FISHERIES ACT, 2007
(NO. 6 OF 2007)

FISHERY PRODUCTS REGULATIONS, 2011

ARRANGEMENT OF REGULATIONS

Regulation

PART V – IMPORT OF FISHERY PRODUCTS

PART VI – EXPORT OF FISHERY PRODUCTS

PART VII - HEALTH CONTROL

PART VIII - THE NATIONAL ENVIRONMENTAL MONITORING PROGRAMME

PART IX - THE CONTROL PLAN FOR PRODUCTION CONDITIONS

PART X - AUTO-CONTROL SYSTEMS GUARANTEED BY THE SECTOR

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

PART XII – QUALITY ASSURANCE SYSTEM AND PRODUC-TION CONDITIONS

Sub-part I - BEST PLANT PRACTICES

88. Location of the establishment
89. Surroundings of the establishment
90. Requirements for establishments
91. Conditions and requirements for working, handling and storage rooms
92. General conditions for working room
93. Conditions for preparation and processing rooms
94. Chill rooms, cold storage rooms, chillers and freezers
95. Specific conditions for chill storage rooms
96. Specific conditions for cold storage rooms
97. Specific conditions for freezers
98. Specific conditions for brine freezing facilities
99. Specific conditions for ice plants and ice storage rooms
100. Conditions for rooms where shell-fish is shucked
101. Conditions for rooms where wrapping and packaging material is stored
102. Conditions for rooms where non refrigerated fishery products are stored
103. Conditions for rooms where toxic chemicals and cleaning equipment are stored
104. Conditions for inspection rooms
105. Conditions for laboratories
106. General conditions for sanitary facilities
107. Conditions for changing facilities, showers, toilets, hand washing facilities and canteens
108. General design and construction of facilities and equipment
109. Machinery and over-head structures
110. Product holding, handling and conveying
111. Work tables, foot stands, and small equipment
112. Monitoring and measuring equipment
113. General prerequisites for hygiene facilities
114. Vehicle wash areas
115. Loading docks

Sub-part II - BEST MAINTENANCE PRACTICES

116. Scope of best maintenance practices
117. Action plan and quality objectives
118. Scheduling of repairs
119. Responsibilities and authorities
120. Procedures
121. Process Control
122. Instructions
123. Documentation and records
124. Training

Sub-part III - BEST POTABLE WATER PRACTICES

125. Scope of best potable water practices

126. Use of potable water
127. Water distribution system within the establishment
128. Storage of water
129. Water recycling, circulation and re-circulation
130. Hot water and steam
131. Action plan and quality objectives
132. Responsibilities
133. Procedures
134. Process control
135. Instructions and standards for chlorinating
136. Instructions for the interpretation of the parametric values
137. Points of compliance
138. Instructions for monitoring
139. Instructions for sampling
140. Sampling method
141. Laboratories
142. Specifications for the analysis
143. Instructions for remedial action
144. Records
145. Training

Sub-part IV - BEST RAW MATERIAL PRACTICE

146. Scope of best raw material practices
147. Action plan and quality objectives
148. Scheduling
149. Responsibilities and authority
150. Procedures
151. Process Control
152. Instructions
153. Raw material specifications
154. Freshness
155. Physical soundness
156. Sanitary soundness
157. Temperature control
158. Seizure
159. Records and documentation
160. Training

Sub-part V - BEST CLEANING AND DISINFECTING PRACTICES

161. Scope of best cleaning and disinfecting practices
162. Action plan and quality objectives
163. Scheduling
164. Responsibilities and authority
165. Procedures and process control
166. Instructions
167. Specifications
168. Documentation and records
169. Training

Sub-part VI - BEST HYGIENE PRACTICES

170. Scope of Best Hygiene Practices
171. Action plan and quality objectives
172. Scheduling
173. Responsibilities and authority
174. Procedures concerning hygiene
175. General conditions applicable to constructions and operation
176. General conditions applicable to staff
177. Protective clothing
178. Personal Hygiene
179. Hand hygiene
180. Food borne diseases
181. Process control
182. Instructions
183. Specifications
184. Documentation and records
185. Hygiene training

Sub-part VII - BEST PEST CONTROL PRACTICES

186. Scope of best pest control practices
187. Action plan and quality objectives
188. Scheduling
189. Responsibilities and authorities
190. Procedures
191. Process control
192. Instructions
193. Specifications
194. Documentation and records
195. Training

Sub-part VIII - BEST MANUFACTURING PRACTICES

196. Scope of best manufacturing practices
197. Action plan and quality objectives
198. Scheduling
199. Responsibilities and authority
200. General conditions and procedures for the preparation and processing of fishery products
201. Conditions for washing and decontamination of the fish skin
202. Procedures
203. Conditions and procedures for the preservation of fresh, chilled fishery products
204. Conditions and procedures for freezing and for the storage of frozen products
205. Condition and procedures for thawing of products
206. Conditions and procedures for the mechanical recovery of fish
207. Conditions and procedures for processed fishery products
208. Conditions and procedures for smoking
209. Polycyclic aromatic hydrocarbons (PAH)
210. Conditions and procedures for salting
211. Conditions and procedures for cooking crustaceans and

molluscan shell fish products
212. Conditions and procedures for processing shrimps
213. Conditions and procedures for cooked shrimp
214. Conditions and procedures for canning
215. Conditions and procedures for parasites
216. Conditions and procedures for wrapping and packaging
217. Traceability, origin and labelling
218. Process control
219. Instructions
220. Final product specifications
221. Documents and records
222. Training

Sub-part IX - BEST STORAGE PRACTICES

223. Scope of best storage practices
224. Action plan and quality objectives
225. Scheduling
226. Responsibilities and authority
227. Procedures
228. Temperature conditions for fishery products during storage
229. Storage conditions for fresh fishery products
230. Storage conditions for frozen fishery products
231. Storage conditions for dry ingredients
232. Storage conditions for packaging materials
233. Storage conditions for hazardous sub-stances
234. Process control
235. Instructions
236. Temperature specification
237. Records
238. Training

Sub-part X - BEST TRANSPORT PRACTICES

239. Scope of best transport practices
240. Quality objectives and action plan
241. Scheduling
242. Responsibilities and authority
243. Procedures
244. Temperature conditions for fishery products during transport
245. Hygienic conditions required for vehicles transporting fishery products
246. General transport conditions for fishery products
247. Specific requirements for specific types of transport
248. Process control
249. Instructions
250. Specifications
251. Documentation
252. Training

Sub-part XI - BEST WASTE DISPOSAL PRACTICES

PART XIII - CONDITIONS FOR THE USE OF FOOD ADDITIVES

PART XIV - PRODUCT SAFETY ASSURANCE SYSTEM FOR PREPARATION AND PROCESSING OF FISHERY PRODUCTS

SCHEDULES

Schedule 10 HACCP plan form

FISHERIES ACT, 2007
(NO. 6 OF 2007)

FISH AND FISHERY PRODUCTS REGULATIONS, 2011.

IN EXERCISE of the powers conferred by section 106 of the Fisheries Act 2007 on the Minister, these Regulations are made.

PART I - PRELIMINARY

Short title

1. (1) These Regulations may be cited as the Fish and Fishery Products Regulations 201.

(2) The Regulations come into force on the date the Minister appoints by notice published in the *Gazette*.

Interpretation

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

"associated operations" in relation to primary production on board fishing vessels, includes the slaughter, bleeding, heading, gutting, removal of fins, refrigeration and wrapping as well as-

- 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;

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

"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;

“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;

“food” or “foodstuff” means a substance or product, whether processed, partially processed or un-processed, intended to be, or reasonably expected to be ingested by humans;

“food law” means the laws, regulations and administrative provisions governing food in general, and food quality and safety in particular;

“feed law” means the laws, regulations and administrative provisions governing feed in general and feed safety in particular;

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

“fishing grounds” means the place in which fishery products have been taken;

“import” means the release for free circulation, of feed or food into the territory of fishery products from other countries;

“ingredient” means a substance used in the processing of fish that ends up in the final product;

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

“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;

“objectionable industry” means an industry neighbour-ing the fish preparation or processing plant that may cause contamination of the product either directly or indirectly;

“placing on the market” means the holding or displaying of fishery products for the purpose of sale

or any other form of transfer, excluding retail sales;

"primary production" means the farming, fishing and collection of live fishery products with a view to placing them on the market;

"retail" means the handling or processing of fishery products and its storage at the point of sale or delivery to the final consumer;

"salt" means food grade sodium chloride;

"shall" means a mandatory requirement;

"should" means a recommended requirement;

"stages of production, processing and distribution" means a stage, from the primary production of a food, its storage, transport and 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.

Definitions in relation to fish business

(2) In the context of fish business-

"establishment" means a unit of a fish business;

"fish business" means an undertaking, whether public or private, carrying out any of the activities related to production, processing and distribution of fishery products;

"fish business operator or manager" means the person responsible for ensuring that the requirements of food law are met within the fish business under his or her control;

Definitions in relation to water

(3) In the context of water-

"clean water" means clean seawater and 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 affecting the health quality of food;

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

Definitions in relation to feed business

(4) In the context of feed business-

“feed” or “feeding-stuff” means a substance or product, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

“feed business” means an undertaking whether public or private, carrying out production, manufacture, processing, storage, transport or distribution of feed;

“feed business operator” means the person responsible for ensuring that the requirements of food law are met within the feed business under his or her control;

Definitions in relation to construction and equip-ment

(5) In the context of construction and equipment-

“bell syphon trap” means a water sealed trap designed to hold a liquid seal that prevents the passage of gas and air, 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;

“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 that is not part of the responsibility of the water supplier;

“gully trap” means a water sealed trap designed to hold a liquid seal that prevent the passage of gas and air;

“syphon air trap” means a fitting or device, bent in the shape of a horizontal S-tube, installed under a sink 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

(6) In the context of vessels-

“factory vessel” means a vessel on board which fishery products undergo filleting, slicing, skinning, shelling, shucking, mincing or processing followed by wrapping or packaging;

“freezer vessel” means a vessel used for freezing of

fishery products after preparatory work such as cleaning, bleeding, heading, gutting and removal of fins and where necessary, followed by wrapping or packaging;

Definitions in relation to products

(7) In the context of products-

“aquaculture products” means all fishery products born and raised in controlled conditions or caught in their natural environment and kept until they reach the desired commercial size to be placed on the market as a foodstuff;

“bivalve molluscs” means filter-feeding lamelli-branch molluscs;

“fish product” means a derivative of fish;

“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 products of such animals;

“High risk product” means a product that has a high likelihood of contamination during the production process.

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

Definitions in relation to bivalves

(8) In the context of bivalves-

“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 sea-water, 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;

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

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

"production area" means a 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;

"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;

"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.

"relaying area" means a 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;

Definitions in relation to the preparation and processing of fishery products

(9) In the context of preparation and processing of fishery products-

"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;

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

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

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

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

"preserve" means the process whereby products

are packed in hermetically sealed containers and subjected to heat treatment to the extent that a micro-organism that might proliferate is destroyed or inactivated, irrespective of the temperature at which the products is to be stored;

"processed products" means fishery products obtained from the processing of unprocessed products.

"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;

Definitions in relation to smoking

(10) In the context of smoking-

"derived smoke flavourings" means 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;

"flavouring" means flavouring substances, flavouring preparations, process flavourings, smoke flavourings or related mixtures.

"primary products" means primary smoke condensates and primary tar fractions;

"primary smoke condensate" means the purified water-based part of condensed smoke;

"primary tar fraction" means the purified fraction of the water-insoluble high-density tar phase of condensed smoke;

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

Definitions in relation to food additives

(11) In the context of food additives-

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

"sweeteners" means food additives which are used to impart a sweet taste to foodstuffs,

Definitions in relation to chilling

(12) In the context of chilling-

"brine" means a mixture of potable water or clean

seawater and food grade salt;

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

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

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

“refrigerated brine” means brine cooled by a suitable refrigeration system;

“refrigerated seawater” means clean seawater cooled by a suitable method;

Definitions in relation to freezing

(13) In the context of freezing-

“cold storage room” means a chamber or room used for the storage of frozen fishery products at a temperature of minus eighteen degrees celcius (18°c) or lower;

“freezer” means a room used for the purpose of reducing fish temperature to minus eighteen degrees celcius (-18°c) or lower;

“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 minus eighteen degrees celcius (-18°c) or lower ;

“frozen products” means products which have undergone a freezing process to reach a core temperature of minus eighteen degrees celcius (-18°c) or lower, after temperature stabilization;

“ice room” means a chamber or room used only for the manufacture or storage of ice;

Definitions in relation to wrapping and packaging

(14) In the context of wrapping and packaging-

“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;

“wrapping” means the placing of fishery product in a

wrapper or container in direct contact with the foodstuff concerned;

Definitions in relation to quality assurance

(15) In the context of quality assurance-

"code of best practices" means 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 and are the prerequisite measures and conditions necessary to control hazards by the safety assurance system;

"CP" means control point,

Definitions in relation to safety assurance

(16) In the context of safety assurance-

"CCP" means Critical Control Point;

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

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

"HACCP" means Hazard Analysis Critical Control Points,

"hazard" means a biological, chemical or physical agent in 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;

"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 of risk assessment, management and communication;

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

"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 and managers, consumers, feed and food businesses, the academic community and other interested parties,

"risk management" means the process 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;

"verification" in relation to HACCP means the application of methods, procedures and tests, in addition to those used in monitoring, to determine compliance with the HACCP plan;

"verification" in relation to inspection means the checking, and consideration of objective evidence, as to whether specified requirements have been fulfilled;

Definitions in relation to parasites

(17) In the context of parasites-

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

"visual inspection" means a non destructive examination of fish or fishery products without optical means under good light conditions for human vision;

Definitions in relation to inspection and control

(18) In the context of inspection and control-

"approved" means an approval by the head of the Competent Authority in writing;

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

"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;

"auto-control" means the quality and safety assurance systems implemented by the management of an establishment;

"Competent Authority" means the central authority of

a country empowered to ensure compliance with the requirements of these Regulations, carry out veterinary checks and to organize official controls or any other authority to which that central authority has delegated that competence;

"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;

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

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

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

"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;

"inspection" means the examination of establishments, animals and food, the processing system of fish and their management, 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;

"Inspectorate" means the unit of the Fisheries Department within the Ministry of Fisheries and Water Resources, responsible for the organisation and the inspection of the quality control and safety assurance systems;

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

“non compliance” means the failure of an establishment to meet the requirements of these Regulations;

“official control” means a form of control that the Competent Authority performs for the verification of compliance with food law;

“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 performing the 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;

“official fish inspector” means a Fisheries Officer qualified in accordance with these Regulations, to act in such a capacity and appointed by the Competent Authority;

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

“sampling for analysis” means taking feed or food or any other substance 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;

“surveillance” means a careful observation of one or more feed or food businesses, feed or food business operators or their activities;
“traceability” means the ability to trace and follow a

food, feed, food-producing animal or substance intended to be incorporated into a food or feed, through all stages of production, processing and distribution;

"verification" in relation to inspection means checking by examination and the consideration of objective evidence whether specified requirements have been fulfilled;

Definitions in relation to laboratories

(19) In the context of laboratories-

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

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

Objectives, principles and procedures forming a common basis for food law

3. The following objectives, principles and procedures for food law shall form a general framework to be followed when measures are taken-

(a) Fishery Product Legislation shall-

(i) pursue a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of the protection of animal health and welfare and the environment;

(ii) aim 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 of these Regulations;

(iii) 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;

(iv) aim at the prevention of -

(aa) fraudulent or deceptive practices,

(ab) the adulteration of food, or

(ac) any other practices which may mislead the consumer.

(v) be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure;

(b) risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner;

(c) 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, in order to achieve the general objectives of the Fishery Products Legislation;

(d) 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 Gambia may be adopted, pending further scientific information for a more comprehensive risk assessment;

(e) measures adopted on the basis of paragragh (d) 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;

(f) 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;

(g) 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;

(h) 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, the Competent Authority may take appropriate steps to inform the general public of the nature of the risk, identifying to the fullest extent possible the fishery product or feed affected, and the measures which are taken or about to be taken to prevent, reduce or eliminate the risk.

PART II - COMPETENT AUTHORITY

Empowerment of Competent Authority

4. (1) The Fisheries Department of the Ministry of Fisheries shall be the Competent Authority in The Gambia and is empowered to enforce these Regulations.

(2) The organisational chart of the Competent Authority is set forth in Schedule 1 to these Regulations.

Responsibilities of the Competent Authority

5. (1) The responsibilities of the Competent Authority shall be in accordance with-

(a) the tasks, duties and responsibilities provided under the Fisheries Act 2007; and

(b) the responsibilities concerning Health control laid down in Part VIII of these Regulations.

(2) The Competent Authority shall ensure-

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

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

(c) that it has or has access to an adequate laboratory for testing and a sufficient number of qualified and experienced staff;

(d) that it has appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively;

(e) that it has the legal powers to carry out official controls and to take the measures

provided for in these Regulations;

(f) that it has contingency plans in place, and is prepared to operate such plans in the event of an emergency; and

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

(3) Where the Competent Authority delegates its powers to other control bodies, it shall ensure-

(a) that there is efficient and effective co-ordination between all the control bodies where competence to carry out official controls is conferred on two or more bodies;

(b) the impartiality, quality and consistency of official controls at all levels;

(c) efficient and effective coordination between the different bodies competent to carry out official controls within a delegated authority; and

(d) that internal and external audits are carried out and take appropriate measures in the light of their result to ensure that the objectives of the Regulations are achieved.

General obligations with regard to the organisation of official controls

6. (1) The Government of The Gambia shall ensure that official controls are carried out regularly on a risk basis, so as to achieve the objectives of these Regulations taking account of-

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

(b) feed or food business operators' past record regarding compliance with feed or food law or with animal health and animal welfare rules;

(c) the reliability of any own checks that have

already been carried out; and

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

(2) Official controls shall be carried out-

(a) without prior warning, except in cases such as audits, where prior notification of the feed or food business operator is necessary;

(b) during any of the stages of production, processing and distribution of feed or food; and

(c) with the same care to exports outside The Gambia as they are to products intended to be placed on the local market.

(3) Official controls shall include controls on-

(a) feed and food businesses;

(b) the use of feed and food;

(c) the storage of feed and food; and

(d) a process, material, substance, activity or operation required to achieve the objectives of these Regulations.

(4) The Government of The Gambia 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 within the Gambia.

(5) The Competent Authority of the country of destination may-

(a) check compliance of feed and food with feed and food law by means of non-discriminatory checks;

(b) take the appropriate measures where it establishes a case of non-compliance

Delegation of specific tasks related to official controls

7. (1) The Competent Authority may delegate specific tasks related to official controls to one or more control bodies if-

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

(b) there is proof that the control body-

(i) has the expertise, equipment and infra-structure required to carry out the tasks delegated to it;

(ii) has a sufficient number of suitably quail-fied and experienced staff; and

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

(c) it works and is accredited in accordance with Standard EN 45004 “General criteria for the operation of various types of bodies perform-ing inspection or another standard if more relevant to the delegated tasks in question”;

(d) its laboratories operate in accordance with International standards ISO 17025 and good Laboratory Practices;

(e) the control body communicates the results of the controls carried out to the Competent Authority on a regular basis and whenever the Competent Authority so requests.

(2) The Competent Authority delegating specific tasks to control bodies shall organise audits or inspections of control bodies whenever necessary.

(3) If, as a result of an audit or an inspection, it app-ears that such bodies are failing to properly carry out the tasks delegated to them, the Competent Authority may withdraw the delegation.

(4) The Competent Authority wishing to delegate a specific control task to a control body shall notify the Government, with a detailed description of-

(a) the Competent Authority;

(b) the task that it intends to delegate; and

(c) the control body to which it intends to delegate the task.

Staff performing official controls

8. The Competent Authority shall ensure that its employees performing official controls receive sufficient training to enable them undertake their duties competently and to carry out official controls in a consistent manner in areas such as-

(a) Legislation relating to the Fisheries Industry;

(b) inspection and controls which includes -

(i) inspection Manual and Codes of Best inspection Practices;

(ii) control procedures;

(iii) different control techniques such as, auditing, sampling and inspection;

(iv) legal proceedings and implications of official controls;

(v) contingency arrangements for emergencies, including communication with overseas authorities;

(vi) any other area including animal health and welfare necessary to ensure that official controls are carried out in accordance with these Regulations; and

(vii) official controls;

(c) implementation of Inspections and Controls relating to-

(i) the different stages of production, processing and distribution, and the possible risks for human health and where appropriate the health of animals and plants and for the environment;

(ii) quality assurance targeting the management systems that feed and food businesses operate and their assessment in so far as these are relevant for feed or food law requirements;

(iii) product safety assurance; and

(iv) hazards in animal feed and food production and the evaluation of the application of HACCP procedures.

(d) laboratories management which includes examination of written 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;

Transparency and Confidentiality

9. (1) The Competent Authority shall carry out its activities with a high level of transparency.

(2) The public shall have access to-

(a) information on the control activities of the Competent Authority and their effectiveness; and

(b) information relating to fishery products that may present a risk to human health and the measures taken or about to be taken to prevent or eliminate the risk.

(3) The Competent Authority shall take steps to ensure that its employees do not disclose information acquired whilst undertaking their official control duties which by its nature is covered by professional secrecy in duly justified cases.

(4) Professional secrecy includes-

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

(b) personal data; and

(c) information protected by any other national legislation.

Control and Verification procedures

10. (1) The Competent Authorities shall carry out official controls in accordance with documented procedures.

(2) These procedures shall contain information and instructions for staff performing official controls

including-

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

(b) the organisation of the Competent Authority and the relationship with the authorities to which they have delegated tasks to carry out official controls;

(c) the relationship between the Competent Authority 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) monitoring and surveillance programmes;

(f) tasks, responsibilities and duties of employees;

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

(h) verification of the appropriateness of methods of sampling, methods of analysis and detec-tion tests;

(i) action to be taken following official controls; or

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

(3) The Government shall put in place legal procedures to ensure that employees of the control bodies have access to premises and documentation kept by fish business operators to enable them accomplish their tasks properly.

(4) The control bodies shall put in place procedures to-

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

(b) ensure that corrective action is taken when needed and that the information referred to in sub-regulation (2) is updated as required;

General Plan and Contingency Plans for crisis management

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

(2) The general plan shall specify the types of situations that pose a risk 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 as-

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

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

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

(d) any other appropriate interim measures.

(3) As soon as possible, and in any case within ten working days the measures taken shall be confirmed, amended, revoked or extended and the reasons for a decision shall be made public without delay.

(4) 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;

(5) For the implementation of the general plan for crisis management referred to in sub-regulations (2), (3) and (4), 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;

(6) The contingency plans shall specify-

(a) the administrative authorities to be engaged;

(b) the powers and responsibilities;

(c) channels and procedures for sharing infor-

mation between relevant parties; and

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

(7) The Government shall review the contingency plans particularly in the light of changes in the organisation of the Competent Authority and of experience, including experience gained from simulation exercises.

PART III - CONDITIONS GUARANTEED AND IMPOSED BY THE COMPETENT AUTHORITY

Registration and approval of establish-ments

12. (1) The Competent Authority 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 airport facilities;

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

Approval of the Ground Plan

13. (1) Before the management of an establishment can build, rebuild or adapt an establishment, an application shall be made to the Competent Authority to inform the Director of Fisheries about the-

(a) activities intended to be carried out in the establishment; and

(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 Director of Fisheries shall-

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

(b) within fourteen days, send an invitation to the management of the establishment to discuss the demand.

(3) Once the Director of Fisheries accepts the final

proposal of the management, he or she shall approve the plans and specifications by fixing the official stamp of the Competent Authority over his or her signature on the plans and specifications.

(4) On completion of the building, renovation, or extension of the establishment the management shall inform the Director of Fisheries in writing, and invite him or her to conduct an onsite audit on the establishment.

(5) After the audit, the Director of Fisheries shall-

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

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

National registration numbers listed on official lists of approvals

14. (1) Where an establishment has been granted approval, it shall be given an approval certificate containing a registration number and listed on the official list of approvals.

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

Review of approvals

15. The Competent Authority shall keep the approval of establishments under review when carrying out official controls.

Withdrawal and suspend-sion of approval

16. (1) If the Competent Authority 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 Competent Authority shall initiate procedures to withdraw the establishment's approval.

(2) The Competent Authority 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

17. (1) An approval procedure shall be established by the Competent Authority for the registration of fishing vessels and the provision of a registration number for these vessels complying with the requirements laid down in Part X.

Approval of Landing sites

18. An approval procedure shall be established by the Competent Authority for the approval and registration of official and Private landing sites 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 of these Regulations.

Approval of seaport and airport

19. (1) An approval procedure shall be established by the Competent Authority for the approval and registration of the sea port and airport facilities for off loading, transport and storage for fishery products and the provision of a registration number for the facilities that comply with the requirements-

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

(b) for transport of fishery products laid down in Part XX; and

(c) for storage of fishery products laid down in Part XIX of these Regulations.

(2) The approval procedure laid down in regulation 12 shall apply mutatis mutandis to the approval procedures described in regulation 17.

Approval of chemicals

20. The competent Authority shall approve chemicals used -

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

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

Official Lists

21. (1) The Competent Authority 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 for the eradication of pests and for clearing and disinfecting purposes; and

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

Inspections and updated lists

22. (1) The inspection of establishments, vessels, official and private landing sites and auctions shall be carried out regularly by the inspection service to verify whether they comply with the requirements.

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

(3) The lists shall be updated when necessary.

PART IV - PLACING OF FISHERY PRODUCTS ON THE MARKET

General Conditions

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

(a) be caught and where appropriate handled for bleeding, heading, gutting and removal of fins; and processed on board vessels in accordance with the hygiene rules establish-ed in Part X;

(b) be handled, during and after landing, in accordance with the requirements laid down in Part XI of these regulations;

(c) be handled and, where appropriate packaged, prepared, processed, frozen, defrosted or stored hygienically in plants approved in accordance with regulation 12 and the requirements of Part XII;

(d) be appropriately packaged in accordance with the requirements laid down in regulation 216 of these Regulations;

(e) be given an identification mark or labelling in accordance with regulation 217 of these Regulations;

(f) be certified in accordance with the conditions laid down in regulation 33 of these Regulations;

(g) be stored and transported under satisfactory conditions of hygiene and temperature in accordance with Part XII of these Regulations;

(h) be prepared or processed in accordance with the Quality Assurance Programme established in Part XII and the Safety Assurance Programme established in Part XXIV of these Regulations;

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

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

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

General conditions for Aqua-culture products

24. Aquaculture products harvested and intended to be placed on the market shall-

(a) 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) be handled and, packaged, prepared, processed, frozen, defrosted or stored hygienically in plants approved in accordance with these Regulations and the requirements of Part XII;

(e) be appropriately packaged in accordance

with the requirements laid down in these Regulations;

(f) be given an identification mark in accordance with these Regulations;

(g) be certified in accordance with the conditions laid down in these Regulations;

(h) be stored and transported under satisfactory conditions of hygiene and temperature in accordance with Part XII of these Regulations;

(i) be prepared or processed in accordance with the Quality Assurance programme establish-ed in Part XII and the Safety Assurance programme established in Part XXIV of these Regulations;

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

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

(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 laid down in of Part XII of these Regulations.

preparation conditions of the products placed on the market

25. (1) Where gutting is possible from a technical, commercial and hygienic viewpoint it shall be carried out as quickly as possible after the products have been caught or landed and put on ice.

(2) Where the products are not gutted they shall be frozen on the vessel immediately after having been caught.

Prohibited products on the market

26. A person shall not place on the market -

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

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

(c) fishery products containing other toxins such as histamine, heavy metals, and other contaminants in an amount higher than the levels established in Part VII of these Regulations.

PART V – IMPORT OF FISHERY PRODUCTS

Import conditions

27. (1) The provisions applicable to the import of fishery products shall in principle be at least equivalent to those governing the production and placing on the local market as described in these Regulations.

(2) The Competent Authority may lay down specific import conditions to-

(a) protect public health of the citizens of The Gambia; and

(b) allow the import of products for local consumption so that these products cannot be re-exported or used as raw material in an establishment approved to export fishery products.

Notification by importer

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

Off shore inspection

29. The Director of Fisheries may enter into an off shore inspection arrangement with a foreign Government, Government agencies or trade organizations if he or she is satisfied, based on verification by the Competent Authority, that the legal requirements, fish inspection systems and infrastructure for preparing fish for export in that country meet the requirements of the laws of The Gambia.

Contents of arrangements

30. An off shore inspection arrangement may include provisions to-

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

Gambia;

(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 a 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

31. The Director of Fisheries may, after consultation with the Competent Authority rely on results of inspections conducted by the inspection agency of a foreign Government or foreign trade organisation for the purpose of –

(a) negotiating or implementing an off-shore arrangement; or

(b) determining whether fishery products imported pursuant to an arrangement meet the requirements of these regulations.

PART VI - EXPORT OF FISHERY PRODUCTS

Export Conditions and product quality

32. The provisions applicable to the export of fishery products shall comply with the conditions laid down in these Regulations and with the requirements of the legislation of the country to which The Gambia exports.

Product quality and safety assurance

33. (1) A person shall not export, process for export or attempt to export, a fishery product unless that fishery product is prepared or processed in an establishment in accordance with the requirements laid down in these Regulations.

(2) A person shall not export, process for export or

attempt to export, a fish that is tainted, decomposed or unwholesome, or otherwise fails to meet the requirements of these Regulations.

(3) A shipment of fishery products of any type, in any presentation, quantity or by any means, should be accompanied by an Export Health Certificate and export permit delivered by the Competent Authority as set forth in the second Schedule of these Regulations.

Requirements for export certificates

34. (1) An export certificate, in addition to the supplementary requirements specified by the importing country, shall -

(a) bear the stamp and signature of a designnated representative of the Competent Authority on each sheet;

(b) 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 languages.

(c) if the country of destination so requests, be accompanied by a certified translation into the official language or languages of that country.

(2) The original version of the certificate shall accompany consignments on entry into the importing country.

(3) The certificate shall contain accurate and authentic information and reflect the contents of the consignment.

(4) The certificate may consist of -

(a) a single sheet of paper;

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

(c) a sequence of pages, numbered to indicate that it is a particular page in a finite sequence (e.g. page 2 of 4 pages).

(5) The certificate shall bear a unique identifying number and where the certificate consists of a sequence of pages, each page must indicate this

number.

(6) The certificate shall be issued before the consignment to which it relates leaves the control of the Competent Authority of the country of dispatch.

PART VII - HEALTH CONTROL

Food quality and safety

35. A fish business operator at all stages of production, processing and distribution shall ensure that fishery products satisfy the quality and safety requirements of these Regulations which are relevant to their activities.

official controls

36. The Government shall ensure that the relevant requirements of fishery product law are fulfilled by fish business operators by maintaining a system of official controls and other activities appropriate to the circumstances such as -

(a) public communication on food safety and risk;

(b) food safety surveillance; or

(c) other monitoring activities covering all stages of production, processing and distribution.

Controls and audits from importing countries

37. An offshore official inspection arrangement with a country importing products from The Gambia may be established to verify the compliance or compatibility of legislation, control systems and laboratory activities with the importing country.

Scope of Health control plan

38. (1) Fishery products caught in their natural environment as well as aquaculture products shall undergo a health control check to monitor the conditions for their production and placing on the market.

(2) The Competent Authority shall establish a coherent, consistent, comprehensive, single, integrated and multi-annual national health control plan consisting of -

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

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

(c) a national residue monitoring programme to monitor the intentional contaminants in the aquaculture sector, at sea or in-land.

Multi-annual national control plans

39. A Multi Annual National Control Plan (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 such as-

(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; and

(v) scientific findings;

(c) shall be kept available in its latest version and provided on request of importing countries.

Content and Implementation of Multi Annual National Control Plans

40. Each Multi Annual National Control Plan shall contain general information on the structure and organisation of the systems of food control, animal health and welfare control, and 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; and

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

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

(ii) general management and recording systems for-

(aa) the official controls covering all stages of production, processing and distribution;

(ab) the national environmental monitoring programme for wild catch;

(ac) 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; and

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

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

(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 these Regulations;

(l) training programmes for staff performing official controls as laid down in these Regulations;

(m) documented procedures referred to in these Regulations;

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

Inspection Manual

41. The inspection requirements, control plans, best control practices and control policies laid down in these Regulations are Codes of Best Inspection Practices, designated as an Inspection Manual for the official inspectors.

Annual reports

42. Each year, the Competent Authority shall draft an annual report and may provide it on request to competent authorities importing fishery products from The Gambia.

(2) The report shall indicate -

(a) any amendments made to multi-annual

national control plans;

(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 the National environmental monitoring programme

43. (1) The health control of environmental conditions called the "National Monitoring Programme" shall -

(a) be carried out annually;

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

(c) be implemented at 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 The Gambia and neighbouring countries;

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

(d) potential microbiological contaminants of the fish skin.

Monitoring of sanitary soundness

44. The National Monitoring Programme shall monitor the sanitary soundness of fishery products, in relation to 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; or

(b) the pollution of the aquatic environment.

Parasites

45. (1) The presence or absence of parasites in the different commercial fish species, their 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.

Fish toxins in general

46. (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 shall not to be placed on the market.

Monitoring plan for Histamine or Scombrotoxin

47. (1) The Competent Authority shall install a monitoring programme of random testing for histamine to test an auto-control system set up by the management of the establishment and to evaluate the risk of histamine to human health.

Sampling plan for histamine

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

(a) nine samples shall be taken from each batch, of which -

(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; and

(iii) a sample shall not have a value exceeding 200 ppm.

(b) these limits apply only to fish species of the scombridae, clupeidae, engraulidae and coryphaenidae families

(c) fish belonging to families mentioned in paragraph (b) which have undergone

enzyme-ripening treatment in brine, may have higher histamine levels but not more than twice the above values; or

(d) examinations shall be carried out in accordance with reliable, scientifically recognised methods, such as “high performance liquid chromatography” (HPLC).

Monitoring poisonous fish

49. A monitoring plan shall be implemented by the Competent Authority to ensure that no poisonous fish-

(a) belonging to the Tetraodontidae, Molidae, Diodontidae, Canthigasteridae families; or

(b) containing ichthyosarcotoxins type tetraodo-toxin;

is placed on the market.

Contaminants present in aquatic environment

50. (1) A monitoring system shall be established by the Competent Authority to check the level of contamination of fishery products in relation to industrial chemicals, heavy metals, medicinal products, food additives, animal feed additives and pesticides.

(2) Without prejudice to the laws regulating water protection and management, and in particular those concerning pollution of the aquatic environment, the edible parts of fishery products shall not contain -

(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 Paragraph at such level that the calculated dietary intake exceeds the acceptable daily or weekly intake for humans.

Standards for chemical contaminants

51. Fishery products shall not contain chemical contaminants on a level higher than that specified below -

(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 plan for polychlorinated bipheny's, dioxins and furans

52. (1) A monitoring plan to check the contamination of fishery products and aquaculture products of polychlorinated bipheny's (PCB's), dioxins and furans shall be implemented by the Competent Authority.

(2) Polychlorinated biphenyls (PCB's) are synthetic organic components sold as complex mixtures of different congeners, in which a variable number (1-10) of C1 atoms are substituted on biphenyl under the following conditions -

(a) the total number of congeners (number and place of C1 atoms) is 209 and PCB's are mostly indicated by numbers e.g. CB 117 is 2, 3', 4, 4', 5 Penta CB;

(b) the seven marker congeners are CB 28, 52,101,118,138,153,180 and they are chosen to be analysed because of their presence in industrial PCB mixture.

(c) Polychlorinated biphenyls (PCB's), are a group of 209 different congeners which can be divided into two groups according to their toxicological properties; and

(d) twelve 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.

(3) Dioxins and furans are not synthetic industrial products, but unwanted environmental conta-

minants formed by uncontrolled heating or burning and they are subject to the following -

(a) in furans the two phenyls are bound by an additional oxygen bridge;

(c) a short indication for furans is PCDF's (Poly Chlorinated Dibenzo Furans; 135 congeners; e.g. 2,3,7,8 TCDF (T=Tetra).

(d) Dioxins consists of two phenyls bound by oxygen bridges;

(d) a short notation of dioxins is PCDD's (Poly Chlorinated Dibenzo Dioxins; seventy five congeners e.g. 2,3,7,8 TCDD).

