parties; and

(iv) the role of stakeholders in the establishment and operation of contingency plans.

(6) The Government shall review these contingency plans as appropriate, particularly in the light of changes in the organisation of the Food Unit and of experience, including experience gained from simulation exercises.

Appointment of health authorities and officers.

8. Sections 5 and 21 of the Act shall apply for the purposes of the appointment of Health Authorities and Health Officers respectively.

Enforcement by virtue of Act and Act No. 19 of 1994.

9. (1) The powers of enforcement conferred by sections 110, 113, 121 and 125 for the purposes of the Act, shall, with the necessary modifications apply for the enforcement of these Regulations.

(2) Regulations 2 to 7 shall be taken to empower the Food Unit within the Environmental Health Division of the Ministry of Health and Sanitation to be the Inspection Service for the enforcement of these Regulations.

(3) Rules on effective, proportionate and dissuasive measures and penalties applicable to infringements of these Regulations are laid down in sections 109, 117 and 126 of the Act.

PART III–CONDITIONS GUARATEED BY COMPETENT AUTHORITY

Registration and approval of establishment.

10. (1) Any person wishing to operate a fish business shall apply to be registered for the purpose and the Food Unit shall establish procedures for fish business operators to follow when applying for the registration of their establishments, fishing vessels, landing sites, vehicles, sea port and air port facilities.

(2) The Food Unity shall draw up and keep up-to-date lists of fish businesses, establishments, fishing vessels, landing sites, vehicles, sea port and air port facilities, which have been registered, any and such list which already exists for other purposes, may also be used for the purposes of these Regulations.

Approval of establishment.

11. The Food Unit shall establish the procedures for business operators to follow when applying for the approval of their establishments, fishing vessels, landing sites, vehicles, sea port and air port facilities. The following approval procedures for establishments as set out in regulations 12 to 16 shall be implemented by the Food Unit.

Approval of establishment.

12. (1) Before the management of any establishment commence to build, rebuild or adapt an establishment, acting on his own initiative or on initiative of the Food Unit, an application shall be made to the Food Unit to inform the Senior Health Superintendent of the Inspection Service about the:–

(a) activities carried out in the establishment;

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

(2) After receiving the application, the Senior Health Superintendent of the Inspection Service within the Food Unit -

(a) shall verify whether the proposal submitted has fulfilled the requirements laid down in Regulations 75 to 103 in Part XII; and

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

(3) Once the Senior Health Superintendent accepts the final proposal of the management, plans and specifications shall be approved by him by fixing the official stamp of the Food Unit over his signature to the plans and specifications.

(4) On completion of the building, whether by construction or renovation, extension or adoption, the management shall inform the Senior Health Superintendent in writing, inviting the Senior Health Superintendent for an onsite audit to be conducted on the establishment.

(5) After the audit, the Senior Health Superintendent of the Inspection Service–

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

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

(6) After approval–

(a) the plant receives an approval certificate or letter, which could have a number and;

(b) the registration number is listed in the official list of approvals as laid down in regulation 16.

(7) The approval shall be reviewed if an establishment decides to carry out activities other than those for which it has received approval.

(8) The Food Unit shall keep the approval of establishments under review when carrying out official controls.

(9) If the Food Unit identifies serious deficiencies or has to stop production at an establishment repeatedly and the feed or food business operator is not able to provide adequate guarantees regarding future production, the Food Unit shall initiate procedures to withdraw the establishment's approval.

(10) Instead of withdrawing, the Food Unit may suspend an establishment's approval if the feed or food business operator can guarantee that it will resolve the deficiencies within a reasonable time.

Approval of vessels.

13. (1) An approval procedure shall be established by the Food Unit for fishing vessels in accordance with regulation 10 and resulting in registration and the provision of a registration number for these vessels complying with the requirements for fishing vessels laid down in regulations 65 to 71 of Part X.

(2) An approval procedure shall be established by the Food Unit 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 XI.

Approval of seaport and airport.

14. (1) An approval procedure shall be established by the Food Unit for the approval of the sea port and airport facilities for off loading, transport and storage for fishery products resulting in registration and the provision of a registration number for these facilities complying with the requirements–

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

(b) for transport of fishery products laid down in regulations 210 to 217 of Part XII; and

(c) for storage of fishery products laid down in regulations 196 to 205 of Part XII.

(2) The approval procedure laid down in regulation 10 shall apply *mutatis mutandis* to the approval procedures described in regulation 13.

Approval of chemicals.

15. Chemicals used for the following purposes shall be approved by the Food Unit:–

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

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

Officials lists.

16. (1) The Food Unit shall draw up an official list of -

(a) approved establishments and cold-stores;

(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 15 -

i. for eradication of pests and

ii. for cleaning and disinfecting purposes;

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

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

(3) The lists shall be updated when necessary.

PART IV–PLACING ON MARKET OF FISHERY PRODUCTS

General conditions.

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

(a) have been caught and where appropriate, handled for bleeding, heading, gutting, and the removal of fins, chilled or frozen, prepared or processed, on board vessels in accordance with the hygiene rules established in regulations 65 to 71of Part X;

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

(c) have been handled and, where appropriate packaged, prepared, processed, frozen, defrosted or stored hygienically in plants approved in accordance with regulation 10 in compliance with the requirements of regulations 75 to 103 of Part XII;

(d) have been appropriately packaged in accordance with the requirements laid down in regulation 197.

(e) have been given an identification mark or labelling in accordance with regulations 198;

(f) have been certified in accordance with the conditions laid down in regulations 24 and 25;

(g) be stored and transported under satisfactory conditions of hygiene and temperature in accordance with regulations 200 to 217 of Part XII;

(h) be prepared or processed or both in accordance with the Quality Assurance Programme established in Part XII and in accordance with the Safety Assurance Programme established in Part XIV;

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

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

(k) be dispatched to harbours, for frozen products, and airports, for fresh products, and stored there under satisfactory conditions of hygiene and temperature in accordance with the requirements laid down in regulations 200 to 217 of Part XII.

General conditions for aquaculture products.

18. Aquaculture products harvested and intended to be placed on the market shall–

(a) where necessary be slaughtered under appropriate conditions of hygiene;

(b) not be spoiled with earth, slime or faeces;

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

(d) have been handled and, where appropriate packaged, prepared, processed, frozen, defrosted or stored hygienically in plants approved in accordance with regulations 10 to 12 in compliance with the requirements of regulations 75 to 93 of Part XII;

(e) have been appropriately packaged in accordance with the requirements laid down in regulation 197;

(f) have been given an identification mark in accordance with regulation 198;

(g) have been certified in accordance with the conditions laid down in regulation 198;

(h) be stored and transported under satisfactory conditions of hygiene and temperature in accordance with regulations 200 to 217;

(i) be prepared processed or both in accordance with the Quality Assurance programme established in Part XI and in accordance with the Safety Assurance programme established in Part XIV;

(j) not contain substances or food additives prohibited by these Regulations or not included in the positive list as referred to in Part XIII.

(k) not contain any substance in excess of any maximum quantity or proportion permitted by Part XIII;

(l) 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 of 200 to 217.

Preparation conditions of products for market.

19. (1) Where gutting is possible from a technical, commercial and hygienic viewpoint–

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

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

(2) The placing on the market of the following products shall be forbidden:–

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

(b) fishery products containing bio-toxins such as ciguatera toxins or muscle paralysing toxin;

(c) fishery products containing other toxins, such as histamine, heavy metals, and other non intentional contaminants in an amount higher than the levels established in regulations 26 to 48.

(3) Detailed requirements regarding the species concerned and concerning levels and methods of analysis, are laid down in regulations 26 to 48.

PART V–IMPORTATION

Conditions for importation.

20. Pursuant to section 100 of the Fisheries Act, 1994, the following are established as additional import conditions: -

The provisions applied to imports of fishery products from other countries–

(a) shall in principle be at least equivalent to those governing the production and placing on the market, as described in these Regulations;

(b) shall protect public health of the citizens of Sierra Leone without prejudice to the possibility that imported products may be exported;

(c) shall allow importation of products for local consumption, under the condition that those products cannot be re-exported or used as raw material in an establishment approved to export fishery products.

Notification by importer.

21. A person who holds an import licence shall notify the Food Unit of each importation of fishery products in the form and manner prescribed and shall not market the fishery product without the approval of the Food Unit.

Off shore inspection.

22. (1) The Minister may enter into an off shore inspection arrangement with one or more foreign governments, government agencies or trade organizations where he is satisfied, based on verification by the Food Unit, that the legal requirements, fish inspection systems and infrastructure for preparing fish for export in that country and the fish imported into this country meet the requirements of the laws of Sierra Leone.

(2) An off shore inspection arrangement may include, after consultation with the Food Unit, the power to–

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

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

(c) establish compliance, monitoring and inspection requirements for imports from the other country or from establishments in that country;

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

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

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

Foreign government inspection.

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

PART VI–EXPORTATION

Export conditions and product quality and safety assurance.

24. Pursuant to section 100 of the Fisheries Act 1994, the following are established as additional export conditions :–

Provisions applied to exports of fishery products from Sierra Leone to other countries shall comply with the conditions laid down in these Regulations and shall be supplementary to the requirements of the legislation of the country to which Sierra Leone exports, as follows:–

(a) no person shall export, process for export or attempt to export , any fishery product unless that fishery product is prepared or processed in an establishment in accordance with the requirements laid down in Part XII;

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

(c) all shipments of fishery products of any type, in any presentation, quantity, and by any means, should be accompanied by an Export Health Certificate delivered by the Competent Authority as set forth in the Second Schedule.

Requirement for export certificate.

25. (1) An export certificate shall comply with the following requirements and with the supplementary requirements specified by the importing country:–

(a) the representative of the Competent Authority of the third country of dispatch, Sierra Leone issuing a certificate to accompany a consignment of fishery products, must sign the certificate and ensure that it bears an official stamp. This

requirement applies to each sheet of the certificate if it consists of more than one. (In the case of factory vessels, the Competent Authority may authorise the captain or another ship's officer to sign the certificate);

(b) certificates must be drawn up in the official language or languages of the country of dispatch and the country of import in which the border inspection takes place, or be accompanied by a certified translation into that language or these languages. If the country of destination so requests, certificates must also be accompanied by a certified translation into the official language or languages of that country. However, a country may consent to the use of an official language other than its own;

(c) the original version of the certificate must accompany consignments on entry into the importing country;

(d) it shall be ensured that -

(i) a link exists between the certificate and the consignment;

(ii) the information in the certificate is accurate and authentic;

(e) certificates must consist of -

(i) a single sheet of paper, or

(ii) two or more pages, that are part of an integrated and indivisible sheet of paper, or

(iii) a sequence of pages numbered so as to indicate that it is a particular page in a finite sequence (e.g. page 2 of 4 pages);

(f) certificates must bear a unique identifying number. Where the certificate consists of a sequence of pages, each page must indicate this number;

(g) the certificate must be issued before the consignment to which it relates leaves the control of the Competent Authority of the third country of dispatch.

(2) In case of failure to present the export certificate, exportation of product shall be forbidden.

PART VII–HEALTH CONTROL

Food quality and safety responsibility.

26. Fish business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that fishery products satisfy the requirements of these Regulations which are relevant to their activities and shall verify that such requirements are met.

Fish business operators and official controls.

27. The Food Unit, on behalf of the Government of Sierra Leone shall enforce fishery products law, and monitor and verify that the relevant requirements of fishery product law are fulfilled by fish business operators at all stages of production, processing and distribution. For that purpose it shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food safety and risk, food safety surveillance and other monitoring activities covering all stages of production, processing and distribution.

Controls and audits from importing countries.

28. An offshore official inspection arrangement with one or more countries importing products from Sierra Leone could be established in order to verify the compliance or equivalence of legislation, control systems and laboratory activities of Sierra Leone with the importing country.

Scope of health control plan.

29. Fishery products caught in natural environment and aquaculture products shall have undergone health control; the conditions for the production and the placing on the market shall be checked and monitored. Therefore the Food Unit shall establish a coherent, consistent, comprehensive convincing, single integrated, and multi-annual national health control plan consisting of–

(a) national control plan for surveillance and monitoring covering stages and conditions of production, processing and distribution, from primary production to dispatch and certification, also indicating the frequency of control and inspection;

(b) national (regional) environmental monitoring programme, monitoring the non intentional contaminants in the environment in relation with fishing and fishery products caught in a wild environment;

(c) national (regional) residue monitoring programme monitoring the intentional contaminants in the aquaculture sector, at sea or inland.

Management and updating of MANCP.