(e) each congener of dioxins or dioxin-like PCB's exhibits a different level of toxicity;

(f) 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;

(g) the analytical results relating to all seventeen individual dioxin congeners and to the twelve dioxin-like PCB congeners are expressed in terms of a single quantifiable unit: 'TCDD toxic equivalent concentration' (TEQ);

(h) the Tolerable Weekly Intake and dioxin like polychrinated bipheny's fixed on the level of 14pg WHO-TEQ/kg body weight;

(4) Fishery products should not when placed on the market, contain higher contaminant levels than the maximum levels specified for Dioxin (sum of polychlorinated dibenzo-*para*dioxins= PCDD's) and polychlorinated dibenzofurans =PCDF's) expressed in WHO Toxic Equivalents, using the WHO Toxic Equivalency Factors such as-

(a) 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;

(b) fish oil intended for human consumption 2pg

WHO-PCDD/F-TEQ/g fat.

(5) The methods of analysis -

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

(b) for determination of dioxins shall be carried as HRGC/HRMS: high resolution gas chromatographyhigh resolution mass spectrometry and ^{13}C marked dioxin standards.

Monitoring plan for Heavy metals

53. A monitoring plan to check the contamination of fishery and aquaculture products by heavy metals shall be established by the Competent Authority.

Method of Analysis

54. (1) The analysis methods, maximum limits and sampling plans for monitoring heavy metals in fishery products shall be established by the Competent Authority.

(2) The analysis method shall conform to the following -

(a) specific methods for the determination of lead, cadmium and mercury contents are not prescribed, but reference methods for detecting heavy metals are laid down, inter alia, under Atomic Absorption Spectrometry (AAS);

(b) laboratories shall use a validated method that fulfils the performance criteria indicated in Schedule 4 of these Regulations; and

(c) where possible, the validation shall include a certified reference material in the collaborative trial test materials.

(3) Maximum limits shall conform to the following -

(a) the mean total mercury content, as determined by the analysis of the edible parts of the fishery products shall not exceed 0.5ppm of fresh products (0.5mg /kg of fresh weight);

(b) the average limit may however increase to1 ppm of fresh products (1 mg/kg of fresh weight) for the edible parts of the following species -

(i) Centromscymnus coelolepis (Portuguese dogfish),

(ii) Euthunnus spp (Little tuna),

(iii) Gempylus serpens (Snake Mackerel or Butterfish),

(iv) Hippoglossus hippoglossus (Halibut),

(v) Hoplostethus spp (Emperor, Orange Roughy, Rosy Soldierfish),

(vi) Istiophorus platypterus (Sail fish),

(vii) Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens (Snake Mackerel or Butterfish),

(viii) Makaira spp (Marlin),

(ix) Mugil spp (Mullet),

(x) Pagellus spp (Seabream, Pandora),

(xi) Raja spp (Rays),

(xii) Sarda sarda (Bonito),

(xiii) Shark (all species),

(xiv)Thunnus spp, Euthunnus spp, Katsuwonus pelamis (Tuna), and

(xv)Xiphias gladius (Swordfish);
(Snake mackerel).

(c) the mean total lead content, as determined by the analysis of the edible parts of the fishery products shall not exceed 0,2ppm of fresh products (0.2 mg/kg of fresh weight);

(d) this average limit is however increased to-

(i) 0.4 ppm (0.4mg/kg of fresh weight) for edible parts of the following species -

(aa) Anguilla anguilla (Eel);

(ab) Dicentrarchus punctatus (Spotted seabass);

(ac) Dicologoglossa cuneata (Wedge sole);

(ad) Diplodus vulgaris (Common two-

banded seabream);

(ae) Mugil labrosus labrosus (grey mullet);

(af) Pomadasys bennetti (Grunt);

(ag) Sardina pilchardus (European pilchard or sardine);

(ah) Sardinops spp; and

(ai) Trachurus spp (Horse mackerel or Scad).

(ii) 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);

(iii) 1 ppm (1 mg/kg of fresh weight) for Bivalve molluscs and Cephalopods (with-out viscera);

(e) the mean total cadmium content as determined by the analysis of the edible parts of the fishery products shall not exceed 0.05 ppm of fresh products (0.05 mg/kg of fresh weight); and

(f) this average limit is however, increased to -

(i) 0.1 ppm (0.1 mg/kg of fresh weight) for edible parts of the following species -

(aa) Anguilla spp (Eel);

(ab) Dicologoglossa cuneata (Wedge sole);

(ac) Diplodus vulgaris (Common two-banded seabream);

(ad) Engraulis spp (Anchovy);

(ae) Luvarus imperialis (Louvar or lu var);

(af) Mugil labrosus labrosus (grey mul-let);

(ag) Sarda sarda (Bonito);

(ah) Sardina pilchardus (European pil-chard or sardine);

(ai) Sardinops spp;

(aj) Thunnus spp, Euthunnus spp, Katsuwonus pelamis (Tuna); and

(ak) Trachurus spp (Horse mackerel or Scad).

(ii) 0,3 ppm(0,30 mg/kg of fresh weight) for edible parts of Muscle meat of Xiphias gladius (Swordfish),

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

(iv)1 ppm (1 mg/ kg of wet weight) for edible parts of bivalve molluscs and cephalo-pods (without viscera).

Sampling plans, methods of sampling, sample preparation, and definitions

55. (1) Sampling plans laid down for fresh and frozen fishery products by the Competent Authority 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 Part I of the fourth Schedule of these Regulations.

(3) Methods of sampling are laid down in Part II of the fourth Schedule of these Regulations.

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

Records and data of monitoring programme

56. (1) Records and data of monitoring results of the national monitoring programme shall be available at any time.

PART IX - CONTROL PLAN FOR PRODUCTION CONDITIONS

Scope of the control plan for production conditions

57. The health control of “Production Conditions” shall -

(a) be carried out on a daily or regular inspection basis;

(b) have a short term approach and; and

(c) be implemented at inspectorate level.

Monitoring of the production chain

58. 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 complies with all the requirements of the whole production chain laid down in these Regulations.

Health checks before first sale

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

(2) An inspection program comprising an organoleptic check shall be carried out to check whether the fishery products are fit for human consumption, in accordance with the requirements laid down in these Regulations -

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

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

(3) If the organoleptic examination reveals any doubt as to the freshness of the product, an inspection comprising physical, chemical or microbiological methods shall be carried out in accordance with the requirements laid down in regulation 154 of these Regulations in relation to the-

(a) physical soundness of the fishery products in accordance with the requirements laid down in regulation 155 of these Regulations; or

(b) sanitary soundness of the fishery products in accordance with the requirements laid down in regulation 156 of these Regulations.

(4) Fishery products shall be declared unfit for human consumption if -

(a) organoleptic, chemical, physical or microbiological checks or checks for parasites have shown that they do not comply 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 are derived from -

(i) poisonous fish,

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

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

(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 the auto-control system guaranteed by the sector on the level of vessels

60. (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 appropriately handled for-

(a) bleeding;

(b) heading;

(c) gutting;

(d) removal of fins; and

(e) chilled frozen, or processed on board vessels;

in accordance with the hygiene rules established in these Regulations.

(2) Such arrangements will include, in particular, a check on factory vessels or fishing vessels on the understanding that such a check may be carried out during the stay in port.

(3) In order to ensure the implementation of a coherent and efficient inspection, the Competent Authority shall -

(a) implement a registration system and keep up-to-date for control purposes, a list of vessels designated as freezing vessels, chilled seawater vessels and refrigerated seawater vessels;

(b) implement an approval procedure for factory vessels in accordance with the approval procedure for establishments as referred to in regulation 12 of these Regulations;

(c) control the auto-control system implemented by a qualified person on board of the factory vessels;

(d) indicate the frequency of inspection;

(e) make records of every inspection; and

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

(4) The registration, official controls and the checks of the vessels flying the flag of The Gambia or another state shall be done by the Competent Authority in a port or at sea.

Control of the auto-control system guaranteed by the sector on the level of landing and off loading

61. The 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 these Regulations.

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

62. The 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 their natural environment have been transported under satisfactory conditions of hygiene and temperature in accordance with the hygienic rules and conditions established in Part XVII of these Regulations.

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

63. The arrangements for the checking, controlling, inspection and monitoring at regular intervals of establishments shall be made by the inspectorate Unit in accordance with the quality assurance programme, safety assurance programme and the requirements for the use of sweeteners, food colours or other food additives laid down in these Regulations in order to establish whether-

(a) the conditions for approval are still fulfilled;

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

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

(d) the cleanliness conditions of premises, faci-lities, instruments and staff hygiene are complied with; and

(f) fishery products, prepared or processed from fish species which are estimated to be a potential hazard are subjected to a visual inspection by way of sample for the purpose of detecting any parasites that are visible, before being released for human consumption.

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

64. The arrangements for controlling and monitoring the approval and registration conditions and requirements laid down in regulation 12 Regulations shall be made by the Competent Authority in order to establish whether these conditions and requirements are fulfilled.

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

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

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

(b) stipulating reliable conditions for certification.

Control of the auto-control

66. The arrangements for checking, controlling and

system guaranteed by the sector on the level of air-ports and sea ports

monitoring the hygiene and storage conditions at air and seaports shall be made by the inspectorate unit in order to establish whether the fishery products have been handled, stored and dispatched in accordance with the hygienic rules and conditions established in Part XVII of these Regulations.

Records

67. (1) The Competent Authority shall report on the official controls, checks and inspections that it has carried out.

(2) The 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 Competent Authority shall provide the fish business operator concerned with a copy of the report referred to in sub-regulation (2).

Official Laboratories

68. The Competent Authority shall, after auditing and on the basis of the audit report, approve laboratories as official laboratories and designate them laboratories that may carry out the analysis of samples taken during official controls.

Approval conditions for official laboratories

69. (1) The Competent Authority may only approve and designate laboratories that -

(a) operate in accordance with the standards of -

(i) EN ISO/IEC 17025 on “General requirements for the competence of testing and calibration laboratories” for food testing laboratories”, or

(ii) good Laboratory practices (GLP) for drug testing laboratories emphasising on more detailed analysis;

(b) are assessed and accredited in accordance with the standards of -

(i) EN 45002 on “General criteria for the assessment of testing laboratories, or

(ii) EN 45003 on “Calibration and testing laboratory accreditation system;

(c) are able to carry out non clinical -

(i) microbiological tests on food, contact surfaces or residues of antibiotics,

(ii) chemical tests on heavy metals, industrial chemicals, medicinal products, food additives, animal feed additives and pesticides,

(iii) biological tests relating to detection and identification of parasites or bio assay for the detection of marine bio-toxins, or

(iv) physical and chemical tests for fresh-ness determination of fishery products on issues like pH measurements, refractometric index of the eye liquid, TVB-N= Total Volatile Basic – N;

(d) equipped to do analysis of -

(i) organic and inorganic chemicals,

(ii) marine and fish toxins,

(iii) biological organisms, and

(iv) microbiological organisms as described in these Regulations;

(e) able to carry out the different reference methods described in these Regulations.

(2) Where the above competencies and facilities are not present in one specific laboratory, differ-rent laboratories may be in charge and approved for different types of tests.

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

(4) The Competent Authority may cancel the design-nation referred to in paragraph (a) of sub-regulation (1) when the conditions referred to in paragraph (b) are no longer fulfilled; and

(5) 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

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

Methods of sampling and analysis of official laboratories

71. (1) Sampling and analysis methods used in the context of official controls shall comply -

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

(b) with internationally recognised rules or protocols like those that the European Committee for Standardisation (CEN) has accepted or those agreed in national legislation; or

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

(2) Where paragraphs (a), (b), and (c) of sub regulation (1) are not applicable, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol.

(3) 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.

(4) The Competent Authority 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.

(5) Samples shall be handled and labelled in a way that guarantees both their legal and analytical validity.

National Reference Laboratories

72. (1) The Competent Authority shall arrange for the designation of one or more national reference

laboratories for each regional reference laboratory.

(2) The Competent Authority may designate a laboratory situated in another country and a single laboratory may be the national reference laboratory for more than one country.

(3) The 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 71;

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

(e) provide scientific and technical assistance to the Competent Authority for the implementation of co-ordinated control plans.

(4) Regulation 69 shall apply to national reference laboratories.

(5) The Competent Authority shall list the name and address of each national reference laboratory to the relevant regional reference laboratory and other collaborating countries;

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

Regional Reference Laboratories

73. (1) The regional reference laboratories for feed and food shall -

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

reference methods;

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

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

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

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

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

(2) Regulation 69 shall apply to regional reference laboratories.

(3) Regional reference laboratories shall -

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

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

(c) have an appropriate administrative infrastructure;

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

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

(f) 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;

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

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

PART X - AUTO-CONTROL SYSTEMS GUARANTEED BY THE SECTOR

General conditions applicable to vessels

74. (1) The sections of the vessels or the containers reserved for the storage of fishery products shall -

(a) be covered and self draining;

(b) be well insulated;

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

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

(c) be designed in a way that allows them to be cleaned easily and to ensure that melt water cannot remain in contact with fishery products.

(2) Decks used for fish handling may be constructed of -

(a) surface-coated aluminium;

(b) fibre-glass; or

(c) timber-sheathed or coated with an epoxy finish or similar material or, where fish does not normally come in contact with the deck and the timber is clean, sound and well-caulked, untreated timber that is sound.

(3) Where operations are carried out during the day, unenclosed fish handling areas on decks shall

be effectively roofed over or protected by a substantial and easily erected awning.

(4) Water used at any stage of processing shall comply with the parameters of potable water laid down in Part XIV of these Regulations or of clean sea water.

(5) Seawater intakes for vessels shall be located in front of any toilet or bilge discharge and in a position that avoids contamination of the water supply.

(6) Surfaces with which fishery products come into contact, such as sinks, processing tables, and equipment used for gutting, heading and the removal of fins 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.

(7) 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.

(8) 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.

Conditions applicable to handling and Storage

75. (1) 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.

(2) The water used to wash fishery products shall be either fresh water or clean seawater that will not impair their quality or wholesomeness.

(3) The fishery products other than those kept alive, must be chilled immediately with ice and stored in insulated containers or holds.

(4) Where cooling is not possible on fishing vessels, the fishery products must be landed as soon as possible.

(5) The fishery products shall be handled and stored in such a way as to prevent bruising and spiked instruments may only be used for moving of large fish or if the flesh of these products is not damaged.

(6) Fishery products shall undergo, if applicable, cold treatment as soon as possible after loading in compliance with the conditions laid down in Regulation 80.

(7) Ice used for chilling of products shall be made from potable water or clean seawater and before use, shall be stored under conditions which prevents its contamination.

(8) Where fish is headed or gutted on board a vessel, it 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.

(9) 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, and the Livers and roes intended for human consumption shall be refrigerated or frozen.

(10) The personnel assigned to handle fishery products shall maintain a high standard of personal cleanliness.

Additional hygiene conditions

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

(2) When additional hygiene conditions are applicable for certain vessels, the general hygiene conditions applicable to fishery products on board all fishing vessels, laid down in regulation 75 of these Regulations are also applicable.

(3) 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.

(4) 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.

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

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

(7) Containers used for the storage of fisheries products shall ensure their preservation under satisfactory conditions of hygiene and in particular, allow drainage of water.

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

(9) A waterproof and separate storage room shall be provided for the storage of cartons, ship-to-shore containers and similar storage materials.

(10) Artificial lighting shall be provided where handling, processing and inspection takes place at night below deck and in enclosed processing areas.

(11) The intensity of illumination shall be a minimum of 220 lux in the processing area, 540 lux where the product is being inspected.

(12) Sanitary and shower facilities shall be provided in sufficient numbers for the whole complement of crew on a vessel including a hand operated wash basin located in the toilet room or immediately outside the door and a berth for each crew member, a Fisheries Officer and an Official Fish Inspector.

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

Use and maintenance of vessels

77. (1) The working decks, equipment, holds, tanks and containers shall be cleaned each time they are used.

(2) The removal of insects or rat extermination shall be carried out whenever necessary.

(3) Cleaning products, detergents, disinfectants, insecticides, rodenticides and all potentially toxic substances shall be stored in locked containers or cupboards separate from fish cartons and ship-to-shore containers.

Handling and storage

78. (1) The ice used for chilling of fishery products shall be used in such a way and in such quantities that maintain the temperature of melting ice, after unloading the products.

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

(3) The operators of fishing vessels who use sea water to wash and process fishery products shall do so in uncontaminated waters whilst the vessel is moving in open waters.

(4) The operators of fishing vessels that use seawater to wash and process fishery products whilst they anchor at secure harbourages shall ensure that -

(a) the water is uncontaminated and meet the requirements of clean seawater;

(b) toilet facilities are not operated unless self contained; and

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

(5) Sub-regulation (4) shall not apply to vessels that use a self-contained water system and water that meets the requirements laid down in Regulations Part XIV of these Regulations.

Hygiene conditions for personnel

79. (1) A person assigned to handle fishery products shall maintain a high standard of personal cleanliness.

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

Fishing vessels equipped for freezing fishery products on board

80. (1) The general hygiene conditions applicable to fishery products on board all fishing vessels laid down in regulation 75 are also applicable to fishery products caught on board fishing vessels equipped for freezing.

(2) The additional hygiene conditions applicable to the fishing vessels designed and equipped to preserve fishery products on board under satisfactory conditions for more than twenty four hours laid down in regulation 76 are applicable.

(3) The freezing of fishery products on board fishing vessels shall be carried out in accordance with following conditions -

(a) the vessels shall have freezing equipment with sufficient capacity -

(i) to achieve rapid reduction in temperature of the fishery products up to minus eighteen degrees celcius (-18°c),

(ii) to keep products in storage rooms at minus eighteen degrees celcius (- 18°c), or

(iii) to freeze whole fish in brine intended for canning at minus nine degrees celcius (-9°c);

(b) fresh products to be frozen shall comply with the requirements of the conditions for the fresh products laid down in regulation 154 of these Regulations;

(c) temperature recording devices in storage rooms shall be located in a place where they can easily be read;

(d) the temperature sensor of the recorder shall be located in the area furthest away from the cold storage room, where the temperature in the is the highest;

(e) temperature charts shall be available during the period in which the products are stored;

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

(g) if the freezer is located within a storage hold where frozen food is stored it shall be -

(i) separately refrigerated, and

(ii) provided with doors of a material that ensures its efficiency when operating and effectively divide the freezer from the hold;

(h) freezer holds, blast freezers and plate freezers shall be capable of reducing the temperature of fish undergoing freezing to minus eighteen degrees celcius (- 18°c) or lower;

(i) a waterproof, hygienic and separate storage room shall be provided for the storage of wrapping and packaging material;

(j) 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, additional and specific hygiene conditions laid down in these Regulations;

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

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

Fishing vessels equiped for chilling of fishery products

81. (1) The general hygiene conditions applicable to fishery products on board all fishing vessels laid down in regulation 75 of these Regulations are applicable for cooked sea water and refrigerated sea water.

(2) The additional hygiene conditions applicable to the fishing vessels designed and equipped to preserve fishery products on board under satisfactory condition for more than twenty four

hours, laid down in regulation 76 of these Regulations are applicable.

(3) Fishing vessels equipped for chilling of fishery products in cooled seawater or in refrigerated sea water shall comply with the following requirements -

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

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

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

(d) after each unloading, the tank`s circulation system 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, made available for the Inspection Service.

Fishing vessels equiped for cooking crustaceans and molluscs on board

82. (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 fishing vessels, laid down in regulation 75 of these Regulations.

(2) The additional hygiene conditions applicable to the fishing vessels designed and equipped to preserve fishery products on board under satisfactory conditions for more than twenty four hours laid down in regulation 76 of these Regulations are also applicable.

(4) Shelling or shucking shall be carried out under hygienic conditions that avoids the contamination of

the product, and

(a) where such operations are done by hand, workers shall their hands and ensure that all working surfaces are cleaned thoroughly,

(b) 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 stored in appropriate premises.

(6) A manufacturer shall carry out micro-biological checks on his or her production at regular intervals in accordance with the following requirements-

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

(b) Sampling programmes shall -

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

(aa) the nature of products (whole shelled or shucked),

(ab) the temperature,

(ac) the time of cooking, and

(ad) the risk evaluation;

(ii) meet the principles of the auto-control system;

(iii) contain an undertaking laid down in paragraph (c) of this regulation in the event of failure to comply with the standards laid down under the following headings-

(aa) pathogens (1); and

(ab) organisms indicating poor hygiene

(2) of Schedule No. 3 to these Regulations;

(c) the manufacturer shall-

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

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

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

Conditions applicable to design and equipment of factory vessels.

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

(a) a receiving area reserved for taking fishery products on board shall be designed and arranged into pounds or pens that are large enough to allow each successive catch to be separated and to protect the products from the sun or the elements and any source of dirt or contamination;

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

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

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

(e) the place for storing, wrapping and packaging materials shall be separate from the preparation and processing areas;

(f) special equipment shall be used 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;

(g) equipment shall provide a supply of potable water within the meaning of Part XIV of these Regulations relating to the quality of water intended for human consumption or pressurised clean seawater.

(h) the seawater intake shall be situated in a position where it is not possible for the water taken in to be affected by discharges into the sea of waste water, waste and engine coolant outlets;

(i) a suitable number of changing rooms, wash basins and toilets not opening directly into areas where fishery products are prepared, processed or stored, shall be provided and equipped with appliances for washing and drying of hands that comply with hygiene requirements.

(2) Areas used for the preparation and processing or 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;

(b) structures and fixtures with limbers that are large enough not to be obstructed by fish waste and to allow water to drain freely;

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

(d) 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;

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

(f) adequate lighting;

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

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

(3) Equipment and tools such as cutting benches, containers, conveyors, gutting or filleting machines, 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; or

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

Conditions relating to on board handling and storage of fishery products

84. (1) An observer on board the factory vessel shall -

(a) be responsible for applying best practices;

(b) ensure that the provisions of this Part are applied;

(c) make available to inspectors the programme for inspecting and checking control points and critical control points; and

(d) keep a register containing the Inspector's comments and the temperature recordings that may be required.

(2) The following general conditions of hygiene are applicable to areas and equipment -

(a) floors, walls or 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;

(c) rodenticides, insecticides, detergents, disinfectants and any other potentially toxic substances shall be stored in cupboards which can be locked;

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

(e) potable water, within the meaning of Part XIV of these Regulations or clean seawater shall be used for all purposes;

(f) non-drinking water may only be used for steam production, fire fighting and the cooling of refrigeration equipment;

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

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

(a) staff handling exposed fishery products shall wear suitable clean working clothes and headgear, which completely enclosed the hair without a watch, bracelet, necklace or earrings;

(b) staff assigned to handle and prepare fishery products shall wash their hands before starting work or each time work is resumed;

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

(d) a person shall not smoke, spit, eat or drink in work and storage premises of fishery product;

(e) a fish business operator shall take all 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;

(f) a person recruited work to on and handle fishery products shall prove by a medical certificate, that there is no impediment to such employment.

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

(a) operations such as heading and gutting shall be carried out hygienically and the products 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;

(c) 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;

(d) fillets and slices to be sold fresh shall be chilled as quickly as possible after preparation; and

(e) 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 these Regulations;

(b) storage rooms shall have temperature-recording devices in a place where it can easily be read;

(c) the temperature sensor of the recorder shall be located in the area furthest away from the cold source; and

(d) temperature charts shall be available for inspection by the supervisory authorities 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 203 of these Regulations;

(b) the conditions of hygiene for frozen products laid down in regulation 204 of these Regulations;

(c) the conditions of hygiene for thawing products laid down in regulation 205 of these Regulations;

(d) the conditions of hygiene for processed products laid down in regulation 207 of these Regulations; and

(e) the conditions concerning parasites laid down in regulation 215 of these Regulations

(7) Fishery products shall be wrapped and package-ed 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 shall not-

(i) impair the organoleptic characteristics of the fishery products,

(ii)transmit to the fishery product substances harmful to human health and they shall be strong enough to protect the fishery products adequately,

(iii) be re-used except if made of impervious smooth and corrosion – resistant material;

(c) 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 minus eighteen degrees celcius (–18°c) or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than three degrees celcius (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 pro-ducts which may contaminate them or affect their hygiene, unless they are package-ed 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

85. (1) Food business operators responsible for the off-loading and landing of fishery products shall ensure that unloading and landing equipment that comes into contact with fishery products is constructed of material which is easy to clean and disinfect and 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 shall avoid contamination of fishery products, and ensure that -

(a) unloading and landing operations proceed rapidly;

(b) fishery products are placed without un-necessary delay in a protected environment at the required temperature, 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

86. (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 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 59 of these Regulations;

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

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

(g) have facilities to provide adequate supplies of potable water within the meaning of part XIV of these Regulations or alternatively clean seawater or seawater treated by an appropriate system, under pressure and in sufficient quantity;

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

(i) an adequately-equipped lockable room, and the equipment necessary for carrying out inspection, 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.

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

(3) If the conditions laid down in sub-regulation (2) of this regulation are not satisfied, chilled and unpackaged products not distributed, dispatched, prepared or processed immediately after reaching an establishment on land, shall be stored under ice in appropriate facilities.

(4) 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 or chill storage rooms which satisfy the following conditions-

(a) waterproof flooring which is easy to clean and disinfect and laid 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 that are easy to clean, durable and impermeable;

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

(d) doors made of 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 tempera-

tures prescribed in these Regulations.

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

(6) Food business operators shall cooperate with the relevant competent authorities to enable official controls to be carried out, in particular as regards any notification procedures for the landing of fishery products.

General hygiene conditions for auctions

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

(a) floors, walls or 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;

(c) rodenticides, insecticides, disinfectants and any other potentially toxic substances shall be stored in containers or cupboards which can be locked and where their use shall not present any risk of contamination of the products.

(d) working areas, instruments and working equipment shall be used only for work on fishery products except where the competent Authority may otherwise permit;

(e) non-potable water may be used 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 purposes and present no risk of contamination of the products; and

(f) detergents, disinfectants and similar substances shall be approved by the Competent

Authority and used in such a way that they do not have adverse effects on the machinery, equipment and products.

(2) The following general conditions of hygiene are applicable to staff -

(a) staff shall wear suitable clean working clothes;

(b) staff assigned to the handling and preparation of fishery products shall wash their hands before starting and each time work is resumed; wounds to the hands shall be covered by a waterproof dressing; or

(c) a person shall not smoke, spit, eat or drink in work or storage areas where fishery products are processed;

(d) 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; and

(e) a person recruited on and handling fishery products shall be required to prove by a medical certificate, that there is no impedement to such employment.

PART XII - QUALITY ASSURANCE SYSTEM AND PRODUC-TION CONDITIONS

Sub-part I - BEST PLANT PRACTICES

Location of the establishment

88. (1) An establishment that prepares or processes fishery products shall be located on sites-

(a) which can be maintained free of floods, obnoxious 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; and

(c) Where there is access to water, power, all weather roads and good evacuation possibilities for waste and wastewater.

(2) Existing establishments exposed to pollution shall take satisfactory measures to prevent contamination of the fishery products.

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

Surroundings of the establishment

89. (1) The areas directly surrounding an establishment (patios, passages, pathways, access ways, yards, roads, parking lots, buildings and other areas) shall be suitably graded, paved grassed or landscaped to prevent dust and litter build up and the grounds provided with adequate drainage facilities.

(2) The surrounding grounds or concreted surfaces should be inclined towards trapped gullies and provided with adequate drainage to permit rapid evacuation of rainwater.

(3) The surroundings should be properly maintained, and the grounds kept clean, tidy free of accumulate of water, or rubbish at all times.

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

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

(6) 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.

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

Requirements for establishments

90. (1) An establishment shall consist of a solid building with adequate materials that can protect the processing line as well as fishery products against contamination.

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

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

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

(i) clean and dirty areas,

(ii) dry and wet areas,

(iii) cold and hot areas,

(iv) pre and post-cooking areas, and

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

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

(4) The processing layout should be designed-

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

(b) 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.

(5) All possible preventive measures and provisions shall be taken on construction level to -

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

(b) minimise the risk of food contamination by contact surfaces, packaging material, offal, drainage systems;

(c) minimise maintenance;

(d) facilitate cleaning and disinfecting;

(e) build in the passive pest-control systems;

(f) minimise airborne contamination;

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

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

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

(j) implement an adequate potable water supply, such as an in plant chlorinating system to ensure the supply of potable water at all times;

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

(l) ensure that-

(i) product flow takes place from dirty areas to clean areas,

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

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

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

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

Conditions and requirements for working, handling and storage rooms

91. (1) The different working, handling and storage rooms needed in an establishment as described in regulation 92 shall comply with the minimum conditions and requirements laid down in regulation 93 to 107 of these Regulations.

(2) An establishment shall provide, in the working and storage rooms mentioned in regulation 92 (1), a number of facilities that comply with the minimum requirements and conditions laid down in regulations 108 to 114 of these Regulations.

General

92. (1) An establishment shall provide-

conditions for working room

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

(b) separate rooms for the preparation or processing activities such as-

(i) reception room;

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

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

(c) ice maker or storage room;

(v) processing room;

(vi) freezing facilities or rooms for freezing prepared or processed products;

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

(viii) freezing facilities or rooms for freezing raw whole fish in brine at minus nine degrees celcius (– 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 to a storage room;

(xiii) laboratory;

(xiv) chill storage room for finished fresh products;

(xv) cold storage room for finished frozen

products connected with the dispatch room;

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

(xvii) dispatch room; and

(xviii) social amenities facilities consisting of a changing room for city clothes and shoes, showers (optional), a changing room for uniforms and boots, toilet block, hand-washing room, eventually laundry and canteen.

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

Conditions for preparation and processing rooms

93. (1) In rooms where products are handled, prepared and processed, an establishment shall provide-

(a) floors that-

(i) have hard impact resistant surfaces,

(ii) are impermeable to grease and water,

(iii) permit easy cleaning and disinfecting,

(iv) are laid down in such a way as to facilitate the drainage of the water,

(v) have a high density, impermeable finish that is maintained in good condition if made from concrete;

(vi)are sufficiently graded and have a gradient of at least 1 : 100 towards drainage channels;

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

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

(ix) have all drainage channels, gullies and gully traps covered with

removable grills;

(b) effluent disposal systems and drains that comply with following requirements-

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

(ii) 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;

(2) The floor drains shall-

(a) be adequate in size, number and location-

(i) to allow the rapid removal of all liquid wastes arising from all processing operations, or

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

(b) be effectively sealed by gully traps installed in every room-

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

(ii) to prevent the entry of rodents;

(c) have solid traps to prevent the passage of solid materials to the external sewage system and designed to enable adequate cleaning;

(d) have adequate access for cleaning;

(e) not be connected to sanitary drainage;

(f) 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).

(3) Where drainage channels are fully or partially open, they shall be designed to ensure that waste does not flow from a contaminated area towards or into a clean area where food likely to present a high risk to the final consumers are handled;

(4) The sanitary drainage shall be directed to a septic tank or sewerage system connected to any other drains within the facility.

(5) 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.

(6) The walls of an establishment shall be made of solid construction to prevent the entry of insects, rodents, birds and other animals.

(7) The interior surfaces and partitions of an establishment 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 sealed that might allow the ingress of water, pests or contaminants (with an impermeable compound);

(iv) be impact resistant or protected from impact;

(v) be resistant to damage; and

(vi) be easy to clean and disinfect.

(8) The angles between walls, walls and floors and walls and ceilings shall be sealed and covered to facilitate cleaning.

(9) Where internal walls are painted or surface coated-

(a) the paint material applied to the walls shall be non-toxic, durable and of light colour; and

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

(10) A piping or tubing should be located either within the wall or fixed at least four centimetres (4cm) from the wall in order to permit easy cleaning behind.

(11) If a facility or 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.

(12) The ceilings of an establishment shall comply with the following requirements-

(a) in buildings where the roof frame and the interior surface of the roof is exposed, a suspended ceiling shall be installed;

(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;

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

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

(ix) be capable of being effectively cleaned;

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

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

(13) Doors shall comply with the following require-

ments-

(a) the doors of the reception room through which raw materials enters, and the doors of the dispatch room through which the finished products leave, shall be of adequate size and well constructed, using suitable materials to protect them from impact damage;

(b) the 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;

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

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

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

(iii) be close fitted, and

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

(d) where doors are painted or surface coated-

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

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

(e) 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.

(14) The windows and external openings shall com-ply with the following requirements-

(a) on construction level-

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

(ii) windowsills shall be as small as possible and inclined in order to prevent the accumulation of dust or other particles;

(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 so as to render the opening pest proof,

(ii) a window which may be opened or which does not have glass and vents shall be covered with an insect-proof mesh screen which is kept in good repair and easily removable,

(iii) a window without pest-proofing that opens, is 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 shall be sealed against the entry of pest and dust.

(15) The stairs, catwalks, platforms, stands to raise personnel to the level of the work tables, and ladders in processing areas shall be-

(i) constructed with 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 products by allowing potential contamination items to fall onto them.

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

(a) 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;

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

(c) the flow of air within an establishment shall always be directed from clean, hygienic area to dirty or less hygienic areas;

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

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

(ii) the installation of an overpressure system is recommended whereby the inlets are controlled and the outlets are uncontrolled,

(iii) all extraction fans, blowing fans and air conditioners shall be protected with filters and meshes to prevent the entry of dust, insects and birds,

(iv) ventilation systems shall be constructed to enable filters, meshes and other parts requiring cleaning or replacement to be readily accessible.

(17) The Illumination system shall comply with the following-

(a) adequate natural or artificial lighting shall be provided throughout an establishment and the light produced shall not distort colours;

(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;

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

(18) Hand washing facilities shall comply with the following-

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

(i) sufficient in number,

(ii) provided in accessible locations through-out the preparation and processing areas,

(iii) located adjacent to the social amenities area;

(b) hand washing facilities shall be provided with-

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

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

(iii) materials for cleaning hands,

(iv) materials for hygienic drying of hands such as paper or 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 provided in a prominent position near food preparation or processing entrances;

(c) the facilities for washing fishery products shall be separate from the hand washing facility.

(19) Where applicable, boot disinfecting facilities or a suitable permanent bath, fitted with a drainage facility for the washing of boots shall be installed at the staff entrance in such a manner that persons entering the preparation or processing rooms cannot avoid passing through the bath.

(20) A room for cleaning and disinfecting work implements, utensils, recipients and small equipment, connected with a room for their storage shall be equipped with all necessary means for cleaning and disinfecting, such as-

(a) hot and cold water points, with hoses where necessary;

(b) sinks with hot and cold water for the washing of the movable equipment and fish boxes;

(c) high-pressure cleaning and disinfecting systems; and

(d) corrosion resistant materials capable of being cleaned effectively.

(21) The sterilising facilities shall comply with the following-

(a) if the sterilising medium used is not water, the Competent Authority shall first approve the method of sterilising; and

(b) sterilising facilities shall be-

(i) constructed of corrosion resistant

materials,

(ii) capable of being easily cleaned, and

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

Chill rooms, cold storage rooms, chillers and freezers

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

(a) waterproof flooring which is easy to clean and disinfect laid down in such a way as to facilitate the drainage of the water as described in regulation 93 (1) and (2);

(b) walls which have smooth surfaces and are easy to clean, durable and impermeable as described in regulation 93 (5);

(c) ceilings which are easy to clean as describe-ed in regulation 93 (10);

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

(e) plastic strip curtains to assist in air retention and to minimise temperature fluctuations when cold storage room or freezer doors are open;

(f) other internal structures constructed of smooth, impervious and corrosion resistant material;

(g) those parts which are exposed to impact damage adequately protected;

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

(i) adequate artificial lighting as described in regulation 93 (15);

(j) where refrigeration equipment is installed in a processing or packaging area, sufficient space allowed for cleaning around and between the equipment.

Specific

95. (1) In chill storage rooms used to store raw

conditions for chill storage room

materials, an establishment shall have following facilities-

(a) adequate facilities, 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 fibre or plastic in which the fish can be mixed with ice in sufficient quantities to maintain the temperature at zero degrees celcius (0°c) in the absence of the chilling facilities mentioned in this regulation;

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

(d) an accessible and easily readable thermo-meter accurate within one degree celcius (1°c), which shall have its temperature taken and recorded at least once every four hours.

Specific conditions for cold storage rooms

96. In cold storage rooms, an establishment shall have 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;

(c) freezing equipment sufficiently powerful and capable of keeping products in cold storage rooms at an internal temperature below minus eighteen degrees celcius (–18°c), whatever the ambient temperature may be and also during extreme operating conditions;

(d) doors to the cold store provided with plastic

curtains in order to minimise the interchange of air during loading and unloading;

(e) temperature recording device in a place where it can easily be read located in the area furthest away form the cold source; and

(f) temperature charts shall be available for inspection by the supervisory authorities at least during the period in which the products are stored.

Specific conditions for freezers

97. In freezers, an establishment shall provide the following facilities-

(a) a freezing facility appropriate to the type of the fishery products and its packaging;

(b) a freezing facility with sufficient capacity to freeze the fish to a temperature of at least minus eighteen degrees celcius (–18°c) within eight hours of loading the freezer; and

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

Specific conditions for brine freezing facilities

98. (1) In brine freezing rooms used solely for brine freezing whole tuna or other species, an establishment shall have the following facilities-

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

(b) areas that are-

(i) suitable clean,

(ii) sealed against dust and pest, or

(iii) 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;

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

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

(e) changing rooms and a clean dry area for the storage of packaging material if applicable.

(2) Specific brining conditions include the following-

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

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

(c) freezing between minus minus eighteen degrees celcius (18°c) and minus nine degrees celcius (9°c), if intended for canning.

Specific conditions for ice plants and ice storage rooms

99. In ice plants and ice storage rooms, an establishment shall have the following facilities-

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

(i) transport of raw material from the port,

(ii) storage of raw material before processing,

(iii) chilling of fish during processing;

(b) insulated ice storage rooms and facilities -

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

(ii) where ice can be stored and removed in an efficient, and hygienic manner,

(iii) with the capacity to store sufficient ice to satisfy the needs of the establishment;

(c) an ice making plant installed in each fish

processing plant made in the form of flakes and if large blocks are produced, they shall be made in a hygienic way and crushed by machine.

Conditions for rooms where shell-fish is shucked

100. In rooms or parts of an establishment where shellfish is shucked, the rooms 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; and

(e) have adequate lighting in accordance with these Regulations.

Conditions for rooms where wrap-ping and packaging material is stored

101. 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 these Regulations.

Conditions for rooms where non refrigerated fishery products are stored

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

(a) constructed in accordance with the require-ments relating to ceilings, walls, floors, and doors laid down in these Regulations; and

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

Conditions for rooms where toxic chemicals and cleaning equipment are stored

103. (1) Rooms designated for storage of cleaning agents, disinfectants, toxic chemicals and cleaning equipment shall be separate from the main storage area.

(2) All toxic chemicals used on-site shall be clearly identified and stored when not in use, in a locked facility.

(3) Cleaning agents and disinfectants shall not to be stored in an area where food is handled.

Conditions for inspection rooms

104. (1) An establishment shall have an inspection service room which, if the volume of products treated requires regular or permanent presence of an official fisheries inspector, shall be a separate room that is-

(a) adequately equipped;

(b) lockable;

(c) adjacent to the processing area;

(d) free from steam and fumes; and

(e) for the exclusive use of the inspection service.

(2) The room shall also be provided with-

(a) lighting intensity of at least 600 lux;

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

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

(d) running water for cleaning instruments.

Conditions for laboratories

105. An establishment shall have, if applicable, laboratory rooms for microbiological or chemical examinations, separated from fishery product handling rooms.

General conditions for sanitary facilities

106. (1) An establishment 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 fishery products.

(2) The facilities shall consist of an adequate

number of suitable and conveniently located changing rooms, flush toilets, showers, hand-washing facilities, and a canteen if meals are taken on the site.

(3) There should be no direct access between the sanitary facilities (changing room and toilets) and any room in which fish, or materials and equipment which come into contact with fish is handled.

(4) The hand washing facilities room shall be the separator room between sanitary facilities and preparation or processing rooms.

(5) The hand washing facilities rooms should not be used for the storage of any processing ingredients or food.

(6) The construction of the floors, walls, ceilings, doors and windows of the sanitary facilities shall be of the same standard specified for the processing areas.

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

107. (1) An establishment shall have changing facilities containing-

(a) a changing room fitted with a locker, that is non absorbent and resistant to corrosion for each worker to store his or her clothes;

(b) a separate room used for storing work clothing and fitted with lockers made from non absorbent and corrosion resistant material; and

(c) showers to be used by the workers between the two rooms.

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

(a) completely separated from food handling areas and not directly accessible to these areas;

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

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

(3) The following formula shall be used by

establishment in providing sanitary facilities-

N° of employees	N° of Water Closets	
1 to 9	2	
10 to 24	3	
25 to 49	4	
50 to 99	6	
for every additional	20	1 more

(4) If an establishment employs both male and female workers, separate sanitary facilities shall be provided for each sex, in accordance with sun regulation (3).

(5) Urinals may be substituted for water closets, up to one third of the required number of water closets.

(6) All toilets and urinals shall be of the flushing variety and constructed of materials which are easy to clean.

(7) To avoid airborne contamination from toilets into areas where food is exposed, preventive measures shall be taken such as the use of double doors, separate toilet room and positive air flow system.

(8) Doors of toilet cubicles, if they are not in a separate toilet room, shall be self-closing and of full height.

(9) Hand washing facilities shall be provided near toilets in each sanitary facility, provided with hot and cold water and adequate quantities of liquid soap.

(10) Adequate quantities of single use paper towels shall be provided or the installation of hot-air hand dryers installed.

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

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

(13) A person coming from the changing rooms, the canteen or a toilet shall pass through the hand washing room before entering the processing room.

(14) A canteen shall have the same hygiene requirements as the processing rooms when connected with the clean changing room.

(15) A separate laundry facility should be provided, together with hot and cold-water facilities, exclusively for the washing of uniforms, unless this is done by external laundry contractors.

General design and construction of facilities and equipment

108. The machinery and manufacturing systems in an establishment such as gravimetric, pneumatic, closed and automated systems, tools, utensils, equipment, cutting boards, instruments, product holding, handling and conveying systems shall be designed, constructed and installed 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) thorough cleaning and disinfecting with hot water, detergent or disinfectant at sufficient frequency to avoid any risk of contamination,

(ii) accessibility for inspection where necessary, and

(iii) maintenance in an appropriate sanitary condition.

(2) A product holding, handling and conveying system, 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; and

(e) capable of withstanding repeated cleaning and disinfecting and easy to clean and disinfect.

(3) The use of wood and timber and other materials which cannot be adequately cleaned and disinfected is prohibited.

(4) The timber used in doors, doorjambs, or windows in processing areas shall be sealed with a durable non-toxic surface coating.

(5) Clean and sound wooden pallets may be permitted-

(a) for the transport and the storage of process-ed food packed in carton boxes to transport them in areas where mastering is done and no unpacked products are handled and to store them in areas where only cardboard packed products are stored;

(b) for the transport and export of fresh products packed in foam boxes; but in the rooms where packing in foam boxes is done, wooden pallets cannot be used; and

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

Machinery and over-head structures

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

(2) The machinery used in an establishment shall be easy to clean and its design shall permit it to be dismantled for cleaning purposes, if necessary.

(3) The 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.

(4) Equipment standing directly on the floor shall be installed-

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

(b) on a raised socle covered at the junction of

the floor and socle; and

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

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

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

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

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

(b) installed so as not to hamper cleaning operations; and

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

Product holding, handling and conveying

110. (1) A suitable system for the internal movement of fish within the plant shall be implemented.

(2) Regard should be given to the need to maintain a regular flow of products by the following means -

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

(b) fish boxes which are used to transport products 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 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 used, they shall be constructed of non-corrodible impermeable materials;

(e) ice shovels should be made of a light coloured plastic or of stainless steel;

(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 –

(i)have a filtered air intake located in a clean place, and

(ii) treated or otherwise controlled in such a way that food is not contaminated with unlawful indirect food additives.

Work tables, foot stands, and small equipment

111. (1) Worktables shall be constructed of materials which are non-corrodible, impermeable and non-toxic (stainless steel is preferable).

(2) Worktables shall be designed to facilitate their cleaning and to avoid areas which may retain particles of the product, grease and dirt.

(3) 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.

(4) Racks for gloves and aprons shall be provided

within the store for small equipment.

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

(6) Every sink or other such facility provided for the washing of fishery products shall have an adequate supply of potable water and be kept clean and disinfected.

Monitoring and measuring equipment

112. (1) The equipment used for monitoring or measuring purposes where accuracy is important, shall-

(a) be checked to ensure that 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; and

(d) be checked on a regular basis for their calibration status

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

General pre-requisites for hygienic facilities

113. (1) An establishment shall also provide the following facilities-

(a) a hygienic waste water disposal system;

(b) appropriate facilities for protection against pests such as insects, rodents, birds;

(c) facilities to provide adequate supplies of drinking water; and

(d) facilities for fishery products not intended for human consumption;

Vehicle wash area

114. (1) An establishment shall have adequate facilities for cleaning and disinfecting vehicles unless there is a requirement for the vehicles 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.

(3) 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; and

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

Loading docks

115. (1) An establishment shall have loading docks-

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

(b) enclosed or provided with a protective shelter to prevent fish from contamination during loading and unloading;

(c) with an illumination of at least 250-lux.

(2) The area used for truck movement shall be finished with a well-drained surface, which is impervious and durable.

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

Sub-part II - BEST MAINTANANCE PRACTICES

Scope of best maintenance practices

116. (1) Buildings, vessels, equipment, utensils, refrigeration and all other physical aspects of an establishment including drains shall be kept in good repair, clean and orderly condition and operated in accordance with these Regulations

Action plan and quality objectives

117. The operators of an establishment shall implement an action plan for the maintenance of the facilities of the establishment.

Scheduling of repairs

118. (1) The operators of an establishment shall carry out repairs on the establishment which does not interfere with the handling and processing of fishery products.

(2) The operators of an establishment shall schedule planned actions on the establishment in a timetable to demonstrate their commitment to the future actions.

(3) The schedules and timetables referred to in sub-regulation (2) shall be approved by the Competent Authority and its execution checked on a regular basis.

Responsib-ilities and authorities

119. The operators of an establishment shall establish a schedule of responsibilities for the implementation, maintenance, monitoring and verification of the maintenance plan.

Procedures

120. (1) The operators of an establishment shall establish procedures to ensure that maintenance will be carried out in such a way that the risk of contamination of the products is eliminated.

(2) A regular preventive maintenance programme shall be implemented whereby equipment, utensils and premises are regularly reviewed for signs of wear and tear and deficiencies are detected prior to a problem occurring.

Process Control

121. (1) A Fail Safe Control system shall be established to control the maintenance process.

(2) A verification exercise shall be carried out to ensure that corrective actions are properly implemented to ensure that the corrective actions are carried out in the good way.

Instructions

122. The operators of an establishment shall document and implement work and control instructions to ensure compliance with laid down procedures.

Documentation and re-cords

123. The operators an establishment shall document checklists for controls, standards, recommendations and verification and records in case of fault.

Training

124. (1) Food business operators shall ensure-

(a) that food handlers and staff are supervised and instructed;

(b) that on the spot, and special training programmes are implemented for food handlers and staff 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 chapter, and Best Maintenance 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; and

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

Sub-part III - BEST POTABLE WATER PRACTICES

Scope of Best Potable Water Practices

125. (1) The aims of Best Potable Water Practices are-

(a) to protect human health from the adverse effects of contaminated potable water by ensuring that it is wholesome and clean; and

(b) to ensure that water used in the fishery product industry does not affect the whole-someness of the finished product.

(2) The operators of an establishment shall provide a permanent supply of potable drinking water, clean seawater, or clean water treated by an appropriate system of filtration, chlorination, UV sterilisation, or ozonisation.

(3) Clean water may be used to treat whole fishery products and clean seawater may be used to treat live bivalve molluscs, echinoderms, tunicates and marine gastropods.

(4) If the water used in an establishment receives additional treatment prior to use, this shall be done in accordance with the instructions of the manufacturer of any equipment and under super-vision of the management of the establishment.

(5) 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.

(6) Non-potable water pipes shall be clearly distinguished from those used for potable water, clean water or clean sea water and shall not connect with or allow reflux into potable water pipes.

Use of Potable Water

126. (1) For the purposes of this part 'potable water' means-

(a) water that is either in its original state or treated and intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, tanker, bottles or containers; or

(b) water certified by the Competent Authority for use in an establishment for the manufacture, processing, preservation or marketing of products or substances intended for human consumption.

(2) The operators of the establishment shall use only potable water for-

(a) contact with fish or fish-contact surfaces;

(b) the manufacture of ice coming in contact with fishery products or fish contact surfaces; and

(c) cleaning and disinfecting the establishment.

Water distribution system within the establishment

127. (1) The pipe work in the water distribution system shall be impermeable, well constructed and in good condition.

(2) Iron pipes shall be painted externally in order to protect them from rusting.

(3) The provision of water to the sanitary facilities shall be isolated from the water system for the rest of the establishment and supplied from a separate circuit.

(4) The operators of an establishment shall put in place mechanisms to prevent backflow or cross contamination between potable and non-potable water within the establishment.

(5) The operators of an establishment shall-

(a) account for the sources of water supply used in the establishment;

(b) be responsible for ensuring that water used in the establishment is potable;

(c) put in place a sound water distribution sys-tem within the establishment; and

(d) provide a water distribution or reticulation map which identifies the pipes and outlets by consecutive numbering to enable their location on the establishment map and in the establishment.

Storage of water

128. (1) An 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.

(2) The tanks or cisterns shall be well constructed and the internal surfaces shall be smooth, imper-meable, easily cleanable and disinfectable.

(3) Each water tank or cistern shall be provided with an inspection hatch that permits entry for cleaning purposes, and the design of the hatch shall protect against the entry of rainwater, ground water and any process water that may flow out of the establishment.

(4) Each water tank or cistern shall be protected against the entry of insects, rodents, other animals and dust.

(5) The area surrounding each water tank or cistern shall be maintained clean and free of accumulation of rubbish, dust, water and other materials that could contaminate the water.

(6) Each water tank or cistern shall have a floor with sufficient slope and drainage to enable proper

cleaning.

(7) Water tanks shall be inspected at regular intervals with the objective of keeping them in good condition.

Water, recycling, circulation and re-circulation

129. (1) Recycled water used in preparing and processing fishery products or as an ingredient, shall be treated and maintained in such condition that –

(a) no health hazard can result from its re-use;

(b) it 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, the operators of the establishment shall ensure that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.

(4) Water can only be used and re-used or re-circulated for cooling of a canned product if-

(a) it is potable;

(b) it is chlorinated to a level of not less than 0.5 pm free residual chlorine at the end of the cooling cycle;

(c) it is filtered before re-use; and

(d) all storage tanks, cooling towers, or pipelines used in handling the water are constructed to facilitate inspection and cleaning, and not have dead ends.

Hot water and steam

130. (1) An establishment shall possess a means of heating water to a temperature of at least eighty

degrees celcius (80°c), in adequate quantities for hand-washing and the washing of equipment, machinery and the premises in general.

(2) An establishment may install either a steam system or pressurized hot water for cleaning of the establishment.

(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 shall not contain any substance that presents a hazard to health or is likely to contaminate the food.

Action plan and quality objectives

131. The operators of an establishment shall –

(a) establish procedures and instructions to implement the chlorinating system; and

(b) organise the scheduling of the free residual chlorine, microbiological and the physico-chemical checks to determine the share of own, private or official laboratories in the analyses.

Responsi-bilities

132. The operators of an establishment shall establish a schedule of responsibilities for the implementation, maintaining, monitoring and verification of the potable water control plan.

Procedures

133. The operators of an establishment shall establish procedures to control and safeguard the safety and the quality of water through-

(a) water analysis on residual chlorine content;

(b) microbiological analysis;

(c) chemical analysis;

(d) physico-chemical analysis; and

(e) biological tests parasites, algae, and other organisms such as animalcules cryptosporium, worms, larvae.

(2) The Competent Authority shall determine sampling points.

(3) The Competent Authority 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 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 for facilities involved in fishery product activities.

Process Control

134. (1) A fail safe control system shall be establish-ed by the operators of an establishment to control the safety and the quality of water and the results com-pared with the standards.

(2) A verification exercise shall be carried out to ensure that the corrective actions are successful.

Instructions and standards for chlorinating

135. (1) The chlorinating system shall comply with the following-

(a) chlorine shall be added on-line by dosing or injection prior to intermediary storage to permit sufficient contact time with the water in order to allow the chlorine to react with the organic matter;

(b) the retention tank shall have the capacity to retain water together with the chlorine added for at least twenty to thirty minutes;

(c) the chlorine not combined after twenty to thirty minutes shall remain as free residual chlorine, available in line to react with whatever contamination present in the piping system;

(d) the cleaning programme for the intermediary storage tanks shall be documented, monitored and demonstrated;

(3) the operators 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 eight hours or at the start of each shift but at least once a day.

(3) An alarm system may be installed to ensure the

functioning of the chlorinating system.

(4) The products (fish, shrimp, molluscs,) shall not be washed, dipped, glazed, or treated with hyper-chlorinated water.

(5) The same residual chlorine level as that authorised for potable water may be used for an in-plant chlorinating system.

Instructions for the interpret-tation of the parametric values

136. (1) The Competent Authority shall take the measures necessary to ensure that the potable water intended for fishery product activities is wholesome and clean.

(2) Potable water intended for fishery product activities shall be considered wholesome and clean if it-

(a) is free from micro-organisms, parasites and substances which, in numbers or concen-trations, constitute a potential danger to human health; and

(b) meets the minimum requirements set out for microbiological and chemical parameter in Schedule 5.

(3) The Competent Authority shall set values for additional parameters where the contamination of fishery products so requires.

(4) The values set shall, 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.

(5) The Government shall take all measures necessary to ensure that 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 do not-

(a) remain in potable water or in concentrations higher than is necessary for the purpose of their use; and

(b) either directly or indirectly, reduce the pro-tection of human health provided for in these Regulations.

Points of compliance

137. The parametric values set in accordance with regulation 136 shall be complied with-

(a) in the case of water supplied from a distribution network, at the point, within the premises of 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; and

(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

138. (1) The Government 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 it meets the requirements of these Regulations and in particular the chemical parametric values set in accordance with regulation 136.

(2) Samples taken shall be representative of the quality of the water used throughout the year.

(3) The Government shall also take all measures necessary to ensure that –

(a) the efficiency of the disinfecting treatment applied is verified;

(b) the use of the substances is regulated; and

(c) any contamination from disinfecting by-products is kept as low as possible without compromising the disinfection in order to avoid harmful effects on human health.

(4) The control bodies shall establish appropriate monitoring programmes for potable water intended in fishery product activities that meet the minimum requirements set out in the fifth Schedule of these Regulations.

(3) The Competent Authority 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 136, 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

139. (1) Without prejudice to the requirements of sampling frequency set out in the fifth Schedule-

(a) the frequency of water sampling in general for the purpose of check monitoring in a fishery product establishment shall-

(i) in the case of water supplied from a public distribution network without intermediary storage, be at least once every three months from various representative outlets within the plant as laid down in regulation 140; or

(ii) in the case of water supplied from a public distribution network with intermediary storage, or from a town water source, be at least once per month from various representative outlets within the plant as laid down in regulation 140;

(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 an establishment shall be left to the judgement of the quality management team, in consultation with the Competent Authority.

(2) The sampling points shall be determined by the competent authorities and shall meet the relevant requirements set out in Schedule 5.

Sampling Method

140. The sampling method shall comply with the following requirements-

(a) the sample shall be collected in a sterile bottle, and the tap to be sampled allowed to run long enough to completely flush the pipe supplying the tap, and in any case for two to three minutes;

(b) 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 five minutes before collection;

(c) in cases where the laboratory test is under-taken three hours or more after sampling, the bottles must be kept in ice;

(d) if a sample is taken from a chlorinated water supply, any trace of chlorine shall be neutralised immediately after collection; and

(e) a crystal of sodium thiosulphate or 0.1ml or two percent solution of sodium thiosulphate shall be introduced into the sampling bottle prior to sterilisation serves to neutralise the chlorine.

Laboratories

141. (1) Samples for check monitoring and audit monitoring laid down in the fifth Schedule shall be collected by an official person and analysed in an official laboratory.

(2) The routinely taken samples shall be collected by the management of the establishment and analysed in the in-plant laboratory or in an external private laboratory approved by the Competent Authority.

(3) The samples shall be taken from various outlets identified on the reticulation map.

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

Specifications for the analysis

142. (1) The Government shall comply with the specifications for the analyses of parameters set out in the fifth Schedule.

(2) Methods other than those specified in the fifth Schedule may be used if the results obtained can be as reliable as those produced by the methods specified.

(3) The Competent Authority that has recourse to alternative methods shall provide all relevant information concerning such methods and their equivalence.

(4) For those parameters listed in the fifth

Schedule, any method of analysis may be used if it meets the requirements set out therein.

Instructions for remedial action

143. (1) The Competent Authority shall ensure that a failure to meet the parametric values set in accordance with regulation 136 of these Regulations is immediately investigated in order to identify the cause and further sampling shall be carried out.

(2) Two consecutive samples should not be positive for coliform organisms.

(3) If the samples show the presence of E. coli or Enterococci, the water of the said source shall not be used until the contamination has been eliminated.

(4) 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 136 of these Regulations, the Competent Authority shall-

(a) ensure that the necessary remedial action is taken as soon as possible to restore its quality; and

(b) give priority to their enforcement action, having regard among other things to the extent to which the relevant parametric value has been exceeded and to the potential danger to human health.

(5) Whether or not a failure to meet the parametric values has occurred, the Competent Authority shall ensure that a 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.

(6) The Competent Authority shall decide the action to be taken under regulation 142 (3), 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.

(7) The Government may establish guidelines to assist the Competent Authority to fulfil their obligetions under sub-regulation (5).

(7) In the event of non-compliance with the parametric values or with the specifications set out in the fifth Schedule, the Competent Authority shall-

(a) consider whether that non-compliance poses a risk to human health; and

(b) shall take remedial action to restore the quality of the water where that is necessary to protect human health.

(8) The Government shall ensure that where remedial action is taken, consumers are notified except where the Competent Authority considers the non-compliance with the parametric value to be trivial.

Records

144. (1) The complete procedure of the control and treatment of sea and potable water used as well as treatment and measurement results shall be documented by the quality management.

(2) Records shall be kept of tests showing that effective treatment was maintained or that the microbiological quality was suitable.

Training

145. Food business operators shall ensure-

(a) that food handlers and staff are supervised and instructed,

(b) that on the spot and special training programmes are implemented for food handlers and staff 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.

Sub-part IV - BEST RAW MATERIAL PRACTICES

Scope of best raw material practices

146. (1) The intake of fishery products shall be organised in accordance with the requirements of the quality and safety of the products stipulated by customers and the requirements of these Regulations.

(2) As far as possible, fish business operators shall ensure that primary products are protected against contamination, having regard to any processing that they will subsequently undergo.

(3) Notwithstanding the general duty laid down in sub-regulation (2), fish business operators shall comply with appropriate legislative provisions relating to the control of hazards in primary production and associated operations including-

(a) 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

(b) measures relating to animal health and welfare that have implications for human health.

(4) Fish business operators harvesting animals or producing primary products of animal origin shall take adequate measures to-

(a) keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed clean and where necessary disinfected;

(b) keep clean and where necessary disinfect-ed, equipment, containers, crates, vehicles and vessels;

(c) use potable water or clean water, whenever necessary to prevent contamination;

(d) ensure that staff handling foodstuffs are in good health and undergo training on health risks;

(e) prevent animals and pests from causing contamination as far as possible;

(f) store and handle waste and hazardous substances to prevent contamination; and

(g) use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.

(5) A fish business operator shall not accept raw materials or ingredients, or any other material used in processing products, if they are known to be or may reasonably be expected to be contaminated with parasites, pathogenic micro-organisms or toxic, decomposed or foreign substances to such an extent that, even after hygienically applying normal sorting or processing procedures, the final product would be unfit for human consumption.

Action plan and quality objectives

147. A Supplier Quality and Safety Assurance Agreement (SQSAA) shall be agreed between a supplier and management of the establishment to work out principles concerning product control, quality standards, maintenance of the cold chain, hygiene and food safety.

Scheduling

148. (1) The operators of an establishment shall schedule planned actions in a timetable to demonstrate the commitment to the future actions.

(2) The schedules and timetables drawn up by the operators of an establishment shall be approved by the Competent Authority and its execution checked on a regular base.

Responsibilities and authority

149. The operators of an establishment shall establish responsibilities and authorities for the implementation, maintenance, monitoring and verification of the best raw material practices.

Procedures

150. (1) The operators of an establishment shall establish a procedure to implement supplier quality and safety assurance, applicable to all steps from fishing ground to raw material storage at the factory, to ensure that raw materials received are safe for

food manufacturing and comply with the required quality and safety standards.

(2) The quality manager of the establishment and supplier shall sign an agreement which guarantees the following-

(a) all raw material shall undergo arrival inspection at the plant based on the specifications agreed in the supplier quality and safety assurance agreement;

(b) products that do not reach the quality and safety standards laid down in the raw material specifications agreed between the supplier and the management of the establishment shall be rejected, returned to the supplier, and disposed of by agreement between the supplier and the operators of the establishment;

(c) 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 the these Regulations;

(d) the products shall be transported, stored and handled under conditions that will protect against contamination and minimise deterioration; and

(e) the fish to ice 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.

(3) The unloading of fishery products at an 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 kept in a good state of repair and cleanliness;

(b) during landing, loading and unloading,

contamination of fishery products shall be avoided and in particular, the operators of an establishment shall ensure that-

(i) unloading and landing operations proceed rapidly,

(ii) fishery products are placed without un-necessary delay in a protected environment at the temperature required 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 its unloading,

(v) all the equipment used in the unloading of such as fish shall be washed and disinfected after each batch (fish boxes, shovels, flume systems, conveyors and other miscellaneous equipment),

(vi) during the unloading of the fish, the doors of the reception of the establishment is open for the minimum time possible,

(vii) the vehicle is unloaded immediately after the approval of the batch.

(3) The inspection, handling and storage of raw material shall be documented by delivery records and product quality records, to enable the tracing of the fishery products.

(4) Before unloading fish for processing, a vehicle arriving at the establishment shall be inspected to ensure that-

(a) the interior of the vehicle is clean and dust free;

(b) the fish has not been exposed to detrimental climatic conditions; and

(c) other materials which could contaminate the fish, are not carried together with the fishery products.

(5) Before unloading of the fish commences-

(a) a sample of fish shall be collected from the vehicle, and the internal temperature measured to ensure that the mean temperature is at least zero degree celcius (0°c), and that no fish has a temperature of more than five degrees celcius (5°c) for fresh fishery products, and minus nine degrees celcius
(- 9°c) for brine frozen fishery products; and

(b) a representative sample of each batch of fish shall be taken for sensory evaluation of smell and appearance, as described in these Regulations.

(6) The quality control manager shall indicate his or her approval of the batch, based on the results of the carried out tests, sign an inspection form and assign a batch code to the fish.

(7) 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.

(8) Fishery products which are not processed immediately upon arrival at an establishment, shall be washed with clean water at zero degree celcius (0°c) (if necessary), and stored with ice in suitable reception tanks or put in fish-bins, iced and stored in a chill room.

(9) The storage of raw material shall comply with the following requirements-

(a) if more fish than can be processed immediately, arrives at an establishment, the excess shall be stored in suitable tanks with ice and water, or alternatively held in a chill storage room, in order that the temperature of the product is kept at zero degree celcius (0°c);

(b) all fish products which are stored for more than one day before processing shall be eviscerated 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 shall be carried out carefully in order to avoid the

contamination of the fish flesh;

(d) only fish complying with the requirements laid down in regulation 154, 155 and 156 of these Regulations shall be stored, and those unfit for human consumption removed and kept separately in a designated room;

(e) fish shall not be stored in heaps, and the depth of storage tanks kept to a minimum to prevent damage.

(f) tanks shall be filled with water before putting in fish in order to prevent damage;

(g) the duration of storage of raw material shall be kept to a minimum.

(h) the water contained in the storage tanks shall be changed at regular intervals during the storage period, and also between the storage of different batches of fish.

Process control

151. A Fail Safe Control system shall be implemented whereby measurements and checks are compared with standards, followed by corrective actions if necessary.

Instructions

152. The operators of an establishment shall implement work instructions and control instructions in detail.

Raw material specifications

153. (1) A raw material shall be checked for its freshness, physical soundness, sanitary soundness and temperature.

(2) Organoleptic, physical and chemical parameters shall be used check the freshness of fishery products.

(3) The physical soundness of fishery products shall be checked visually.

(4) The sanitary soundness of fishery products 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 check whether the fishery products are in the

condition of warming up or cooling down.

Freshness

154. (1) Organoleptic specifications concerning freshness of fishery products shall be established.

(2) Each batch of fishery products shall be submitted for inspection by the Competent Authority at the time of landing or before first sale to check whether they are fit for human consumption.

(3) Fish business operators shall carry out an organoleptic examination of fishery products to ensure that fishery products comply with any freshness criteria.

(4) The criteria that may be used for the organoleptic check are general appearance, colour, consistency, smell and eventually taste and flavour.

(5) 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.

(6) After the first sale, fishery products shall comply with the following minimum freshness requirements-

(a) the freshness category of each lot of fishery products shall be determined on the basis of organoleptic criteria;

(b) 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 of these Regulations;

(c) on the basis of ratings referred to in paragraph (a) above, fishery products shall be classified by lot in one of the following freshness categories-

(i) Extra, A or B in the case of fish, Selachii, and cephalopods, and

(ii) Extra or A in the case of shrimps;

(d) 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 of these Regulations.

(7) Each lot of fishery products shall contain products of the same degree of freshness; otherwise the lot shall be placed in the lowest freshness category represented herein.

(8) Product categories shall be established under the following conditions-

(a) fish, Selachii, and cephalopods placed by lot in freshness category "Extra" shall be free of pressure marks, injuries, blemishes and bad discoloration.

(b) fish, Selachii and cephalopods placed by lot in freshness category "A" shall be free of blemishes and bad discoloration, although very small proportion with slight pressure marks and Superficial injuries shall be tolerated

(9) The operators of an establishment shall establish 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.

(10) If the organoleptic examination reveals a doubt as to the freshness of the fishery products, samples shall be taken and subjected to laboratory tests, physical, chemical or other necessary checks or microbiological analysis may be established in the following manner-

(a) physical methods such as refractometric index of the eye-liquid (refractometer), skin resistance for alternative current (fish tester), and pH of the fish meat;

(b) chemical methods such as TVB-N (Total Volatile Basic Nitrogen) and TMA-N (trimethylamine nitrogen).

(11) Unprocessed fishery products belonging to the species categories designed by the Competent Authority shall be regarded as unfit for human consumption and shall not be placed on the market where-

(a) organoleptic assessment raises doubts as

to their freshness; and

(b) chemical checks reveal that the TVB-N or TMA-N limits set by the Competent Authority have been exceeded.

(12) 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 to these Regulations.

(13) Distillation as referred to in sub-paragraph (11) shall be performed using apparatus which complies with the principles of the diagram set forth in the seventh Schedule to these Regulations or can be performed by an equivalent automatic steam distillation apparatus;

(14) The routine methods which may be used to check the TVB-N limits are-

(a) microdiffusion method described by Conway and Byrne (1933);

(b) direct distillation method described by Antonacopoulos (1968); and

(c) distillation of an extract deproteinised by trichloracetic acid (Codex alimentarius Committee on Fish and Fishery Products (1968).

(15) The sample shall consist of about one hundred grams (100g) of flesh, taken from at least three different points and mixed together by grinding.

(16) The Competent Authority shall recommend to official laboratories the use, as a matter of routine, of the reference method referred to in the seventh Schedule to these Regulations and in case of doubt or in the event of dispute regarding the results of analysis performed by one of the routine methods, only the reference method may be used to check the results.

Physical soundness

155. Fish shall be free of-

(a) heavy injuries and scratches;

(b) bad discoloration; and

(c) blemishes and dirt.

Sanitary Soundness

156. (1) The operators of an establishment shall check the sanitary soundness, presence of parasites, toxins, microbes, viruses, and contaminants which could endanger human health.

(2) The sanitary soundness may be checked by a systematic control, through random sampling or by implementing a national monitoring programme.

(3) The operators in the fishery industry shall check and control the sanitary soundness of the fishery products and the Competent Authority shall collect all necessary information from the national monitoring programme to inform and assist the industry.

(4) Fishery products shall not contain parasites, which are harmful to human health.

(5) Fish business operators shall ensure that fishery products have been subjected to a visual examination for the purpose of detecting visible parasites before being placed on the market.

(6) Fish business operators shall ensure that the limits with regard to histamine are not exceeded by establishing the following sampling plan-

(a) nine samples shall be taken from each batch which 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, and

(iii) a sample shall not have a value exceeding 200 ppm;

(b) the histamine limits apply only to fish species of the scombridae, clupeidae, engraulidae and coryphaenidae families.

(c) 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; and

(d) examinations shall be carried out in accordance with reliable, scientifically recognised

methods, such as “high performance liquid chromatography” (HPLC).

(2) Live bivalve molluscs shall not contain marine bio-toxins in quantities (measured in the whole body or any part edible separately) that exceed the following limits-

(a) for Paralytic Shellfish Poison (PSP), 800 micrograms per kilogram;

(b) for Amnesic Shellfish Poison (ASP), 20 milligrams of domoic acid per kilogram;

(c) for okadaic acid, dinophysistoxins and pectenotoxins together, 160 micrograms of okadaic acid equivalents per kilogram;

(d) for yessotoxins, 1 milligram of yessotoxins equivalent per kilogram; and

(e) for azaspiracids, 160 micrograms of aza-spiracids equivalents per kilogram.

(3) 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.

(4) The edible parts of molluscs shall not contain any Diarrethic shellfish poison (DSP), after using the customary biological testing methods.

(5) A person shall not place on the market, Poisonous fish of the Tetraidibtudae, molidae, Diodontidae, Canthigasteride families.

(6) A person shall not place on the market fishery products containing biotoxins such as cigratera toxins, muscle paralysing toxins or other toxins dangerous to human health.

(7) The checks on contaminants present in the aquatic environments shall be carried out under following conditions-

(a) without prejudice to the laws 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 sub-stances at such a

level that the calculated dietary intake exceeds the acceptable daily or weekly intake for humans;

(b) a national monitoring system shall be established by the Competent Authority to check the level of contamination of fishery products; and

(c) monitoring heavy metals in fishery products shall be done as described in regulation 53;

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

Temperature control

157. The operators in the fishery industry shall carry out temperature control after fishing and during –

(a) transport in the fish-holds;

(b) landing and off loading at sale points;

(c) storage and transport; and

(d) processing;

to check if the temperature of the fishery products complies with the requirements laid down in these Regulations.

Seizure

158. 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, the operators of on establishment shall take measures to withdraw them from the market and denature them in such a way that they cannot be re-used for human consumption.

Records and documentation

159. (1) A “supplier quality assurance agreement” document, which is signed by both the supplier and the customer shall be available.

(2) The operators of an establishment shall keep a record of the species, weight, origin, temperature, quality condition of product, accepted and rejected fish, and reason for rejection.

(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

safety carried out by the quality managers at the reception of the establishments and recorded in the registers.

Training

160. Food business operators shall ensure -

(a) that fishermen, transporters, off-loaders, inspection team, food handlers and staff are supervised and instructed;

(b) that 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 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 programmmes for per-sons working in certain food sectors; and

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

Sub-part V - BEST CLEANING AND DISINFECTING PRACTICES

Scope of best cleaning and disinfecting practices

161. (1) In dry processing, when food contact surfaces are used for manufacturing or holding low-moisture food, they shall be in a dry and sanitary condition at the time of use.

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

(3) In wet processing when cleaning is necessary to protect against the introduction of micro-organisms into food, all food-contact surfaces shall

be cleaned and disinfected before use and after any interruption during which they may have become contaminated.

(4) In processing, where equipment and utensils are used in a continuous production operation, the utensils and food contact surfaces of the equipment shall be cleaned and disinfected as necessary.

(5) Food and non food contact surfaces such as-

(a) processing equipment and instruments used for working on fishery products in the preparation or processing areas;

(b) crates, bins, baskets, containers used in auctions, preparation and processing facilities for transporting, carrying, salting, brining, shelling, or shucking crustaceans or molluscan shellfish;

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

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

(e) buildings and the fixtures ;

(f) social amenities such as changing facilities, toilets, canteens;

(g) floors, drains, walls, ceilings, additional structures; and

(h) waste containers

shall be kept in a good state of repair, kept clean at all times and disinfected.

(6) The clearing and disinfection shall be carried out either immediately after the end of each working day or at such times as may be appropriate to maintain hygienic conditions as worked out in the instructions-

(a) so that they do not constitute a source of contamination for the products; and

(b) in a manner that adequate precautions are

taken to prevent food, food contact surfaces or food packaging materials from being contaminated during cleaning or disinfecting of rooms, equipment or utensils.

(7) Cleaned and disinfected portable equipment and utensils shall be stored in a location and manner that protects food-contact surfaces from contamination after cleaning and disinfecting.

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

(9) The operators of an establishment shall provide adequate facilities for cleaning and disinfecting buildings, fixtures, utensils, food contact surfaces and means of transport.

(10) The operators of an establishment shall select and test detergents and disinfectors for their effectiveness and use them in such a way that they do not have adverse effects on the machinery, equipment, products or impart any flavours, odours or toxic residues.

(11) The Competent Authority shall approve the use of detergents and disinfectants after receiving information about the trade name, type of chemical compound, active ingredients and method of use.