30. Multi-annual national control plans (MANCP)–

(a) may be adjusted during implementation;

(b) may be amended and regularly updated in the light of developments or in order to take account of factors including-

(i) new legislation;

(ii) the emergence of new diseases; food borne disease emergencies or other health risks;

(iii) significant changes to the structure, management or operation of the Competent Authority;

(iv) the results of whatever type of audit carried out;

(v) scientific findings;

(c) must be kept available in their latest version and provided on request to importing countries.

Content and implementation. of MANCP.

31. Each multi-annual national control plan shall contain general information on the structure and organisation of the systems of food control, and of animal health and animal welfare control in Sierra Leone in particular on–

(a) the strategic objectives of the plan and on how the prioritisation of controls and allocation of resources reflect these objectives;

(b) the risk categorisation of the activities concerned and the risk-based priorities and criteria for the risk categorisation of the activities and the most effective control procedures;

(c) the designation of competent authorities and their tasks at central, regional and local level, and on the resources available to these authorities;

(d) control systems applied to different sectors and co-ordination between the different services of competent authorities responsible for official controls in these sectors;

(e) the general organisation and management of official controls at national, regional and local level, including official controls in individual establishments and effective controls on traceability systems;

(f) the development and establishment of management systems for official controls preferentially based on a software (db) system for inspection services providing-

(i) inspection tools (checklists, forms etc.) to be used on a daily basis by the official inspectors;

(ii) general management and recording systems for–

* the official controls covering all stages of production, processing and distribution;

* the national environmental monitoring programme for wild catch;

* the residue monitoring programme for aquaculture;

(iii) results of official controls as inspection reports, official lists of vessels, establishments, landing sites, means of transport;

(iv) reports automatically generated following different parameters or issues (follow-up of corrective actions);

(v) management and records for the product traceability systems;

(vi) recording the performance and results of official control actions;

(g) where appropriate, the delegation of tasks to control bodies;

(h) the adoption of best practices at all levels of the control system;

(i) the organisation and operation of contingency plans for animal or food-borne disease emergencies, feed and food contamination incidents and other human health risks;

(j) the organisation of internal or external audits by the Competent Authority and the appropriate measures taken in the light of the results;

(k) methods to ensure compliance with the operational criteria for the Competent Authority laid down in regulation 2;

(l) training programmes for staff performing official controls as laid down in regulation 4;

(m) documented procedures referred to in regulation 6 and in regulation 58;

(n) establishment of the main performance indicators to be applied assessing multi-annual control plans.

Inspection manual.

32. Inspection requirements, control plans, best control practices and control policies laid down in Regulations 16 to 31 are Codes of Best Inspection Practices, designated as Inspection Manual for the official inspectors.

Annual CA reports.

33. Every year the Competent Authority shal–

* draft an annual report

* keep it available, and

* provide it on request of competent authorities importing fishery products from Sierra Leone covered in the control plan indicating–

(a) any amendments made to multi-annual national control plans to take account of the factors referred to in Regulation 30;

(b) the results of controls and audits conducted in the previous year under the provisions of the multi-annual national control plan;

(c) the type and number of cases of non-compliance identified; and

(d) actions to ensure the effective operation of multi-annual national control plans, including enforcement action and its results.

PART VIII–NATIONAL ENVIRONMENTAL MONITORING PROGRAMME

Scope of national monitoring programme.

34. (1) The health control of Environmental Conditions named "National Monitoring Programme" shall–

(a) be programmed annually;

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

(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 Sierra Leone and neighbouring countries;

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

(d) potential microbiological contaminants of the fish skin.

Monitoring sanitary soundness.

35. The National Monitoring Programme shall monitor the sanitary soundness of the fishery products, that is, 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.

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

(2) Fish or fish species, which are obviously infested with parasites, shall not be placed on the market for human consumption. The conditions and procedures for inspection are laid down in regulation 196.

Fish toxins in general.

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

(2) Fishery products containing bio-toxins such as, ciguatera or other toxins dangerous to human health are not to be placed on the market.

Monitoring for histamine or scombrotoxin.

38. The Competent Authority shall install a monitoring programme, random testing for histamine as a control of the auto-control system implemented by the management of the establishment and to evaluate the risk of histamine to human health.

Sampling plan for histamine

39. In order to put in place a monitoring system for histamine, the following conditions shall be implemented:-

nine samples shall be taken from each batch. These shall fulfil the following requirements:–

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

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

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

Species hazardous in relation to histamine product.

40. (a) The limits specified in regulation 39 apply only to fish species of the following families: scombridae, clupeidae, engraulidae and coryphaenidae. However fish belonging to these families, which have undergone enzyme-ripening treatment in brine, may have higher histamine levels but not more than twice the values specified in regulation 39;

(b) Examinations shall be carried out in accordance with reliable, scientifically recognised methods, such as "high performance liquid chromatography" (HPLC).

Monitory poisonous fish.

41. A monitoring plan shall be implemented by the Competent Authority to ensure that no poisonous fish is placed on the market–

(a) of the following families:- Tetraodontidae, Molidae, Diodontidae, Canthigasteridae.

(b) containing ichthyosarcotoxins, type tetraodotoxin.

Contaminants present in acquatic enviroment.

42. A monitoring system shall be established by the Competent Authority to check the level of contamination of fishery products on 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 shall not contain in their edible parts–

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

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

Standards for chemicals contaminants.

43. Fishery products shall not contain chemical contaminants on a level higher than that specified in this regulation as follows:–

(a)	aldrin/dieldrin	0.10 mg/kg
(b)	chlordane	0.10 mg/kg
(c)	chlordecone	0.10 mg/kg
(d)	DDT, TDE, DDE	0.10 mg/kg
(e)	diquat	0.10 mg/kg
(f)	flouridone	0.10 mg/kg
(g)	heptachlor epoxide	0.10 mg/kg
(h)	glyphosphate	0.10 mg/kg
(i)	mirax	0.10 mg/kg
(j)	PCB	0.10 mg/kg
(k)	simazine	0.10 mg/kg

Monitoring for PCB's dioxins and furans.

44. (a) A monitoring plan to check the contamination of fishery products and aquaculture products of PCB's, dioxins and furans shall be implemented.

(b) Definitions:

(i) PCB's (polychlorinated biphenyls) are synthetic organic components sold as complex mixtures of different congeners, in which a variable number of C1 atoms are substituted on biphenyl. The number of C1 atoms may vary between 0 and 10. The total number of congeners (number and place of C1 atoms) is 209. PCB's are mostly indicated by numbers e.g. CB 117 is 2,3',4,4',5 Penta CB. The 7 marker congeners are: CB 28,52,101,118,-138,153,180. The 7 marker congeners are chosen to be analysed because of their presence in industrial PCB mixture. Polychlorinated biphenyls (PCB's), are a group of 209 different congeners which can be divided into two groups according to their toxicological properties: 12 congeners exhibit toxicological properties to dioxins and are

therefore often termed "dioxin-like PCB's". the other PCB's do not exhibit dioxin-like toxicity but have a different toxicological profile.

(ii) Furans and dioxins:
In contrast to PCB's, dioxins and furans are not synthetic industrial products, but unwanted environmental contaminants. They are formed by uncontrolled heating or burning (e.g. incineration ovens) also in nature (e.g. forest fires, vulcano eruptions). In furans the two phenyls are bound by an additional oxygen bridge. A short indication for furans is PCDF's (Poly Chlorinated Dibenzo Furans; 135 congeners; e.g. 2,3,7,8 TCDF (T=Tetra). Dioxins consists of two phenyls bound by oxygen bridges. A short notation of dioxins is PCDD's (Poly Chlorinated Dibenzo Dioxins; 75 congeners e.g. 2,3,7,8 TCDD).

(iii) Each congener of dioxins or dioxin-like PCB's exhibits a different level of toxicity. In order to be able to sum up the toxicity of these different congeners, the concept of toxic equivalency factors (TEF's) has been introduced to facilitate risk assessment and regulatory control. This means that the analytical results relating to all 17 individual dioxin congeners and to the 12 dioxin-like PCB congeners are expressed in terms of a single quantifiable unit: 'TCDD toxic equivalent concentration' (TEQ).

(c) The TWI (Tolerable Weekly Intake) and dioxin like PCB's is fixed on the level of 14pg WHO-TEQ/kg body weight.

(d) Fishery products should not when placed on the market, contain higher contaminant levels than the maximum levels specified in this clause for Dioxin (sum of polychlorinated dibenzo-paradioxins= PCDD's) and polychlorinated dibenzofurans =PCDF's) expressed in WHO Toxic Equivalents, using the WHO-TEF's (Toxic Equivalency Factors).

(i) muscle meat of fish and fishery products and products thereof: 4pg WHO-PCDD/F-TEQ/g fresh weight, where fish are intended to be eaten whole, the maximum level shall apply to the whole fish.

(ii) Fish oil intended for human consumption: 2pg WHO-PCDD/F-TEQ/g fat.

(e) Methods of analysis:

(i) for determination of PCB's: the determination of PCB's must be carried out in the low ppb area (ìg/kg) with a MPL (Maximum Permissible Level) of 200 ppb. In most cases GC-ECD (Electron Capture Detection) is used. GC-MS must be used for confirmation and quantification of suspect results.

(ii) For determination of dioxins: HRGC/HRMS: high resolution gas chromatography/high resolution mass spectrometry and ^{13}C marked dioxin standards.

(f) Sampling plans, sample preparation and requirements for methods of analysis used in official control of the levels of dioxins and the determination of dioxin-like PCB's in certain foodstuffs are laid down in the Fourth Schedule, sub schedule B.

45. (1) A monitoring plan to check the contamination of fishery and aquaculture products by heavy metals shall be implemented. Monitoring plan for heavy metals.

(2) Analysis methods, maximum limits and sampling plans for monitoring heavy metals in fishery products shall be established and the analysis method shall be as follows:–
specific methods for the determination of lead, cadmium and mercury contents are not prescribed. Nevertheless, reference methods for detecting heavy metals are laid down, inter alias, Atomic Absorption Spectrometry (AAS). Laboratories shall use a validated method that fulfils the performance criteria indicated in the Fourth Schedule Part III, Table 3. Where possible, the validation shall include a certified reference material in the collaborative trial test materials.

46. Maximum limits shall be as follows:–

(a) The mean total mercury content, as determined by the analysis of the edible parts of the fishery products must not exceed 0.5ppm of fresh products (0.5mg/kg of fresh weight). This average limit is, however, increased to - Limits

(A) 1 ppm of fresh products (1 mg/kg of fresh weight) for the edible parts of the following species:
Acipenser spp (Sturgeon)
Anarhichas lupus (Atlantic catfish)
Anguilla spp (Eel)
Centromscymnus coelolepis (Portuguese dogfish)
Coryphaenoides rupestris (Grenadier)
Esox lucius (Pike)
Euthunnus spp (Little tuna)
Gempylus serpens (Snake Mackerel or Butterfish)

Hippoglossus hippoglossus (Halibut)
Hoplostethus spp (Emperor, Orange Roughy, Rosy Soldierfish) Istiophorus platypterus (Sail fish)
Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens (Snake Mackerel or Butterfish)
Lepidopus caudatus, Aphanopus carbo (Scabbard fish)
Lepidorhombus spp (Megrim)
Lophius spp (Anglerfish)
Makaira spp (Marlin)
Mugil spp (Mullet)
Orcynopsis unicolor (Plain bonito)
Pagellus spp (Seabream, Pandora)
Raja spp (Rays)
Sarda sarda (Bonito)
Sebastes marinus, S. mentella, S. viviparus (Redfish)
Shark (all species)
Thunnus spp, Euthunnus spp, Katsuwonus pelamis (Tuna)
Tricopterus minutus (Poor cod)
Xiphias gladius (Swordfish)
(Snake mackerel)

(b) The mean total lead content, as determined by the analysis of the edible parts of the fishery products must not exceed 0,2ppm of fresh products (0.2 mg/kg of fresh weight). This average limit is however, increased to

(A) 0.4 ppm (0.4mg/kg of fresh weight) for edible parts of the following species:
Anguilla anguilla (Eel) Dicentrarchus punctatus (Spotted seabass)
Dicologoglossa cuneata (Wedge sole)
Diplodus vulgaris (Common two-banded seabream)

Mugil labrosus labrosus (grey mullet)
Pomadasys bennetti (Grunt)
Sardina pilchardus (European pilchard or sardine)
Sardinops spp
Trachurus spp (Horse mackerel or Scad)

(B) 0.5 ppm (0.5 mg/kg of fresh weight) for: Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (Nephropidae and Palinuridae).

(C) 1 ppm (1 mg/kg of fresh weight) for: Bivalve molluscs and Cephalopods (without viscera).