(12) 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.

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

(14) Surfaces that come into contact with food shall be adequately rinsed after the use of detergents and disinfectants prior to handling of the food.

Action plan and quality objectives

162. 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 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) to prevent the build up of dirt such as scales and maggots and other residues as well as resistant microbiological populations; and

(c) to ensure that the inner surfaces of the tanks shall not be a source of contamination for the potable water.

Scheduling

163. (1) The operators of an establishment shall schedule planned actions 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

164. The operators of an establishment shall establish responsibilities and authorities for the implementation, maintenance, monitoring and verification of the cleaning and disinfecting practices.

Procedures and process control

165. (1) The operators of an establishment shall establish a procedure to ensure that an adequate work method for cleaning and disinfecting and a fail safe control system is used, in all sections of the establishment.

(2) The method of cleaning and disinfecting shall consist of the following steps-

(a) preparatory work before cleaning;

(b) documented visual checks before cleaning;

(c) cleaning with detergents;

(d) rinsing to remove the 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) the final phase which ensures-

(i) that equipment is reassembled and

allowed to dry

(ii) documented checks to evaluate the cleaning and disinfecting activities through quick tests or by hygienogram.

(3) 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

166. (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 and the hygienograms to evaluate the cleaning and disinfecting activities described in this chapter.

Specifications

167. The operators of an establishment shall establish specifications such as the 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.

Documentation and records

168. (1) The operators of an establishment shall document all procedures, instructions, specifications and control activities used in the establishment.

(2) A documented predetermined programme shall be in place at each establishment.

Training

169. (1) Food business operators shall ensure-

(a) that food handlers and staff are supervised and instructed;

(b) that 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 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; and

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

Sub-part VI - BEST HYGIENE PRACTICES

Scope of best hygiene practices

170. (1) To avoid contamination of fishery product a high standard of hygiene of the personnel, premises and equipment shall be maintained.

(2) This regulation applies to persons who-

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

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

(c) enter the establishments (including management staff, cleaners, inspectors and visitors).

(3) The persons mentioned in sub-regulation (2) shall maintain a high level of personal hygiene and cleanliness and take all the necessary precautions to prevent the contamination of the fishery products.

(4) The operators of an establishment shall display the requirements of this regulation in visible notices inside the working and handling rooms.

Action plan and quality objectives

171. The operators of an establishment shall implement and maintain procedures and instructions to

avoid the contamination of the products by personnel, equipment and premises, and ensure optimal personal hygiene in all production steps.

Scheduling

172. (1) The operators of an establishment shall schedule planned actions in a timetable to demonstrate commitment to 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

173. (1) The operators of an establishment shall allocate responsibility to competent supervisory personnel to ensure compliance with these Regulations.

(2) It is the responsibility of the supervisor and of each member of staff to conduct him or her self in a responsible manner with respect to the products and equipment.

(3) The operators of an establishment shall establish responsibilities and authorities for the implementation, maintenance, monitoring and verification of the plan for best hygiene practices.

Procedures concerning hygiene

174. The operators of an establishment shall document procedures relating to the general conditions of hygiene applicable –

(a) to the construction and operations; and

(b) to staff, such as the wearing of protective clothing, personnel hygiene, and awareness about food borne diseases.

General conditions applicable to constructions and operation

175. (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

176. (1) The operators of an establishment shall establish procedures for-

(a) entering the plant, changing clothes, reception of uniforms and boots, storage of personal effects and showering;

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

(c) leaving the plant in relation to changing clothes, cleaning and disinfecting uniforms and boots; and

(d) the use of toilets during processing.

Protective clothing

177. (1) An employee or visitor entering the preparation or processing rooms shall at all times wear-

(a) suitable, clean and where necessary protective 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 and if involved in medium or high risk product processing, a head covering that encloses the scalp, hair , beard and moustache; and

(d) an impermeable apron for the handing of fish and unpacked fish products.

(2) Protective clothing worn by personnel in an establishment shall-

(a) not have outer pockets and outer buttons;

(b) be clean and lightly coloured, washable or disposable, and maintained in a clean condition and in good repair;

(c) not be worn outside the preparation or processing areas;

(d) be changed and laundered daily or earlier when contaminated; and

(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) The gloves worn by personnel who handle fish shall -

(a) be made of plastic or rubber;

(b) either be of a disposable type or capable of being easily cleaned and disinfected;

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

(4) The disposable gloves or protective clothing worn by personnel shall be discarded after use.

Personal hygiene

178. (1) An employee 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 such as rings, necklaces, bracelets, brooches or earrings;

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

(c) a watch.

(3) An employee with long hair shall tie it back and cover it with a hair net as well as protective head covering.

(4) A person working within fishery product handling, work or storage areas shall not -

(a) smoke or use any tobacco related product ;

(b) chew anything;

(c) spit;

(d) eat;

(e) drinking; or

(f) engage in any unhygienic behaviour.

(5) The operators of an establishment shall prominently display clear notices and signs that prohibit the activities mentioned in Sub-regulation (4).

Hand hygiene

179. (1) The personnel working in an establishment shall wash their hand 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; and

(e) after using detergents and similar clean up chemicals.

(2) The wearing of clean gloves shall not exempt the wearer from having to thoroughly wash his or her hands.

(3) Gloves and outer garments that come into contact fish or contact surfaces shall be made of an impermeable material and maintained in a clean and sanitary condition.

(4) A person who has an injury, a cut, an open wound or a wound that is infected shall not 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.

(5) The operators of an establishment shall provide a first aid box containing-

(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

180. (1) A person recruited to work on and handle fishery products shall prove by a medical certificate, that there is no impediment to his or her employment.

(2) A person suffering from a disease likely to be transmitted through food or afflicted with infected wounds, skin infections, sores or diarrhoea shall not be permitted to handle food or enter a food-handling area in any capacity if there is a likelihood of direct or indirect contamination.

(3) If the operators of an establishment engaged in direct handling of fish have reason to suspect that an employee is likely to transmit a disease producing organism to the product, the manager shall ensure the employee does not enter the facility until he or she produces a certificate from a medical practitioner indicating that he or she is free from infection.

(4) A person shall not prepare, pack or handle any material likely to be used in processing the product, until-

(a) he or she obtains a current (semi-annual) medical certificate stating that he or she is free of any communicable disease;

(b) he or she is shown by medical examination or supervisory observation 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

(iii) to suffer from a condition causing a discharge of pus or serum from any part of the head, neck, hands, or arms, and

(iv) be a source of micro-biological contamination by which there is a reasonable possibility that fish, fish-contact surfaces or fish-packaging

materials will become contaminated.

(5) An employee who resumes duty after sick leave shall follow the measures laid down in the instructions defined in the quality manual of the establishment.

(6) An employee working in a pathogen testing laboratory shall change his or her uniform prior to entering food-handling areas.

Process control

181. (1) The operators of an establishment shall establish a fail safe control system whereby the activities of the personnel are checked and controlled by the supervisors, with regard to their compliance with the activities described in the procedures and the instructions in the establishment.

(2) A supervisor shall ensure compliance with all the steps described in the procedures and instructions.

Instructions

182. (1) The instructions in an establishment shall define the measures necessary to ensure the hygiene of the employees and the safety (pathogens) and shelf life (spoilage bacteria) of the fishery products.

(2) The instructions shall contain steps on 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

183. The operators of an establishment shall draw up specifications for uniforms, boots, detergents and disinfectants.

Documentation and records

184. The operators of an establishment shall record and document all procedures, instructions, specifications, control and check-activities.

Hygiene training

185. Food business operators shall ensure-

(a) that food handlers and staff are supervised and instructed;

(b) that adequate on the spot, and special training programmes are implemented to ensure that food handlers and personnel are trained in personal hygiene and hygienic handling of fishery products;

(c) that staff are continually reminded of the risks and their responsibility within the fish industry so they can 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; and

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

Sub-part VII - BEST PEST CONTROL PRACTICES

Scope of best pest control practices

186. (1) A food business operator shall-

(a) provide appropriate facilities to guard against pests such as insects, rodents, birds, or other animals;

(b) take effective measures to exclude pests from the processing areas and to protect the products against the contamination by pests;

(c) not allow a dog within his or her premises unless its presence is unlikely to result in contamination of fish, fish contact surfaces or fish packaging materials; and

(d) 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 -

(i) the passive level, (prevention, protection, proofing, construction measures); and

(ii) the active level, through extermination by mechanical, electrical or chemical methods (poisons).

(2) The operators of an establishment shall carry out prevention and extermination of pests 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

187. An action plan shall be established-

(a) on a passive level, in a manner that ensures that the establishment is protected 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

188. (1) The operators of an establishment shall establish a time schedule 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 establishment.

(3) The schedules and timetables shall be approved by the competent authority and checked on its execution on a regular basis.

Responsibilities and authority

189. (1) The operators of an establishment shall establish responsibilities and authorities for the implementation, maintenances, monitoring and

verification of the Pest control practices.

(2) The operators of an establishment are responsible for pest control of the action plan even if it is contracted out.

Procedures

190. (1) The operators of an establishment shall document and implement a procedure to ensure a consistent pest control plan and a proper work method on the passive and active level.

(2) The method of working shall consist of-

(a) on the passive level, a building that is pest proof and complies with the following specifications-

(i) when the door is closed it shall fit tightly so that the gap between the door and frame is larger than three millimetres,

(ii) exit doors shall be closed when not in use for transporting products in or out of the premises or people passing through,

(iii) all windows that can be opened shall be covered with a tight fitting fly screen of mesh size less than or equal to one millimetre and the frames with the fly-screen shall be displaceable for clean-ing purposes,

(iv) the space between where the ventilation duct opens to the outside of the premises to the point where it opens into the inside shall be closed with a screen of mesh size no larger than one millimetre,

(v) all drain openings shall be covered with grates of hole size not larger than ten millimetres across, and

(vi) there shall be a water lock (gully traps) in the drain pipings between the drain opening to the collecting well;

(b) on the active level, a systematic extermination of rodents, insects and other vermin’s in the premises or on equipment.

(3) The operators of an establishment shall prepare a documented plan for extermination of pests incorporating-

(a) a list of numbered traps and a map showing their location or a bait map;

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

(c) inspection of infestation in areas adjacent to premises; and

(d) inspection of incoming material for pest infestation.

(4) There shall be a responsible person within the establishment who has knowledge about pest control and the pests likely to be present within the premises even if outside expertise on pest control is employed.

(5) Storage areas shall be organised in such a way that they can be easily inspected for possible rodent infestation.

(6) Rodent traps shall be strategically placed, with the assistance of an external expert if necessary, to exterminate rodents that may get into the establishment.

(7) An electric flytrap shall be installed at every entrance to rooms where processing takes place and where packaging material is stored, in line with the following specifications-

(a) the fly killer shall not be placed over processing lines or in front of fans;

(b) the distance between the electric trap and the floor shall be two and a half to three metres;

(c) the fly killer shall be on twenty hours a day;

(d) the bulbs in fly killers shall be replaced at least every year or according to manufacturers specifications; and

(e) the catch basin should be cleaned regularly.

(8) Rodenticides, insecticides and any other potentially toxic substances shall be stored in premises or cupboards which can be locked, and their use shall not present any risk of contamination of the products.

Process control

191. A fail safe control system shall be implemented by the operators of an establishment to check whether the pest-control plan is in compliance with the requirements described in these Regulations.

Instructions

192. (1) The operators of an establishment shall be put in place Instructions to implement on a daily basis, the principles and work methods designed in the procedures.

(2) Instructions shall be defined by operators together with personnel to deal with the active and passive pest control.

Specifications

193. The operators of an establishment shall provide specifications such as the trade name, compound active ingredient, methods of use, instructions concerning concentration or dilution and safety instructions concerning the pesticides.

Documentation and records

194. The operators of an establishment shall record and document all procedures, instructions, specifications, control and check activities, in particular the trap-map, bait map and the routine check records and make them available at all times for the inspection services.

Training

195. (1) Food business operators shall ensure-

(a) that food handlers and staff are supervised and instructed;

(b) that on the spot, and special training programmes are implemented to ensure that personnel involved in pest control are trained in 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 relevant parts of this section;

(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.

Sub-part VIII - BEST MANUFACTURING PRACTICES

Scope of best manufacturing practices

196. (1) The operators of an establishment shall implement and maintain preparation and processing practices that produce a safe and high quality finished product.

(2) The best manufacturing practices include the organisation of the preparation, processing and packing rooms as well as weighing, sorting, washing, preparation, chilling, freezing, thawing, packing, expedition and control activities.

Action plan and quality objectives

197. (1) Good manufacturing practices shall be Implemented-

(a) to avoid a cross-contamination of the product (fillet) with contaminants from the fish (skin) or from the work and factory environment.

(b) to build up a logical and practical flow of the products from raw material to finished product.

(c) to build up a logical and practical flow of waste products that leave the processing line and additives and packaging materials

that join the processing line;

(d) to organise a logical and practical flow of dirty recipients and equipment that leave the processing line and clean recipients and equipment that join the processing line; and

(e) to avoid temperature violence exceeding the requirements specified for the process.

Scheduling

198. (1) The operators of an establishment shall schedule planned actions in a timetable to demonstrate commitment to future actions.

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

Responsibilities and authority

199. The operators of an establishment shall establish responsibilities and authorities for the implementation, maintenance, monitoring and verification of the best manufacturing practices.

General conditions and procedures for the preparation and processing of fishery products

200. (1) Fishery products shall be processed rapidly and treated in a hygienic manner.

(2) The operators of an establishment shall take necessary and reasonable actions and precautions to minimise the contamination of fish products

(3) A person shall not place fish on the floor without the protection of appropriate fish boxes.

(4) Fishery products from different harvests or from different fishing boats shall not be kept together to prevent contamination between lots and enable easier identification in case of subsequent rejection.

(5) Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins shall not to be kept at temperatures that may pose a risk to human health.

(6) Fish may be placed outside temperature control for limited periods to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not pose a risk to health.

(7) During preparation or processing, the temperature of the fishery products shall be maintained at a temperature determined by the operators of an establishment and approved by the Competent Authority using the time-temperature combination as a guideline.

(8) Where an operation in an establishment has ceased, the processing of fish which has started shall be completed and the fish adequately iced or transferred to a chill room.

(9) A product or extraneous material that is damaged or has irreparably deteriorated shall be removed from the processing area immediately to avoid contamination of the fish.

(10) The operators of an establishment shall not bring into the establishment a fishery product which is spoilt, contaminated or not fit for human consumption and if such product is discovered at the processing stage, it shall be immediately isolated and disposed of without contaminating acceptable quality products.

Conditions for washing and decontamination of the fish skin

201. (1) The fishery products shall be decontaminated as soon as they arrive in the preparation area through-

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

(b) washing with adequate quantities of clean potable water and chilled to temperature of less than five degrees celcius (5° c).

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

Procedures

202. (1) The operators of an establishment shall document and implement procedures that ensure that the necessary preventive measures relating to quality control are taken to process a safe and high quality product.

(2) The procedures shall ensure that during the flow of the products through the factory, there is no contamination, cross-contamination and rise in the temperature of the products (time-temperature control).

Conditions and procedures for the preservation of fresh, chilled fishery products

203. (1) The chilling of fishery products shall be carried out-

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

(b) to ensure that at the end of the chilling cycle, the temperature of the fishery product reaches that of melting ice with a tolerance of plus or minus one degree celcius (1°c).

(2) To control histamine formation, the internal temperature of the fishery products shall be brought from ambient temperature to ten degrees celcius (10°c) or below, within six hours, and once chilled be maintained as close to the temperature of melting ice as possible.

(3) After chilling, the fishery products shall not be exposed to a temperature above four degrees celcius (4°c), for a cumulative period of more than two hours during preparation or processing.

(4) Chill storage rooms shall comply with following conditions-

(a) establishments preparing fresh fish as a final product shall have a chill room for raw material and a chill storage room for finished fresh products;

(b) a chill storage room used to store chilled fish shall be operated at the temperature of melting ice;

(c) a chill storage room shall not be used for the purpose of the initial freezing of fish or fish product; and

(d) chill storage rooms shall be kept clean and free from accumulation of ice and the floor and general structure of chill storage room maintained in good condition.

(5) The chilling of unpackaged fishery products shall be carried out under following conditions-

(a) where chilled, unpackaged fishery products (raw material) are not dispatched, prepared

or processed immediately after reaching the establishment, they shall be stored under ice in the establishment's chill storage room; and

(b) the ice used, with or without salt, shall be made from potable water or clean sea water and be stored under hygienic conditions in containers provided for the purpose.

(6) Pre-packed fresh products shall be chilled with ice or mechanical refrigeration that creates similar temperature conditions.

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

(a) if they are not carried out on board, operations such as heading and gutting shall be carried out hygienically and immediately after the products have been caught or landed;

(b) the products shall be washed thoroughly with potable water immediately after such operations;

(c) the quantities of fish on the worktables at any one time should be kept to a minimum and must not remain there beyond the time necessary for their preparation;

(d) fillets and slices shall be wrapped and where necessary, packaged and chilled as quickly as possible after their preparation;

(e) fish, which is held on the tables awaiting processing, shall be protected by adequate quantities of ice both below and on top of them;

(f) where an operation in an establishment ceases, the processing of fishery products already begun shall be completed before the workers leave their posts;

(g) the internal temperature of the fishery products shall be maintained below a limit designated by the operators and approved by the Competent Authority during processing and handling on the worktables;

(h) 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;

(i) filets and slices shall not remain on work-tables any longer than is necessary for their preparation;

(j) equipment used for the filleting of fish should be washed and disinfected regularly during the process;

(k) if the fillets are not immediately packed or frozen they shall be stored at a temperature of zero degree celcius (0°c) with adequate quantities of ice or in a chilled storage room, different from the chill storage room for raw material; and

(l) containers used for the dispatch or storage of fresh fishery products shall be designed in such a way as to ensure both their protection from contamination and their preservation under sufficiently hygienic conditions.

Conditions and procedures for freezing and for the storage of frozen products

204. (1) Freezing of fishery products shall be carried out under the following conditions-

(a) an establishment shall have freezing equip-ment in blast, contact, plate, tunnel or brine freezers with sufficient power to achieve a rapid reduction in the temperature as laid down in this regulation;

(b) fresh products which are frozen or quick-frozen shall comply with the requirements, and conditions for fresh products laid down in regulation 203; and

(c) the freezing process shall be carried out in a way that minimises undesirable, chemical and microbiological changes and in particular-

(i) fish shall be frozen in a room or chamber specifically designed for that purpose, kept clean and free from accumulation of ice,

(ii) blocks of fish or fish products for freezing shall not have a thickness of more than eighty millimetres,

(iii) if the fish is packed and frozen immediately it shall be stored with sufficient ice to maintain its temperature at Zero degree celcius (0°c),

(iv) any glaze water, which is added to the fish, shall first be chilled to zero degree celcius (0°),

(v) during the unloading of the freezer, the internal temperature of the fish shall not be permitted to rise above minus eighteen degrees centigrade (-18°c), and

(vi) the packing of master cartons shall be done rapidly to prevent the internal temperature of fish rising above minus eighteen degrees celcius (-18°c).

(2) When freezing fishery products, the operators of an establishment shall take into account the following conditions-

(a) freezing chambers or other freezing equipment used for the initial freezing of fishery products shall reduce the product temperature through the zone of maximum crystallisation (in most products from minus one [-1°c] to minus five degrees celcius [-5°c]) preferably within four to six hours from the commencement of the refrigeration process;

(b) where the refrigeration process is continued in order to reduce the thermal core temperature to minus eighteen degrees celcius (-18°c) or colder, the whole refrigeration process shall be completed between eight to twelve hours;

(c) the process shall not be regarded as completed unless the product temperature has reached minus eighteen degrees celcius (-18°c) at the thermal centre after thermal stabilisation;

(d) brine frozen fish used for canning may be frozen at a higher temperature of up to minus nine degrees celcius (-9° c); and

(e) a blast freezer shall not be loaded with fish in excess of the capacity designated by the refrigeration equipment or beyond seventy percent of the internal volume.

(3) The freezing of fishery products in cold storage rooms shall comply with the following requirements-

(a) an establishment shall have freezing equipment sufficiently powerful to keep products in the storage rooms at a temperature not exceeding those laid down in these Regulations, whatever the ambient temperature may be;

(b) the floor and general structure of the cold storage rooms shall be maintained in good condition;

(c) the cold storage room shall be kept clean and free from accumulation of ice;

(d) the cold storage room shall be well organised with separation of different products and batches;

(e) in order to permit the free circulation of air within the cold storage room, fishery product shall not be stored in contact with the walls or floor;

(f) poultry, meat and other products which may contaminate the fishery products shall not be stored in the cold storage room unless the product is packaged and physically separated from the seafood product.

(g) a cardboard shall not be placed on the floor for the purposes of keeping it clean.

(h) whenever possible, a product which has been stored longest shall be the first to be distributed (first in, first out principle).

(i) effective measures shall be taken to keep temperature variations to a minimum after the freezing process and during handling and transport.

(j) cold storage rooms shall have a temperature-recording device in a place where it can easily be read;

(k) the temperature sensor of the recorder shall be located in the area furthest away from the cold source; and

(l) temperature charts shall be available for inspection by the supervisory authorities during the period in which the products are stored.

Condition and procedures for thawing products

205. (1) The thawing of fishery products shall be carried out in such a way as to minimise the risk of growth of pathogenic micro-organisms or the formation of toxins in the foods.

(2) During thawing, fishery products shall not be subjected to temperatures that would not result in a risk to health.

(3) After thawing, fishery products shall be handled in such a manner as to minimise the risk of growth of pathogenic micro-organisms or the formation of toxins.

(4) An establishment carrying out thawing operations shall comply with the following requirements-

(a) fishery products shall be thawed under hygienic and controlled time-temperature conditions;

(b) fishery products shall be brought to its thawed state as quickly as possible without causing undesirable physical, biochemical and microbial changes to the food;

(c) if water is used to thaw the fishery products, a control system shall be implemented;

(d) after thawing, fishery products shall be handled in accordance with the requirements of this regulation; and

(e) if thawed fishery products are placed directly onto the market, particulars of the thawed

state of the fish shall be clearly marked on the packaging.

Conditions and procedures for the mechanical recovery of fish

206. (1) Food business operators manufacturing mechanically separated fishery products shall ensure compliance with the following conditions-

(a) the raw materials used must satisfy the following requirements-

(i) only whole fish and bones after filleting may be used to produce mechanically separated fishery products, and

(ii) the raw materials must be free from guts;

(b) the manufacturing process must satisfy the following requirements -

(i) mechanical separation shall take place without undue delay after filleting,

(ii) if whole fish is used, it must be gutted and washed before processing,

(iii) after production, mechanically separated fishery products shall be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment, and

(iv) the machinery shall be cleaned at least every two hours.

Conditions and procedures for processed fishery products

207. (1) Fresh, frozen and thawed products used for processing shall comply with the requirements laid down for fresh, frozen and thawed products in these Regulations.

(2) Where the processing is carried out to inhibit the development of pathogenic micro-organisms, or if it is a significant factor in the preservation of the product, it shall be scientifically recognised by the inspection service.

(3) Contamination, cross-contamination and deterioration of fishery products shall be prevented through the following processes-

(a) operating practices shall be designed to

avoid contamination of products, product surfaces and packaging materials;

(b) processes in which there is risk of contamination to the final product such as -

(i) prawn heading, de-veining and peeling,

(ii) lobster heading, gutting and de-veining, or

(iii) dismembering, gutting and scaling of fish;

shall take place in areas physically separated by location or partition from where the product is further processed or packed.

(c) pet food and fish meal preparation and packing shall take place in a building separated from that used for processing fishery products for human consumption;

(d) effective measures shall be taken to prevent raw material or semi processed material from contaminating the end product;

(e) the steps in the production process shall be performed without unnecessary delay and under conditions which will minimise the possibility of contamination, deterioration and growth of micro-organisms; and

(f) for the preparation or processing of high risk products-

(i) contaminated protective clothing worn by a person handling raw materials or partially processed fishery products shall be discarded before he or she comes in contact with high risk processed food,

(ii) if there is a likelihood of contamination, a person shall wash his or her hands thoroughly between handling processed fishery products at different stages of processing; and

(iii) equipment which comes into contact with raw materials or contaminated material shall be thoroughly cleaned

and sanitised prior to being used on processed food.

Conditions and procedures for smoking

208. (1) The smoking of fishery products shall be carried out under the following conditions -

(a) the smoking shall be carried out in separate premises or a special place equipped in such a way as to prevent the smoke and heat affecting other areas in the premises where fishery products are prepared, processed or stored;

(b) materials used for the smoking of fish shall be stored away from the place of smoking and used in such a way as to avoid contamination of the products;

(c) materials that have been painted, varnished, glued, or have undergone preservation treatment or other chemical treatment shall not be used to produce smoke; and

(d) products shall be cooled rapidly after smoking to the temperature required for their preservation before being packaged.

(2) The use of smoke flavourings shall conform to the following conditions-

(a) a smoke flavouring shall not be used in or on food unless it is proved that it does not pose a risk to human health;

(b) a smoke flavouring shall not be placed on the market or used on any fishery product if it is not made from a primary product authorised by the Competent Authority;

(c) the Competent Authority shall authorise the use of a smoke flavouring after confirming that it is made from a primary product authorised to be used on fishery products;

(d) a list of authorised primary products shall be drawn up by the Competent Authority that shows-

(i) a unique code for each product,

(ii) the name,

(iii) the name and address of authorised dealers,

(iv) a clear description and characterisation of each product,

(v) date of authorisation, and

(vi) the conditions under which it an be used on fishery products;

(e) after an authorisation has been issued in accordance with this Regulation, a fish business operator using the authorised primary product or derived smoke flavourings shall comply with any condition or restriction attached to such authorisation;

(f) the granting of an authorisation does not affect the civil and criminal liability of a food business operator in respect of the authorised primary product, derived smoke flavouring or food containing the authorised primary product or derived smoke flavouring;

(g) at the time of the placing on the market of an authorised primary product or smoke flavouring derived from the authorised products specified in the list referred to in paragraph (d), the Competent Authority shall ensure that the following information is transmitted to the fish business operator receiving the product-

(i) the code of the authorised product, and

(ii) the conditions of use of the authorised product;

(h) in the case of a derived smoke flavouring, the quantitative relation to the primary product shall be expressed in clear and easily understandable terms so that the receiving fish business operator can use the derived smoke flavouring in compliance with the conditions of use set out in the list referred to in paragraph (d).

Polycyclic Aromatic Hydrocarbons (PAH)

209. (1) The maximum level of benzo(a) pyrene in-

(a) muscle meat of smoked fish and smoked fishery products, excluding bivalve molluscs

shall be 5 ppb;

(b) muscle meat of fish, other than smoked fish shall be 2 ppb;

(c) crustaceans cephalopods, other than smoked shall be 5 ppb;

(d) bivalve molluscs shall be 10 ppb.

(2) The Competent Authority shall take all measures necessary to ensure that-

(a) the sampling for the official control of the levels of benzo(a)pyrene in foodstuffs is carried out in accordance with the methods described in the fourth Schedule to these Regulations; and

(b) sample preparation and methods of analyses used for the official control of the levels of benzo(a) pyrene in foodstuffs comply with the criteria described in the fourth Schedule to these Regulations.

Conditions and procedures for salting

210. (1) Salting operations shall take place in premises that are sufficiently removed from the premises where the other operations are carried out.

(2) Salt used in the treatment of fishery products shall be clean and stored in such a way as to preclude contamination.

(3) A container used for salting or brining shall be constructed in such a way as to avoid contamination during the salting or brining process.

(4) A Container or an area used for salting or brining shall be cleaned before use.

Conditions and procedures for cooking crustaceans and molluscan shell fish products

211. (1) The heating of molluscan shell fish products shall be carried out under the correct temperature and time regime to ensure that it achieves the desired safety, functionality and shelf life.

(2) The cooking of molluscan shell fish products shall be followed by a rapid cooling process using potable or sea water until it reaches the temperature of melting ice in the absence of any

other preservation method.

(3) The shelling of mollusccan shell fish products shall be carried out under the conditions of hygiene that will prevent contamination.

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

(5) A manufacturer shall carry out microbiological checks on his or her production at regular intervals, and comply with the standards set forth in schedule 3 of these Regulations.

Conditions and procedures for processing shrimps

212. (1) All tanks or sinks used for the washing of shrimp shall be supplied with a constant flow of water that is sufficient to replace the contents of the tank every thirty minutes.

(2) Tanks used for the washing of shrimp should be emptied completely and washed and disinfected during every cessation in the process and between different batches of shrimp.

(3) A product which is stored for more than one day before processing should be de-headed.

(4) If shrimp intended for peeling and de-veining is not to be processed immediately, it should be stored with sufficient quantity of ice to maintain its temperature at zero degree celcius (0°c).

(5) The shrimp should be peeled and de-veined rapidly in order to minimise the rise in temperature.

(6) If the peeled and de-veined shrimp is not intended to be frozen immediately it should be stored at zero degree celcius (0°c) with adequate quantities of ice.

(7) Higher standards of hygiene and cleanliness should be maintained at the worktables on which shrimp is peeled and de-veined due to the higher risk of contamination of the shrimp flesh itself.

(8) Chilled water shall be used for the washing of head-on shrimp at all stages of the production process.

(9) An area in which cooked or head-on shrimp is processed shall be air-conditioned in order to maintain an air temperature of less than twenty-five degrees celcius (25°c).

Conditions and procedures for cooked shrimp

213. (1) Cooked shrimp shall only be handled in an area separate to that in which the raw product is processed and there shall be no direct access for personnel between the two areas.

(2) All personnel who handle cooked shrimp or who work in or enter the area in which it is processed, shall wear coats, boots, hats and aprons used exclusively by them and which are kept separate from the protective clothing used in the processing of raw shrimp.

(3) A person entering the cooked products area shall wash his or her hands and boots.

(4) An equipment or other article (including fish boxes, knives etc.) shall not be transferred from an area in which raw shrimp is handled to the cooked product area, without first receiving a thorough cleaning and disinfecting.

(5) If the final product is to be head-on shrimp, this should be processed immediately without a period of storage.

Conditions and procedures for canning

214. (1) Food placed on the market in hermetically sealed containers shall comply with the following requirements-

(a) a heat treatment process used to process an unprocessed product or to further process a processed product shall -

(i) raise every part of the product treated to a given temperature for a given period of time, and

(ii) prevent the product from becoming contaminated during the process;

(b) to ensure that the process employed achieves the desired objectives, fish business operators shall regularly check the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including the use of automatic devices;

(c) the process used shall conform to an internationally recognised standard such as pasteurisation, ultra high temperature or sterilisation.

(2) A scheduled process for low acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low acid foods in hermetically sealed containers.

(3) A "Standard Operating Procedure" Manual shall be compiled and approved by the competent Authority specifying the-

(a) establishment of the thermal process with-

(i) heat penetration, and

(ii) heat distribution study;

(b) process control system with-

(i) equipment description,

(ii) monitoring system, and

(iii) general operations in thermal process room;

(c) container integrity checks for-

(i) incoming containers,

(ii) seaming machines,

(iii) evaluation of double seam integrity,

(iv) cooling water monitoring,

(v) cooling of containers, and

(vi) post-process handling of containers;

(d) documentation and records for-

(i) processing and production records,

(ii) management review of records, and

(iii) process deviation records.

(4) Canning conditions shall comply with following requirements-

(a) potable water shall be used for the preparation of cans;

(b) the process used for heat treatment shall be appropriate, having regard to such criteria as the heating time, temperature, filling and the size of containers;

(c) the heat treatment shall be capable of destroying or inactivating pathogenic organisms and the spores of pathogenic micro-organisms;

(d) the heating equipment shall be fitted with devices for verifying whether the containers have in fact undergone appropriate heat treatment;

(e) potable water shall be used to cool containers after heat treatment, without prejudice to the presence of any chemical additives used in accordance with good technological practice to prevent corrosion of the equipment and container; and

(f) the maximum level for inorganic tin -

(i) in canned fishery products shall be 200ppm (mg/kg)), or

(ii) in canned foods for infants, young children and babies shall be 50ppm (mg/kg).

(5) The Competent Authority shall take all measures necessary to ensure that-

(a) the sampling for the official control of the levels of inorganic tin in foodstuffs is carried out in accordance with the methods described in the fourth Schedule to these Regulations; and

(b) sample preparations and methods of analysis used for the official control of the levels of inorganic tin in foodstuffs comply with the criteria described in the fourth Schedule to these Regulations.

(6) The following checks shall be carried out during the canning process-

(a) checks shall be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat treatment through -

(i) an incubation test carried out at thirty seven degrees celcius (37°c) for seven days or at thirty-five degrees celcius (35°c) for ten days or at any other equivalent combination, and

(ii) microbiological examination of the contents of the containers in the establishment's laboratory or in another approved laboratory;

(b) samples shall be taken of production each day at predetermined intervals to ensure the efficiency of sealing or of any other method of hermetic closure;

(c) checks shall be carried out to ensure that containers are not damaged; and

(d) all containers which have undergone that treatment under practically identical conditions during the same period of time shall be given a batch identification mark.

Conditions and procedures for parasites

215. (1) A visual inspection shall carried out on fishery products in the following manner -

(a) before they are released for human consumption fish and fish products shall be subject to a visual inspection for the purpose of detecting and removing any parasites that are visible;

(b) visual inspection shall be performed on a representative number of samples; and

(c) the person in charge of on-shore plants and qualified persons on board factory vessels shall determine the scale and frequency of the inspections required in paragraph (b) by reference to the nature of the fishery products, their geographical origin and their use.

(2) Visual inspection of eviscerated fish shall be carried out as follows-

(a) during production, the visual inspection of eviscerated fish shall be carried out by qualified persons on the abdominal cavity and livers and roes intended for human consumption;

(b) according to the system of gutting used, the visual inspection shall be carried out-

(i) in case of manual evisceration in a continuous manner by the operative at the time of evisceration and washing, or

(ii) in the case of mechanical evisceration by sampling carried out on a representtative number of samples being not less than ten fish per batch;

(c) the visual inspection of fish fillets or fish slices shall be carried out by qualified persons during trimming, after filleting or slicing;

(d) where an individual examination is not possible because of the size of the fillets or the filleting operations, a sampling plan shall be drawn up and kept available for the Competent Authority; and

(e) where candling of fillets is possible from a technical viewpoint, it shall be included in the sampling plan.

(3) The following measures shall be taken before fish products are released for consumption-

(a) fish or parts of fish which are obviously infested with parasites and which are removed shall not be placed on the market for human consumption;

(b) the fish and fish products referred to in paragraph (c) shall in addition, be subjected to freezing at a temperature of not more than minus twenty degrees centigrade (-20°c) in all parts of the product for no less than twenty four hours;

(c) fish and fish products subject to the condition in paragraph (b) are-

(i) those intended to be consumed raw or almost raw,

(ii) herring, mackerel, sprat, (wild), Atlantic and Pacific salmon, if they are to undergo a cold smoking process at which the internal temperature of the fish is less than sixty degrees celcius (60°C), or

(iii) marinated or salted herring where this process is insufficient to destroy the larvae of the nematodes;

(d) a manufacturer shall ensure that fish and fish products listed in paragraph (c) or the raw materials for use in their manufacture are subject to the treatment described in paragraph (b) prior to their release for consumption; and

(e) the fishery products listed in paragraph (c) shall, when they are placed on the market, be accompanied by a document from the manufacturer stating the type of process they have undergone, except when supplied to the final consumer.

(4) Fish business operators need not carry out the treatment under sub- regulation (3) if -

(a) epidemiological data is available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites; and

(b) the Competent Authority so authorises.

Conditions and procedures for wrapping and packaging

216. (1) The time between processing and packaging shall be such that no undesirable physical, chemical or microbiological deterioration takes place on fishery products.

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

(3) Labels, tags and adhesives used in packaging shall not contaminate fish.

(4) A container of fish for export shall not contain any foreign objects.

(5) Material used for wrapping and packaging shall not be a source of contamination.

(6) Wrapping and packaging materials and products liable to enter into contact with fishery products shall comply with the rules of hygiene and in particular they shall-

(a) not impair the organoleptic characteristics of the fishery products; and

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

(7) The ink used to apply description markings and the inks and colorants applied to fish shall not contaminate the fish and shall be non-toxic.

(8) The inks applied to fish or packaging shall not contain antimony, arsenic, cadmium, chromium, lead, mercury, or other toxic metals.

(9) Fluorescent brighteners or carcinogens, mutagens and teratogens shall not be used in inks applied to fish or packaging.

(10) A lacquer applied to the inner surface or part of the inner surface of covering shall-

(a) cover the inner surface in a continuous film;

(b) be uniform in thickness;

(c) leave no area of the surface uncoated;

(d) firmly adhere to the covering; or

(e) be compatible and non-toxic with the food being packed,

(f) be strong enough to protect the fishery products adequately;

(11) The first envelope (wrapping), which is in direct contact with the fish may be made from a plastic

packaging materials, a foam box or a can.

(12) The second envelope (packaging), which is not in direct contact with the fish shall be a cardboard box or a master carton.

(13) Fishery products shall not be transported unless they are packed and covered in such a way that will enable them reach their destination in a satisfactory and wholesome condition.

(14) Packaging materials may not be re-used. except containers made of impervious, smooth and corrosion-resistant materials which are easy to clean and disinfect,

(15) Receptacles in which fresh fishery products are kept under ice must be water-resistant and ensure that melted water does not remain in contact with the products.

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

(17) Unused wrapping and packaging materials shall be stored in premises connected with the production area and protected from dust and contamination in accordance with the requirements laid down in regulation 101 of these Regulations.

(18) Wrapping materials shall be stored in such a manner that they are not exposed to a risk of contamination.

(19) Frozen blocks prepared on board vessels shall be adequately wrapped before landing.

(20) When fishery products are wrapped on board fishing vessels, fish business operators shall ensure that the wrapping material-

(a) is not a source of contamination;

(b) is stored in such a manner that it is not exposed to a risk of contamination; and

(c) intended for re-use is easy to clean and where necessary, to disinfect.

Traceability, origin and labeling

217. (1) Fishery products may be traced by means of its labelling or packaging, or through a

commercial document or invoice accompanying them which indicates-

(a) the scientific name and commercial designation of the species;

(b) the production method (caught at sea, caught in inland freshwater or farmed or cultivated); and

(c) the catch area.

(2) The indication of catch area shall consist of the following-

(a) in the case of products caught at sea, a reference shall be made to one of the following areas-

Catch Area	**Identification of the Area**
North West Atlantic……	FAO area 21
North East Atlantic [(1)]	FAO area 27
Black Sea	FAO area 27; IIId
Central Western Atlantic	FAO area 31
Central Eastern Atlantic	FAO area 34
South West Atlantic	FAO area 41
South East Atlantic	FAO area 47
Mediterranean Sea	FAO areas 37.1, 37.2 and 37.3
Black Sea	FAO area 37.4
Indian Ocean	FAO area 51 and 57
Pacific Ocean	FAO areas 61, 67, 71, 77, 81 and 87
Antartica	FAO areas 48, 58 and 88

(b) in the case of products caught in freshwater, a reference shall be made to the country of origin; and

(c) in the case of farmed products, a reference shall be made to the country in which the product undergoes the final development stage.

(3) Where a combination of different species is

offered for sale, the following indications shall be provided for each species -

CN code	Description of goods
0301	Live fish
0302	Fish, fresh or chilled excluding fish fillets and other fish meat of heading No. 0304
0303	Fish, frozen excluding fish fillets and other meat of heading No. 0304
0304	Fish fillets & other fish meat (whether or not minced) fresh, chilled or frozen;
0305	Fish dried, salted or in brine, smoked fish, whether or not cooked before or during the smoking process, flours, meals and pellets of fish, fit for human consumption;
0306	Crustaceans, whether in shell or not, live, fresh, chilled, frozen, dried, salt-ed or in brine; Crustaceans in shell, cooked by steaming or boiling in water, whether or not chilled, frozen, dried, salted or in brine, flours, meals and pellets of fish fit for human consumption;
0307	Molluscs, whether in or not, live, fresh, chilled, frozen, dried, salted or in brine, aquatic invertebrates other than crustaceans and molluscs, live, fresh, chilled, frozen, dried,

salted or in

brine; flours, meals and pellets and aquatic invertebrates other than crustaceans fit for human consumption.

(4) Where a combination is offered for sale consisting of the “same species”, but derived from a variety of “production methods”, the method for each batch must be indicated.

(5) Where a combination is offered for sale consisting the “same species” but derived from a variety of catch areas or fish farming countries, the area of the batch which is most representative in terms of quantity shall be stated, together with an indication that the products also came from different catch or fish farming areas.

(6) The labels and documents accompanying fishery products shall indicate the plant of dispatch of the consignments.

(7) Without prejudice to the provisions concerning labelling of food products laid down in other Regulations and in sub regulation (1), the following information shall appear on the packaging or in the case of non-packaged products, in the accompanying documents -

(a) country of dispatch which may be written out in full or shown as an abbreviation using capitals;

(b) identification of the establishment or factory vessel by its official approval number ; and

(c) identification of the freezer vessel in case of marketing from a freezer vessel, by its official registration number.

(8) All the letters and figures shall be fully legible and grouped together on the packaging in a place where they are visible from the outside without any need to open the said packaging.

Process control

218. (1) A fail-safe pre-control system shall be implemented as part of the auto-control system, whereby measurements and checks are compared

with standards, followed by corrective actions.

(2) Cross contamination shall be pre-controlled by implementing the other prerequisite programmes (best practices) and shall be controlled by sampling and microbiological analysis.

(3) Time-temperature abuse shall be pre-controlled by implementing the procedures and instructions laid down in this chapter, and shall be controlled by temperature measuring.

(4) All measuring equipment, gauges and devices used in connection with fish shall be graduated so as to be read easily and calibrated so as to be accurate.

(5) A calibration system shall be applied either in-house or by an external authority and the results of the calibration kept for two years unless otherwise specified in these Regulations.

Instructions

219. The following instructions shall be documented and implemented in detail for every specific case.

(a) work instructions -

(i) for chilling, freezing, thawing fishery products,

(ii) for preparation of fishery products such as rinsing, filleting, skinning, trimming, grading, packing, and mechanical recovery of fish,

(iii) for processing of fishery products such as canning, smoking, salting and cooking;

(iv) to prevent cross contamination, temperature abuse, and

(v) for the use of sweeteners, colours and food additives other than colours and sweeteners.

(b) control instructions for -

(i) controlling time-temperature conditions,

(ii) candling, and

(iii) visual checks.

Final product specifications

220. (1) Product quality specifications such as process description, (nature of the packing, unit packing, volume or weight per unit packing) shelf life, and storage conditions, transport conditions, distribution conditions, and label information shall be in place if applicable.

(2) Product safety specifications for-

(a) potential chemical hazards such as -

(i) environmental chemical and pesticides,

(ii) sweeteners, colours and food additives other than colours and sweeteners,

(iii) ichthyotoxins,

(iv) scombrotoxins, or

(v) ciguatera;

(b) potential biological hazards such as microbes and parasites; and

(c) potential physical hazards;

shall be in place, if applicable.

Documents and records

221. All procedures, instructions, and specifications, control and monitoring activities shall be thoroughly documented and recorded.

Training

222. (1) Food business operators shall ensure -

(a) that food handlers and staff are supervised and instructed;

(b) 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 preparation and processing of fishery products and the best manufacturing 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; and

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

Sub-part IX - BEST STORAGE PRACTICES

Scope of Best Storage Practices

223. (1) The storage of fishery products, packaging materials, cleaned recipients, tubs, baskets, equipment and other products such as ingredients, additives, and chemicals, shall be organised in accordance with this regulation.

(2) Fishery products shall be stored under conditions that protect them against physical, chemical and microbiological contamination as well as against deterioration of the materials and the containers.

(3) The raw materials and ingredients shall be kept in appropriate conditions designed to prevent deterioration and protect them from contamination.

(4) The containers used for the dispatch or storage of unpackaged fresh fishery products under ice shall be designed in such a way that melted ice water does not remain in contact with the products.

(5) Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins shall not to be kept at a temperature that poses a risk to health.

(6) Fish businesses manufacturing, handling and wrapping processed fishery products shall have separate rooms that are large enough for the storage of all materials.

Action plan and quality objectives

224. (1) Procedures and instructions shall be implemented and maintained by the fish business operators -

(a) for the storage of raw materials and finished products to -

(i) avoid decrease of shelf life of the products,

(ii) avoid deterioration or decomposition of fishery products, and

(iii) eliminate or minimise possible occurrence of contamination and proliferation of micro-organisms;

(b) for the storage of packaging material to prohibit the possibility of damage or contamination; and

(c) for storage of chemicals-

(i) to identify, hold, use and store toxic compounds in a manner that protects against contamination of fish, contact surfaces of fish packaging materials, or

(ii) to identify, hold and store toxic cleaning compounds, disinfecting agents and pesticide chemicals in a manner that protects against contamination of fish, fish contact surfaces or packaging materials;

(d) for the storage of ice to protect it from contamination.

(2) Only those toxic materials -

(a) required to maintain clean and sanitary conditions;

(b) necessary for use in laboratory testing procedures;

(c) necessary for plant and equipment maintenance; and

(d) necessary for use in the plant's operations;

shall be used and stored in the plant.

Scheduling

225. (1) The operators of an establishment shall schedule planned actions in a timetable to demonstrate commitment to future actions.

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

Responsibilities and authority

226. The operators of an establishment shall establish responsibilities and authorities for the implementation, maintenance, monitoring and verification of the best storage practices described in these Regulations.

Procedures

227. Procedures shall be defined to ensure that the hygienic requirements with respect to storage of fishery products, dry ingredients, chemicals, packaging material and finished products are met.

Temperature conditions for fishery products during storage

228. (1) Fishery products shall, during storage, be kept at the temperatures laid down in these Regulations and in particular -

(a) fresh or thawed unprocessed fishery products and cooked and chilled products from crustaceans and molluscs shall be kept at the temperature of melting ice;

(b) fresh or thawed unprocessed fishery products shall always be chilled with ice, whether or not completed with mechanical refrigeration;

(c) pre-packed fishery products may be chilled with ice or with mechanical refrigeration;

(d) frozen fishery products with the exception of frozen fish in brine intended for the manufacture of canned fish shall be kept at an even temperature of minus eighteen degrees Celsius or less in all parts of the product;

(e) fish shall not be exposed to a temperature above 4.4 degrees Celsius from the time it is frozen for a cumulative period of more than twelve hours;

(f) processed products shall be kept at the temperature specified by the manufacture;

and

(g) fishery product kept alive shall be kept at a temperature and in a manner that does not adversely affect food safety or their viability.

Storage conditions for fresh fishery products

229. (1) Fresh fishery products shall -

(a) be maintained under conditions that prevent spoilage;

(b) be protected against damage;

(c) be protected against contamination; and

(d) not be processed or used unless inspected for contamination, decomposition and parasites and found to be in a sound condition.

(2) The nature and frequency of such inspections shall be set by the exporter and approved by the Competent Authority.

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

(4) Materials other than those used for immediate processing shall not be stored in an area used for processing.

Storage conditions for frozen fishery products

230. (1) The freezing of fish shall not be carried out in a cold store.

(2) Frozen fish shall be protected from dehydration and freezer burn by -

(a) the application of a glaze; and

(b) nclosure in an impervious wrap.

(3) The cold store rooms and warehousing for quick-frozen products shall be fitted with suitable recording instruments to monitor, at frequent and regular intervals, the air temperature to which the frozen fishery products are subjected.

(4) All measuring instruments used for the purpose of monitoring the temperature, as provided for in sub regulation (3) shall comply with EN 12830, EN

13485 and EN 13486 standards.

(5) Fish business operators shall keep all relevant documents that verify that the instruments referred to above conform to the relevant EN standards.

(6) A temperature recording shall be dated and stored by a fish can operator for a minimum period of one year, or for a longer period taking into account the nature and the shelf-life of the frozen fishery products.

(7) The air velocity in cold store rooms shall be moderate and no higher than necessary to achieve uniform temperatures within the rooms.

(8) Products shall be stacked so that air circulation within the storage room is not impaired and except in jacketed rooms, no direct contact with ceilings and floors shall be allowed.

(9) A system of controlled stock rotation shall be employed in cold stores and chill rooms.

Storage conditions for dry ingredients

231. Dry ingredients shall be stored in a closed, ventilated, pest proof and clean area with the required room temperature and humidity.

Storage conditions for packaging materials

232. (1) Packaging materials shall be stored in a closed, ventilated, pest proof, dust-free and clean area with the required room temperature and humidity.

(2) Packaging materials shall be protected by polysheets in a way that the inside of the boxes are protected against contamination.

(3) Empty cans shall not be exposed at ambient conditions without protection.

Storage conditions for hazardous substances

233. (1) Pesticides, cleaning agents or other substances which may present a hazard to health shall be suitably labelled with a warning about their toxicity and use and the care that needs to be taken to avoid the chemicals contaminating fish, fish contact surfaces and ingredients.

(2) Hazardous substances shall be stored in rooms or cabinets used only for that purpose and handled only by authorised and properly trained persons.

(3) Except when necessary for hygienic or

preparation purposes, a substance which may contaminate fish shall not be used or stored in food handling areas or be stored with any product, ingredients or product packaging material.

Process Control

234. (1) A fail-safe Control system shall be implemented-

(a) to control the temperature of chill rooms and cold rooms; and

(b) to control the compliance with the requirements for chemicals and packaging materials laid down in the Supplier Quality Assurance Agreement for chemicals, ingredients and packaging materials.

(2) Cold rooms (storage rooms for frozen products) shall have a temperature recording device in place and temperature charts shall be available for inspection by the supervisory authorities during the period in which the products are stored.

Instructions

235. Control instructions shall be put in place-

(a) to implement the daily temperature control activities in the fish storage facilities for fresh and frozen fish; and

(b)to implement the control activities for the hygiene and storage organisation in the storage rooms.

Temperature specifications

236. Temperature standards and tolerances shall be implemented in every establishment.

Records

237. The temperature conditions, hygienic conditions and the piling practices in chill storage rooms, cold storage rooms and other storage facilities shall be recorded.

Training

238. Food business operators shall ensure-

(a) that food handlers and staff are supervised and instructed;

(b) that 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 about storage in 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 the 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.

Sub-part X - BEST TRANSPORT PRACTICES

Scope of best transport practices

239. (1) The transport of fishery products shall be organised in accordance with the requirements of temperature, humidity, quality and safety of the products laid down by this regulation.

(2) The means of transport for quick-frozen products shall be fitted with suitable recording instruments to monitor, at frequent and regular intervals, the air temperature to which the frozen fishery products are subjected.

(3) All measuring instruments used for the purpose of monitoring the temperature, as provided for in sub regulation (2), shall comply with EN 12830, EN 13485 and EN 13486 standards.

(4) Fish business operators shall keep all relevant documents that can verify that the instruments referred to above conform to the relevant EN standards.

(5) A temperature recording shall be dated and stored by a fish operator for a minimum period of one year, or for a longer period taking into account the nature and the shelf-life of the frozen fishery products.

(6) The transport of fishery products shall be carried out under conditions that will protect materials against physical, chemical and microbiological

contamination as well as against deterioration of the containers.

Quality objectives and action plan

240. Procedures and instructions shall be implemented and maintained by the fish business operators-

(a) for the transport of raw materials and finished products -

(i) to avoid decrease of shelf life of the products,

(ii) to avoid decomposition of fishery pro-ducts,

(iii) to prevent contamination;

(b) for the transport of packaging material to prevent damage or contamination.

Scheduling

241. (1) The operators of an establishment shall schedule planned actions in a timetable to demonstrate commitment to future actions.

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

Responsibilities and authority

242. (1) The operators of an establishment shall establish responsibilities and authorities for the implementation, maintenance, monitoring and verification of the transport practices described in these Regulations.

(2) It is the responsibility of the owner of the vehicle to comply with this regulation, but the operators of an establishment shall supervise the unloading of vehicles and communicate to its owner the existence of any infractions.

Procedures

243. The operators of an establishment shall lay down procedures to ensure that the hygienic requirements for contamination prevention and temperature maintenance with respect to transport of raw materials, finished products and packaging materials are met.

Temperature conditions for fishery products during

244. Fishery products shall, during transport, be kept at the temperature laid down in this regulation and, in particular -

transport

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

(b) fresh or thawed fishery products shall be chilled with ice whether or not completed with mechanical refrigeration;

(c) prepared fishery products may be chilled with ice or with mechanical refrigeration;

(d) 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 minus eighteen degrees celcius or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than three degrees celcius;

(e) processed products shall be kept at the temperature specified by the manufacturer; and

(f) whole and gutted fresh fishery products may be transported and stored in cooled water on board vessels.

Hygienic conditions required for vehicles transporting fishery products

245. The parts of the vehicle in which chilled or frozen fish is transported shall -

(a) be clean and in good state of repair;

(b) be covered during transport of the product in order to prevent exposure to dust, birds, insects and sunlight;

(c) be of adequate size and have sections or containers designed specifically for storage of fishery products;

(d) be constructed and equipped in such a way that the temperature laid down in this regulation can be maintained throughout the period of transport;

(e) be constructed from smooth, corrosion resistant impervious materials, free from cracks and crevices and easy to clean;

(f) not be made of wood unless it is painted with gloss paint of a light colour and the fish

are carried in fish boxes.

(g) have internal surface joints that are smooth or flush and sealed to prevent the entry of moisture and finished in such a way that they do not adversely affect the fishery products;

(h) have adequate drainage if ice is used to chill the products, in order to ensure that water from melted ice does not stay in contact with the products; and

(i) have light sources covered by a shatterproof shield if lighting is supplied.

General transport conditions for fishery products

246. (1) The transport used for fishery products may not be used for transporting other products likely to impair, transmit harmful properties or contaminate fishery products, except where it is thoroughly cleaned and disinfected to prevent contamination.

(2) The operators of an establishment shall ensure that the smell or odour of the mechanical cooling system does not adversely affect fishery products.

(3) Animals shall not be carried in the cargo area of vehicles used to transport fishery products.

(4) Ramps shall not be stowed in the cargo area.

(5) Fishery products shall not be transported in a vehicle or container which is not clean or disinfected.

(6) Vehicles may transport only fishery products which are fit for human consumption.

(7) After each journey, the vehicle and the fish boxes used shall be washed with water and detergent, and disinfected.

Specific requirements for specific types of transport

247. (1) The transport of raw fishery products in ice by road shall be carried out -

(a) in closed insulated containers in open means of transport; or

(b) in open insulated containers stored in insulated and dust free means of transport, provided with mechanical refrigeration

where the distance to be covered is so long that melting of ice cannot be avoided without mechanical refrigeration.

(2) Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice shall be such that melted ice water does not remain in contact with the products.

(3) Raw fresh frozen fishery products shall be transported in clean and closed pre-cooled containers, holds or other means of transport at the appropriate temperature laid down in this regulation, and provided with a thermometer to be able to control temperature.

(4) Live fishery products to be placed on the market shall be transported in such a way as not to adversely affect fish safety or viability.

(5) Packed frozen finished products shall be transported in clean and closed pre-cooled containers or other means of transport, at the appropriate temperature laid down in this regulation, and provided with a thermometer to be able to control temperature.

(6) Fishery products which have been subjected to sterilisation in hermetically sealed containers shall be transported in clean and closed containers or other means of transport on ambient temperature in a way that cartons and the cans are not damaged during loading, transport and off loading.

(7) The shipment containers used to transport frozen products shall be made of easy to clean material, and checked and pre-cooled before loading.

(8) After stuffing, the container is again cooled down to minus eighteen degrees celcius before leaving the establishment for the harbour.

Process control

248. The operators of an establishment shall establish a Fail Safe Control system whereby the transport activities of raw materials and finished products are checked and controlled on their compliance with the activities described in the procedures and the instructions.

Instructions

249. Fish business operators shall be put in place

Instructions for -

(a) the measurement of temperature in chilled and frozen products;

(b) transporting fish by transport boats;

(c) off loading boats;

(d) loading carrier;

(e) transport by carrier; and

(f) cleaning and disinfecting means of transport.

Specifications

250. Specifications shall be defined for all means of transport and their use.

Documentation

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

Training

252. Food business operators shall ensure-

(a) that food handlers and staff are supervised and instructed;

(b) 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 understanding how to take precautions necessary to prevent contamination and deterioration of fishery products during transport;

(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.

Sub-part XI - BEST WASTE DISPOSAL PRACTICES

Scope of best waste disposal practices

253. An establishment shall have appropriate facilities-

(a) to treat the by-products destined for human consumption in an appropriate manner;

(b) to separate guts, non edible by-products and other waste that may constitute a danger to public health and remove them from the vicinity of products intended for human consumption; and

(c) to drain the liquid waste water and treat the sewage.

Quality objectives and action plan

254. (1) The operators of an establishment shall implement and maintain procedures and instructions-

(a) to treat the by-products (if applicable);

(b) to prevent the contamination of fishery products with bacteria from residues and wastes; and

(c) to deal with wastewater drainage and sewage treatment.

Scheduling

255. (1) The operators of an establishment shall schedule planned actions in a timetable to document commitment to future actions.

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

Responsibilities and authority

256. The operators of an establishment shall establish responsibilities and authorities for the implementation, maintenance, monitoring and verification of regulations described in the best waste disposal practices.

Procedures

257. (1) The operators of an establishment shall

define procedures to ensure that the hygienic requirements with respect to by-products, solid and liquid waste disposal are met.

(2) Waste containers and their use shall comply with the following hygienic requirements-

(a) unless special facilities are provided for the continuous disposal of waste, the latter shall be placed in leak-proof, impermeable containers which-

(i) are provided with tight fitting lids to prevent the entry of insects, rodents and other animals;

(ii) are designed to facilitate cleaning and disinfecting;

(iii) are clearly marked for that purpose only or be of a different colour to boxes used for fish intended for human consumption;

(iv) when used for temporary storage of viscera and offal in the work room, it shall be kept below the level of the work tables to avoid splashing and contamination of the product; and

(v) shall be always thoroughly cleaned and disinfected after use.

(3) Disposal of waste shall comply with the following hygienic requirements-

(a) waste shall be removed as soon as the containers are full or at the end of each working day whichever is earlier, from the main work room to the premises allocated for the storage of such containers;

(b) waste shall be removed from the vicinity of the establishment at regular intervals in a hygienic and environmentally friendly way in order to ensure that it does not constitute a source of contamination for the establishment or pollution of its surroundings through foul odours or the presence of insects and rodents; and

(c) the room in which residues and wastes are stored shall-

(i) have a permanent water supply and adequate drainage,

(ii) be kept clean and free of animals and pests, or

(iii) be regularly inspected to ensure that this requirement is met.

Process control

258. The operators of an establishment shall install a Fail Safe Control system to control the compliance with the requirements laid down in regulations 154, 254 and 257.

Instructions

259. The operators of an establishment shall document and implement Instructions shall on how to -

(a) treat the by-products if applicable;

(b) dispose of guts, offal and waste;

(c) deal with waste water and sewage;

(d) store and remove waste; and

(e) organise the cleaning and disinfecting of containers, waste storage rooms, waste water drainage channels, solid mesh traps, gully traps and manholes.

Specifications

260. Specifications shall be in place concerning identifications and the use of the waste containers.

Records and documentation

261. All procedures and instructions, control and check activities shall be thoroughly documented and recorded.

Training

262. Food business operators shall ensure-

(a) that food handlers and staff are supervised and instructed;

(b) that 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 hygienic handling of by-products and/or waste 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) receive 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.

PART XIII - CONDITIONS FOR THE USE OF FOOD ADDITIVES

Food additives in general

263. (1) Fishery products intended to be placed on the market shall not contain sweeteners, colours or food additives -

(a) not included in these Regulations; and

(b) in excess of the maximum quantity permitted by the regulations in this Part.

(2) In the context of these Regulations, “quantum satis” means that no maximum level is specified.

(3) Colouring matters shall be used according to best manufacturing practices at a level not higher than is necessary to achieve the intended purpose and provided that they do not mislead the consumer.

(4) Maximum levels indicated in these Regulations refer to fishery products as marketed unless otherwise stated.

Sweeteners

264. (1) Within the context of these Regulations “sweeteners” means food additives which are used to impart a sweet taste to processed fishery products.

(2) Only the following sweeteners in the following concentrations may be used in the manufacture of sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs -

(a) E950 Acesulfame K at 200 mg/kg;

(b) E951 Aspartame at 300 mg/kg;

(c) E954 Saccharine and its Na, K and Ca salts at 160 mg/kg; and

(d) E959 Neohesperidine DC at 30 mg/kg.

Colours

265. (1) Within the context of these Regulations "colours" means-

(a) substances which add or restore colour in a food, and include natural constituents of foodstuffs and natural sources which are normally not consumed as foodstuffs as such and not normally used as characteristic ingredients of food; and

(b) preparations obtained from foodstuffs and other natural source materials obtained by physical or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents.

(2) The following substances shall not be considered as colours for the purposes of these Regulations-

(a) foodstuffs, whether dried or in concentrated form and flavourings, incorporated during the manufacturing of compound foodstuffs, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect such as paprika, turmeric and saffron; or

(b) colours used for the colouring of the inedible external parts of foodstuffs.

(3) The colour, E160 b Annatto, Bixin, Norbixin may be used at 10 mg/kg in smoked fishery products.

(4) The following processed fishery products-

(a) fish paste and crustacean paste;

(b) precooked crustaceans;

(c) salmon substitutes;

(d) surimi;

(e) fish roe;

(f) smoked fish;

may be used at quantum under the following colours-

(i) E101 Riboflavin or Riboflavin-5'- phosphate,

(ii) E140 Chlorophylls and chlorophyllins,

(iii) E141 Copper complexes of chlorophylls and chlorophyllins,

(iv) E150a Plain caramel,

(v) E150b Caustic sulphite caramel,

(vi) E150c Ammonia caramel,

(vii) E150d Sulphite ammonia caramel,

(viii) E153 Vegetable carbon,

(ix) E160a Carotenes,

(x) E160c Paprika extract, capsanthin, capsorubin,

(xi) E162 Beetroot red, betanin,

(xii) E163 Anthocyanins,

(xiii) E170 Calcium carbonate,

(xiv) E171 Titanium dioxide, or

(xv) E172 Iron oxides and hydroxides.

(5) The following colours-

(a) E100 Curcumin;

(b) E102 Tartrazine;

(c) E104 Quinoline Yellow;

(d) E110 Sunset Yellow FCF;
Orange Yellow S;

(e) E120 Cochineal, Carminic acid, Carmines;

(f) E122 Azorubine, Carmoisine;

(g) E124 Ponceau 4R, Cochneal Red A;

(h) E129 Allura Red AC;

(i) E131 Patent Blue V;

(j) E132 Indigotine, Indigo carmine;

(k) E133 Brilliant Blue FCF;

(l) E142 Green S;

(m) E151 Brillant Black BN, Black PN;

(n) E155 Brown HT;

(o) E160d Lycopene;

(p) E160c Beta-apo-8'-carotenal (C30);

(q) E160f Ethyl ester of Beta-apo-8'-carotenic acid (C30);

(r) E161b Lutein;

may be used individually or in combination in-

(i) fish paste and crustacean paste up to the maximum level of 100 mg/kg,

(ii) precooked crustaceans up to the maximum level of 250 mg/kg,

(iii) salmon substitutes up to the maximum level of 500 mg/kg,

(iv) surimi up to the maximum level of 500 mg/kg,

(v) fish roe up to the maximum level of 300 mg/kg, or

(vi) smoked fish up to the maximum level of 100 mg/kg.

Food additives other than colours and sweeteners

266. (1) Food additives other than colours and sweeteners within the context of these Regulations include-

(a) "preservatives" which are substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by micro-organisms;

(b) “antioxidants” which are substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes;

(c) “carriers”, including carrier solvents, which are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive without altering its technological function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;

(d) “acids” which are substances which increase the acidity of a foodstuff or impart a sour taste to it;

(e) “acidity regulators” which are substances which alter or control the acidity or alkalinity of a foodstuff;

(f) “anti-caking agents” which are substances which reduce the tendency of individual particles of a foodstuff to adhere to one another;

(g) “anti-foaming agents” which are substances which prevent or reduce foaming;

(h) “bulking agents” which are substances which contribute to the volume of a foodstuff with-out contributing significantly to its available energy value;

(i) “emulsifiers” which are substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff;

(j) “emulsifying salts” which are substances which convert proteins contained in cheese into a dispersed form and thereby bring about homogenous distribution of fat and other components;

(k) “firming agents” which are substances which make or keep tissues of fruit or vegetables firm or crisps, or interact with gelling agents to produce or strengthen a gel;

(l) “flavour enhancers” which are substances which enhance the existing taste or odour of a foodstuff;

(m) “foaming agents” which are substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff;

(n) “gelling agents” which are substances which give a foodstuff texture through formation of a gel;

(o) “glazing agents” (including lubricants) which are substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating;

(p) “Humectants” which are substances which prevent foodstuffs from drying out by counteracting the effect of an atmosphere having a low degree of humidity, or promote the dissolution of a powder in an aqueous medium;

(q) “Modified starches” which are substances obtained by one or more chemical treatments of edible starches, which may have under-gone a physical or enzymatic treatment, and may be acid or alkali thinned or bleached;

(r) “packaging gases” which are gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container;

(s) “propellants” which are gases other than air which expel a foodstuff from a container;

(t) “raising agents” which are substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter;

(u) “sequestrants ” which are substances which form chemical complexes with metallicions;

(v) “stabilizers” which are substances which make it possible to maintain the physico-

chemical state of a foodstuff; stabilizers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a food, substances which stabilize, retain or intensify an existing colour of a foodstuff; and

(w) ”thickeners” which are substances that increase the viscosity of a foodstuff.

(2) For the purpose of these Regulations, the following are not considered as food additives-

(a) substances used for treatment of potable water;

(b) products containing pectin and derived from dried apple pomace or peel of citrus fruits, or from a mixture of both, by the action of dilute acid followed by partial neutralisation with sodium or potassium salts (“liquid pectin”);

(c) chewing gum bases;

(d) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolitic enzymes;

(e) ammonium chloride;

(f) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten;

(g) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts and having no additive function;

(h) caseinates and casein; and

(i) inulin.

(3) The presence of a food additive is permissible -

(a) in a compound fish foodstuff to the extent to which the food additive is permitted in one of the ingredients of the compound fish foodstuff;

(b) in a foodstuff where a flavouring has been

added to the extent to which the food additive is permitted in the flavouring and has been carried over to the foodstuff via the flavouring, provided the food additive has no technological function in the final foodstuffs; and

(c) if the foodstuff is destined to be used solely in the preparation of a compound fish foodstuff.

(2) The level of additives in flavourings shall be limited to the minimum necessary to guarantee the safety and quality of flavourings and to facilitate their storage.

(3) The presence of additives in flavourings shall not mislead consumers or present a hazard to their health.

(4) If the presence of an additive in a foodstuff as a consequence of adding flavourings has a technological function in the foodstuff, it shall be considered as an additive of the foodstuff and not as an additive of the flavouring.

(5) In processed fishery products the following food additives may be used at quantum satis-

(a) E170 Calcium carbonate such as calcium carbonates or calcium hydrogen carbonate;

(b) E260 Acetic acid;

(c) E261 Potassium acetate;

(d) E262 Sodium acetates such as

(i) Sodium acetate, or

(ii) Sodium hydrogen acetate (diace (tate);

(e) E263 Calcium acetate;

(f) E270 Lactic acid;

(g) E290 Carbon dioxide;

(h) E296 Malic acid;

(i) E300 Ascorbic acid;

(j) E301 Sodium ascorbate;

(k) E302 Calcium ascorbate;

(l) E304 Fatty acid esters of ascorbic acid such as-

(i) Ascorbyl palitate, or

(ii) Ascorbyl stearate;

(m) E306 Tocopherol-rich extract;

(n E307 Alpha-tocopherol;

(o) E308 Gamma-tocopherol;

(p) E309 Delta-tocopherol;

(q) E322 Lecithins;

(r) E325 Sodium lactate;

(s) E326 Potassium lactate;

(t) E327 Calcium lactate;

(u) E330 Citric acid;

(v) E331 Sodium citrates such as

(i) Monosodium citrate,

(ii) Disodium citrate, or

(iii) Trisodium citrate;

(w) E332 Potassium citrates;

(i) Monopotassium citrate, or

(ii) Tripotassium citrate;

(x) E333 Calcium citrates such as-

(i) Monocalcium citrate,

(ii) Dicalcium citrate, or

(iii) Tricalcium citrate;

(y) E334 Tartaric acid;

(z) E335 Sodium tartrates such as-

(i) Monosodium tartrate, or

(ii) Disodium tartrate;

(aa) E336 Potassium tartrates such as

(i) Monopotassium tartrate, or

(ii) Dipotassium tartrate;

(ab) E337 Sodium malates such as

(i) Sodium malate, or

(ii) Sodium hydrogen malate;

(ac) E351 Potassium malate; and

(ad) E352 Calcium malate such as

(i) Calcium malate, or

(ii) Calcium hydrogen malate.

(6) In processed fishery products the following food additives may be used individually or in combination up to a maximum level of 10g/kg-

(a) E620 Glutamic acid;

(b) E621 Monosodium glutamate;

(c) E622 Monopotassium glutamate;

(d) E623 Calcium diglutamate;

(e) E624 Monoammonium glutamate; and

(f) E625 Magnesium diglutamate;

(7) The following food additives may be used individually or in combination expressed as guanylic acid up to a maximum level of 500 mg/kg-

(a) E626 Guanylic acid;

(b) E627 Disodium guanylate;

(c) E628 Dipotassium guanylate;

(d) E629 Calcium guanylate;

(e) E630 Inosinic acid;

(f) E631 Disodium inosinate;

(g) E632 Dipotassium inosinate;

(h) E633 Calcium mesinate;

(i) E634 Calcium 5'-ribonucleotides; and

(j) E635 Disodium 5'-ribonucleotides.

(8) In raw or prepared fishery products, the following food additives may be used at quantum satis-

(a) E290 Carbon dioxide;

(b) E938 Argon;

(c) E939 Helium;

(d) E941 Nitrogen;

(e) E948 Oxygen;

(f) E331 Sodium citrates;

(g) E332 Potassium citrates;

(h) E333 Calcium citrates;

(i) E420 SorbitolorSorbitol syrup;

(j) E421 Mannitol;

(k) E953 Isomalt;

(l) E965 MaltiolorMaltiol syrup;

(m) E966 Lactitol; and

(n) E967 Xylitol.

(9) In frozen, raw, prepared or processed fish, crustaceans, molluscs and cephalopods, the following food additives may be used at quantum satis-

(a) E420 SorbitolorSorbitol syrup;

(b) E421 Mannitol;

(c) E953 Isomalt such as

(i) Maltitol,or

(ii) Maltitol syrup;

(d) E966 Lactitol; and

(e) E967 Xylitol.

Preservatives

267. (1) The following groups of preservatives mentioned in this regulation can be used to prolong the shelf-life of fishery products-

(a) sorbates such as-

(i) E200 Sorbic acid,

(ii) E202 Potassium sorbate, or

(iii) E203 Calcium sorbate;

(b) benzoate such as-

(i) E210 Benzoic acid,

(ii) E211 Sodium benzoate,

(iii) E212 Potassium benzoate, or

(iv) E213 Calcium benzoate.

(2) The presenatives mentioned in sub-regulation (1) may be used individually or in combination in -

(a) semi preserved fish products up to a maximum level of 2000 mg/kg or mg/l;

(b) salted dried fish up to a maximum level of 200 mg/kg;

(c) cooked shrimps up to a maximum level of 2000 mg/kg;

(d) cooked Crangon crangon and Crangon vulgaris up to a maximum level of 6000 mg/kg; or

(e) cooked crayfish tails up to a maximum level of 2000mg/kg.

(3) The levels of all substances mentioned above are expressed as the free acid.

(4) The following preservative food additives described as sulphur dioxide and sulphites -

(a) E220 Sulphur dioxide;
(b) E221 Sodium sulphite;
(c) E222 Sodium hydrogen sulphite;
(d) E223 Sodium metabisulphite;
(e) E224 Potassium metabisulphite;
(f) E226 Calcium sulphite;
(g) E277 Calcium hydrogen sulphite; and
(h) E228 Potassium hydrogen sulphite;

may be used individually or in combination in-

(i) fresh and frozen crustaceans and cephalopods up to a maximum level of 150 mg/kg in the edible parts,

(ii) crustaceans, family of penaeidae, solenoceridae, aristeidae-

(aa) up to 80 units/kg, up to a maximum level of 150mg/kg in the edible parts,

(ab) between 80 and 120 units/kg, up to a maximum level of 200mg/kg in the edible parts,

(ac) over 120units/kg, up to a maximum level of 300mg/kg in the edible parts, or

(ad) cooked up to a maximum level of 50mg/kg in the edible parts.

(4) Maximum levels are expressed as SO_2 in mg/kg and relate to the total quantity available from all sources and SO_2 content of not more than 10 mg/kg is not considered to be present.

(5) The preservative food additives, E251 Sodiumnitrate and E252 Potassiumnitrate may be used at 200 mg/kg in pickled herring and sprat whereby residual amount, nitrite formed from nitrate included, is expressed as $NaNO_2$.