(c) The mean total cadmium content as determined by the analysis of he edible parts of the fishery products must not exceed 0.05 ppm of fresh products (0.05 mg/kg of fresh weight). This average limit is however, increased to-

(A) 0.1 ppm (0.1 mg/kg of fresh weight) for edible parts of the following species:
Anguilla spp (Eel)
Dicologoglossa cuneata (Wedge sole)
Diplodus vulgaris (Common two-banded seabream)
Engraulis spp (Anchovy)
Luvarus imperialis (Louvar or lu var)
Mugil labrosus labrosus (grey mullet)
Sarda sarda (Bonito)
Sardina pilchardus (European pilchard or sardine)
Sardinops spp
Thunnus spp, Euthunnus spp, Katsuwonus pelamis (Tuna)
Trachurus spp (Horse mackerel or Scad)

(B) 0.3 ppm(0.30 mg/kg of fresh weight) for edible parts of the following species: Muscle meat of Xiphias gladius (Swordfish)

(C) O.5 ppm (0.5 mg/:kg wet weight) for edible parts of crustaceans, excluding brown meat of crab

(D) 1 ppm (1 mg/ kg of wet weight) for edible parts of bivalve

Sampling plans methods etc.

47. (1) Sampling plans shall be laid down for fresh and frozen fishery products by the Competent Authority. These shall take into account the results obtained from national checks.

(2) A number of the most commonly used definitions in describing methods of sampling and definitions that the laboratory will be required to use in establishing procedures for sample preparation and criteria for methods of analysis are laid down in the Fourth Schedule Part I.

(3) Methods of sampling are laid down in the Fourth Schedule Part II.

(4) Sample preparations and criteria for methods of analysis are laid down in the Fourth Schedule Part III.

Records and data of monitoring programme.

48. Records and data of monitoring results of the national monitoring programme shall be available at any time.

PART X–CONTROL PLAN FOR PRODUCTION CONDITIONS

Scope of control; plan for production conditions.

49. (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 on inspectorate level.

(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 till dispatch, laid down in these Regulations.

Health checks before first sale.

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

(a) an inspection comprising an organoleptic check which shall be carried out to check whether the fishery products are fit for human consumption, in accordance with the requirements laid down in regulations 113 to 147 of Part XII-

(i) by the Competent Authority of each batch of fishery products at the time of landing or before first sale, or,

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

(b) if the organoleptic examination reveals any doubt as to the freshness of the product, an inspection comprising physical, chemical or microbiological methods in accordance with the requirements laid down in regulation 141;

(c) an inspection of the physical soundness of the fishery products in accordance with the requirements laid down in regulation 142;

(d) an inspection of the sanitary soundness of the fishery products in accordance with the requirements laid down in regulation 143.

(2) Fishery products are to be declared unfit for human consumption if–

(a) organoleptic, chemical, physical or microbiological checks or checks for parasites have shown that they are not in compliance with the requirements in these Regulations;

(b) they contain in their edible parts contaminants or residues in excess of the limits laid down in these Regulations or at levels where the calculated dietary intake would exceed the acceptable daily or weekly intake for humans;

(c) they derive from–

(i) poisonous fish;

(ii) ishery products containing bio-toxins such as, ciguatera or other toxins dangerous to human health;

(iii) bivalve molluscs, echinoderms, tuni-cates or marine gastropods conta-ining marine bio-toxins in total quantities exceeding the limits referred to in these Regulations;

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

Control of auto-control system etc.

51. (1) Arrangements for checking, controlling and monitoring the hygiene rules applicable to fishery products caught on board fishing vessels shall be made by the inspection service in order to establish whether the fishery products, have been caught and where appropriately handled for bleeding, heading, gutting and the removal of fins, chilled or frozen, prepared or processed on board vessels in accordance with the hygiene rules established in regulations 65 to 70.

(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 a coherent and efficient inspection, the Food Unit shall–

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

The registration, the official controls and the checks of the vessels flying the flag of an EC member state or a third country shall be done by–

(i) the Competent Authority of a third country in a port or at sea, on condition such country appears on the community list of the third countries authorised to import fishery products into the EC community,

(ii) the Competent Authority of an EC member state.

When the Competent Authority of a Member State authorises the Competent Authority of another Member State or of a third country to carry out inspections on its behalf in accordance with this paragraph, the two competent authorities are to agree on the conditions governing such inspections. These conditions are to ensure, in particular, that the Competent Authority of the Member State the flag of which the vessel is flying receives reports on the results of inspections and on any suspected non-compliance without delay, so as to enable it to take the necessary measures;

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

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

(d) indicate the frequency of inspection;

(e) make records of every inspection;

(f) control and inspect all vessels landing fishery products at ports in Sierra Leone, irrespective of flag.

Control of auto-control system of landing and off-loadings.

52. Arrangements for regular checking, controlling and monitoring the hygiene rules and conditions of landing and first sale shall 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 in Part XI.

Control of auto-control system of transport.

53. Arrangements for checking, controlling and monitoring the hygiene rules of transport conditions shall be made by the inspection service in order to establish whether fishery products, caught in natural environment, have been transported under satisfactory conditions of hygiene and temperature in accordance with the hygienic rules and conditions established in regulations 210 to 217.

Control of auto-control system of establishments.

54. Arrangements for checking, controlling, inspection and monitoring at regular intervals of establishments shall be made by the inspectorate in accordance with the quality assurance programme established in Part XII and in accordance with the safety assurance programme established in Part XIV and in accordance with the requirements for the use of sweeteners, food colours and/or other food additives laid down in Part XIII in order to establish–

(a) whether the conditions for approval are still fulfilled;

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

(c) whether there is compliance with hygiene and temperature requirements;

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

(e) whether fishery products, prepared or processed from fish species which are estimated to be a potential hazard in relation to regulations 17 to 19, 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.

Control of auto-control system of approval conditions.

55. Arrangements for controlling and monitoring the approval and registration conditions and requirements, laid down in regulations 10 to 12 shall be made by the Competent Authority in order to establish whether these conditions and requirements are still fulfilled.

Control of auto-control system of certification.

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

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

(b) stipulation of reliable conditions for certification.

Control of auto-control system of airports and seaports.

57. Arrangements for checking, controlling and monitoring the hygiene, chilling storage conditions, and the frozen storage conditions on airport and seaports shall be made by the inspectorate in order to establish whether the fishery products have been handled, stored and dispatched in accordance with the hygienic rules and conditions established in regulations 210 to 217, Part XII.

Records.

58. (1) The Food Unit shall draw up reports on the official controls, checks and inspections, that it has carried out.

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

(3) The Food Unit shall provide the business operator concerned with a copy of the report referred to in sub-regulation (2) at least in case of non-compliance.

Official laboratories.

59. The Food Unit shall, after auditing and on the basis of the audit report, approve laboratories as official laboratories and designate these laboratories that may carry out the analysis of samples taken during official controls.

Approval conditions for official laboratories.

60. (1) The Competent Authority may only approve and designate laboratories that–

(a) operate in accordance with the following standards:–

(i) EN ISO/IEC 17025 on "General requirements for the competence of testing and calibration laboratories" for food testing laboratories";

(ii) Good Laboratory Practices (GLP) for drug testing laboratories emphasising on more detailed analysis– documentation and information;

(b) are assessed and accredited in accordance with the following standards:–

(i) EN 45002 on "General criteria for the assessment of testing laboratories;

(ii) EN 45003 on "Calibration and testing laboratory accreditation system – General requirements for operation and recognition";

(c) are able to carry out non clinical
(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 Basic–N)

(d) are equipped to do analyses of–
(i) organic and inorganic chemicals
(ii) marine and fish toxins
(iii) biological organisms
(iv) microbiological organisms as described in these Regulations;

(e) are able to carry out the different reference methods described in these Regulations. These competencies and facilities may not be present in one specific laboratory; different laboratories could be in charge and approved for different types of test or tests.

(2) The accreditation and assessment of testing laboratories referred to in sub-regulation (1) may relate to individual tests or groups of tests.

(3) The Food Unit may cancel the designation referred to in sub regulation (1) when the conditions referred to therein are no longer fulfilled.

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

List of approved official laboratories.

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

Method of sampling etc.

62. Sampling and analysis methods used in the context of official controls shall comply–

(a) with sampling and analysis laid down in these Regulations,

(b) if no such rules exist, with internationally recognised rules or protocols, for example those that the European Committee for Standardisation (CEN) has accepted or those agreed in national legislation;

(c) in the absence of the above, with other methods fit for the intended purpose or developed in accordance with scientific protocols;

Where paragraphs (a), (b), and (c) do not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol.

(8) The Competent Authority shall establish adequate procedures in order to guarantee the right of feed and food business operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion, without prejudice to the obligation of the Competent Authority to take prompt action in case of emergency.

(9) In particular they shall ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate.

(10) Samples shall be handled and labelled in such a way as to guarantee both their legal and analytical validity.

National reference laboratories

63. (1) The Competent Authority shall arrange for the designation of one or more national reference laboratories for each regional reference laboratory. The Competent Authority may designate a laboratory situated in another country and single laboratory may be the national reference laboratory for more than one country.

(2) These national laboratories shall–

(a) collaborate with the regional reference laboratory in the area of competence;

(b) co-ordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with regulation 62;

(c) where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;

(d) ensure the dissemination to the Competent Authority and official national laboratories of information that the regional reference laboratory supplies;

(e) provide scientific and technical assistance to the Competent Authority for the implementation of co-ordinated control plans adopted in accordance with regulations 26 to 33.

(3) Regulation 60 shall apply to national reference laboratories.

(4) The Food Unit shall list the name and address of each national reference laboratory to the relevant regional reference laboratory and other collaborating countries.

(5) Countries that have more than one reference laboratory for a regional reference laboratory must ensure that these laboratories work closely together, so as to ensure efficient co-ordination between them, with other national laboratories and with the regional reference laboratory.

Regional reference laboratories.

64 (1) The regional reference laboratories for feed and food shall be responsible fo–

(a) providing national reference laboratories with details of analytical methods including reference methods;

(b) co-ordinating application by the national reference laboratories of the methods referred to in (a), in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;

(c) co-ordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;

(d) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from countries in the region;

(e) providing scientific and technical assistance especially in cases where national laboratories contest the results of analyses;

(f) collaborating with national laboratories responsible for analysing feed and food in neighbouring countries.

(2) Regulation 60 shall apply to regional reference laboratories.

(3) Regional reference laboratories shall fulfil the following requirements. They shall–

(i) have suitably qualified staff with adequate training in diagnostic and analytical techniques applied in their area of competence;

(ii) possess the equipment and products needed to carry out the tasks assigned to them;

(iii) have an appropriate administrative infrastructure;

(iv) ensure that their staff respect the confidential nature of certain subjects, results or communications;

(v) have sufficient knowledge of international standards and practices;

(vi) have available, if appropriate, an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents;

(vii) take account of research activities at national and regional level;

(viii) have trained personnel available for emergency situations occurring within the region.

PART IX–AUTO-CONTROL SYSTEMS GUARANTEED BY SECTOR

General conditions applicable to vessels.

65. (1) The following conditions concerning construction and equipment shall apply to vessels:–

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

(i) be covered and self draining

(ii) be well insulated

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

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

These sections or containers shall be designed as to allow them to be cleaned easily and to ensure that melt water cannot remain in contact with fishery products.

(b) Decks used for fish handling may be constructed of one or more of the following materials, namely surface-coated aluminium, fiber-glass, timber-sheathed or coated with an epoxy finish or similar. Where fish does not normally come in contact with the deck and the timber is clean, sound and well-caulked, untreated timber is allowed on exposed decks.

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

(d) Water used at any stage of processing shall comply with the parameters of potable water, laid down in regulations 113 to 132 of Part XII or of clean sea water, Seawater intakes for vessels shall be located forward of any toilet or bilge discharge and in a position that avoids contamination of the water supply.

(e) Surfaces with which fishery products come into contact, such as sinks, processing tables, equipment used for gutting, heading and the removal of fin and containers and equipment in contact with the fishery products, shall be made of or coated with a suitable corrosion resistant material which is waterproof, resistant to decay, smooth and easy to clean and disinfect. When used they shall be completely clean.