(6) The preservative food additive E284 Boric acid and E285 Sodium tetraborate (borax) may be used at 4 g/kg, expressed as boric acid in Sturgeon's eggs (caviar).

Additives necessary for the storage of and use of flavourings

268. (1) The presence of an additive in a foodstuff due to the use of a flavouring, is generally low and the additive does not have a technological function in the foodstuff.

(2) If under certain circumstances, the additive does have a technological function in the compound foodstuff, it shall be considered as an additive of the compound foodstuff and not as an additive of the flavouring and the relevant rules relating to the additive in the particular foodstuff shall apply.

(3) The following additives can be added to flavour-rings-

(a) sorbates, benzoates and phydroxy ben-zoates which may be used individually or in combination in flavourings up to the maximum level of 1500mg/kg;

(b) E310 (propylgallate);

(c) E311 (octylgallate);

(d) E312 (dodecylgallate);

(e) E320 (butylated);

(f) hydroxyanisole (BHA) which may be used in flavourings other than essential oils up to a maximum of 100mg/kg (gallates individually

or in combination) or 200mg/kg (BHA);

(g) E338 to E452 which may be used in flavourings up to a maximum of 40g/kg;

(h) E416 which may be used in flavourings up to a maximum of 50g/kg;

(i) E432 to E436 (polysorbates) which may be used in flavourings, except liquid smoke flavourings and flavourings based on spice and oleoresins up to a maximum of 10g/kg;

(j) E432 to 436 (polysorbates) which may be used to foodstuffs containing liquid smoke flavourings and flavourings based on spice oleoresins up to a maximum of 1g/kg;

(k) E551, silicon dioxide which may be used in flavourings up to a maximum of 50g/kg;

(l) E900, dimethylpoly-siloxane which may be used in flavourings up to a maximum of 10mg/kg;

(m) E1505 triethyl citrate;

(n) E1517 glyceryl diacetate (diacetin);

(o) E1518 glyceryl triacetate (triacetin); and

(p) E1520 propane 1,2 diol (propylene glycol),

up to a maximum of 3g/kg from all sources in foodstuffs as consumed or as reconstituted according to the instructions of the manufacturer individually or in combination.

Antioxidants

269. (1) The antioxidants E315 Erythorbic acid and E316 Sodium erythorbate may be used at 1500 mg/kg, expressed as erythorbic acid, in-

(a) preserved and semi-preserved fish products; and

(b) frozen fish with red skin.

(2) The antioxidant E385 Calcium disodium ethylene diamine tetra-acetate (Calcium disodium EDTA) may be used up to a maximum level of 75 mg/kg in-

(a) canned and bottled crustaceans and molluscs; and

(b) canned and bottled fish.

Polyphos-phates

270. The following polyphosphates (E452)-

(a) sodium polyphosphate;

(b) potassium polyphosphate;

(c) sodium calcium polyphosphate;

(d) calcium polyphosphates;

may be used in –

(i)surimi up to a maximum level of 1g/kg,

(ii)fish and crustacean paste up to a maximum level of 5g/kg,

(iii)frozen fillets of unprocessed fishery products up to a maximum level of 5g/kg,

(iv) frozen crustacean products up to a maximum level of 5g/kg.

PART XIV - PRODUCT SAFETY ASSURANCE SYSTEM FOR PREPARATION AND PROCESSING OF FISHERY PRODUCTS

Product safety assurance system

271. (1) The implementation of a Product Safety Assurance System for the preparation and processing of fishery products means implementing all those actions aimed at ensuring and demonstrating that a fishery product satisfies the

product safety requirements of these Regulations.

(2) A Product Safety Assurance Programme (HACCP – Hazard Analysis Critical Control Points) shall be implemented if the hazard analysis reveals that processors have food safety hazards that they might control.

The seven principles

272. (1) A model of a logical approach shall be followed of which the following principles form the essential components -

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

(b) identification of critical points;

(c) establishment of critical limits for each critical point;

(d) establishment of monitoring and checking procedures;

(e) establishment of corrective action to be taken when necessary;

(f) establishment of verification and review procedures; and

(g) establishment of documentation concerning all procedures and records.

(2) The model or the principles on which it is based should be issued with the flexibility appropriate to each situation.

Hazards

273. (1) A hazard is a biological, chemical or physical property that may cause a food to be unsafe for consumption.

(2) A direct hazard causes a problem by the consumption of the concerned fishery product

(3) An indirect hazard causes a problem by transferring pathogens or other hazards to products which are not cooked before consumption (cross contamination) in working areas or kitchen during handling and preparation.

(4) Hazards may be-

(a) biological hazards such as pathogenic micro-

organisms (e.g. bacteria, viruses) and parasites;

(b) chemical hazards such as-

(i) natural toxins,

(ii) chemicals,

(iii) pesticides,

(iv) drug residues,

(v) unapproved food and colour additives, and

(vi) decomposition (safety only, e.g. histamine);

(c) physical hazards such as metal and glass,

(6) Hazards may be-

(a) unacceptable contamination (or recontamination) of a biological (micro-organisms, parasites), chemical or physical nature of raw, intermediate or final products;

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

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

(6) Species related hazards are potential hazards that are associated with specific species of fishery products.

(7) Species related hazards include-

(a) chemical contamination;

(b) heavy metals (Mercury,Cadmium, Lead); or

(c) natural toxins such as-

(i) paralytic Shellfish Poisoning (PSP),

(ii) neurotoxic Shellfish Poisoning (NSP),

(iii) diarrheic Shellfish Poisoning (DSP),

(iv) amnesic Shellfish Poisoning (ASP),

(v) ciguatera Food Poisoning (CFP),

(vi) clupeotoxin,

(vii) chondrichthytoxin,

(viii) tetrodotoxin (Puffer fish), and

(ix) gempylotoxin (Escolar).

(8) Primary production related hazards are-

(a) parasites (safety hazard);

(b) aquaculture drugs; or

(c) histamine.

(9) Process related hazards are potential hazards that are associated with inadequate food handling, preparation or processing.

(10) Process related hazards include-

(a) inadequate drying, pathogen growth, toxin formation as a result of inadequate salt, sugar, or nitrite concentration;

(b) pathogen survival through cooking;

(c) cross-contamination (pathogens);

(d) temperature abuse during processing of cooked products and raw molluscan shellfish and pathogen growth;

(e) temperature abuse during processing of non-cooked products;

(f) microbiological pathogen growth in batter;

(g) pathogen survival through pasteurisation;

(h) recontamination after pasteurization by pathogens;

(i) temperature abuse during final cooling and

pathogen growth;

(j) temperature abuse during finished product storage and pathogen growth;

(k) temperature abuse during distribution and pathogen growth; and

(l) food and colour additives.

The seven (7) preliminary steps

274. (1) The following preliminary steps shall be taken to consolidate the implementation of the HACCP plan -

(a) preliminary step 1 which defines the terms of reference of the plan by asking the following questions-

(i) will the study cover a whole process or one specific part,

(ii) will the study cover one product or a group of products,

(iii) will all types of hazard categories initially (microbiological, chemical and physical) be covered,

(iv) should the HACCP study stop at the end of the production line or continue through distribution, retail and consumer handling;

(b) preliminary step 2 which involves the selection and assembly of a multidisciplinary team under the following conditions-

(i) the team shall include the whole range of specific knowledge and expertise appropriate to the product under consideration, its production (manufacture, storage and distribution), consumption and the associated potential hazards,

(ii) where necessary, the team will be assisted by specialists who will help it to solve difficulties relating to assessment control of critical points,

(iii) the team may consist of -

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

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

(ac) a technician who has a working knowledge of the hygiene and operation of the process plant and equipment, or

(ad) any other person with specialist knowledge of microbiology, hygiene and food technology;

(c) preliminary step 3 which describes the food distribution and storage in terms of –

(i) composition (raw material ingredients, additives),

(ii) structure and physicochemical characteristics (solid, liquid, gel emulsion, pH, Aw),

(iii) processing (heating, freezing, drying, salting, smoking, and to what extent),

(iv) packaging (hermetic, vacuum, modified atmosphere),

(v) storage and distribution conditions,

(vi) required shelf life (sell by date and best before date),

(vii) instruction for use, and

(viii) any microbiological or chemical criteria applicable;

(d) preliminary step 4 which identifies the intended use of the product;

(e) preliminary step 5 under which the multidis-

ciplinary team shall define the normal or expected consumer target groups for which the product is intended, particularly the suitability of the product for particular groups of consumers such as institutional caterers, travellers or vulnerable groups of the population;

(f) preliminary step 6 which involves the development of a flow diagram (description of manufacturing process) which incurporates all steps involved in the process, including delays during or between steps, from receiving the raw materials to placing the end product on the market;

(g) the types of data included in the flow diagram under paragraph (f) include -

(i) plan of working premises and adjacent or adjoining premises,

(ii) equipment layout and characteristics,

(iii) sequence of all process steps (including the incorporation of raw materials, ingredients or additives and delays during or between steps),

(iv) technical parameters of operations (in particular time and temperature including delays),

(v) flow of products (including potential cross-contamination),

(vi) segregation of clean and dirty areas (or high/low risk areas), and

(vii) personnel routes;

(h) preliminary step 7 which involves the verifycation and confirmation of the flow diagram on-site, by the multidisciplinary team.

The seven hazard analysis steps

Schudele 8

275. (1) The Hazard analysis steps shall include –

(a) the Setting up of a hazard analysis worksheet (column 1 – column 6) and recording of each processing step such as-

(i) column 1: processing step,

(ii) column 2: potential hazard at this step,

(iii) column 3: significance of the potential food safety hazard (risk assessment),

(iv) column 4: justification of this decision,

(v) column 5: preventive (control) measures, and

(vi) column 6: is this step a critical control point (Yes or No).

(2) The second step (column 2) involves the identification of the potential species related hazards which includes listing all potential species related biological, chemical or physical hazards that may be reasonably expected to occur.

(3) The third step (column 3) involves identification of the potential process related hazards that may be reasonably expected to occur at each process step.

(4) The fourth step requires an understanding of the potential hazards by using two essential ingredients-

(a) an appreciation of the hazard (pathogenic organism or any disease agent that could harm the consumer); and

(b) a detailed understanding of how these hazard could arise.

(5) The fifth step involves determining if the potential hazard is significant (risk assessment) and recording the information in column 3 and 4.

(6) The sixth step (column 5) involves identifying preventive measures, if any, which can be applied for each hazard-

(a) preventive measures are those actions and activities that can be used to prevent hazards, eliminate, or reduce their impact or occurrence to acceptable levels;

(b) more than one preventive measure may be required to control an identified hazard and more than one hazard may be controlled by one control measure. (pasteurisation or

controlled heat treatment may provide sufficient assurance of reduction of the level of both Salmonella and Listeria); or

(c) preventive measures need to be supported by detailed procedures and specifications to ensure their effective implementation. (precise heat treatment specifications, maximum concentrations of preservatives used in compliance with the applicable legislation on additives);

(7) The seventh step (column 6) involves identification of the critical control point (CCP)-

(a) a critical control point may be a location, a point, a procedure or processing step in the process flow where, by taking preventive measures, effective control can be installed and a food safety hazard can be prevented, eliminated or reduced to an acceptable level;

(b) the identification of a critical point for the control of a hazard requires a logical approach, and such approach may be facilitated by the use of the decision tree set forth in Schedule 9 of these Regulations (other methods can be used by the team, according to their knowledge and experience);

(c) for the application of the decision tree, each process step identified in the flow diagram shall be considered in sequence and at each step, the decision tree must be applied to each hazard that may be reasonably expected to occur or be introduced and each control measure identified;

(d) application of the decision tree shall be flexible and requires common sense, having consideration for the whole manufacturing process in order to avoid, whenever possible, unnecessary critical points; and

(e) examples of critical control points include a specific heat process, chilling, specific sanitation procedures, and adjustment of food to a given pH or salt content.

Actions to be taken after

276. (1) If no critical control points are detected or identified in Hazard Analysis Step seven, HACCP

Hazard analysis Step 7

analysis is finished and there is no need to implement a HACCP Plan.

(2) The identification of critical control points shall ensure that -

(a) appropriate preventive measures are effectively designed and implemented;

(b) if a hazard has been identified at a step where control is necessary for product safety and no control measure exists at that step or at any other, then the product or process should be modified at that step, or a later stage to include a control measure; and

(c) an appropriate monitoring and checking system is established at each critical point to ensure effective control and proceed to the activities specified in the HACCP Plan steps.

The 7 HACCP plan form steps

277. The HACCP plan has the following steps-

(1) setting up the HACCP plan form with the following columns-

Schedule 10

(a) Critical Control Point (CCP) = Processing step (column 1);

(b) significant hazards (column 2);

(c) parameter and Critical Limits for each preventive measure (column 3);

(Monitoring) -

(d) what (column 4);

(e) how (column 5);

(f) frequency : when (column 6);

(g) who (column 7);

(h) corrective actions (column 8);

(i) records (column 9); and

(j) verification (column 10).

(2) The implementation of HACCP plan form

(column 1) shall -

(a) find the processing steps, which we have identified as CCP in column 6 of the Hazard Analysis Worksheet and record the names of these processing steps in column 1 of the HACCP plan form;

(b) enter the significant hazard(s) for which these processing steps were identified as CCP's in column 2 of the HACCP plan form, which information can be found in column 2 of the Hazard Analysis Worksheet; and

(c) enter the preventive measures in column 3 of the HACCP plan form.

(3) Set up the critical factors (parameters) and critical limits for each preventive measure associated with each CCP (principle 3) under the following conditions -

(a) each control measure associated with critical control points shall give rise to the specification of critical limits;

(b) those critical limits correspond to the extreme values acceptable with regard to product safety and they separate acceptability from unacceptability;

(c) they are set for observable or measurable parameters that can readily demonstrate that the critical point is under control;

(d) they should be based on substantiated evidence that chosen values will result in process control;

(e) examples of such parameters include temperature, time, pH, moisture level, additive, preservative or salt level, sensory parameters such as visual appearance or texture;

(f) in some cases, to reduce the risk of exceeding a critical limit due to process variations, it may be necessary to specify more stringent levels (target levels) to assure that critical limits are observed; and

(g) critical limits may be derived from a variety of

sources, and when not taken from regulatory standards (e.g. frozen storage temperature) or from existing and validated guides of best practices, the team shall ascertain their validity relative to the control of identified hazard and critical points.

(4) Establishment of a monitoring procedure under the following conditions (principle 4)-

(a) an essential part of own-checks is a programme of observations or measurements performed at each critical point to ensure compliance with specified critical limits;

(b) observations or measurements shall be able to detect loss of control at critical points and provide information in time for corrective action to be taken;

(c) observations or measurements shall be made continuously or periodically and when they are periodic in nature, it is necessary to establish a frequency of observations or measurements, which provides reliable information; and

(d) the programme of observations or measurements should properly identify for each critical point -

(i) what will be monitored (column 4),

(ii) how monitoring and checking is perform-ed (column 5),

(iii) when monitoring and checking is perform-ed, and (column 6), and

(iv) who is to perform monitoring and checking (column 7).

(5) Establishment of a corrective action plan (principle 5) in case a deviation from a critical limit occurs-

(a) observations or measurements may indicate-

(i) that the parameter monitored tends to deviate from its specified critical limits, indicating a trend toward loss of control,

and so Appropriate corrective action to maintain control shall be taken before the occurrence of a hazard, or

(ii) that the parameter monitored has deviated from its specified critical limits, indicating a loss of control thereby making it necessary to take appropriate corrective action to regain control;

(b) corrective action has to be planned in advance by the multidisciplinary team, for each critical point so that it can be taken without hesitation when a deviation is observed;

(c) such corrective action shall include-

(i) proper identification of the person responsible for the implementation of the corrective action,

(ii) description of means and action required to correct the observed deviation,

(iii) action to be taken with regard to products that have been manufactured during the period when the process was out of control, or

(iv) written record of measures taken;

(d) corrective actions shall be entered in column 8 of the HACCP plan form.

(6) Establishment of record keeping (principle 6)-

(a) the approved HACCP plan and associated documentation and records shall be in file and available for inspection by regulatory agencies;

(b) three kinds of records are kept as part of the HACCP system-

(i) records of CCP monitoring,

(ii) records of corrective actions, and

(iii) records of verification activities;

(c) type of records shall be entered in column 9 of the HACCP plan form.

(7) HACCP own checks system verification is necessary to ensure that the system is working effectively-

(a) usable methods may include in particular-

(i) random sampling and analysis,

(ii) reinforce-ed analysis or tests at select-ed critical points, and

(iii) intensified analysis of intermediate or final products, surveys on actual conditions during storage, distribution and sale and on actual use of the product;

(b) verification procedures may include-

(i) inspection of operations,

(ii) validation of critical limits,

(iii) review of deviations,

(iv) corrective action and measures taken with regard to the product, and

(v) audits of the HACCP own checks system and its records;

(c) verification shall provide for confirmation of the suitability of the own check system established and ensure, with an appropriate frequency, that the provisions laid down are still being properly applied;

(d) any change to the HACCP auto-control system arising shall be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is available;

(e) where criteria are specified in regulations, such criteria are to be used as reference values for the verification process; or

(f) verification shall be entered in column 10 of

the HACCP plan form.

Review of the HACCP own checks system

278. (1) A review of the HACCP plan is necessary to determine whether the plan is still appropriate and valid in case of change and is additional to the process of verification.

(2) When necessary such a review must result in the amendment of the provision stipulated.

(3) A HACCP review is undertaken in when a change occurs in the following situations-

(a) factory lay-out and environment;

(b) change in raw material or finished product;

(c) processing system and conditions (packaging, storage or distribution conditions,);

(d) process equipment;

(e) cleaning and disinfecting programme; and

(f) health or spoilage risk associated with the product.

(4) Each version of the HACCP plan shall be dated and signed by the most senior person in an establishment and approved by the head of the Competent Authority.

(5) Once the HACCP plan is signed, the operators of an establishment commit themselves to implement the plan and take the consequences of the implementation.

Documentation and records

279. (1) All procedures, instructions, specifications control and check activities shall be thoroughly documented.

(2) The operators of an establishment shall take all necessary measures to comply with these regulations.

(3) The operators of an establishment shall keep a record of each lot of fish processed and a register of the processing carried out.

(4) The operators of an establishment shall keep a written record relating to the auto control systems and the checks (HACCP) laid down in these

Regulations, with a view to submitting them to the Competent Authority.

(5) Records shall show processing details including records of quantities, and depending on the type of process employed-

(a) processing temperatures and time;

(b) salt content;

(c) pH;

(d) water content; and

(e) details of sampling and other records relevant to show that fishery products have been processed in accordance with this regulation.

(6) Records of the different checks and tests shall be kept for the expected storage life of the products and shall, for a period of two years be available to the inspection service.

(7) For products, which are preserved for a limited period by a treatment such as salting, drying or marinating, the appropriate conditions for storage must be clearly marked on the packaging.

Training

280. (1) Food business operators shall ensure-

(a) that food handlers and staff are supervised and instructed;

(b) 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 chapter, Best Manufacturing 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; and

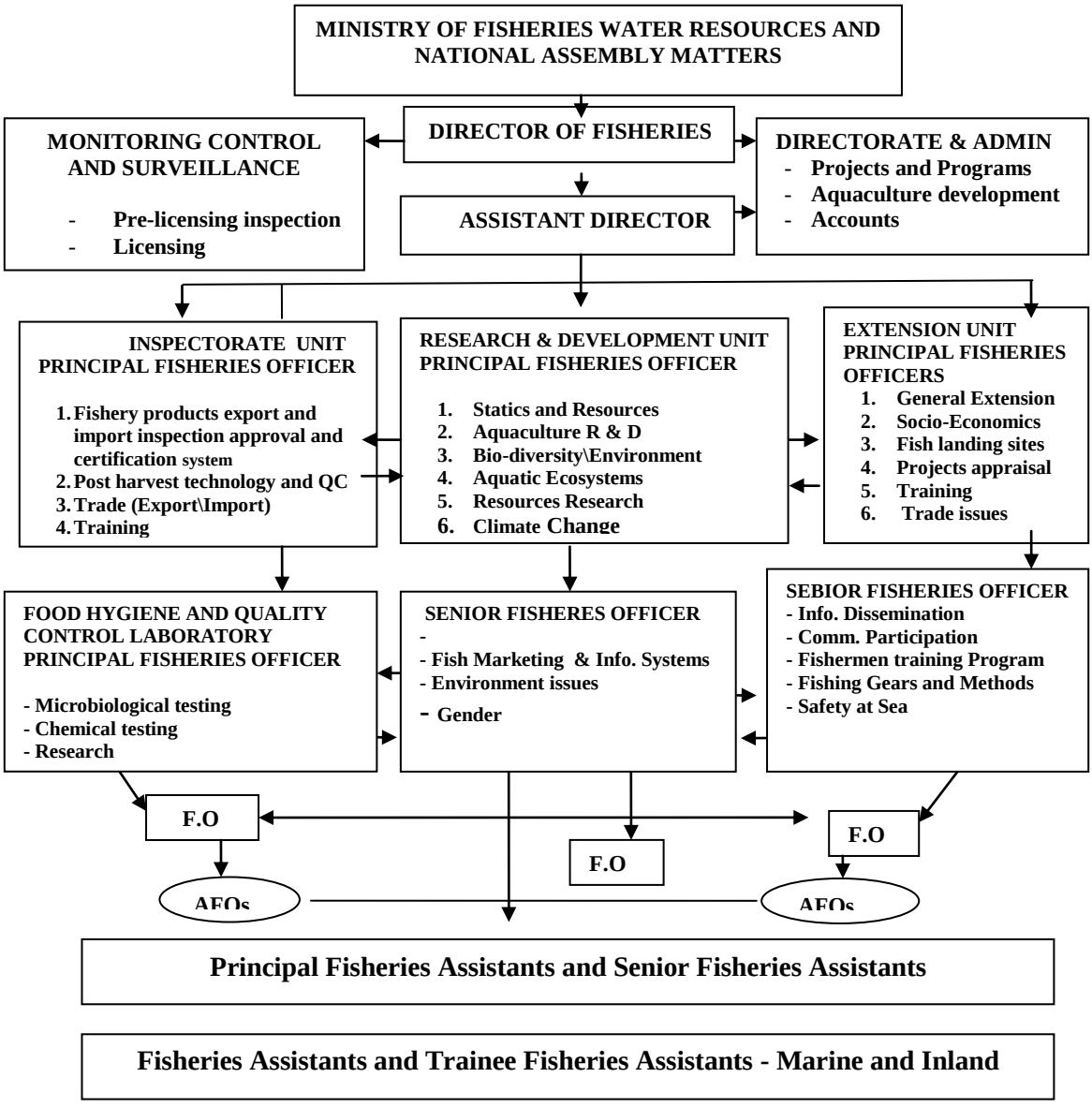
(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

Schedule 1 (regulation 4)

ORGANISATIONAL CHART OF THE COMPETENT AUTHORITY FOR THE GAMBIA

THE COMPETENT AUTHORITY

This Schedule lays down the organisational chart of the Fisheries Department, under the Ministry of Fisheries, Water Resources and National Assembly Matters, being the Competent Authority.



Schedule 2 (regulation 33)

Export Health Certificate **Regulation 12**

MODEL HEALTH CERTIFICATE FOR IMPORT / EXPORT OF FISHERY PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Country : THE GAMBIA Veterinary certificate

Part I : details of dispatched consignment

1.1 consigor Name: **Adress.** ***Tél* No**			1.2 Certificate reference number:	1.2.a.
			1.3 Central Competent Authority: **Ministry of Agriculture& Natural Resources-Fisheries Department**	
			1.4 Local Competent Authority: **N/A**	
1.2 consignee *Name* Adres**s** **Tel No**			*1.6.*	
1.7 Country of origin **THE GAMBIA**	ISO Code **GM**	*1.*8 Region of origin **EC ATLANTIC**	Code **FA034**	*1.9* Country of destination	ISO Code	*1.10.*
1.11 Place of 'origin Name Approval number Address:				*1.12.*		
1.13 Place of loading				1.14 Date of departure		
1.15 Means of transport Aeroplane ☐ Ship ☐ Railway Wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references:				1.16 Entry BIP in (country of Destination) 1.17.		
1.18 Description of commodity/:.				1.19 Commodity code (SH code) 1.20 Quantity		
1.21 Temperature of product Ambient ☐ Chilled ☐ Frozen ☐				1.22 Number of packages		
1.23 Identification of container number Cont no. Seal number				1.24 Type of packaging		
1.25 Commodities certified for: Human consumption ☐						
1.26.				1.27 For import or admission into: ☐		

1.28 Identification of the commodities WILD ORIGIN

Approval number of establishments

Species Scientific name	Nature of commodity	Treatment type	Manufacturing plant	Number of packages	Net weight

COUNTRY : THE GAMBIA

Certificate reference number:

Species Scientific name	Number of packages	Net weight	Manufacturing plant	Nature of commodity	Treatment type

COUNTRY : THE GAMBIA **Fishery products**

Partie II : Certification

II. Health attestation	I.a. Certificate Reference number	II.b

II.1 (1) Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the fishery products described above were produced in accordance with those requirements and those in the The Gambia Fishery Products Regulations 2011, in particular that they:

- come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004; and those in the The Gambia Fishery Products Regulations 2011,
- have been caught and handled on board vessels, landed, handled and where appropriate prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters I to IV of Annex III to Regulation (EC) No 853/2004; and those in the The Gambia Fishery Products Regulations 2011,
- satisfy the health standards laid down in Section VIII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs; ; and those in the The Gambia Fishery Products Regulations 2011
- have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII of Annex III to Regulation (EC) No 853/2004; ; and those in the The Gambia Fishery Products Regulations 2011
- have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004; ; and those in the The Gambia Fishery Products Regulations 2011
- the guarantees covering live animals and products thereof, if from aquaculture origin, provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled; and those in the The Gambia Fishery Products Regulations 2011 and
- have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004.

II.2 (2)(4)Animal health attestation for fish and crustaceans of aquaculture origin

II.2.1 (3)(4)[Requirements for susceptible species to Epizootic ulcerative syndrome (EUS), Epizootic haematopoietic necrosis (EHN), Taura syndrome and Yellowhead disease

I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:

(5) originate from a country/territory, zone or compartment declared free from (4)[EUS] (4)[EHN (4)[Taura syndrome] (4)[Yellowhead disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,

(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the official services,

(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and

(iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases]

II.2.2 (3)(4)[Requirements for species susceptible to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV) and White spot disease intended for a Member State, zone or compartment declared disease free or subject to a surveillance or eradication programme for the relevant disease

I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:

(6) originate from a country/territory, zone or compartment declared free from (4)[VHS] (4)[IHN] (4)[ISA] (4)[KHV] (4)[White spot disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,

(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,

(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and

(iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases]

II.2.3 Transport and labelling requirements

I, the undersigned official inspector, hereby certify that:

II.2.3.1 the aquaculture animals referred to above are placed under conditions, including with a water quality, that do not alter their health status;

II.2.3.2 the transport container or well boat prior to loading is clean and disinfected or previously unused; and

II.2.3.3 the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.7 to I.11 of Part I of this certificate, and the following statement:

"(4)[Fish](4)[Crustaceans] intended for human consumption in the Community".

COUNTRY : THE GAMBIA

II. Health attestation	I.a. Certificate Reference number	II.b

Notes

Part I :

- Box reference I.8: Region of origin: For frozen or processed bivalve molluscs, indicate the production area.
- Box reference I.11: Place of origin: name and address of the dispatch establishment.
- Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in the event of unloading and reloading.
- Box reference I.19: use the appropriate HS codes: 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, 05.11.91, 15.04, 15.18.00, 16.03, 16.04, 16.05.
- Box reference I.23: Identification of container/Seal number: Where there is a serial number of the seal it has to be indicated.
- Box reference I.28: Nature of commodity: Specify whether aquaculture or wild origin.

  Treatment type: Specify whether live, chilled, frozen or processed.

  Manufacturing plant: includes factory vessel, freezer vessel, cold store, processing plant.

Part II :

(1) Part II.1 of this certificate does not apply to countries with special public health certification requirements laid down in equivalence agreements or other Community legislation.

(2) Part II.2 of this certificate does not apply to :

a) non-viable crustaceans, which means crustaceans no longer able to survive as living animals if returned to the environment from which they were obtained,
b) fish which are slaughtered and eviscerated before dispatch,
c) aquaculture animals and products thereof, which are placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Regulation (EC) No 853/2004,
d) crustaceans destined for processing establishments authorised in accordance with Article 4(2) of Directive 2006/88/EC, or for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system inactivating the pathogens in question, or where the effluent is subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level,
e) crustaceans which are intended for further processing before human consumption without temporary storage at the place of processing and packed and labelled for that purpose in accordance with Regulation (EC) No 853/2004.

(3) Parts II.2.1 and II.2.2 of this certificate only apply to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Annex IV to Directive 2006/88/EC.

(4) Keep as appropriate.

(5) For consignments of species susceptible to EUS, EHN, Taura syndrome and/or Yellowhead disease this statement must be kept for the consignment to be authorised into any part of the Community.

(6) To be authorised into a Member State, zone or compartment (boxes I.9 and I.10 of Part I of the certificate) declared free from VHS, IHN, ISA, KHV or Whitespot disease or with a surveillance or eradication programme established in accordance with Article 44(1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain species susceptible to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farm and mollusc farming area in the Community are accessible at

http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm

- The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Date:

Name (in capitals letters) qualification and title

Official Stamp

Signature of Official inspector

Schedule 3 (regulations 82 and 211)

This Schedule lays down the microbiological standards applicable to the production of cooked crustaceans and molluscan shellfish provided for in regulations 82 and 211 of these Regulations.

1. Pathogens

Type of pathogen	Standard
Salmonella spp.	Absent in 25 g n = 5 c = 0

(a) Pathogens and toxins which are to be sought according to the risk evaluation, shall not be present in quantities such as to affect the health of consumers.

2. Organisms indicating poor hygiene (shelled or shucked products)

Type of organism	Standard (per g)
Staphylococcus aureus	m = 100 M = 1000 n = 5 c = 2
Thermo tolerant coli form (44° C on solid medium)	m = 10 M = 100 n = 5 c = 2
Escherichia coli (on solid medium)	m = 10 M = 100 n = 5 c = 1

(a) parameters n, m, M and c are defined as follows -

"n" means - number of units comprising the samples;

"m" means - limit below which all results are considered Satisfactory;

"M" means - acceptability limit beyond which the results are considered satisfactory;

"c" means - number of sampling units giving bacterial counts between m and M;

(b) The quality of a batch is considered to be-

(i) satisfactory where all the values observed are 3m or less; and

(ii) acceptable where the values observed are between 3m and 10m (= M) and where c/n is 2/5 or less;

(c) The quality of a batch is considered to be unsatisfactory-

(i) in all cases where the values are above M; and

(ii) where c/n is greater than 2/5;

3. Indicator organisms (Guidelines) -

Type of organism	Standard (per g)
Meso-philic aerobic bacteria (30° C)	
(a) Whole products	m = 10.000 M = 100.000 n = 5 c = 2
(b) Shelled or shucked products with the exception of crab meat	m = 50.000 M = 500.000 n = 5 c = 2
(c) Crab meat	m = 100.000 M = 1.000.000 n = 5 c = 2

These guidelines are to help manufacturers decide whether their perators are operating satisfactorily and to assist them in imple-menting the production monitoring procedures.

SCHEDULE 4 (regulation 54)

This Schedule lays down definitions, methods of sampling, sample preparation and the criteria for methods of analysis for official control of the levels of Lead, Cadmium and Mercury in fishery and aquaculture products provided for in regulation 23 of these Regulations.

CHAPTER I

PART I – DEFINITIONS

(1) In this Part, unless the context otherwise requires -

(a)	"Lot" means	an identifiable quantity of food delivered at one time and determined by the official to have common characteristics such as origin, variety, type of packaging, packer, consignor or markings;
(b)	"Sub-lot" means	designated part of a larger lot to be used to apply the sampling method. (Each sub-lot must be physically separated and identifiable);
(c)	"Incremental sample" means	a quantity of material taken from a single place in a lot or sub-lot;
(d)	"Aggregate sample" means	the combined total of all the incremental samples taken from a lot or sub-lot; and
(e)	"Laboratory sample" means	Sample intended for the laboratory.

(2) In establishing procedures for sample preparation and criteria for methods of analysis-

(a)	"r "means	repeatability, the value below which the absolute difference between two single test results obtained under repeatability conditions (ie. same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95%) and hence $r = 2,8 \times S_r$;
(b)	"S_r" means	Standard deviation calculated from results generated under repeatability conditions.
(c)	"RSD_r" means	relative standard deviation, calculated from results generated under repeatability conditions [(S_r / $\bar{x}$)

× 100], where $\bar{x}$ is the average of results over all laboratories and samples;

(d) "R" means reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); $R = 2,8 \times S_R$;

(e) "S_R" means standard deviation calculated from results under reproducibility conditions;

(f) "RSD_r" means relative standard deviation calculated from results generated under reproducibility conditions [(S_R / $\bar{x}$) x 100];

(g) "HORRAT r" means the observed RSD_r divided by the RSD_r value estimated from the Horwitz equation using the assumption r = 0,66R;and

(h) "HORRAT $_R$": means the observed RSD_R value divided by the RSD_R value calculated from the Horwitz equation ([a]).

PART II - METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF LEAD, CADMIUM AND MERCURY IN FISHERY AND AQUACULTURE PRODUCTS

The Government shall take all necessary measures to ensure that the sampling for the official control of the levels of lead, cadmium and mercury in fishery and aquaculture products is carried out in accordance with the methods described in this part.

1. Personnel

Sampling shall be performed by an authorised qualified person.

2. Material to be sampled

Each lot that is to be examined shall be sampled separately.

3. Precautions to be taken

In the course of sampling and preparation of laboratory samples, precautions shall be taken to avoid any changes that would affect the lead, cadmium and mercury contents, adversely, affect the analytical determination or make the aggregate samples unrepresentative.

4. Incremental samples

As far as possible, incremental samples shall be taken at various places distributed throughout the lot or sub-lot and any departure from this procedure shall be recorded.

5. Preparation of the aggregate sample

The aggregate sample is made up by uniting all incremental samples weighing at least 1 kg unless not practical, (e.g. when a single package has been sampled).

6. Subdivision of aggregate sample into laboratory samples for enforcement, defence and referee purposes

The laboratory samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised aggregate sample and the size of the laboratory samples for enforcement shall be sufficient to allow at least for duplicate analyses.

7. Packaging and transport of aggregate and laboratory samples

(1) Each aggregate and laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage in transit.

(2) All necessary precautions shall be taken to avoid change of composition of the aggregate and laboratory samples that might arise during transportation or storage.

8. Sealing and labelling of aggregate and laboratory samples

(1) Each sample taken for official use shall be sealed at the place of sampling and identified following the national instructions.

(2) A record including the date and place of sampling, together with any additional information likely to be of assistance to the analyst shall be kept for each sampling, so that each lot can be identified unambiguously.

9. Place of sampling

(1) Sampling shall take place at the point where the commodity enters the food chain and a discrete lot becomes identifiable.

(2) The sampling method applied shall ensure that the aggregate sample is representative of the lot that is to be controlled.

10. Number of incremental samples

(1) In the case of liquid products for which a homogeneous distri-bution of the contaminant in question can be assumed within a given lot, it is sufficient to take

one incremental sample per lot which forms the aggregate sample (Reference to the lot number shall be given).

(2) For other products, the minimum number of incremental samples to be taken from the lot shall be as given in Table 1.

(3) The incremental samples shall be of similar weight and any departure from this procedure must be recorded in the record provided for under paragraph 8 of Part II of this Schedule.

Table 1: Minimum number of incremental samples to be taken from the lot.

Weight of lot (kg)	Minimum number of incremental samples to be taken
< 50	3
50 to 500	5
> 500	10

(4) If the lot consists of individual packages, then the number of packages that shall be taken to form the aggregate sample is given in Table 2.

Table 2: Number of packages (incremental samples) which shall be taken to form the aggregate sample if the lot consists of individual packages.

Number of packages or units in the lot	Number of packages or units to be taken
1 to 25	1 package or unit
26 to 100	About 5 %, at least 2 packages or units
> 100	About 5 %, at maximum 10 packages or units

11. Laboratory sample for enforcement

The control laboratory shall analyse the laboratory sample for enforcement at least in two independent analyses, and calculate the mean of the results.

12. Accepted and rejected lot

(1) The lot is accepted if the mean does not exceed the respect-tive maximum levels laid down in regulation 54 of these Regula-tions taking into account the expanded measurement, uncertainty and correction for recovery.

(2) The lot is rejected if the mean exceeds the respective maxi-mum level beyond reasonable doubt, taking into account the expanded measurement, uncertainty and correction for recovery and conforms to the respective maximum level as laid down in regulation 54 of these Regulations.

(3) The present interpretation rules are applicable for the analy-tical result

obtained on the sample for official control.

(4) In case of analysis for defence or referee purposes, the national rules apply.

PART III - SAMPLE PREPARATION AND CRITERIA FOR METHODS OF ANALYSIS USED IN OFFICIAL CONTROL OF THE LEVELS OF LEAD, CADMIUM AND MERCURY IN FISHERY AND AQUACULTURE PRODUCTS.

13. Duty of the Government

The Government shall take all necessary measures for sample preparation and methods of analyses used for the official control of the levels of lead, cadmium and mercury in fishery and aquaculture products to comply with the criteria described in this part of this Schedule.

14. Sample preparation procedures

The specific sample preparation procedures described in the draft CEN Standard 'Foodstuffs — Determination of trace elements — Performance criteria and general consideration' may be used for the products under consideration although others may be equally valid.

15. Specific sample preparation for bivalve molluscs, crustaceans and small fish

For any procedure used where bivalve molluscs, crustaceans and small fish are normally eaten as a whole, the viscera shall be included in the material to be analysed.

PART IV - METHOD OF ANALYSIS TO BE USED BY THE LABORATORY AND LABORATORY CONTROL REQUIRE-MENTS

16. General requirements

Methods of analysis used for food control purposes shall be in accordance with reliable and scientifically recognised methods.

17. Specific requirements for lead, cadmium and mercury analyses

Laboratories shall use a validated method that fulfils the perfor-mance criteria indicated in the following table-

Table 3: Performance criteria of methods for lead, cadmium and mercury analysis.

PARAMETER	VALUE/COMMENT
Applicability	Fishery and aquaculture products.
Detection limit	No more than one tenth of the value of the specification except if the value of the specification for lead is less than 0,1 mg/kg. For the latter, no more than one fifth of the value of the specification.
Limit of quantification	No more than one fifth of the value of the specification except if the value of the specification for lead is less than 0,1 mg/kg. For the latter, no more than two fifths of the value of the specification.
Precision	$HORRAT_r$ or $HORRAT_R$ values of less than 1,5 in the validation collaborative trial.
Recovery	80-120 % (as indicated in the collaborative trial).
Specificity	Free from matrix or spectral interferences.

18. Estimation of the analytical trueness, recovery calcula-tions and reporting of results

(1) Wherever possible the trueness of the analysis shall be estimated by including suitable certified reference materials in the analysis.

(2) The analytical result shall be reported corrected or uncorrected for recovery and the manner of reporting and the level of recovery must be reported.

(3) The analyst shall note the "European Commission Report on the relationship between analytical results, the measurement of uncertainty, recovery factors and the provision in European Union food legislation" [(1)].

(4) The analytical result shall be reported as x +/- U whereby x is the analytical result and U is the measurement uncertainty.

19. Laboratory quality standards

Laboratories shall implement the Good Laboratory Practices.

20. Expression of results

The results shall be expressed in the same units as the maximum levels laid down in regulation 54 of these Regulations, (that is ppm (mg/kg).

CHAPTER II

PART I - METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF DIOXINS (PCDD/PCDF) AND THE DETERMINATION OF DIOXIN-LIKE PCBs IN CERTAIN FOODSTUFFS

1. Purpose and scope

(1) Samples intended for the official control of the levels of dioxins (PCDD/PCDF) content as well for the determination of the content of dioxin-like PCBs ([1]) in foodstuffs shall be taken according to the methods described below.

(2) Aggregate samples obtained shall be considered as representative of the lots or sub-lots from which they are taken.

(3) Compliance with maximum levels laid down in Commission Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs shall be established on the basis of the levels determined in the laboratory samples.

2. Definitions

In this Part unless the context otherwise requires -

“Lot” means an identifiable quantity of food delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packaging, packer, consignor or markings.

“Sub-lot” means a designated part of a large lot in order to apply the sampling method on that designated part.

“Incremental sample” means a quantity of material taken from a single place in the lot or sub-lot.

“Aggregate sample” means the combined total of all the incremental samples taken from the lots or sub-lots.

“Laboratory sample” means a representative part of the aggregate sample intended for the laboratory.

Dibenzo-p-dioxins (PCDD’s)

2,3,7,8-TCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0,1
1,2,3,6,7,8-HxCDD	0,1
1,2,3,7,8,9-HxCDD	0,1
1,2,3,4,6,7,8-HpCDD	0,01
OCDD	0,0001

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

Dibenzofurans (PCDF's)

2,3,7,8-TCDF	0,1
1,2,3,7,8-PeCDF	0,05
2,3,4,7,8-PeCDF	0,5
1,2,3,4,7,8-HxCDF	0,1
1,2,3,6,7,8-HxCDF	0,1
1,2,3,7,8,9-HxCDF	0,1
2,3,4,6,7,8-HxCDF	0,1
1,2,3,4,6,7,8-HpCDF	0,01
1,2,3,4,7,8,9-HpCDF	0,01
OCDF	0,0001

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

'Dioxin-like' PCBs Non-ortho PCB's + Mono-ortho PCB's

PCB 77	0,0001
PCB 81	0,0001
PCB 126	0,1
PCB 169	0,01

Mono-ortho PCB's

PCB 105	0,0001
PCB 114	0,0005
PCB 118	0,0001
PCB 123	0,0001
PCB 156	0,0005
PCB 157	0,0005
PCB 167	0,00001
PCB 189	0,0001

Abbreviations used: T = tetra; Pe = penta; Hx = hexa; Hp = hepta; O = octa; CDD = chlorodibenzodioxin; CDF = chlorodibenzofuran; CB = chlorobiphenyl.

3. General provisions

(1) Sampling shall be performed by an authorised qualified person as specified by the Member States.

(2) Each lot, which is to be examined, must be sampled separa-tely.

(3) In the course of sampling and preparation of laboratory samples, precautions shall be taken to avoid any changes which would affect the content of dioxins and dioxin-like PCBs, adversely affect the analytical determination or make the aggregate samples unrepresentative.

(4) As far as practical incremental samples shall be taken at various places distributed throughout the lot or sub-lot and any departure from this procedure must be recorded in the record provided for.

(5) The aggregate sample is made up by uniting all incremental samples and It shall be at least 1 kg unless not practical, (e.g. when a single package has been sampled).

(6) The laboratory samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised aggregate sample unless this conflicts with Member States' regulations on sampling.

(7) The size of the laboratory samples for enforcement shall be sufficient to allow at least for duplicate analyses.

(8) Each aggregate and laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, from loss of analyses by adsorption to the internal wall of the container and against damage in transit.

(9) All necessary precautions shall be taken to avoid change of composition of the aggregate and laboratory samples, which might arise during transportation or storage.

(10) Each sample taken for official use shall be sealed at the place of sampling and identified following the Member States' regulations.

(11) A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

4. Sampling plans

(1) The sampling method applied shall ensure that the aggregate sample is representative for the lot that is to be controlled.

(2) In the case of oils for which a homogeneous distribution of the contaminants in question can be assumed within a given lot, it is sufficient to take three incremental samples per lot which forms the aggregate sample.

(3) Reference to the lot number shall be given, and for other products, the minimum number of incremental samples to be taken from the lot shall be as given in Table 1.

(4) The aggregate sample uniting all incremental samples shall be at least one kilogram (see point 3.5) and the incremental samples shall be of similar weight.

(5) The weight of an incremental sample shall be at least one hundred grams and is dependent on the size of the particles in the lot.

5. Specific provisions for the sampling of lots containing whole fishes

(1) The number of incremental samples to be taken from the lot is defined in Table 1.

(2) The aggregate sample uniting all incremental samples shall be at least one kilogram.

(3). In case the lot to be sampled contains small fish (individual fish weighing < 1kg), the whole fish is taken as incremental sample to form the aggregate sample.

(4) In case the resulting aggregate sample weighs more than three kilograms, the incremental samples may consist of the middle part, weighing each at least one hundred grams, of the fish forming the aggregate sample. The whole part to which the maximum level is applicable is used for homogenisation of the sample.

(5) In case the lot to be sampled contains larger fish (individual fish weighing more than 1 kg), the incremental sample shall consist of the middle part of the fish and each incremental sample weighs at least one hundred grams.

(6) In case the lot to be sampled consist of very large fish (e.g. > 6kg) and taking a piece of the middle part of the fish would result in significant economic damage, taking three incremental samples of at least three hundred and fifty grams each can be considered sufficient, independently of the size of the lot.

TABLE 1

Minimum number of incremental samples to be taken from the lot

Weight of lot (in kg)	**Minimum number of incremental samples to be taken**
<50	2
50 to 500	5
> 500	10

If the lot consists of individual packages, then the number of packages, which shall be taken to form the aggregate sample, is given in Table 2.

TABLE 2

Number of packages (incremental samples) which shall be taken to form the aggregate sample if the lot consists of individual packages

Number of packages or units to be taken	**Number of packages or units to be taken**
1 to 25	1 package or unit
26 to 100	About 5 %, at least 2 packages or units
> 100	About 5 %, at maximum 10 packages or units

6. Compliance of the lot or sub-lot with the specification

(1) The control laboratory shall analyse the laboratory sample for enforcement in duplicate analysis in case the obtained result of the first analysis is less than twenty percent below or above the maximum level, and calculate the mean of the results.

(2) The lot is accepted if the result of the first analysis is more than twenty percent below the maximum level or, where duplicate analysis is necessary, if the mean conforms to the respective maximum level as laid down in regulation 52 (3).

(3) The lot is non-compliant with the maximum level as laid down in regulation 52 (3). if the analytical result confirmed by duplicate analysis and calculated as the mean of at least two separate determinations exceeds the maximum level beyond reasonable doubt, taking into account the measurement uncertainty.

(4) Taking account of the measurement uncertainty may be done according to one of the following approaches -

(a) by calculating the expanded uncertainty, using a coverage factor of 2, which gives a level of confidence of approxi-mately ninety-five percent ; or

(b) by establishing the decision limit (CCα).

(5) The present interpretation rules apply for the analytical result obtained on the sample for official control and in case of analysis for defence or referee purposes, the national rules apply.

PART II - SAMPLE PREPARATION AND REQUIREMENTS FOR METHODS OF ANALYSIS USED IN OFFICIAL CONTROL OF THE LEVELS OF DIOXINS (PCDD/PCDF) AND THE DETERMINATION OF DIOXIN-LIKE PCBs IN CERTAIN FISHERY PRODUCTS

7. Objective and field of application

(1) These requirements shall be applied where fishery products are analysed for the official control of the levels of dioxins (polychlorinated dibenzo-p-dioxins (PCDD) and polychlorinated dibenzofurans (PCDF)) and the determination of dioxin-like PCBs.

(2) Monitoring for the presence of dioxins in fishery products can be performed by a strategy involving a screening method in order to select those samples with levels of dioxins and dioxin-like PCBs that are less than thirty to forty percent below or above the level of interest.

(3) The concentration of dioxins in those samples with significant levels needs to be determined by a confirmatory method.

(4) Screening methods are methods that are used to detect the presence of dioxins and dioxin-like PCBs at the level of interest.

(5) These methods have a capacity for a high sample throughput and are used to sift large numbers of samples for potential positives.

(6) They are specifically designed to avoid false negatives. Confirmatory methods are methods that provide full or complementary information enabling the dioxins and dioxin-like PCBs to be identified and quantified unequivocally at the level of interest.

8. Background

(1) Because environmental and biological samples (including samples of fishery products) in general contain complex mixtures of different dioxin congeners, the concept of Toxic Equivalency Factors (TEFs) has been developed to facilitate risk assessment.

(2) These TEFs have been established to express concentrations of mixtures of 2,3,7,8-substituted PCDDs and PCDFs, and more recently, some non-ortho and mono-ortho chlorine substituted PCBs which possesses dioxin-like activity in toxic equivalents (TEQs) of 2,3,7,8-TCDD (see Annex I, footnote 1).

(3) The concentrations of the individual substances in a given sample are multiplied by their respective TEF and subsequently summed to give the total concentration of dioxin-like compounds expressed as TEQs.

(4) The concept of 'upper-bound' requires using the limit of quantification for the contribution of each non-quantified congener to the TEQ.

(5) The concept of 'lower-bound' requires using zero for the contribution of each non-quantified congener to the TEQ.

(6) The concept of 'medium-bound' requires using half of the limit of quantification calculating the contribution of each non-quantified congener to the TEQ.

(7) For the purpose of this schedule, the accepted specific limit of quantification of an individual congener is the concentration of an analyte in the extract of a sample which produces an instrumental response at two different ions, to be monitored with an S/N (signal/noise) ratio of 3:1 for the less sensitive signal and fulfilment of the basis requirements such as, e.g. retention time, isotope ratio.

9. Quality assurance requirements to be complied with for sample preparation

(1) Measures shall be taken to avoid cross-contamination at each stage of the sampling and analysis procedure.

(2) The samples must be stored and transported in glass, aluminium, polypropylene or polyethylene containers, traces of paper dust removed from the sample container and glass-ware should be rinsed with solvents previously controlled for the presence of dioxins.

(3) The sample storage and transportation has to be performed in a way that maintains the integrity of the foodstuff sample.

(4) Insofar as relevant, finely grind and mix thoroughly each laboratory sample using a process that has been demon-strated to achieve complete homogenisation (e.g. ground to pass a 1 mm sieve); samples have to be dried before grinding if moisture content is too high.

(5) Perform a blank analysis by carrying out the entire analytical procedure omitting only the sample.

(6) Sample weight used for the extraction must be sufficient to fulfil the requirements with respect to sensitivity.

(7) There are many satisfactory specific sample preparation procedures, which may be used for the products under consideration and the procedures have to be validated according to internationally accepted guidelines.

10. Requirements for laboratories

(1) Laboratories shall demonstrate the performance of a method in the range of the level of interest, e.g. 0,5 ×, 1 × and 2 × the level of interest with an acceptable coefficient of variation for repeated analysis.

(2) Limit of quantification for a confirmatory method shall be in the range of about one fifth of the level of interest, to make sure that acceptable coefficients of variations are met in the range of the level of interest.

(3) Regular blank controls and spiking experiments or analysis of control samples (preferably certified reference material, if available) shall be performed as internal quality control measures.

(4) Successful participation in inter-laboratory studies that assess laboratory proficiency is the best way to prove the competence in specific analyses.

(5) Laboratories shall be accredited by a recognised body operating in accordance with ISO Guide 58 to ensure that they are applying analytical quality assurance.

11. Requirements to be met by analytical procedure for dioxins and dioxin-like PCBs

(1) In the case of high sensitivity and low limits of detection, PCDDs and PCDFs, detectable quantities shall be in the pico-gram TEQ (10-12 g) range because of extreme toxicity of some of these compounds. PCBs are known to occur at higher levels than the PCDDs and PCDFs. For most PCB congeners sensitivity in the nanogram (10-9 g) range is already sufficient.

(2) For the measurement of the more toxic dioxin-like PCB con-geners (in particular non-ortho substituted congeners), the same sensitivity must be reached as for the PCDDs and PCDFs.

(3) In the case of high selectivity (specificity), a distinction is required for PCDDs, PCDFs and dioxin-like PCBs from a multitude of other, co-extracted and possibly interfering compounds present at concentrations up to several orders of magnitude higher than those of the analytes of interest.

(4) For gas chromatography/mass spectrometry (GC/MS) methods, a differentiation among various congeners is necessary, such as between toxic (e.g. the seventeen 2, 3, 7, 8-substituted PCDDs and PCDFs and dioxin-like PCBs) and other congeners. Bioassays should be able to determine TEQ values selectively as the sum of PCDDs, PCDFs and dioxin-like PCBs.

(5) The case of high accuracy (trueness and precision), the determination shall provide a valid estimate of the true concentration in a sample.

(6) High accuracy (accuracy of the measurement; the closeness of the agreement between the result of a measurement with the true or assigned value of the measurement) is necessary to avoid the rejection of a sample analysis result on the basis of poor reliability of the estimate of TEQ.

(7) Screening methods may comprise of bioassays and GC/MS methods; confirmatory methods are high-resolution gas chromato-graphy/high resolution mass spectrometry (HRGC/ HRMS) methods.

(8) The following criteria shall be complied with on total TEQ value-

	Screening methods	Confirmatory methods
False negative rate	< 1 %	
Trueness		– 20 % to + 20 %
CV	< 30 % < 15 %	

12. Specific requirements for GC/MS methods to be complied with for screening or confirmatory purposes

(1) Addition of 13C-labelled 2,3,7,8-chlorine substituted internal PCDD/F standards (and of 13C-labelled internal dioxin-like PCB standards, if dioxin-like PCBs have to be determined) shall be carried out at the very beginning or start of the analytical method e.g. prior to extraction in order to validate the analytical procedure.

(2) At least one congener for each of the tetra to octachlorinat-ed homologous groups for PCDD/F (and at least one congener for each of the homologous groups for dioxin-like PCBs, if dioxin-like PCBs have to be determined) shall be added (alternatively, at least one congener for each mass spectrometric selected ion recording function used for monitoring PCDD/F and dioxin-like PCBs).

(3) There is a clear preference, in case of confirmatory methods, of using all 17 13C-labelled 2,3,7,8-substituted internal PCDD/F standards and all 12 13C-labelled internal dioxin-like PCB standard (if dioxin-like PCBs have to be determined).

(4) Relative response factors shall also be determined for those congeners for which no 13C-labelled analogue is added by using appropriate calibration solutions.

(5) For foodstuffs of plant origin and foodstuffs of animal origin containing less than 10 % fat, the addition of the internal standards is mandatory prior to extraction.

(6) For foodstuffs of animal origin containing more than ten percent fat, the internal standards can be added either before extraction or after fat extraction.

(7) An appropriate validation of the extraction efficiency shall be carried out, depending on the stage at which internal standards are introduced and on whether results are reported on product or fat basis.

(8) Prior to GC/MS analysis, one or two recovery (surrogate) standard(s) shall be added.

(9) Control of recovery is necessary in the following cases -

(a) for confirmatory methods, the recoveries of the individual internal standards shall be in the range of sixty to one hundred and twenty percent;

(b) lower or higher recoveries for individual congeners, in parti-cular for some hepta- and octa- chlorinated dibenzodioxins and dibenzofurans, are acceptable on the condition that their contribution to the TEQ value does not exceed ten percent of the total TEQ value (based on PCDD/F only); and

(c) for screening methods, the recoveries should be in the range of thirty to one hundred and forty percent.

(10) Separation of dioxins from interfering chlorinated com-pounds such as PCBs and chlorinated diphenyl ethers shall be carried out by suitable chromatographic techniques (preferably with a florisil, alumina and/or carbon column).

(11) Gas-chromatographic separation of isomers shall be suffi-cient (< 25 % peak to peak between 1,2,3,4,7,8-HxCDF and 1,2,3,6,7,8-HxCDF).

(12) Determination shall be performed according to EPA Method 1613 revision B: Tetra- through octa-chlorinated dioxins and furans by isotope dilution HRGC/HRMS or another with equivalent performance criteria.

(13) The difference between upper-bound level and lower bound level -

(a) shall not exceed twenty percent for foodstuffs, with a dioxin contamination of about 1 pg WHO-TEQ/g fat (based on PCDD/ PCDF only);

(b) for foodstuffs with a low fat content, the same require-ments for contamination levels of about 1 pg WHO-TEQ/g product shall be applied; and

(c) for lower contamination levels, for example 0,50 pg WHO-TEQ/g product, bound level may be in the range of twenty-five to fourty percent .

13. Screening methods of analysis

Different analytical approaches may be performed using a screening method: (a pure screening approach and a quantitative approach) -

(a) Screening approach

The response of samples is compared to that of a reference sample at the level of interest and samples with a response less than the reference are declared negative, while those with a higher response are suspected positives-

(i) a blank and a reference sample(s) shall be included in each test series, which is extracted and tested at the same time under identical conditions. The reference sample must show a clearly elevated response in comparison to a blank,

(ii) extra reference samples 0,5 × and 2 × the level of interest shall be included to demonstrate the proper performance of the test in the range of interest for the control of the level of interest,

(iii) when testing other matrices, the suitability of the reference sample(s) shall be demonstrated, preferentially by including samples shown by HRGC/HRMS to contain a TEQ level around that of the reference sample or else a blank spiked at this level,

(iv) since no internal standards can be used in bioassays, tests on repeatability are very important to obtain information on the standard deviation within one test series. The coefficient of variation shall be below thirty percent, or

(v) for bioassays, the target compounds, possible inter-ferences and maximum tolerable blank levels shall be defined;

(b) Quantitative approach

(i) the quantitative approach requires standard dilution series, duplicate or triplicate clean up and measuring as well as blank and recovery controls,

(ii) the result may be expressed as TEQ, thereby assuming that the compounds responsible for the signal correspond to the TEQ principle,

(iii) this can be performed by using TCDD (or a dioxin/furan standard mixture) to produce a calibration curve to calculate the TEQ level in the extract and thus in the sample,

(iv) this is subsequently corrected for the TEQ level calcu-lated for a blank sample (to account for impurities from solvents and chemicals used), and a recovery (calculated from the TEQ level in a quality control sample around the level of interest), and

(v) it is essential to note that part of the apparent recovery loss may be due to matrix effects and/or differences between the TEF values in the bioassays and the official TEF values set by WHO.

14. (1) The requirements for methods of analysis used for screening include the following -

(a) GC/MS methods of analysis and bioassays may be used for screening;

(b) information on the number of false-positive and false- negative results of a large set of samples below and above the maximum level or action level is necessary in comparison to the TEQ content as determined by a confirmatory method of analysis;

(c) actual false negative rates shall be under one percent and the rate of false positive samples shall be low enough to make the use of a screening tool advantageous; and

(d) positive results have always to be confirmed by a confir-matory method of analysis (HRGC/HRMS) and in addition, samples from a wide TEQ-range shall be confirmed by HRGC/HRMS (approximately two percent to 10 % of the negative samples).

(2) Specific requirements for cell-based bioassays include the following -

(a) when performing a bioassay, every test run requires a series of reference concentrations of TCDD or a dioxin/furan mixture (full dose-response curve with a R2 > 0,95) and for screening purposes an expanded low level curve for analysing low level samples could be used;

(b) a TCDD reference concentration (about 3 × limit of quanti-fication) on a quality control sheet shall be used for the outcome of the bioassay over a constant time period. An alternative could be the relative response of a reference sample in comparison to the TCDD calibration line since the response of the cells may depend on many factors;

(c) quality control (QC) charts for each type of reference material shall be recorded and checked to make sure the outcome is in accordance with the stated guidelines;

(d) in particular for quantitative calculations, the induction of the sample dilution used shall t be within the linear portion of the response curve and Samples

above the linear portion of the response curve must be diluted and re-tested;

(e) the percent standard deviation shall not be above fifteen percent in a triplicate determination for each sample dilution and not above thirty percent between three independent experiments;

(f) the limit of detection may be set as 3 × the standard devia-tion of the solvent blank or of the background response;

(g) another approach is to apply a response that is above the background (induction factor 5 × the solvent blank) calculated from the calibration curve of the day; and

(h) the limit of quantification may be set as 5 × to 6 × the standard deviation of the solvent blank or of the background response or to apply a response that is above the background (induction factor 10 × the solvent blank) calculated from the calibration curve of the day.

(3) Specific requirements for kit-based bioassays include the following -

(a) manufacturer's instructions for sample preparation and analyses shall be followed;

(b) test kits shall not be used after the expiration date;

(c) materials or components designed for use with other kits shall not be used;

(d) test kits shall be kept within the specified range of storage temperature and used at the specified operating temperature;

(e) the limit of detection for immunoassays is determined as 3 × the standard deviation, based on ten replicate analysis of the blank, to be divided by the slope value of the linear regression equation; and

(f) reference standards shall be used for tests at the laboratory to make sure that the responsiveness to the standard is within an acceptable range.

15. Reporting of the result

(1) Insofar as the used analytical procedure makes it possible, the analytical results shall contain the levels of the individual PCDD/F and PCB congeners and be reported as lower-bound, upper-bound and medium-bound in order to include a maximum of information in the reporting of the results and thereby enabling the interpretation of the results according to specific requirements.

(2) The report shall also include the lipid content of the sample as well the method used for lipid extraction.

(3) The recoveries of the individual internal standards shall be made available in case the recoveries are outside the range mentioned in point (12) in case the maximum level is exceeded and in other cases upon request.

SCHEDULE 4

CHAPTER III

PART I – METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF BENZO (A) PYRENE IN FOODSTUFFS

1. Purpose and scope

(1) Samples intended for the official control of the levels of benzo (a) pyrene in foodstuffs shall be taken according to the methods described below.

(2) Aggregate samples thus obtained shall be considered as representative of the lots.

(3) Compliance with maximum levels laid down in Regulation (EC) No 466/2001 shall be established on the basis of the levels determined in the laboratory samples.

2. Definitions

In this Part unless the context otherwise requires -

“Lot” means an identifiable quantity of food commodity delivered at one time and determined by the official to have common characteristics such as origin, variety, type of packing, packer, consignor or markings.

“Sub-lot” means designated part of a larger lot used to apply the sampling method; each sub-lot must be physically separated and identifiable.

“Incremental sample” means a quantity of material taken from a single place in the lot or sub-lot.

“Aggregate sample” means the combined total of all the incremental samples taken from the lot or sub-lot.

“Laboratory sample” means a sample intended for the laboratory.

3. General provisions

(1) Sampling shall be performed by an authorised qualified per-son as specified by the Member States.

(2) Each lot which is to be examined shall be sampled separa-tely.

(3) In the course of sampling and preparation of laboratory samples precautions must be taken to avoid any changes, which would affect the benzo (a) pyrene

content, adversely affect the analytical determination or make the aggregate samples unrepresentative.

(4) As far as practical incremental samples shall be taken at various places distributed throughout the lot or sublot and any departure from this procedure shall be recorded in the record.

(5) The aggregate sample is made up by uniting all incremental samples, and this aggregate sample is homogenised in the laboratory unless this is incompatible with implementation of sub paragraph 3.6.

(6) Replicate laboratory samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised aggregate sample unless this conflicts with Member States' rules on sampling.

(7) Each sample shall be placed in a clean, inert container offering adequate protection from contamination and against damage in transit, and all necessary precautions shall be taken to avoid change in composition of the sample, which might arise during transportation or storage.

(8) Each sample taken for official use shall be sealed at the place of sampling and identified following the Member States' rules.

(9) A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

4. Sampling plans

(1) The sampling method applied shall ensure that the aggregate sample is representative for the lot that is to be controlled.

(2) In the case of oils for which a homogeneous distribution of benzo (a) pyrene can be assumed within a given lot -

(a) it is sufficient to take three incremental samples per lot to form the aggregate sample;

(b) reference to the lot number shall be given; and

(c) for olive oil and oil pomace oil, further information on samp-ling is given in Commission Regulation (EC) no 1989/2003 ([1]).

(3) For other products -

(a) the minimum number of incremental samples to be taken from the lot shall be as given in Table 1; and

(b) the incremental samples shall be of similar weight, no less than 100g each, resulting in an aggregate sample of no less than 300g (see point 3.5).

TABLE 1

Minimum number of incremental samples to be taken from the lot

Weight of lot (in kg)	**Minimum number of incremental samples to be taken**
<50	3
50 to 500	5
> 500	10

If the lot consists of individual packages, then the number of packages which shall be taken to form the aggregate sample, is given in Table 2.

TABLE 2

Number of packages (incremental samples) which shall be taken to form the aggregate sample if the lot consists of individual pac-kages

Number of packages or units to be taken	**Number of packages or units to be taken**
1 to 25	1 package or unit
26 to 100	About 5 %, at least 2 packages or units
> 100	About 5 %, at maximum 10 packages or units

(4) Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the above sampling provisions and where this is not possible, other effective sampling procedures at retail stage may be used, provided that they are sufficiently representative of the sampled lot.

([1]) OJ L 295, 13.11.2003, p. 57

5. Compliance of the lot or sub-lot with the specification

(1) The control laboratory shall analyse the laboratory sample for enforcement in duplicate analysis in cases where the obtained result of the first analysis is less than twenty percent below or above the maximum level, and calculate the mean of the results.

(2) The lot is accepted if the result of the first analysis or where duplicate analysis is necessary, if the mean does not exceed the respective maximum level (as laid down in Regulation (EC) No 466/2001) taking into account the measurement uncertainty and correction for recovery.

(3) The lot is non-compliant with the maximum level (as laid down in Regulation (EC) 466/2001) if the result of the first analysis or where duplicate analysis is necessary, if the mean exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty and correction recovery.

PART II – SAMPLE PREPARATION AND CRITERIA FOR METHODS OF ANALYSIS USED IN OFFICIAL CHECKING OF THE LEVELS OF BENZO(A)PYRENE IN FOODSTUFFS

6. Precautions and general consideration for benzo (a) pyrene in food samples

(1) The basic requirement is to obtain a representative and homogenous laboratory sample without introducing secondary contamination.

(2) The analyst shall ensure that samples do not contaminate during sample preparation.

(3) Containers shall be rinsed with high purity acetone or hexane (p.A., HLPC grade or equivalent) before use to minimise the risk on contamination.

(4) Wherever possible, apparatus coming into contact with the sample shall be made of inert materials (aluminium, glass or polished stainless steel). Plastics such as polypropylene or PTFE should be avoided because the analyte can absorb onto these materials.

(5) All of the sample material received by the laboratory shall be used for the preparation of test material. Only very finely homogenised samples give reproducible results.

(6) The replicate samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised material unless this conflicts with Member States' rules on sampling.

7. Definitions

In this Part unless the context otherwise requires –

"r" means	Repeatability, the value below which the absolute difference between two single test results obtained under repeatability conditions (ie. Same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95%) and hence $r = 2{,}8 \times S_r$;
"S " means	Standard deviation, calculated from results generated under repeatability conditions;
"RSD " means	Relative standard deviation, calculated from results generated under repeatability conditions $[(S_r / \bar{x}) \times 100]$;

"R" means	Reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); $R = 2,8 \times S_R$;
"S_R" means	Standard deviation calculated from results under reproducibility conditions;
"RSD_R" means	Relative standard deviation calculated from results generated under reproducibility conditions [(S_R / $\bar{x}$) x 100], where $\bar{x}$ is the average of results over all laboratories and samples;
"HORRAT"$_r$ means	the observed RSD_r divided by the RSD_r value estimated from the Horwitz equation using the assumption r = 0,66R;
"HORRAT $_R$" means	the observed RSD_R value divided by the RSD_R value calculated from the Horwitz equation ([a]);
" U" means	The expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately ninety five percent.

8. General requirements

Methods of analysis used for food control purposes shall comply with points 1 and 2 of the Annex to Council Directive 85/591/EEC.

9. Specific requirements

Where no specific methods for the determination of benzo (a) pyrene in food are prescribed at Community level, laboratories may select any validated method provided the selected method meets the performance criteria indicated in the Table. The validation should ideally include a certified reference material.

TABLE 1

Performance criteria for methods of analysis for benzo (a) pyrene

Parameter	Value/comment
Applicability	Food specified in Regulation (EC) no…./2005
Detection limit	No more than 0,3 µg/kg
Limit of quantification	No more than 0,9 µg/kg
Precision	$HORRAT_r$ or $HORRAT_R$ values of less than 1.5 in the validation collaborative trial
Recovery	50% - 120%
Specificity	Free from matrix or spectral interferences, verification of positive detection

10. Performance Criteria – Uncertainty Function Approach

(1) An uncertainty approach may also be used to assess the suitability of the method of analysis to be used by the laboratory.

(2). The laboratory may use a method which will produce results within a maximum standard uncertainty. The maximum standard can be calculated using the following formula:

$$Uf = \sqrt{[(LOD/2)^2 = (0.2C)^2]}$$

(U*f* is the square root of $[(LOD/2)^2 = (0.2C)^2]$)

Where:

U*f* is the maximum standard uncertainty
LOD is the limit of detection of the method
C is the concentration of interest

(3) If an analytical method provides results with uncertainty measurements less than the maximum standard uncer-tainty the method will be equally suitable to one which meets the performance characteristics given in the Table.

11. Recovery calculation and reporting of results

(1) The analytical result may be reported corrected or uncorrected for recovery.

(2) The manner of reporting and the level of recovery shall be reported and the analytical result corrected for recovery is used for checking compliance (see Annex 1, point 5).

(3) The analyst should note the 'European Commission Report on the relationship between analytical results, the measurement of uncertainty, recovery factors and the provisions in EU food legislation' (2).

(4) The analytical result shall be reported as x +/- U whereby x is the analytical result and U is the measurement uncertainty.

12. Laboratory quality standards

Laboratories must comply with Directive 93/99/EEC.

13. Other considerations

The other considerations for the analysis are –

(a) Proficiency testing

Participation in appropriate proficiency testing schemes which comply with the 'International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories' (3) developed under the auspices of IUPAC/ISO/AOAC.

(b) Internal quality control

Laboratories should be able to demonstrate that they have internal quality control procedures in place. Examples of these are the 'ISO/AOAC/IUPAC Guidelines on Internal Quality in Analytical Chemistry Laboratories' (4).

SCHEDULE 4

CHAPTER IV

PART I – METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF TIN IN FOODSTUFFS

1. Purpose and scope

(1) Samples intended for official checking of the levels of tin in canned foodstuffs shall be taken according to the methods described below' and aggregate samples obtained shall be considered as representative of the lots.

(2) Compliance with maximum levels laid down in Regulation (EC) No 466/2001 shall be established on the basis of the levels determined in the laboratory samples.

2. Definitions

In this Part unless the context otherwise requires -

"Lot" means an identifiable quantity of food commo-dity delivered at one time and having been determined by the official to have common characteristics such as origin, variety, type of packing, packer, consignor or markings.

"Sub-lot" means designated part of a large lot in order to apply the sampling method on that designated part; each sublot must be physically separated and identifiable.

"Incremental sample" means a quantity of material taken from a single place in the lot or sublot.

"Aggregate sample" means the combined total of all the incremental samples taken from the lot or sublot.

"Laboratory sample" means a sample intended for the laboratory.

3. General provisions

(1) Sampling shall be performed by an authorised qualified person as specified by the Member States.

(2) Each lot which is to be examined shall be sampled separately.

(3) In the course of sampling and preparation of laboratory samples precautions shall be taken to avoid any changes which would affect the tin content, adversely affect the analytical determination or make the aggregate samples unrepresentative.

(4) As far as practical incremental samples shall be taken at various places distributed throughout the lot or sub-lot. Departure from this procedure shall be recorded in the record.

(5) The aggregate sample is made up by uniting all incremental samples. This aggregate sample is homogenised in the labora-tory.

(6) Replicate laboratory samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised aggregate sample unless this conflicts with Member States' rules on sampling.

(7) Each sample shall be placed in a clean, inert container offering adequate protection against contamination and damage in transit.

(8) All necessary precautions shall be taken to avoid change in composition of the sample which might arise during transport-tation or storage.

(9) Each sample taken for official use shall be sealed at the place of sampling and identified following the Member States' regula-tions.

(10) A record shall be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

4. Sampling plans

(1) The sampling method applied shall ensure that the aggregate sample is representative for the lot that is to be controlled.

(2) The minimum number of incremental samples to be taken from the lot shall be as given in Table 1.

(4) The incremental samples taken from each shall be of similar weight, resulting in an aggregate sample (see point 3.5).

TABLE 1

Number of cans (incremental samples) which shall be taken to form the aggregate sample

Number of cans in the lot or sublot	**Number of cans to be taken**
1 to 25	At least 1 can
26 to 100	At least 2 cans
> 100	5 cans

Note that the maximum levels apply to the contents of each can; but for feasibility of testing, it is necessary to use an aggregate sampling approach. If the test result for the aggregate sample is less than but close to the maximum level and if it is suspected that individual cans might exceed the maximum level then it might be necessary to conduct further investigations.

(4) Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the above sampling provisions. Where this is not possible, other effective sampling procedures at retail stage may be used provided that they are sufficiently representative of the sampled lot.

5. Compliance of the lot or sub-lot with the specification

(1) The control laboratory shall analyse the laboratory sample for enforcement in at least two independent analyses and calculate the mean of the results.

(2) The lot is accepted if the mean does not exceed the respect-tive maximum level (as laid down in Regulation (EC) No 466/2001) taking into account the measurement uncertainty and correction for recovery.

(3) The lot is non-compliant with the maximum level (as laid down in Regulation (EC) 466/2001) if the mean exceeds the maximum level beyond reasonable doubt taking into account the measure-ment uncertainty and correction recovery.