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

(a) when used, the section of vessels or the containers reserved for the storage of fishery products shall be completely cleaned and, in particular, shall not be capable of being contaminated by the fuel used for the propulsion of the vessel or bilge water, sewage, smoke, oil, grease or other objectionable substances;

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

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

(a) as soon as they are taken on board, the fishery products shall be protected from contamination and from the effects of the sun or any other source of heat. When they are washed, the water used shall be either fresh water complying with the parameters set out in regulations 113 to 132 of Part XII or clean seawater, so as not to impair their quality or wholesomeness;

(b) the fishery products other than those kept alive, must be chilled immediately with ice, and stored in insulated containers or holds. However in the case of fishing vessels where cooling is not possible, the fishery products must be landed as soon as possible;

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

(d) fishery products shall undergo, if applicable, cold treatment as soon as possible after loading; complying with the conditions laid down in regulation 67 (3) (a),

(e) ice used for chilling of products shall be made from potable water or clean seawater. Before use it shall be stored under conditions which prevents its contamination, and

(f) where fish is headed and/or gutted on board where possible from a technical viewpoint such operations shall be carried out hygienically as soon as possible after capture and the products shall be washed thoroughly with potable water or clean sea water immediately after these operations. In that event the viscera and parts, which may pose a threat to public health, shall be removed as soon as possible and set apart from products intended for human consumption. Livers and roes intended for human consumption shall be refrigerated or frozen.

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

Additional hygiene conditions.

66. (1) Additional hygiene conditions are applicable to the fishing vessels designed and equipped to preserve fishery products on board under satisfactory conditions for more than twenty-four (24) hours, other than those equipped for keeping fish, shellfish and molluscs alive without other means of conservation on board.

(2) When additional hygiene conditions are applicable for certain vessels, the general hygiene conditions applicable to fishery products on board all fishing vessels, laid down in regulation 65 are also applicable.

(3) The following conditions concerning construction and equipment shall apply to vessels:–

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

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

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

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

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

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

(g) Artificial lighting shall be provided where necessary and where handling, processing and inspection takes place at night and below deck and in enclosed processing areas. 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 shall be equipped with not hand/elbow operable wash basin 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 a Fisheries Officer and an Official Fish Inspector.

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

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

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

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

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

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

(b) The water inlet for vessels, having an intake system for seawater, shall be located in front of the outlet for waste and sewage water and in a position that avoids contamination of the water supply.

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

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

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

(ii) toilet facilities are not operated unless self contained

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

Clauses (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 regulations 113 to 132 of Part XII.

(6) The following conditions concerning personnel shall apply:–

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

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

Specific hygiene conditions applicable to fishing vessels with freezing facilities.

67. (1) General hygiene conditions applicable to fishery products on board all fishing vessels laid down in regulation 65 are applicable to fishery products caught on board fishing vessels equipped for freezing.

(2) Additional hygiene conditions applicable to the fishing vessels designed and equipped to preserve fishery products on board under satisfactory conditions for more than 24 hours laid down in regulation 66 are applicable.

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

(a) Fishing vessels shall have freezing equipment with sufficient capacity:

(i) to achieve rapid reduction in temperature (till-18° C) of the fishery products

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

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

(b) Fresh products to be frozen shall comply with the requirements of the conditions for the fresh products laid down in regulation 185.

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

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

(e) If the freezer is located within 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 –18° C or lower.

(f) A waterproof, hygienic and separate storage room shall be provided for the storage of wrapping and packaging material (first and second envelope).

(g) On prawn trawlers, prawns can be packed and frozen whole or headed when the hygienic conditions comply with the requirements laid down in the general, the additional and the specific hygiene conditions laid down in regulation 65, 66 and 67. When prawns are headed before packing and freezing, special hygiene measures have to be taken to prevent contamination by the environmental circumstances.

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

Specific hygiene conditions applicable to fishing vessels with chilling facilities etc.

68. (1) General hygiene conditions applicable to fishery products on board all fishing vessels laid down in regulation 65 are applicable for CSW and RSW vessels.

(2) Additional hygiene conditions applicable to the fishing vessels designed and equipped to preserve fishery products on board under satisfactory condition for more than 24 hours, laid down in regulation 66 are applicable.

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

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

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

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

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

(e) the date and the number of the tank shall be clearly indicated on the temperature recordings, which shall be kept available for the Inspection Service.

Specific hygiene conditions applicable to fishing vessels equipped for cooking crustaceans etc.

69. (1) Fishing vessels equipped for cooking, chilling and wrapping crustaceans and molluscs on board shall comply with the general hygiene conditions applicable to fishery products on board all fishing vessels, laid down in regulation 65 and do not need to meet the requirements for factory vessels.

(2) Additional hygiene conditions applicable to the fishing vessels designed and equipped to preserve fishery products on board under satisfactory conditions for more than 24 hours laid down in regulation 66 are also applicable.

(3) Rapid cooling shall follow any cooking. Water used for this purpose shall be potable water or clean seawater. Cooling shall continue until the temperature approaching that of melting ice is reached (if no other method of preservation is used).

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

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

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

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

(b) Sampling programmes–

(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 auto-control system and

(iii) shall contain, in the event of failure to comply with the standards laid down under the following headings:–

- pathogens (1)

- organisms indicating poor hygiene (2) of THE Third Schedule; an undertaking laid down in paragraph (c).

(c) The manufacturer shall–

(i) notify the Food Unit of the findings made and the action taken with regard to unsatisfactory batches

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

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

Conditions applicable to design and equipment of factory vessels.

70. (1) The minimum requirements for design and equipment needed on factory vessels are the following:–

(a) a receiving area reserved for taking fishery products on board, designed and arranged into pounds or pens that are large enough to allow each successive catch to be separated. This area and its movable parts shall be easy to clean. It shall be designed in such a way as to protect the products from the sun or the elements and from any source of dirt or contamination;

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

(c) work areas that are large enough for the hygienic preparation and processing of fishery products in proper conditions of hygiene. They shall be designed and arranged in such a way as to prevent any contamination of the products;

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

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

(f) special equipment for disposing or 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 its sanitation, separate areas shall be allocated for that purpose;

(g) equipment providing a supply of potable water within the meaning of regulations 113 to 132 of Part XII relating to the quality of water intended for human consumption or pressurised clean seawater. The seawater intake shall be situated in a position where it is not possible for the water being taken in, to be affected by discharges into the sea of waste water, waste and engine coolant outlets;

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

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

(a) a non-slip floor that is also easy to clean and disinfect and equipped for easy drainage of water. Structures and fixtures shall have limbers that are large enough not to be obstructed by fish waste and to allow water to drain freely;

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

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

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

(e) adequate lighting;

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

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

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

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

(a) a refrigeration plant sufficiently powerful to lower the temperature rapidly so as to achieve a core temperature that complies with the specification of these Regulations

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(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 shall be equipped with a temperature recording system placed so that it can easily be consulted.

Conditions for on board handling and stroage of fishery products.

71. (1) An Observer on board the factory vessel shall 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 the following:–

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

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

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

(d) Potable water, within the meaning within regulations 113 to 132 Part XII, or clean seawater shall be used for all purposes. However, by way of an exception, non-drinking water may be used for steam production, fire fighting and the cooling of refrigeration equipment, provided that the pipes installed for purpose preclude the use of such water for other purposes and present no risk of contamination of the products.

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

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

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

(i) Staff shall wear suitable clean working clothes and headgear, which completely enclosed the hair and shall not wear wear watch, bracelet, necklace or earrings. This applies particularly to persons handling exposed fishery products.

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

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

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

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

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

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

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

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

(a) Fresh products to be frozen or quick-frozen shall comply with the requirements for fresh products laid down in regulation 185.

(b) Storage rooms shall have temperature-recording devices in a place where it can easily be read. The temperature sensor of the recorder shall 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 shall be available for inspection by the supervisory authorities at least during the period in which the products are stored.

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

(a) the conditions of hygiene for fresh products laid down in regulation 184;

(b) the conditions of hygiene for frozen products laid down in regulation 185;

(c) the conditions of hygiene for thawing products laid down in regulation 186;

(d) the conditions of hygiene for processed products laid down in regulations 188 to 195;

(e) the conditions concerning parasites laid down in regulation 196.

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

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

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

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

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

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

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

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

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

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

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

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

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

PART XI–REQUIREMENTS FOR LANDING AND OFF-LOADING OF FISHERY PRODUCTS

General conditions for landing and off-loading.

72. (1) Food business operators responsible for the off-loading and landing of fishery products must ensure that unloading and landing equipment that comes into contact with fishery products shall be constructed of material which is easy to clean and disinfect and shall be kept on a good state of repair and cleanliness.

(2) During unloading and landing food business operators responsible for the unloading and landing of fishery products must avoid contamination of fishery products. It shall in particular be ensured that–

(a) unloading and landing operations proceed rapidly;

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

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

General conditions for auctions.

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

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

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

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

(d) be well lit to facilitate the inspection of fishery products provided for in regulation 50;

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

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

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

(h) have facilities to provide adequate supplies of potable water within the meaning of regulations 113 to 132 of part XII 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-drinking water is permissible for steam production, fire fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purpose and present no risk of contamination of the products. Non-drinking water pipes shall be clearly distinguished from those used for drinking water or clean sea water;

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

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

(2) After landing or, where appropriate, after first sale, fishery products shall be transported without delay, under the conditions laid down in regulations 210 to 217 of Part XII to their place of destination.

(3) However, if the conditions laid down in sub regulation (2) are not fulfilled and chilled, unpackaged products are not distributed, dispatched, prepared or processed immediately after reaching an establishment on land, they must be stored under ice in appropriate facilities. The facilities in which fishery products may be stored before being displayed for sale or after being sold and pending transport to their place of destination shall have sufficiently large cold and/or chill storage rooms which satisfy the following conditions. The facilities shall have –

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

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

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

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

(e) adequate natural or artificial lighting, and

(f) where necessary a sufficiently powerful refrigeration plant to keep products at temperature prescribed in these Regulations. In such cases, fishery products shall be stored at a temperature approaching that of melting ice and re-icing must be carried out as often as necessary.

(4) When chilling was not possible on board the vessel, fresh fishery products, other than those kept alive, must undergo chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice.

(5) Food business operators must cooperate with relevant competent authorities so as to permit them to carry out official controls in accordance with Part VII, in particular as regards any notification procedures for the landing of fishery products that the Competent Authority of the country the flag of which the vessel is flying or the Competent Authority of the country where the fishery products are landed might consider necessary.

General hygiene conditions for auctions.

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

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

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

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

(d) Potable water, satisfying regulations 113 to 132 shall be available. However, by way of exception, non-potable water may be used for steam production, all fire fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products.

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

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

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

(i) Staff shall wear suitable clean working clothes;

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

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

(b) The fish business operator 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.

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 XII–QUALITY ASSURANCE SYSTEM AND PRODUCTION CONDITIONS

(A) BEST PLANT PRACTICES

Location of establishment.

75 (1) Establishments, preparing or processing fishery products should be located on sites,

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

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

(c) where–

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

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

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

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

Surroundings of establishment.

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

(a) or suitably graded, grassed or landscaped.
In this 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 this 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 surroundings should be properly maintained, i.e.

- the grounds should be kept clean, tidy at all times and free of accumulation of water,

- equipment should be stored properly,

- litter, rubbish and waste should be regularly removed.

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

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

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

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

Requirements for establishment.

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

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

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

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

(i) between clean and dirty areas;

(ii) between dry and wet areas;

(iii) between cold and hot areas;

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

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

(b) there is a good layout and flow from raw materials through finished products and dispatch.

The processing layout should be designed–

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

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

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

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

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

(iii) to minimise maintenance;

(iv) to facilitate cleaning and disinfecting;

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

(vi) to minimise airborne contamination;

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

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

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

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

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

(xii) to ensure that–

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

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

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

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

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

Working handling and storage rooms and their facilities, etc.

78. (1) The different working, handling and storage rooms needed in the establishments as described in regulation 79 shall comply with the minimum conditions and requirements laid down in regulations 80 to 94.

(2) The establishments shall afford in the working and storage rooms mentioned in regulation 79 a number of facilities complying with the minimum requirements and conditions laid down in regulations 95 to 103.

General conditions for working room.

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

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

(b) In general and pending the preparation or processing or both activities, completely separated working rooms should be needed such as–

(i) reception room

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

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

(iv) ice maker/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 processed products;

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

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

(ix) dry room for packaging;

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

(xi) dry room for the storage of chemicals;

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

(xiii) laboratory;

(xiv) chill storage room for finished fresh products;

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

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

(xvii) dispatch room;

(xviii) social amenities with–

(A) changing room for city clothes and shoes

(B) showers (optional)

(C) changing room for uniforms and boots

(D) toilet block

(E) hand-washing room

(F) eventually laundry and canteen

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

Conditions for preparation and processing rooms.

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

(2) Floors shall have hard impact resistant surfaces, impermeable to grease and water, which permit easy cleaning and disinfecting 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.

Floors–

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

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

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

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

(3) Effluent disposal systems and drains shall comply with following requirements. The establishment shall have–

(a) an efficient and hygienic effluent and waste water disposal system adequate for the purpose intended, maintained in good order and repair;

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

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

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

(e) floor drains shall

(i) be adequate in size, number and location

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

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

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

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

(B) to prevent the entry of rodents

An open drainage system vented through an opening in the wall, without sealed outlet by gully traps is not allowed.

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

(iv) have adequate access for cleaning;

(v) where drainage channels are fully or partially open, they are to be so designed to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumers are handled;

(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.

(f) sanitary drainage, but–

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

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

(4) Walls shall comply with the following requirements:–

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

(b) The interior surfaces of walls and the partitions shall–

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

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

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

(iv) be impact resistant or protected from impact

(v) be resistant to damage

(vi) be easy to clean and disinfect

(c) Angles between walls, between walls and floors and between walls and ceilings, shall be sealed and covered to facilitate cleaning

(d) Where internal walls are painted or surface coated,

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

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

(e) Any piping or tubing should be located either within the wall or fixed at least 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.

(5) Ceilings shall comply with the following requirements:–

(a) In buildings in which the roof frame and the interior surface of the roof is exposed, the installation of a suspended ceiling should be considered. Otherwise all parts of the structure shall be smooth and painted in a light colour. There should be easy access to all parts of the roof structure to facilitate cleaning.

(b) Ceilings and overhead structures shall be designed, constructed, sealed and finished so as to:

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

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

(iii) prevent or minimises accumulation of dust and dirt

(iv) be capable of being effectively cleaned

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

(vi) minimise and reduce condensation, mould development, flaking and shedding of particles.

(6) Doors shall comply with the following requirements:–

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

(b) The doors and hatches inside the factory shall–

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

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

(iii) be close fitted

(iv) be impact resistance or protected from impact damage

(c) Where doors are painted or surface coated–

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

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

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

(7) Windows and external openings shall comply with the following requirements:–

(a) On construction level

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

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

(b) On pest-proofing level–

(i) windows, hatches, ventilation openings and other openings to the outside of the building or where physical separation is required shall be constructed to render the opening pest proof

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

(A) kept in good repair;

(B) which are easily removable for easy cleaning;

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

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

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

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

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

(9) The ventilation system shall comply with following requirements:–

(i) Adequate and sufficient natural or mechanical ventilation shall be provided to minimise the accumulation of odours, vapours, gases, dust and to prevent excessive build up of heat, steam, condensation, contaminated air and other hazards where they may contaminate fishery products;

(ii) 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;

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

(iv) Where fans, air conditioning systems and other air-blowing equipment are located and operated–

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

(B) the installation of an over- pressure system is recommended whereby the inlets are controlled and the outlets are uncontrolled

(C) all extraction fans, blowing fans and air conditioners shall be protected with filters and meshes to prevent the entry of dust, insects and birds. Ventilation systems are to be so constructed as to enable filters, meshes and other parts requiring cleaning or replacement to be readily accessible.

(10) Illumination:

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

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

(i) 400 lux in the processing areas

(ii) 600 lux where the product is being inspected

(iii) 250 lux in other areas.

(c) Light fittings shall be–

(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

(iii) readily accessible for cleaning purposes

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

(11) Hand washing facilities:

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

The location of these hand washing facilities shall be arranged in a way that they are–

(i) sufficient in number;

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

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

(b) These hand washing facilities shall be provided with–

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

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

(iii) materials for cleaning hands: soap dispenser;

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

(v) properly trapped waste pipes leading to drains;

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

(c) The facilities for washing fishery products are to be separate from the hand washing facility.

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

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

Washing and disinfecting work implements, recipients, small equipment and utensils in stagnant water is forbidden.

(14) If sterilising facilities are required, adequate provision for sterilising work implements/equipment shall be provided.

If the sterilising medium used is not water, the Competent Authority shall first approve the method of sterilising.

Sterilising facilities shall be–

(a) constructed of corrosion resistant materials;

(b) capable of being easily cleaned; and

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

(15) Where necessary, there shall be provided suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining fishery products at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.

Chill rooms, cold storage rooms, chillers and freezers.

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

(a) waterproof flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of the water as described in regulation 80 (1) and (2). Where under floor ventilation pipes are provided they shall be protected against pests;

(b) walls which have smooth surfaces and are easy to clean, durable and impermeable as described in regulation 80 (4);

(c) ceilings which are easy to clean as described in regulation 80 (5);

(d) doors in durable materials which are easy to clean. Plastic strip curtains or similar shall be installed to assist in air retention and to minimise temperature fluctuations when cold storage room or freezer doors are open;

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

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

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

(h) adequate artificial lighting as described in regulation 80 (10);

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

Specific conditions for chill storage room.

82. In chill storage rooms for the storage of raw material the establishment shall have at least following facilities:–

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

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

(ii) to ensure adequate protection from contamination;

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

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

(d) an accessible and easily readable thermometer accurate within 1° C, shall have its temperature taken and recorded at least once every 4 hours.

Specific conditions for cold storage room.

83. In cold storage rooms, the establishment shall have at least the following facilities:–

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

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

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

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

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

Specific conditions for chill freezers.

84. In freezers, the establishment should afford at least following facilities:–

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

(b) a freezing facility with sufficient capacity to freeze the fish to a temperature of at least – 18° C within 8 hours of loading the freezer.

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

Conditions for brine freezing.

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

(a) General construction conditions are–

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

(ii) Areas:

(A) suitably clean,

(B) sealed against dust and pest,

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

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

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

(b) Specific brining conditions are–

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

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

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

Conditions for ice plants and ice storage rooms.

86. (1) In ice plants and ice storage rooms, the establishment shall have at least the following facilities:–

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

(i) transport of raw material from the port;

(ii) storage of raw material before processing; and

(iii) chilling of fish during processing.

(b) Insulated ice storage rooms and storage facilities shall–

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

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

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

(c) It is recommended that–

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

(ii) the ice should be made in the form of flakes. 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.

Conditions for shellfish shucking rooms.

87. (1) In rooms or parts of establishments where shellfish is shucked, the rooms in the establishments shall–

(a) be satisfactorily clean;

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

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

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

(e) have lighting in accordance with regulation 80 (10).

Conditions for storage of wrapping and packaging material.

88. Rooms designated for storage of wrapping and packaging material shall be–

(a) dust and pest proof;

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

(c) equipped with shelves, racks or pallets to store wrapping and packaging material designed and constructed in accordance with regulation 97.

Conditions for storage of non refrigerated fishery products.

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

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

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

Conditions for storage of toxic chemicals and cleaning equipment.

90. Rooms designated for storage of cleaning agents, disinfectants, toxic chemicals and cleaning equipment shall be separate to the main storage area. All toxic chemicals used on-site should be clearly identified and stored, when not in use, in a locked facility. Cleaning agents and disinfectants are not to be stored in areas where food is handled.

Conditions for inspection rooms.

91. (1) The establishments shall have, if applicable, an inspection service room complying with and used under following conditions:–

(2) If the volume of products treated requires regular or permanent presence of an official health 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;

(e) for the exclusive use of the inspection service; shall be provided, with–

(i) lighting intensity of at least 600 lux;

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

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

(iv) running water for cleaning instruments.

Conditions for laboratories.

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

General conditions for sanitary facilities.

93. (1) Establishments shall have adequate sanitary facilities for the personnel who handle fish as well as for those who handle materials and equipment, which come into contact with the product.

(2) These social amenities consist of an adequate number of suitable and conveniently located changing rooms, flush toilets, showers, hand-washing facilities, and canteen (if meals are taken on the site).

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, or materials or equipment, which come into contact with fish, is handled. The hand washing facilities room should be the separator room between sanitary facilities and preparation/processing rooms.

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

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

Conditions for changing facilities showers, etc.

94. (1) Establishments shall have changing facilities containing–

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

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

(c) Between the two sections, showers shall be available to be used after leaving the section for undressing city clothes and before entering the section for dressing uniforms.

(2) Toilet and toilet areas shall be adjacent 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 lighted naturally or mechanically, ventilated and maintained in a clean and tidy condition.

Toilets should be connected with the dirty (city clothes) or the clean changing room section (uniforms). 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:–

N° of employees	N° of WC's
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, up to 1/3 of the required number of WC's.

All toilets and urinals shall be of the flushing variety. They should be constructed of materials, which are easy to clean.

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

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

(3) Hand washing facilities (i.e. hand-wash basins) shall be provided near toilets in 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 a 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 from the changing rooms, or from the canteen, or from the toilets shall be forced by a proper flow to pass through the hand washing facilities room before entering the processing room;

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

(5) Canteen should have 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.

95 The establishment shall afford in the working and storage rooms stipulated in regulation 79, machinery, tools, utensils, equipment, instruments, product holding, handling and conveying systems complying with the requirements laid down in following regulations.

General design and construction of facilities and equipment.

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

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

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

(c) permit and enable–

(i) easy thorough cleaning and disinfecting with hot water, detergent and disinfectant taking place at a frequency sufficient to avoid any risk of contamination;

(ii) accessibility for inspection where necessary; and

(iii) maintenance in an appropriate sanitary condition.

Where necessary, equipment is to be fit with any appropriate control device to guarantee fulfillment of these Regulations' objectives.

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

Above-mentioned working areas, instruments and working equipment shall 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 which are–

(a) smooth, non absorbent and resistant to corrosion;

(b) free from pits, crevices and loose scale;

(c) made of materials which do not transmit odour, taste and are non-toxic;

(d) unaffected by food products;

(e) capable of withstanding repeated cleaning and disinfecting, and easy to clean and disinfect.

(3) The use of wood and timber in general and other materials, which 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, doorjambs, 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 could be permitted–

(a) for the transport and the storage of processed food, packed in carton boxes, to transport them in this areas where mastering is done and no unpacked products are handled and to store them in areas where only cardboard packed products are stored and unpacked products are absent;

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

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

Racks and storage systems in cold storage rooms to store carton 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 and overhead structures.

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

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

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

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

(b) on a raised socle covered at the junction of the floor and socle, or

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

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.

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

All overhead structures, services and fittings including lighting shall be easy to clean and–

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

(b) installed as not to hamper cleaning operations;

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

(5) Requirements under (a), (b) and (c) may be met by locating all 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.

Production, holding, handling and conveying.

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

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

(b) Fish boxes, which are used to transport product to the plant, and for the movement of fish within the plant, shall be constructed of a high-density plastic and be of a light colour. They shall have a smooth finish and their design shall avoid areas, which 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 utilised they shall 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;

(iii) made of high-density nylon, stainless steel or fibreglass 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 stand, and small equipment.

99. (1) Worktables shall be constructed of materials, which are non-corrodible, impermeable and non-toxic. Stainless steel is preferable.

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

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

(5) Adequate provision is to be made, where necessary for washing fishery products. Every sink or other such facility provided for the washing of fishery products is to have an adequate supply of potable water and be kept clean and disinfected.

Monitoring and measuring equipment.

100. (1) All equipment to be used for monitoring or measuring purposes where accuracy is important (e.g. 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 calibrated regularly;

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

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

General prerequisites for hygienic facilities

101. Establishments shall also afford the following facilities:–

(a) Hygienic waste water disposal system as described in regulations 218 to 221, Part XII;

(b) Appropriate facilities for protection against pests such as insects, rodents, birds, as described in regulations 173 to 178 of Part XII;

(c) Facilities to provide adequate supplies of drinking water as described in regulations 113 to 132 of Part XII;

(d) Facilities for fishery products not intended for human consumption as described in regulations to 218 to 221 of Part XII.

Vehicle wash area.

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

(2) Where vehicles and container system units used to carry fish are cleaned, a paved and drained area shall be used.

The surface of the vehicle wash area shall–

(a) be durable and impervious;

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

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

Loading docks.

103. (1) Establishments shall have loading docks. The loading dock shall be–

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

(b) enclosed or provided with a protective shelter to prevent fish from contamination during loading and unloading; and

(c) the loading dock shall have an illumination of at least 250-lux.

(2) The area nominated for truck movement shall be finished with a well-drained surface, which is impervious and durable.

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

B - BEST MAINTANANCE PRACTICES

Scope of best maintenance practices.

104. (1) Buildings, vessels, equipment, utensils, refrigeration and all other physical aspects of an establishment, including drains shall be kept in good repair, in a clean and orderly condition and operated in accordance with these Regulations.

Action plan and quality objectives.

105. An action plan to maintain the establishment has to be implemented.

Scheduling of planned actions.

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

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

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

Responsibilities and authority.

107. Responsibilities and authorities have to be established for the implementation, maintaining, monitoring and verification of the maintenance plan.

Procedures.

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

Process control.

109. A Fail Safe Control system shall be worked out to control the maintenance process. The measures taken shall be compared with the standards. Verification has to be done to ensure that the corrective actions are done in the proper manner.

Instructions.

110. Work instructions and control instructions shall be documented and implemented to establish on a daily basis the principles designed in the procedures.

Documentation and records.

111. Checklists for controls, standards, recommendations and verification and records in case of fault shall be documented.

Training.

112. Food business operators are to ensure–

(a) that food handlers and staff are supervised and instructed;

(b) that training on the spot and special training programmes are implemented to ensure that food handlers and staff are trained in food hygiene matters commensurate with their work activity;

(c) that staff are continually reminded of the risks and their responsibility within the fish industry especially concerning the provisions of this part;

(d) that quality managers responsible for the development and maintenance of the quality assurance system (Best Practices) and the product safety assurance system (HACCP) have received adequate training in the application of the HACCP principles and the prerequisite requirements;

(e) compliance with any requirements of national law concerning training programmes for persons working in certain food sectors; and

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

(C) - BEST POTABLE WATER PRACTICES

Scope of best water practices.

113. (1) The objective of regulations 113 to 132 shall be–

(a) to protect human health from the adverse effects of any contamination of potable water intended for human consumption, to be observed in fishery product activities by ensuring that it is wholesome and clean; and

(b) to include water used in the fishery product industry unless it can be established that the use of such water does not affect the wholesomeness of the finished product.

(2) Facilities shall be required to provide a permanent supply of potable drinking water or water intended for human consumption within the meaning of these Regulations or alternatively of clean seawater or clean water treated by an appropriate system (filtration and chlorination, UV sterilisation, ozonisation) under pressure and in sufficient quantity.

(3) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When such water is used, adequate facilities are to be available for its supply.

(4) If the water used in the establishment receives additional treatment prior to use, this shall be done in accordance with the instructions of the manufacturer of any equipment or chemicals utilised and under supervision of the management of the establishment.

(5) 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 shall be clearly distinguished from those used for potable water, clean water or clean sea water and are not to connect with or allow reflux into potable water pipes.

Use.

114. (1) ‘potable water’ means–

(a) all water either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, from a tanker, or in bottles or containers;

(b) all water used in any establishment for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the competent national authorities are satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.

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

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

(b) that is used in the manufacture of ice coming in contact with fishery products or fish contact surfaces. To chill whole fishery products, ice made from clean water can be used. It is to be made, handled and stored under conditions that protect it from contamination; and

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

Application.

115. (1) This division shall not apply to–

(a) natural mineral waters;

(b) medicinal water.

Water distribution system within establishment.

116. (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 from rusting.

(2) The provision of water to the sanitary facilities shall be isolated from the water system for the rest of the establishment and should be supplied from a separate circuit.

(3) There shall be provision to prevent backflow or cross contamination between potable and non-potable water within the establishment.

(4) The management of an establishment shall–

(a) account for the sources of water supply whether–

(i) municipal water (mains) with or without intermediary storage;

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

(iii) desalinated sea water with or without intermediary storage or a combination of different sources.

(b) be responsible for ensuring that water used in the establishment is potable

(c) be able to demonstrate the water distribution system within the establishment, and

(d) provide a water distribution or reticulation map whereon the pipes and outlets shall be identified by consecutive numbering enabling location on the establishment map and in the establishment.

Water storage

117. (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-chlorine.

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

(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 accumulation of rubbish, dust, water and other materials that could contaminate the water.
Each water tank or cistern shall have a floor with sufficient slope and drainage to enable proper cleaning.

(6) Water tanks shall be inspected at regular intervals with the objective of keeping them in good condition. A cleaning and disinfecting plan shall be implemented as mentioned in regulation 149.

Recycling, circulation and recirculation of water.

118. (1) Recycled water used in preparing and processing or as an ingredient, circulated within a facility, is not to present a risk of contamination, shall be treated and maintained in a condition so that no health hazard can result from its reuse and shall be potable if it comes into contact with food.

(2) Water re-circulation and circulation systems shall be clearly identified and have:

(a) no cross connection between potable and non-potable water;

(b) non-return devices installed to prevent back flow into the systems;

(c) no dead ends;

(d) non-potable water outlets clearly identified.

(3) Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.
Water can only be used and reused or re-circulated for cooling of a canned product if it is:

(a) potable;

(b) chlorinated to a level of not less than 0.5 ppm free residual chlorine at the end of the cooling cycle;

(c) filtered before re-use;

(d) and all storage tanks, cooling towers, pipelines or the like utilised in handling the water are constructed to facilitate inspection and cleaning and

(e) don't have dead ends.

Hot water and steam facilities.

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

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

(3) Where steam or pressurized hot water is used, it shall be supplied in sufficient volume and pressure for the operation of the equipment and contain no hazardous substances.

(4) Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food.

Action plan and quality objectives.

120. Procedures and instructions shall be implemented by management to implement the chlorinating system, to organize the scheduling of the free residual chlorine checks, the microbiological checks and the physicochemical checks and to determine the share of own, private or official laboratories in the analyses.

Scheduling.

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

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

Resposibilities and authority.

122. Responsibilities and authorities have to be established for the implementation, maintaining, monitoring and verification of the potable water control plan.

Procudures.

123. (1) Procedures shall be installed to control and safeguard the safety and the quality of water by-

(a) water analysis on residual chlorine content;

(b) microbiological analysis

(c) chemical analysis

(d) physico-chemical analysis

(e) biological tests (parasites, algae, and other organisms such as animalcules (cryptosporidium, worms, larvae).

(2) The Food Unit shall determine sampling points.

(3) The Food Unit shall ensure that additional monitoring is carried out on a case by case basis of substances and micro-organisms for which no parametric value has been specified if there is reason to suspect that they are present in amounts or numbers which constitute a potential danger to human health.

(4) The Government of Sierra Leone shall take the measures necessary to ensure that adequate and up-to-date information on the quality of water intended for human consumption is available to facilities involved in fishery product activities.

Process control.

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

Instructions and standards for chlorinating.

125. (1) The chlorinating system shall comply with the following:

(a) chlorine shall be added on-line by dosing or injection (gas or liquid) prior to intermediary storage to permit sufficient contact time with the water in order to allow the chlorine to react with the organic matter;

(b) the retention tank shall have the capacity to retain water together with the chlorine added for at least 20 - 30 minutes;

(c) the chlorine not combined after 20 – 30 minutes remains as free residual chlorine available in line to react with whatever contamination present in the piping system (back syphonages, dead ends, for example).

(d) the cleaning programme for the intermediary storage tanks shall be documented, monitored and demonstrated;

(e) the management of an establishment shall put in place measures to ensure the functioning of the chlorinating 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 chlorinating system.

(3) The products (fish, shrimp, molluscs, etc.) shall not be washed, dipped, glazed, or treated with hyper-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 Sierra Leone for potable water intended for direct human consumption.

Instructions for interpretation of parametric values.

126. (1) The Food Unit shall take the measures necessary to ensure that the potable water intended for fishery product activities is wholesome and clean. For the purposes of the minimum requirements of these Regulations potable water intended for fishery product activities shall be wholesome and clean if it:

(a) is free from any micro-organisms and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health, and

(b) meets the minimum requirements set out for microbiological and chemical parameter in the Fifth Schedule Part I, Chapters 1 and 2.

(2) As regards the parameters set out in Part I, Chapter 1 of the Fifth Schedule, the values need to be fixed only for monitoring purposes and for the fulfilment of the obligations imposed in case of remedial actions laid down in regulation 130.

(3) The Food Unit shall set values for additional parameters not included in Part I of the Fifth Schedule where the contamination of fishery products so requires. The values set should, as a minimum guarantee that the potable water is free from any micro-organism and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health.

(4) The Government of Sierra Leone shall take all measures necessary to ensure that no substances or materials for new installations used in the preparation or distribution of water intended for human consumption or impurities associated with such substances or materials for new installations remain in potable water intended for human consumption or in concentrations higher than is necessary for the purpose of their use and do not, either directly or indirectly, reduce the protection of human health provided for in these Regulations.

(5) The parametric values set in accordance with sub regulations (1), (2), (3) and (4) shall be complied with-

(a) in the case of water supplied from a distribution network, at the point, within premises or an establishment, at which it emerges from the taps that are normally used for fishery product activities;

(b) in the case of water supplied from a tanker, at the point at which it emerges from the tanker;

(c) in the case of water used in a food-production undertaking, at the point where the water is used in the establishment.

Instructions for monitoring.

127. (1) The Government of Sierra Leone shall take all measures necessary to ensure that regular monitoring of the quality of water intended for human consumption is carried out, in order to check that the water available to consumers meets the requirements of these Regulations and in particular the chemical parametric values set in accordance with regulation 126.

Samples should be taken so that they are representative of the quality of the water used throughout the year.

In addition, the Government of Sierra Leone shall take all measures necessary to ensure that, where disinfecting and the use of certain substances or materials forming part of the preparation or distribution of water intended for human consumption, the efficiency of the disinfecting treatment applied is verified, the use of the substances is governed and that any contamination from disinfecting by-products is kept as low as possible without compromising the disinfecting in order to avoid harmful effects on human health.

(2) To meet the obligations imposed in sub regulation (1), appropriate monitoring programmes shall be established by the competent authorities for potable water intended in fishery product activities. These monitoring programmes shall meet the minimum requirements set out in the Fifth Schedule Part II.

(3) The Food Unit shall ensure that additional monitoring is carried out on a case-by-case basis of substances and micro-organisms for which no parametric value has been set in accordance with regulation 126, if there is reason to suspect that they may be present in amounts or numbers which constitute a potential danger to human health.

Instructions for sampling.

128. (1) Without prejudice to the requirements of sampling frequency set out in Table 2 of Part II of the Fifth Schedule,

(a) the frequency of water sampling in general for the purpose of check monitoring in a fishery product establishment–

(i) in the case of water supplied from a public distribution network, without intermediary storage, shall be at least once per three months from various representative outlets within the plant as laid down in sub regulation (3).

(ii) In the case of water supplied from a public distribution network with intermediary storage, or from a town water source, shall be at least once per month from various representative outlets within the plant as laid down in this sub regulation (3).

(b) the frequency of water sampling for the purpose of audit monitoring in a fishery product establishment shall be at least once per year.

(c) the frequency of the routine water sampling, in connection with the auto-control system or own checks established under the quality assurance programme installed in the establishments, shall be left to the judgement of the quality management team in consultation with the Food Unit.

(2) The sampling points shall be determined by the competent authorities and shall meet the relevant requirements set out in the Fifth Schedule Part II.

(3) The sampling method can be described as follows:–

(a) The sample shall be collected in a sterile bottle. The tap to be sampled shall be run for long enough to completely flush the pipe supplying the tap, and in any case for 2 – 3 minutes. Before a water sample is drawn from the tap, the tip of the tap shall be flamed using spirit and water shall be allowed to flow for 5 minutes before collection. In cases where the laboratory test is undertaken 3 hours or more after sampling, the bottles must be kept in ice. If a sample is to be taken from a chlorinated water supply, any trace of chlorine shall be neutralised immediately after collection. A crystal of sodium thiosulphate or 0,1ml of 2% solution of sodium thiosulphate introduced into the sampling bottle prior to sterilisation serves to neutralise the chlorine.

(4) (a) Samples for check monitoring and audit monitoring laid down in Part II, Table 1 of the Fifth Schedule are to be collected by an official person and analysed in an official laboratory.

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

(c) The samples shall be taken from various outlets identified on the reticulation map. A rotation is organised between the identified outlets from which the water is in contact with the product. Ice shall also be regularly tested.

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

Specifications for analysis.

129. (1) The Government of Sierra Leone shall comply with the specifications for the analyses of parameters set out in Part III of the Fifth Schedule.

(2) Methods other than those specified in Part III, Chapter 1 of the Fifth Schedule, may be used, provided that the results obtained can be demonstrated are at least as reliable as those produced by the methods specified. The Food Unit that has recourse to alternative methods shall provide all relevant information concerning such methods and their equivalence.

(3) For those parameters listed in Part III, Chapters 2 and 3 of the Fifth Schedule any method of analysis may be used provided that it meets the requirements set out therein.

Instructions for remedial action.

130. (1) (a) The Food Unit shall ensure that any failure to meet the parametric values set in accordance with regulation 126 is immediately investigated in order to identify the cause and further sampling shall be carried out.

(b) Two consecutive samples should not be positive for coliform organisms. If the samples show the presence of E. coli or Enterococci, the water of the said source(s) shall not be used until the contamination has been eliminated.

(2) If, despite the measures taken to meet the obligations imposed, water intended for human consumption does not meet the parametric values set in accordance with regulation 126, the Food Unit shall ensure that the necessary remedial action is taken as soon as possible to restore its quality and shall give priority to their enforcement action, having regard inter alia to the extent to which the relevant parametric value has been exceeded and to the potential danger to human health.

(3) Whether or not any failure to meet the parametric values has occurred, the Food Unit shall ensure that any supply of water intended for human consumption which constitutes a potential danger to human health is prohibited or its use restricted or such other action is taken as is necessary to protect human health.

(4) The Food Unit shall decide what action under sub regulation (3) should be taken, bearing in mind the risks to human health which would be caused by an interruption of the supply or a restriction in the use of water intended for human consumption.

(5) The Government of Sierra Leone may establish guidelines to assist the Food Unit to fulfil their obligations under sub regulation (4).

(6) In the event of non-compliance with the parametric values or with the specifications set out in Part I, Chapter 3 of the Fifth Schedule, the Food Unit shall consider whether that non-compliance pose any risk to human health. They shall take remedial action to restore the quality of the water where that is necessary to protect human health.

(7) The Government of Sierra Leone shall ensure that, where remedial action is taken, consumers are notified except where the Food Unit considers the non-compliance with the parametric value to be trivial.

Records.

131. 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.

Training requirements.

132. 1. Food business operators are to ensure–

(a) that food handlers and staff are supervised and instructed,

(b) that training on the spot and special training programmes are implemented to ensure that food handlers and staff are trained in food hygiene matters commensurate with their work activity, and

(c) that staff are continually reminded of the risks and their responsibility within the fish industry especially concerning the assurance of water quality and safety;

(d) that quality managers responsible for the development and maintenance of the quality assurance system (Best Practices) and the product safety assurance system (HACCP) have received adequate training in the application of the HACCP principles and the prerequisite requirements;

(e) compliance with any requirements of national law concerning training programmes for persons working in certain food sectors;

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

(D) –BEST RAW MATERIAL PRACTICES

Scope of best raw material practices.

133. The intake of fishery products has to be organised in accordance with the requirements regarding the quality and safety of the products stipulated by customers but at least to the requirements imposed by these Regulations as follows:–

(a) As far as possible, fish business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo.

(b) Notwithstanding the general duty laid down in paragraph (a), fish business operators are to comply with appropriate national legislative provisions relating to the control of hazards in primary production and associated operations including–

(i) measures to control contamination arising from the air, soil, water, feed, fertilizers, veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste; and

(ii) measures relating to animal health and welfare that have implica-tions for human health.

(c) Fish business operators harvesting animals or producing primary products of animal origin are to take adequate measures, as appropriate–

(i) to keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed clean and where necessary after cleaning to disinfect them in an appropriate manner;

(ii) to keep clean and where necessary after cleaning to disinfect in an appropriate manner, equipment, containers, crates, vehicles and vessels;

(iii) to use potable water or clean water, whenever necessary to prevent contamination;

(iv) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;

(v) as far as possible to prevent animals and pests from causing contamination;

(vi) to store and handle waste and hazardous substances so as to prevent contamination;

(vii) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.

(d) A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic micro-organisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.

Action plan and quality objectives.

134. A Supplier Quality and Safety Assurance Agreement (SQSAA) has to be agreed between supplier and management of the establishment to work out principles concerning product control, quality standards, maintaining the cold chain, hygiene and food safety.

Scheduling.

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

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

Responsibilities and authority.

136. Responsibilities and authorities shall be established for the implementation, maintaining, monitoring and verification of the described best raw material practices.

Procedures.

137. (1) A procedure to implement 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 level.

There shall be a documented agreement which is signed by both quality manager of the establishment and supplier ensuring guarantees about–

(a) quality standards and product control: All raw material has to undergo arrival inspection at plant based on its specifications agreed in the supplier quality and safety assurance agreement. Products that do not reach the quality and safety standards that are laid down in the raw material specifications, agreed between the supplier and the management of the establishment, will be rejected and returned to the supplier, or will be disposed of by agreement between the supplier and the management of the establishment.

(b) maintaining the cold chain: The raw material shall be handled in accordance with the temperature regimes laid down in the specifications mentioned in the supplier quality and safety assurance agreement and at least in accordance with the temperature regimes laid down in these Regulations.

(c) hygiene and food safety: The products shall be transported, stored and handled under conditions that will protect against contamination and minimise deterioration.

(d) raw material specifications as: Ice/fish ratio, maximum core temperature allowed at arrival in the factory, maximum time between catch and icing, maximum time between catch and intake at the establishment, maximum rejects allowed before the whole batch is refused, specifications about species related hazards, organoleptic specifications, chemical specifications concerning freshness determination, microbiological specifications, the way and the method of transport.

(e) origin of the primary products

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

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

(b) During landing, loading and unloading, contamination of fishery products shall be avoided. It shall in particular be ensured that

(i) unloading and landing operations proceed rapidly;

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

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

(iv) personnel shall endeavour to protect the fishery products from physical damage during the unloading of the vehicle; they should not stand on the fish and should prevent it from falling on the floor;

(v) all the equipment used in the unloading of fish shall be washed and disinfected after each batch. 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. Neither should fish be left outside the establishment.

(3) Raw material inspection, handling and storage of accepted raw material shall be worked out in instructions, and shall be documented by delivery records and product quality records, enabling also traceability of the products.

(a) Before unloading, each vehicle arriving at the establishment with fish for processing, shall be inspected, to ensure that–

(i) the interior of the vehicle is clean and dust free;

(ii) the fish has not been exposed to detrimental climatic conditions;

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

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

The temperature of brine frozen fishery products shall not be higher than –9° C.

(c) Before unloading commences a representative sample of each batch of fish shall be taken for sensory evaluation of smell and appearance of raw fish, as described in regulations 141 to 143;

(d) The quality control manager shall indicate his approval of the batch, based on the results of the above tests. He or she shall sign an inspection form and assign a batch code to the fish before 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 0° C (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 shall comply with the following requirements:–

(a) If more fish than can be processed immediately should arrive at the establishment, the excess shall be stored in suitable tanks with ice and water, or alternatively be held in a chill storage room, in order that the temperature of the product is kept at 0° C.

(b) It is recommended that all products which 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 done carefully in order to avoid the contamination of the fish flesh.

(d) Only fish complying with the requirements laid down in regulations 141 to 143 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 control.

138. A Fail Safe Control system shall be implemented whereby measurements and checks are compared with standards followed by corrective actions if necessary.

Instructions.

139. Work instructions and control instructions shall be implemented in detail.

Raw material specifications.

140. (1) Raw material shall be specified by its freshness, physical soundness, sanitary soundness and temperature.

(2) Organoleptic, physical and chemical parameters shall check the freshness.

(3) The physical soundness shall be checked visually.

(4) The sanitary soundness comprises the parasite and toxin checks, the 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.

Frenshness.

141. (1) Organoleptic specifications concerning freshness shall be established. Each batch of fishery products shall be submitted for inspection and inspected by the Food Unit 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.

Also fish business operators shall carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.

The criteria that can be used for the organoleptic check are general appearance, colour, consistency, smell and eventually taste and flavour.

The organoleptic examination shall be repeated after the first sale of fishery products and at all stages of production, processing and distribution, if it is found that the requirements of this regulation have not been complied with or when considered necessary. After the first sale, fishery products shall at least comply with the minimum freshness requirements mentioned in this regulation. The Following categories can be mentioned:–

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

(i) Fishery products shall be marketed only if they meet the requirements of this standard for the freshness categories. 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.)

(ii) The freshness category of each lot shall be determined on the basis of organoleptic criteria.

(iii) Freshness shall be defined by reference to the special ratings for different types of products set out in the tables set forth in the Sixth Schedule

(iv) On the basis of ratings referred to in this sub paragraph, products as specified in sub paragraph (ii) herein shall be classified by lot in one of the following freshness categories:–

(A) Extra, A, B in the case of fish, Selachii, cephalopods;

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

(v) The criteria for fish that is unfit for human consumption are set out in the 'not permitted" category in tables set forth in the Sixth Schedule;

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

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

(i) Fish, Selachii, and cephalopods placed by lot in freshness category Extra shall be free of pressure marks, injuries, blemishes and bad discoloration;

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

(2) Physical, chemical or other checks to determine freshness and to prevent fishery products, which are unfit for human consumption, from being placed on the market, shall be established.

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

(a) Physical methods are–

(i) Refractometric index of the eye-liquid (refractometer)

(ii) Skin resistance for alternative current (fish tester)

(iii) pH of the fish meat

(b) The chemical methods are TVB-N (Total Volatile Basic Nitrogen) and TMA-N (trimethylamine nitrogen). Unprocessed fishery products belonging to the species categories designed by the Food Unit shall be regarded as unfit for human consumption and must not be placed on the market where, organoleptic assessment having raised doubts as to their freshness and chemical checks reveal that the TVB-N or TMA-N limits or both set by the Food Unit 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 the Seventh Schedule;

(ii) Distillation as referred to in sub paragraph (i) shall be performed using apparatus, which complies with the principles of the diagram as set forth in the Seventh Schedule or can be performed by an equivalent automatic steam distillation apparatus.

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

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

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

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

(iv) The sample shall consist of about one hundred grams (100g) of flesh, taken from at least three different points and mixed together by grinding.

(3) The Food Unit shall recommend to official laboratories the use, as a matter of routine, of the reference method referred to in the Seventh Schedule. 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.

When the organoleptic examination gives cause to suspect the presence of other conditions which may affect human health; appropriate samples are to be taken for verification purposes.

Physical soundness.

142. Fish shall be free of –

(a) heavy injuries and scratches;

(b) bad discoloration;

(c) blemishes and dirt;

Sanitary soundness.

143. (1) Controlling sanitary soundness, the presence of parasites, toxins, microbes, viruses, accidental and intentional contaminants which could endanger human health, shall be checked.

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

(2) Fishery products shall not contain parasites, which could be harmful for human health. Fish business operators must ensure that fishery products have been subjected to a visual examination for the purpose of detecting visible parasites before being placed on the market. They must not place fishery products that are obviously contaminated with parasites on the market for human consumption.

(3) Toxin checks to be established are–

(a) Histamine (toxin of enzymatic origin) Fish business operators must ensure that the limits with regard to histamine are not exceeded.

(i) The following sampling plan has to be established:–

Nine samples shall be taken from each batch. These shall fulfil the following requirements:–

(A) the mean value shall not exceed 100 ppm

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

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

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

(iii) Examinations shall be carried out in accordance with reliable, scientifically recognised methods, such as “high performance liquid chromatography” (HPLC).

(b) Marine bio-toxins: type DSP (Diarrhetic Shellfish Poison) and PSP (Paralytic shellfish poison).

(i) live bivalve molluscs must not contain marine bio-toxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:

- for Paralytic Shellfish Poison (PSP), 800 micrograms per kilogram;
- for Amnesic Shellfish Poison (ASP), 20 milligrams of domoic acid per kilogram;
- for okadaic acid, dinophysistoxins and pectenotoxins together, 160 micrograms of okadaic acid equivalents per kilogram;
- for yessotoxins, 1 milligram of yessotoxins equivalent per kilogram; and
- for azaspiracids, 160 micrograms of azaspiracids equivalents per kilogram.

If the results are challenged the reference method shall be the biological method.

(ii) The customary biological testing methods shall not give a positive result to the presence of Diarrethic Shellfish Poison (DSP) in the edible parts of molluscs (the whole body or any part edible separately).

(c) ichthyosarcotoxins : type tetraodotoxin
The placing on the market of poisonous fish of the following families: Tetraodontidae, Molidae, Diodontidae, Canthigasteridae shall be forbidden.

(d) ichthyosarcotoxins : bio-toxin type ciguatoxin or other muscle-paralysing toxins
The placing on the market of fishery products containing bio-toxins such as ciguatera toxins or muscle paralysing toxins or other toxins dangerous to human health shall be forbidden.

(4) Checks on contaminants present in the aquatic environments shall be done under following conditions:–

(a) 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 shall not contain in their edible parts contaminants present in the aquatic environment such as heavy metals and organo-chlorinated substances at such a level that the calculated dietary intake exceeds the acceptable daily or weekly intake for humans.

A national monitoring system shall be established by the Competent Authority to check the level of contamination of fishery products.

(b) Monitoring heavy metals in fishery products shall be done as described in regulation 45.

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

Temperature control.

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

Seizure.

145. If the organoleptic examination, physical and chemical checks, checks on physical and sanitary soundness or temperature checks, reveal that the fishery products are not fit for human consumption, measures shall be taken to withdraw them from the market and denature in such a way that they cannot be re-used for human consumption.

Records and documentation.

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

(2) The following shall be recorded: species, weight, origin, temperature, quality condition of product, accepted and rejected fish, reason of reject, etc.

(3) When there is no official inspection on the landing sites, the official inspectors will cross-check the control and the evaluation of the fish quality and the safety done by the quality managers at the reception of the establishments and recorded in the registers.

Training of fishers, transporters, etc.

147. Food business operators are to ensure–

(a) that fishers, transporters, off-loaders, inspection team, food handlers and staff are supervised and instructed,

(b) that training on the spot and special training programmes are implemented to ensure that food handlers and staff are trained in food hygiene matters commensurate with their work activity, and

(c) that staff are continually reminded of the risks and their responsibility within the fish industry especially concerning the provisions of this chapter;

(d) that quality managers responsible for the development and maintenance of the quality assurance system (Best Practices) and the product safety assurance system (HACCP) have received adequate training in the application of the HACCP principles and the prerequisite requirements;

(e) compliance with any requirements of national law concerning training programmes for persons working in certain food sectors;

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

(E)–BEST CLEANING AND DISINFECTING PRACTICES

Scope of best cleaning and disinfecting practices.

148. (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.

(2) In wet processing when cleaning is necessary to protect 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) Food contact surfaces such as:

- processing equipment and instruments used for working on fishery products in the preparation or processing areas or both;

- crates, bins, baskets, containers used in auctions, preparation and processing facilities for transporting, carrying, salting, brining, shelling, or shucking crustaceans or molluscan shellfish;

- cutting boards, working tables and work surfaces where fishery products come in contact with;

- machinery that make contact with food during processing and machinery used for mechanical recovery of fish flesh and non-food contact surfaces such as:

- the building and the fixtures ;

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

- floors, drains, walls, ceilings, additional structures; and

- waste containers–

shall be kept in a good state of repair and shall be cleaned and be kept clean at all times and disinfected:–

(a) with effective cleaning and disinfecting preparations;

(b) 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 adequate precautions are taken to prevent food, food contact surfaces or food packaging materials from being contaminated during cleaning or disinfecting of rooms, equipment or utensils.

(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 disinfecting. Cleaned and disinfected and to be 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) Establishments shall afford adequate facilities for cleaning and disinfecting buildings, fixtures, utensils, food contact surfaces and means of transport.

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

(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 shall be adequately rinsed after the use of detergents and disinfectants prior to handling of the food.

Action plan and quality objectives.

149. (1) A cleaning and disinfecting procedure for food-contact surfaces, non-food contact surfaces and intermediary storage water tanks shall be documented and implemented–

(a) to ensure that the plant, after cleaning and disinfecting is free from pathogens and that the Total Plate Count from food contact surfaces is below a level (cfu/cm2) approved by the Competent Authority,

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

(c) to ensure that the inner surfaces of the tanks shall not be a source of contamination for the potable water,

Scheduling.

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

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

Responsibilities and authority.

151. Responsibilities and authorities shall be established for the implementation, maintaining, monitoring and verification of the cleaning and disinfecting practices.

Procedures and process control.

152. (1) A procedure defined out to ensure that in all sections in the establishment an adequate work method for cleaning and disinfecting and a fail safe control system will be used.

(2) The method of cleaning and disinfecting shall at least consist in and the different steps shall be established in the 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 sterilising agent after the appropriate contact time;

(h) final phase

(i) equipment is reassembled and allowed to dry

(ii) documented checks to evaluate the cleaning and disinfecting activities by quick tests/checks or by hygienogram.

(3) Cleaning shall be carried out as frequently as necessary, cleaning and disinfecting shall be carried out either immediately after the end of each working day, when there is a risk of contamination or at such times as may be appropriate to maintain hygienic conditions as documented, but not less than daily.

(4) The machinery used for mechanical recovery of fish flesh shall be cleaned at frequent intervals and at least every two hours.

Instructions.

153. (1) In operation instructions, a hygiene work plan shall be defined for the cleaning and disinfecting of each area and room in the establishment.

(2) In control instructions, instructions shall be documented to define, establish and illustrate how to carry out the quick tests/checks and the hygienograms to evaluate the cleaning and disinfecting activities described in this chapter.

Specifications.

154. (1) Specifications, such as trade name, compound active ingredient, methods of use, titration instructions, instructions concerning concentration and dilution and safety instructions, concerning cleaning and disinfecting agents used in the establishment shall be provided.

Documentation and records.

155. (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 of handlers, etc.

156. (1) 1. Food business operators are to ensure-

(a) that food handlers and staff are supervised and instructed,

(b) that training on the spot and special training programmes are implemented to ensure that food handlers and staff are trained in food hygiene matters commensurate with their work activity, and

(c) that staff are continually reminded of the risks and their responsibility within the fish industry especially concerning the cleaning and disinfecting practices;

(d) that quality managers responsible for the development and maintenance of the quality assurance system (Best Practices) and the product safety assurance system (HACCP) have received adequate training in the application of the HACCP principles and the prerequisite requirements;

(e) compliance with any requirements of national law concerning training programmes for persons working in certain food sectors;

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

(F) - BEST HYGIENE PRACTICES

Scope of best hygiene practices.

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

(2) The regulations of this Section 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; and

(c) enter the establishments (including management staff, cleaners, inspectors and visitors).

(3) The persons mentioned above shall maintain a high level of personal hygiene and personal cleanliness and shall take all the necessary precautions to prevent the contamination of the fishery products.

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

Action plan and quality objectives.

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

Scheduling.

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

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

Responsibilities and authority.

160. (1) The management of an establishment shall allocate responsibility for ensuring personnel compliance with the requirements of this Section, to a competent supervisory personnel.

(2) It shall be the responsibility of the supervisor and of each member of staff to conduct him or herself in a responsible manner with respect to the products and equipment.
All personnel shall understand and comply with the requirements of these Regulations.

(3) Responsibilities and authorities shall be established for the implementation, maintaining, monitoring and verification of the plan for Best Hygiene Practices.

Procedures concerning hygiene.

161. Procedures concerning the following shall be documented to ensure that measures to maintain the highest possible standard of cleanliness and hygiene are implemented:–

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

(b) general conditions of hygiene applicable to staff as protective clothing, personnel hygiene, hand hygiene, food borne diseases,

General conditions of construction and operation.

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

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

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

(4) Potable water or clean seawater shall be used for all purposes.

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

General conditions applicable to staff.

163. (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, showering);

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

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

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

Protective clothing.

164. (1) All personnel and visitors entering the preparation or processing rooms shall at all times wear-

(a) suitable, clean and where necessary protective working clothing of a light colour, which covers the minimum outdoor clothing or replaces it;

(b) impermeable boots or footwear which are kept clean and in good condition;

(c) head-covering (headgear) which completely encloses all hair. If involved in medium or high risk product processing personnel shall wear a head covering that encloses the scalp, hair , beard and moustache;

(d) in addition, an impermeable apron for personnel who handle fish and unpacked fish products.

(2) Protective clothing shall–

(a) be provided by the management of the establishment;

(b) not have outer pockets and outer buttons, be clean and lightly coloured, be either washable or disposable, be maintained in a clean condition and in good repair;

(c) not be worn outside the preparation/ processing areas;

(d) be changed and laundered daily or earlier when contaminated;

(e) be stored in a clean locker or similar space or hung on a hanger in the clean changing room, away from contamination and the processing area.

(3) If the personnel who handle fish also wear gloves, these shall–

(a) be made of plastic or rubber,

(b) either be of a disposable type or alternatively, be capable of being easily cleaned and disinfected,

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

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

Personal hygiene.

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

(2) The personnel who handle fish shall not wear–

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

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

(c) watches; and

(d) other personal effects and clothing

(3) Long hair shall be tied back and covered with a hair net, as well as protective head covering as mentioned in regulation 164 (1) (c).

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

(a) smoking;

(b) use of tobacco;

(c) chewing;

(d) spitting;

(e) eating and drinking; and

(f) other unhygienic behaviour;

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

Clear legible notices and signs shall be prominently displayed to indicate and advise that these activities are prohibited.

Hand hygiene.

166. (1) All personnel shall wash their hands with hot water and soap frequently and in particular–

(a) on entering product processing areas;

(b) immediately after using the toilets;

(c) after handling dirty or contaminated materials;

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

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

(f) whenever contaminated; but

the wearing of clean gloves does not exempt the wearer from having thoroughly washed their hands, and workers shall maintain hand hygiene during production and have facilities to wash their hands during work.

(2) Gloves and outer garments that contact fish or contact surfaces shall be made of an impermeable material and shall be maintained in clean and sanitary conditions.

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 transmitting contaminants.

(3) Any person with an injury, a cut, an open wound or a wound that is infected shall not continue to handle fish or fish contact surfaces until the injury is covered with a clean, waterproof, impermeable dressing of a bright colour 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) antiseptic cream;

(c) cotton wool and adhesive tape; and

(d) alcohol or other disinfectant lotion.

Food borne diseases.

167. (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.

No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms to the food business operator.

If the management of an establishment engaged in direct handling of fish has reason to suspect that any person is likely to transmit a disease producing organism to the product, the manager shall ensure the person does not enter the facility until he produces a certificate from a medical practitioner indicating that he is free from infection and is non infective;

(2) 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.

(3) No person shall prepare, pack or handle any material likely to be used in constructing the product, until–

(a) a current (semi-annual) medical certificate stating that he is free of any communicable disease is obtained;

(b) by medical examination or supervisory observation he is shown not 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 by which there is a reasonable possibility that fish, fish-contact surfaces or fish-packaging materials will become contaminated.

(4) Workers, who resume duty after sick leave, shall follow the measures laid down in the instructions defined 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.

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

Process control.

168. (1) A fail safe control system shall be implemented whereby the activities of the personnel are checked and controlled by the supervisors, on their compliance with the activities described in the procedures and the instructions.

(2) A supervisor shall be responsible to check all the steps described in the procedures and instructions.

Instruction on personal and other hygiene.

169. (1) The instructions shall define the measures to assure the hygiene of the personnel, and to contribute to the safety (pathogens) and the shelf life (spoilage bacteria) of the fishery products.

(2) Instructions shall be given to personnel how to–

(a) enter the factory;

(b) clean and disinfect hands;

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

(d) report after sick-leave; and

(e) leave the factory.

Specifications.

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

Documentations and records.

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

Hygiene training.

172. 1. Food business operators shall ensure that–

(a) food handlers and staff are supervised and instructed,

(b) adequate and continuous training on the spot and special training programmes are implemented to ensure that all food handlers and all personnel are trained in personal hygiene and hygienic handling of fishery products; and

(c) staff are continually reminded of the risks and their responsibility within the fish industry so that it is understood how to take the precautions necessary to prevent contamination of fishery products;

(d) that quality managers responsible for the development and maintenance of the quality assurance system (Best Practices) and the product safety assurance system (HACCP) have received adequate training in the application of the HACCP principles and the prerequisite requirements;

(e) compliance with any requirements of national law concerning training programmes for persons working in certain food sectors;

(f) that records of courses and training sessions attendance are kept for inspection and evaluation

(G) - BEST PEST CONTROL PRACTICES

Scope of best pest control practices.

173. (1) Food business operators–

(a) shall afford appropriate facilities against pests such as insects, rodents, birds, or other animals

(b) shall take effective measures to exclude pests from the processing areas and to protect the products against the contamination by pests. Animals, with exception of the live animals

such as crustaceans and fish, kept to be placed on the market alive are 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.

(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) passive level, that means prevention, protection, proofing, construction measures

(ii) active level, that means extermination by use of–

(A) mechanical methods : trapping (rodents)

(B) electrical methods : electro-cuter (insects)

(C) chemical methods : poisons (rodenticides and 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 chemicals shall only be undertaken by personnel who have a complete understanding of the health hazards these chemicals may pose to the product.

Action plan and quality objectives.

174. An action plan shall be defined-

(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.

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

Scheduling of central activities.

175. (1) A time schedule shall be defined to organise and to control the actions on active and passive levels.

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

(3) These schedules and timetables shall be approved by the competent authority and checked on its execution on a regular basis.

Responsibilities and authority.

176. (1) Responsibilities and authorities shall be established for the implementation, maintaining, monitoring and verification of the Pest Control Practices.

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

Procedures.

177. (1) A procedure shall be documented and implemented to assure a consistent pest control plan and a proper work method on the passive and active level.