PART II - SAMPLE PREPARATION AND CRITERIA FOR METHODS OF ANALYSIS USED IN OFFICIAL CHECKING OF THE LEVELS OF TIN IN CANNED FOODSTUFFS

6. Precautions and general considerations for tin

(1) The basic requirement is to obtain a representative and homogenous laboratory sample without introducing secondary contamination.

(2) The analyst shall ensure that samples do not contaminate during sample preparation.

(3) Wherever possible, apparatus coming into contact with the sample shall be made of inert materials (plastics such as polypropylene and PTFE) and these shall be acid cleaned to minimise the risk of contamination. High quality stainless steel can be used for cutting edges.

(4) All of the sample material received by the laboratory shall be used for the preparation of test material. Only very finely homo-genised samples give reproducible results.

(5) There are many satisfactory specific sample preparation procedures which may be used. Those described in the CEN Standard on the 'Determination of trace elements – Performance criteria and general consideration' have been found to be satisfactory (1) but others may be equally valid.

7. Treatment of the sample as received in the laboratory

Finely grind (where relevant) and mix thoroughly the complete aggregate sample using a process that has been demonstrated to achieve complete homogenisation.

8. Subdivision of samples for enforcement and defence purposes

The replicate samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised material unless this conflicts with Member States' rules on sampling.

9. Definitions

In this Part-

"r" means Repeatability, the value below which the absolute difference between two single test results obtained under repeatability conditions (ie. same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95%) and hence $r = 2{,}8 \times S_r$.

"S_r" means	Standard deviation, calculated from results generated under repeatability conditions.
"RSD_r"	Relative standard deviation, calculated from results generated under repeatability conditions [(S_r / $\bar{x}$) × 100].
"R" means	Reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); R = 2,8 × S_R.
" S_R " means	Standard deviation calculated from results under reproducibility conditions.
"RSD_R" means	Relative standard deviation calculated from results generated under reproducibility conditions [(S_R / $\bar{x}$) x 100].
"$HORRAT_r$" means	the observed RSD_r divided by the RSD_r value estimated from the Horwitz equation using the assumption r = 0,66R
"$HORRAT_R$" means	the observed RSD_R value divided by the RSD_R value calculated from the Horwitz equation (2).
"U" means	The expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95%.

10. General requirements

Methods of analysis used for food control purposes shall comply with the provisions of items 1 and 2 of the Annex to Council Directive 85/591/EEC of 20 December, 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption.

11. Specific requirements

Where no specific methods for the determination of tin in canned foodstuffs are prescribed at Community level, laboratories may select any validated method provided the selected method meets the performance criteria indicated in Table 2. The validation should ideally include a certified reference material.

TABLE 2

Performance criteria for methods of analysis for tin

Parameter	**Value/comment**
Applicability	Food specified in Regulation (EC) no 242/2004
Detection limit	No more than 5 mg/kg
Limit of quantification	No more than 10 mg/kg
Precision	$HORRAT_r$ or $HORRAT_R$ values of less than 1.5 in the validation collaborative trial
Recovery	80% - 105% (as indicated in the collaborative trial)
Specificity	Free from matrix or spectral interferences

12. Performance Criteria – Uncertainty Function Approach

(1) An uncertainty approach may also be used to assess the suitability of the method of analysis to be used by the laboratory. The laboratory may use a method which will produce results within a maximum standard uncertainty.

(2) The maximum standard uncertainty can be calculated using the following formula-

$$Uf = \sqrt{[(LOD/2)^2 = (0.1C)^2]}$$

(U*f* is the square root of $[(LOD/2)^2 = (0.2C)^2]$)

Where:
U*f* is the maximum standard uncertainty
LOD is the limit of detection of the method
C is the concentration of interest

(3) If an analytical method provides results with uncertainty measurements less than the maximum standard uncertainty the method will be equally suitable to one which meets the performance characteristics given in Table 2.

13. Recovery calculation and reporting of results

(1) The analytical result shall be reported, corrected or uncorrected, for recovery. The manner of reporting and the level of recovery shall be reported. The analytical result corrected for recovery is used for checking compliance (see Annex 1, point 5).

(2) The analyst shall note the 'Harmonised Guidelines for the Use of Recovery Information in Analytical Measurement' (3) developed under IUPAC/ISO/AOAC. These Guidelines assist when determining recovery factors.

(3) The analytical result shall be reported as x +/- U whereby x is the analytical result and U is the measurement uncertainty.

14. Laboratory quality standards

Laboratories shall comply with Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs.

15. Other considerations for the analysis are –

(1) Proficiency testing

Participation in appropriate proficiency testing schemes which comply with the 'International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories' (4) developed under the auspices of IUPAC/ISO/AOAC.

(2) Internal quality control

Laboratories shall be able to demonstrate that they have internal quality control procedures in place such as the 'ISO/AOAC/IUPAC Guidelines on Internal Quality in Analytical Chemistry Laboratories' (5).

SCHEDULE 5

This Schedule lays down the microbiological, chemical, organoleptic, physico–chemical and biological quality and safety parameters with values and limits, monitoring procedures, minimum frequency of sampling and analyses, specifications for analysis and sampling methods for potable water, provided for in these Regulations.

PART I

PARAMETERS AND PARAMETRIC VALUES

Chapter 1

Microbiological Parameters for fishery products

This part lays down the microbiological criteria for certain micro-organisms to be complied with by food business operators when implementing the general and specific hygiene measures**.** The competent authority shall verify compliance with the rules and criteria laid down in this schedule, without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other micro-organisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis. These criteria shall apply without prejudice to other specific rules for the control of micro-organisms laid down elsewhere in these Regulation and other relevant regulations in the territory of The Gambia.

One of the fundamental objectives of these Regulations is to provide a high level of public health protection. As microbiological hazards in fishery products are a major source of food-borne diseases in humans:

(1) fishery products should not contain micro-organisms or their toxins or metabolites in quantities that present an unacceptable risk to human health.
(2) food must not be placed on the market if it is unsafe.
(3) Food business operators have an obligation to withdraw unsafe food
(4) from the market.
(5) In order to contribute to the protection of public health, food safety criteria is are established on the acceptability of fishery products as regards the presence of certain pathogenic micro-organisms.
(4) Microbiological criteria also give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures

(5) The safety of foodstuffs is mainly ensured by a preventive approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point (HACCP) principles.

(6) Microbiological criteria can be used in validation and verification of HACCP procedures and other hygiene control measures. Microbiological criteria are set to define the acceptability of the processes. Food safety microbiological criteria set limits above which a foodstuff should be considered unacceptably contaminated with the microorganisms for which the criteria are set.

(7) Food business operators are to comply with microbiological criteria. This should include testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective actions, in accordance with requirements under these Regulations and instructions given by the competent authority. These regulations provide guidance concerning the analytical methods, including, where necessary, the measurement uncertainty, the sampling plan, the microbiological limits, the number of analytical units that should comply with these limits. Furthermore, the regulations provide guidance concerning the foodstuff to which the criterion applies, the points of the food chain where the criterion applies, as well as the actions to be taken when the criterion is not met. The measures to be taken by the food business operators in order to ensure compliance with criteria defining the acceptability of a process may include, among other things, controls of raw materials, hygiene, temperature and shelf-life of the product.

(8) The competent authority must ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency. Those controls should take place at appropriate stages of the production, processing and distribution of fishery products to ensure that the criteria laid down in this these regulation are complied with by food business operators.

(9) The concentration of *Listeria monocytogenes* in the relevant food product should be below 100 cfu/g. Although no specific criteria are set for *Vibrio vulnificus* and *Vibrio parahaemolyticus*, codes of practice should be followed to ensure that good hygiene practice is applied.

(10) As regards indicators for faecal contamination the use of E. coli rather than faecal coliforms to indicate faecal contamination in shellfish growing and harvesting should be applied as bacterial indicator.

(11) For the protection of consumer health a mandatory microbiological criterion for salmonella is to be complied with by fish business operators producing cooked crustaceans and molluscan shellfish and live bivalve molluscs and live echinoderms, tunicates and gastropods as indicated in Annex I, Chapter 1 to this schedule.

(12) The producer or manufacturer of a food product shall decide whether the product is ready to be consumed as such, without the need to cook or otherwise process it in order to ensure its safety and compliance with the microbiological criteria. In the labelling, presentation and advertising of foodstuff, the instructions for use of a foodstuff are compulsory on the labelling when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions. Such instructions should be taken into account by food business operators when deciding appropriate sampling frequencies for the testing against microbiological criteria.

(13) Sampling of the production and processing environment can be a useful tool to identify and prevent the presence of pathogenic micro-organisms in foodstuffs.

(14) Food business operators should decide themselves the necessary sampling and testing frequencies as part of their procedures based on HACCP principles and other hygiene control procedures.

(15) Test results are dependent on the analytical method used, and therefore a given reference method should be associated with each microbiological criterion. However, food business operators should have the possibility to use analytical methods other than the reference methods, in particular more rapid methods, as long as the use of these alternative methods provides equivalent results. Notwithstanding, sampling plans are defined for each criterion in order to ensure harmonised implementation of the standard.

(16) It is nevertheless necessary to allow the use of other sampling and testing schemes, including the use of alternative indicator organisms, on condition that these schemes provide equivalent guarantees of food safety.

(17) Trends in test results should be analysed, as they are able to reveal unwanted developments in the manufacturing process enabling the food business operator to take corrective actions before the process is out of control.

(18) The microbiological criteria set in this Regulation should be open to review and revised or supplemented, if appropriate, in order to take into account developments in the field of food safety and food microbiology. This includes progress in science, technology and methodology, changes in prevalence and contamination levels, changes in the population of vulnerable consumers, as well as the possible outputs from risk assessments.

(19) In particular, criteria for pathogenic viruses in live bivalve molluscs should be established when the analytical methods are developed sufficiently. There is a need for development of reliable methods for other microbial hazards too, e.g. *Vibrio parahaemolyticus*

Definitions

The following definitions shall apply:

(a) ‘micro-organisms’ means bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, microscopic parasitic helminths, and their toxins and metabolites;

(b) ‘microbiological criterion’ means a criterion defining the acceptability of a product, a batch of fish or fishery products or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch;

(c) ‘food safety criterion’ means a criterion defining the acceptability of a product or a batch of fish or fishery products produced for placing on the market;

(d) ‘process hygiene criterion’ a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process.

(e) ‘batch’ means a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period;

(f) ‘shelf-life’ means either the period corresponding to the period preceding the ‘use by’ or the minimum durability date**.**

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

(h) ‘food intended for infants’ means food specifically intended for infants;

(i) ‘food intended for special medical purposes’ means dietary food for special medical purposes;

(j) ‘sample’ means a set composed of one or several units or a portion of matter selected by different means in a population or in an important quantity of matter, which is intended to provide information on a given characteristic of the studied population or matter and to provide a basis for a decision concerning the population or matter in question or concerning the process which has produced it;

(k) ‘representative sample’ means a sample in which the characteristics of the batch from which it is drawn are maintained. This is in particular the case of a simple random sample where each of the items or increments of the batch has been given the same probability of entering the sample;

(l) ‘compliance with microbiological criteria’ means obtaining satisfactory or acceptable results set in **Annex I** when testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective action, in accordance with these Regulations and instructions given by the competent authority.

General requirements

1.Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in **Annex I**. To this end the food business operators at each stage of food production, processing and distribution, including retail, shall take measures, as part of their procedures based on HACCP principles together with the implementation of good hygiene practice, to ensure the following:

(a) that the supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that the process hygiene criteria are m e t ,
(b) that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.

2. As necessary, the food business operators responsible for the manufacture of the product shall conduct studies in accordance with **Annex II** in order to investigate compliance with the criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods that are able to support the growth of Listeria monocytogenes and that may pose a *Listeria monocytogenes* risk for public health.

Testing against criteria

1. Food business operators shall perform testing as appropriate against the microbiological criteria set out in **Annex I**, to verify the correct functioning of their procedures based on HACCP principles and good hygiene practices.

2. Food business operators shall decide the appropriate sampling frequencies, except where **Annex I** provides for specific sampling frequencies, in which case the sampling frequency shall be at least that provided for in **Annex I**. Food business operators shall make this decision in the context of their procedures based on HACCP principles and good hygiene practice, taking into account the instructions for use of the foodstuff. The frequency of sampling may be adapted to the nature and size of the food businesses, provided that the safety of foodstuffs will not be endangered.

Specific rules for testing and sampling

1. The analytical methods and the sampling plans and methods in **Annex I** shall be applied as reference methods.

2. Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that the criteria are met. In that sampling the ISO standard 18593 shall be used as a reference method. Food business operators producing ready-to-eat foods, which may pose a *Listeria monocytogenes* risk for public health, shall sample the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme.

3. The number of sample units of the sampling plans set out in **Annex I** may be reduced if the food business operator can demonstrate by historical documentation that he has effective HACCP-based procedures.

4. If the aim of the testing is to specifically assess the acceptability of a certain batch of foodstuffs or a process, the sampling plans set out in **Annex I** shall be respected as a minimum.

5. Food business operators may use other sampling and testing procedures, if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. Those procedures may include use of alternative sampling sites and use of trend analyses if this is only for process hygiene criteria and the methods are validated against the reference method in **Annex I** and certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols, and their use authorised by the competent authority.

Unsatisfactory results

1. When the results of testing against the criteria set out in Annex I are unsatisfactory, the food business operators shall take the necessary corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers. In addition, they shall take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination. Those corrective actions may include modifications to the HACCP-based procedures or other food hygiene control measures in place.

2. When testing against food safety criteria set out in **Chapter 1 of Annex I** provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in

Product Category	Micro-organisms/their	Sampling-plan (1)	Limits (2)	Analytical reference	Stage where the criterion applies

accordance with procedures and as in Regulation 116 (1) of these Regulations. However, products placed on the market, which are not yet at retail level and which do not fulfil the food safety criteria, may be submitted to further processing by a treatment eliminating the hazard in question where this is acceptable. This treatment may only be carried out by food business operators other than those at retail level.

3. The food business operator may use the batch for purposes other than those for which it was originally intended, provided that this use does not pose a risk for public or animal health and provided that this use has been decided within the procedures based on HACCP principles and good hygiene practice and authorised by the competent authority.

4. In the event of unsatisfactory results as regards process hygiene criteria, the actions laid down in **Annex I, Chapter 2** shall be taken.

ANNEX I - Microbiological criteria for fishery products as foodstuff
Chapter 1. Food safety criteria

	toxins, metabolites	n	c	M	M	method (3)	
1.1. Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes (4)	*Listeria monocytogenes*	10	0	Absence in 25 g	Absence in 25 g	EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2. Ready-to-eat foods able to support the growth of L. monocytogenes, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	5	0		100 cfu/g	EN/ISO 11290-2 (5)	Products placed on the market during their shelf-life
		5	0	Absence in 25 g (6)	Absence in 25 g (6)	EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
1.3. Ready-to-eat foods unable to support the growth of L. monocytogenes, other than those intended for infants and for special medical purposes (4) (7)		5	0	100 cfu/g	100 cfu/g	EN/ISO 11290-2 (5)	Products placed on the market during their shelf-life
1.4. Cooked crustaceans and molluscan shellfish	*Salmonella*	5	0		Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1,5. Live bivalve molluscs and live echinoderms, tunicates and gastropods	*Salmonella*	4	0		Absence in 25 g	EN/ISO 6579	Products placed on the market during their their shelf-life
1.6. Live bivalve molluscs and live echinoderms, tunicates and gastropods	*E. coli*	1	0	230 MPN/100 g of flesh and intra-valvular liquid	230 MPN/100 g of flesh and intra-valvular liquid	ISO TS 16649-3	Products placed on the market during their during their shelf-life
1.7. Fishery products from fish species associated with a high amount of histidine (8)	*Histamine*	9 (17)	2	100 mg/kg	200 mg/kg	HPLC (18)	Products placed on the market during their shelf-life
1.8. Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine (8)	*Histamine*	9	2	200 mg/kg	400mg/kg	HPLC (18)	Products placed on the market during their shelf-life

(1) n = number of units comprising the sample; c = number of sample units giving values over m or between m and M.

(2) For points 1.1-1.6 m=M.

(3) The most recent edition of the standard shall be used.

(4) Regular testing against the criterion is not useful in normal circumstances for the following ready-to-eat foods:

— those which have received heat treatment or other processing effective to eliminate L. monocytogenes, when recontamination is not possible after this treatment (e.g. products heat treated in their final package),

(5) 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.
(6) This criterion applies to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.
(7) Products with pH ≤ 4,4 or aw ≤ 0,92, products with pH ≤ 5,0 and aw ≤ 0,94, products with a shelf-life of less than five days are automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.
(8) Particularly fish species of the families: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombresosidae.
(9) References: 1. Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49.
2. Duflos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination of biogenic amines in plaice (Pleuronectes platessa) and whiting (Merlangus merlangus). J. AOAC Internat. 1999, 82, 1097-1101.

1.1 Interpretation of the test results

The limits given refer to each sample unit tested, excluding live bivalve molluscs and live echinoderms, tunicates and gastropods in relation to testing E. coli, where the limit refers to a pooled sample.
The test results demonstrate the microbiological quality of the batch tested (1).
L. monocytogenes in ready-to-eat foods intended for infants and for special medical purposes:
— satisfactory, if all the values observed indicate the absence of the bacterium,
— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.
L. monocytogenes in ready-to-eat foods able to support the growth of L. monocytogenes before the food has left the immediate control of the producing food business operator when he is not able to demonstrate
that the product will not exceed the limit of 100 cfu/g throughout the shelf-life:
— satisfactory, if all the values observed indicate the absence of the bacterium,
— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.
L. monocytogenes in other ready-to-eat foods and E. coli in live bivalve molluscs:
— satisfactory, if all the values observed are ≤ the limit,
— unsatisfactory, if any of the values are > the limit.
Salmonella in different food categories:
— satisfactory, if all the values observed indicate the absence of the bacterium,
— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

(1) The test results can be used also for demonstrating the effectiveness of the HACCP or good hygiene procedure of the process.
Histamine in fishery products from fish species associated with a high amount of histidine:
— satisfactory, if the following requirements are fulfilled:
1. the mean value observed is ≤ m
2. a maximum of c/n values observed are between m and M
3. no values observed exceed the limit of M,
— unsatisfactory, if the mean value observed exceeds m or more than c/n values are between m and M or one or more of the values observed are >M.

Chapter 2: Process hygiene criteria

Product Category	Micro-organisms/their toxins, metabolites	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
		n	C	m	M		
2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish	E.coli	5	2	1 cfu/g	10 cfu/g	ISO TS 16649-3	End of the manufacturing process Process
	Coagulase-positive Staphylococci	5	2	100 cfu/g	1000 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process Process

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) The most recent edition of the standard shall be used.

2.1 Interpretation of the test results

The limits given refer to each sample unit tested.
The test results demonstrate the microbiological quality of the process tested.
E. coli in shelled and shucked products of cooked crustaceans and molluscan shellfish:
— satisfactory, if all the values observed are < m,
— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,
— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.
Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:
— satisfactory, if all the values observed are < m,
— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are < m,
— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

Chapter 3. Rules for sampling and preparation of test samples

3.1. General rules for sampling and preparation of test samples

In the absence of more specific rules on sampling and preparation of test samples, the relevant standards of the ISO (International Organisation for Standardisation) and the guidelines of the Codex Alimentarius shall be used as reference methods.

ANNEX II

(1) The studies referred to in the General requirements (2) shall include:

(a) specifications for physico-chemical characteristics of the product, such as pH, aw, salt content, concentration of preservatives and the type of packaging

system, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life, and

(b) consultation of available scientific literature and research data regarding the growth and survival characteristics of the micro-organisms of concern.

(2) When necessary on the basis of the abovementioned studies, the food business operator shall conduct additional studies, which may include:

(a) predictive mathematical modelling established for the food in question, using critical growth or survival factors for the micro-organisms of concern in the product,

(b) tests to investigate the ability of the appropriately inoculated micro-organism of concern to grow or survive in the product under different reasonably foreseeable storage conditions,

(c) studies to evaluate the growth or survival of the micro-organisms of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use.

The above mentioned studies shall take into account the inherent variability linked to the product, the microorganisms in question and the processing and storage conditions.

PART I - PARAMETERS AND PARAMETRIC VALUES

Table 1

Microbiological Parameters

Parameter	Parametric value (number/100 ml)
Escherichia coli (E. coli)	0
Enterococci	0

Table 2

Chemical Parameters

Parameter	Parametric value	Unit	Notes
Acrylamide	0,10	μg/1	Note 1
Antimony	5,0	μg/1	
Arsenic	10	μg/1	
Benzene	1,0	μg/1	
Benzo(a)pyrene	0,010	μg/1	
Boron	1,0	mg/1	
Bromate	10	μg/1	Note 2
Cadmium	5,0	μg/1	
Chromium	50	μg/1	
Copper	2,0	mg/1	Note 3
Cyanide	50	μg/1	
1,2-dichloroethane	3,0	μg/1	
Epichlorohydrin	0,10	μg/1	Note 1
Fluoride	1,5	mg/1	
Lead	10	μg/1	Note 3 and 4
Mercury	1,0	μg/1	
Nickel	20	μg/1	Note 3
Nitrate	50	mg/1	Note 5
Nitrite	0,50	mg/1	Note 5
Pesticides	0,10	μg/1	Note 6 and 7
Pesticides – Total	0,50	μg/1	Note 6 and 8
Polycyclic aromatic hydrocarbons	0,10	μg/1	Sum of concentrations of specified compounds; Note 9
Selenium	10	μg/1	Sum of concentrations of specified parameters
Tetrachloroethene and Trichloroethene	10	μg/1	Sum of concentrations of specified compounds; Note 10
Trihalomethanes – Total	100	μg/1	
Vinyl chloride	0,50	μg/1	Note 1

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

Note 2: Where possible, and without compromising disinfecting, The Government shall strive for a lower value.

Note 3: (1) The value applies to a sample of water intended for fishery product activities obtained by an ade-quate sampling method at the tap and taken so as to be representative of a weekly average value.

(2) Where appropriate, the sampling and monitoring methods shall be applied in a harmonised fashion.

(3) The Government shall take into account the occurrence of peak levels that may cause adverse effects on human health.

Note 4: (1) The Government shall ensure that appropriate measures are taken to reduce the concentration of lead in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value.

(2) When implementing the measures to achieve compliance with that parametric value, The Government shall progressively give priority to areas where lead concentrations in water intended for human consumption are highest.

Note 5: The Government shall ensure that the conditiont [nitrate]/50 + [nitrite]/3 $\leq$ 1, the square brackets signifying the concentrations in mg/1 for nitrate (NO_3) and nitrite (NO_2), is complied with and that the value of 0,10 mg/1 for nitrites is complied with ex water treatment works.

Note 6: 'Pesticides' means –

(a) organic insecticides;

(b) organic herbicides;

(c) organic fungicides;

(d) organic nematocides;

(e) organic acaricides;

(f) organic algicides;

(g) organic rodenticides;

(h) organic slimicides; or

(i) related products (*inter alia,* growth regulators) and their relevant metabolites, degradation and reaction products.

(2) Only those pesticides that are likely to be present in a given water supply need to be monitor-ed.

Note 7: The parametric value applies to each individual pesticide and in the case of aldrin, dieldrin, hepta-chlor and heptachlor epoxide the parameter value is 0,030 μg/1.

Note 8: 'Pesticides – Total' means the sum of all individual pesticides detected and quantified in the monitoring procedure.

Note 9: The specified compounds are –

(a) benzo(b)fluoranthene;

(b) benzo(k)fluoranthene;

(c) benzo(ghi)perylene; and

(d) indeno(1,2,3-cd)pyrene

Note 10: (1) Where possible, without compromising disin-fecting, The Government shall strive for a lower value.

(2) The specified compounds are chloroform, bro-moform, dibromochloromethane, bromodichlorome-thane.

11. The Government shall ensure that appropriate measures are taken to reduce the concentration of THMs (Trihalomethanes) in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value.

12. When implementing the measures to achieve this value, The Government shall progressively give priority to those areas where THM (Trihalomethane) compounds in water intended for human consumption are highest.

Table 3

Indicator Parameters

Parameter	Parametric value	Unit	Notes
Aluminium	200	μg/1	
Ammonium	0,50	mg/1	
Chloride	250	mg/1	Note 1
Clostridium perfringens (including spores)	0	number/100 ml	Note 2
Colour	Acceptable to consumers and no abnormal change		
Conductivity	2 500	μS cm $^{-1}$ at 20^{o} C	Note 1
Hydrogen ion concentration	≥ 6,5 and ≤ 9,5		Notes 1 and 3
Iron	200	μg/1	
Manganese	50	μg/1	
Odour	Acceptable to consumers and no abnormal change		
Oxidisability	5,0	mg/1 O_2	Note 4
Sulphate	250	mg/1	Note 1
Sodium	200	mg/1	
Taste	Acceptable to consumers and no abnormal change		
Colony count 22^{o}	No abnormal change		
Coliform bacteria	0	number/100 ml	Note 5
Total organic carbon (TOC)	No abnormal change		Note 6
Turbidity	Acceptable to consumers and no abnormal change		Note 7

Table 4

Radioactivity

Parameter	Parametric value	Unit	Notes
Tritium	100	Bq/1	Notes 8 and 10
Total indicative dose	0,10	mSv/year	Notes 9 and 10

Note 1: The water shall not be aggressive.

Note 2: (1) This parameter need not be measured unless the water originates from or is influenced by surface water.

(2) In the event of non-compliance with this parametric value, The Competent Authority shall investigate the supply to ensure that there is no potential danger to human health arising from the presence of pathogenic micro-organisms, e.g. cryptosporidium, giardia (lamblia), algae and other possible pathogenic animalcules.

Note 3: (1) For still water put into bottles or containers, the minimum value may be reduced to 4, 5 pH units.

(2) For water put into bottles or containers which is naturally rich in or artificially enriched with carbon dioxide, the minimum value may be lower.

Note 4: This parameter need not be measured if the parameter TOC is analysed.

Note 5: For water put into bottles or containers, the unit is number/250 ml.

Note 6: This parameter need not be measured for supplies of less than 10 000 m^3 a day.

Note 7: In the case of surface water treatment, The Gambia shall strive for a parametric value not exceeding 1, 0 NTU (nephelometric turbidity units) in the water ex treatment works.

Note 8: Monitoring frequencies shall be set later in Annex II.

Note 9: Excluding tritium, potassium –40, radon and radon decay products; monitoring frequencies, monitoring methods and the most relevant locations for monitoring points to be set later in Annex II.

Note 10: The Gambia is not required to monitor drinking water for tritium or radioactivity to establish total indicative dose where it is satisfied that, on the basis of other monitoring carried out, the levels of tritium of the calculated total indicative dose are well below the parametric value.

PART II - MONITORING

Parameters to be analysed

1. Check monitoring

(1) The purpose of check monitoring is to provide information on the organoleptic and microbiological quality of the water supplied for human consumption as well as information on the effectiveness of drinking-water treatment (particularly of disinfecting) where it is used, in order to determine whether or not water intended for human consumption complies with the relevant parametric values laid down in this Schedule.

(2) The following parameters shall be subject to check monitoring, although the Competent Authority may add other parameters to this list if they deem it appropriate -

(a) Aluminium (Note 1);

(b) Ammonium;

(c) *Clostridium perfringens* (including spores) (Note 2);

(d) Colour;

(e) Conductivity;

(f) Escherichia coli (E. coli);

(g) Hydrogen ion concentration;

(h) Iron (Note 1);

(i) Nitrite (Note 3);

(j) Odour;

(k) Pseudomonas aeruginosa (Note 4);

(l) Taste;

(m) Colony count 22 ^{o}C and 37 ^{o}C (Note 4);

(n) Coliform bacteria; and

(0) Turbidity.

Note 1: Necessary only when used as flocculant (*).

Note 2: Necessary only if the water originates from or is influenced by surface water (*).

Note 3: Necessary only when chloramination is used as a disinfectant (*).

Note 4: Necessary only in the case of water offered for sale in bottles or containers.

(*) In all cases, the parameters are in the list for audit monitoring.

2. Audit monitoring

(1) The purpose of audit monitoring is to provide the infor-mation necessary to determine whether or not all the parametric values laid down in this Schedule are being complied with.

(2) All parameters set in accordance with regulation clause 1 and 3 shall be subject to audit monitoring unless it can be established by the Competent Authority, for a period of time to be determined, that a parameter is not likely to be present in a given supply in concentrations which could lead to the risk of a breach of the relevant parametric value.

(3)paragraph (2) does not apply to the parameters for radioactivity, which, subject to Notes 8, 9 and 10 in Part I Chapter 3 of this Schedule will be monitored in accordance with monitoring requirements adopted laid down later.

Table 1

(1) Table 1 lays down the conditions for the minimum frequency of sampling and analyses for water intended for human consumption supplied from a distribution network or from a tanker or used in a food-production undertaking.

(2) The Government shall take samples at the points of compliance as defined in regulation clause 5 to ensure that water intended for human consumption meets the requirements of these Regulations.

(3) In the case of a distribution network, the authority may take samples within the supply zone or at the treatment works for particular parameters if it can be demonstrated that there would be no adverse change to the measured value of the parameters concerned.

Table 1

Volume of water distributed or produced each day within a supply zone. **(Notes 1 and 2)** **m^3**	**Check monitoring number of samples per year.** **(Notes 3, 4 and 5)**	**Audit monitoring number of samples per year. (Notes 3 and 5)**
≤ 100	(Note 6)	(Note 6)
> 100 ≤ 1 000	4	1
> 1 000 ≤ 10 000	4 + 3 for each 1 000 m^3/d and part thereof of the total volume	1 + 1 for each 3 300 m^3/d and part thereof of the total volume
> 10 000 ≤ 100 000		3 + 1 for each 10 000 m^3/d and part thereof of the total volume
> 100 000		10 + 1 for each 25 000 m^3/d and part thereof of the total volume

Note 1: A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and within which water quality may be considered as being approximately uniform.

Note 2: The volumes are calculated as average taken over a calendar year. The Government may use the number of inhabitants in a supply zone instead of the volume of water to determine the minimum frequency, assuming a water consumption of 200 l/day/capita.

Note 3: In the event of intermittent short-term supply, the monitoring frequency of water distributed by tankers is shall decided by The Government.

Note 4: For the different parameters in Part I, The Government may reduce the number of samples specified in the table if-

(a) the values of the results obtained from samples taken during a period of at least two successive years are constant and significantly better than the limits laid down in Annex I; and

(b) no factor is likely to cause a deterioration of the quailty of the water.

(2) The lowest frequency applied shall not be less than fifty percent of the number of samples specified in the table except in the particular case of Note 6.

Note 5: As far as possible, the number of samples shall be distributed equally in time and location.

Note 6: The frequency is shall decided by Government.

PART III - SPECIFICATIONS FOR THE ANALYSIS OF PARAMETERS

The Government shall ensure that a laboratory at which samples are analysed has a system of analytical quality control that is subject from time to time to checking by a person who is not under the control of the laboratory and who is approved by the Competent Authority for that purpose.

1. Parameters for which methods of analysis are specifi-ed

The following principles for methods of microbiological parameters are given either for reference whenever a CEN/ISO method is given or for guidance of further CEN/ISO international methods for these parameters. The Government may use alternative methods, provided the provisions of regulation 100 are met.

a. Coliform bacteria and *Escherichia coli (E. coli)* (ISO 9308-1);

b. Enterococci (ISO 7899-2);

c. *Pseudomonas aeruginosa* (prEN ISO 12780);

d. Enumeration of culturable micro-organisms – Colony count 22 ^{o}C (prEN ISO 6222);

e. Enumeration of culturable micro-organisms – Colony count 37 ^{o}C (prEN ISO 6222);

f. *Clostridium perfringens* (including spores); and

g. Membrane filtration followed by anaerobic incubation of the membrane on m-CP agar (Note 1) at 44 $\pm$ 1 ^{o}C for 21 $\pm$ 3 hours; Count opaque yellow colonies that run pink or red after exposure to ammonium hydroxide vapours for 20 to 30 seconds.

Note 1: (1) The composition of m-CP agar is-

(a) Basal medium;

(b) Tryptose 30g;

(c) Yeast extract 20g;

(d) Sucrose 5g;

(e) L-cysteine hydrochloride 1g;

(f) $MgSO_4 \cdot 7H_2O$ 0,1g;

(g) Bromocresol purple 40g;

(h) Agar 1.5g; and

(i) Water 1 000g.

(2) Dissolve the ingredients of the basal medium; adjust pH to 7,6 and autoclave at one hundred and twenty on degrees celcive for fifteen minutes.

(3) Allow the medium to cool and add the following supplements after being sterilised through membrane filter of pores diameter of 0.20 μm-

D-cycloserine	400mg
Polymyxine-B sulphate	25mg
Indoxyl-β-D-glucose	60mg

to be dissolved in 8 ml sterile water before addition

Filter – sterilised 0,5% phenolphthalein 20ml diphosphate solution

Filter – sterilised 4,5 % $FeCl_3 \cdot 6H_2O$1 2ml

2. Parameters for which performance characteristics are specified -

(1) For the following parameters, the specified perfor-mance characteristics are that the method of analysis used shall, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness, precision and limit of detection specified.

(2) Whatever the sensitivity of the method of analysis used, the result shall be expressed using at least the same number of decimals as for the parametric value considered in Annex I, Parts B and C.

Parame-ters	Trueness % of parametric value (Note 1)	Precision % of parametric value (Note 2)	Limit of detection % of parametric value (Note 3)	Conditions	Notes
Acryla-mide				To be con- trolled by product specifica-tion	
Alumi-nium	10	10	10		
Ammoni-um	10	10	10		
Antimony	25	25	25		
Arsenic	10	10	10		
Benzo(a)pyrene	25	25	25		
Benzene	25	25	25		
Boron	10	10	10		
Bromate	25	25	25		
Cadmium	10	10	10		
Chloride	10	10	10		
Chromium	10	10	10		
Conduc-tivity	10	10	10		
Copper	10	10	10		
Cyanide	10	10	10		Note 4
, 2-dichloroethane	25	25	10		
Epichlorohydrin				To be con- trolled by product specification	
Fluoride	10	10	10		
Iron	10	10	10		
Lead	10	10	10		
Manganese	10	10	10		
Mercury	20	10	20		
Nickel	10	10	10		
Nitrate	10	10	10		
Nitrite	10	10	10		
Oxidisa-bility	25	25	10		Note 5
Pesticides	25	25	25		Note 6
Polycyclic aromatic hydrocarbons	25	25	25		Note 7
Selenium	10	10	10		
Sodium	10	10	10		
Sulphate	10	10	10		
Tetrachloroethene	25	25	10		Note 8
Trichloro-ethene	25	25	10		Note 8
Trihalome-thanes – Total	25	25	10		Note 7
Vinyl chloride				To be controlled by product spe-cification	

(3) For hydrogen ion concentration, the specified perfor-mance characteristics are that the method of analysis used shall be capable of measuring concentrations equal to the parametric value with a trueness of 0,2 pH unit and a precision of 0,2 pH unit.

Note 1: Trueness is the systematic error and is the difference between the mean value of the large number of repeated measurements and the true value.

Note 2: Precision is the random error and is usually expressed as the standard deviation (within and between batch) of the spread of results about the mean. Acceptable precision is twice the relative standard deviation.

(*) These terms are further defined in ISO 5725

Note 3: Limit of detection is either -

(a) three times the relative within batch standard deviation of a natural sample containing a low concentration of the parameter, or

(b) five times the relative within batch standard deviation of a blank sample.

Note 4: The method shall determine total cyanide in all forms.

Note 5: Oxidation shall be carried out for ten minutes at hundred degrees celcius (100 ^{o} c) under acid conditions using permanganate.

Note 6: The performance characteristics apply to the individual pesticide and will depend on the pesticide concerned. The limit of detection may not be achievable for all pesticides at present, but The Gambia should strive to achieve this standard.

Note 7: The performance characteristics apply to the individual substances specified at two and a half percent (2.5%) of the parametric value in Annex I.

Note 8: The performance characteristics apply to the individual substances specified at fifty percent of the parametric value in Annex I.

3. Parameters for which no method of analysis is specified are-

Colour;

Odour;

Taste;

Total organic carbon; and

Turbidity (Note 1).

Note 1: For turbidity monitoring in treated surface water, the specified performance characteristics are that the method of analysis used shall, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness, precision, and limit of detection of two and a half percent (2.5%) each.

SCHEDULE 6 (regulation 154)

This Schedule lays down Freshness Rating Tables for White Bony Fish, Bluefish, Selachii, Cephalopods, and Crustaceans provided for in regulation 154.

Freshness Rating Tables for -

(1) White Bony Fish

	Freshness category			
Criteria	**Extra**	**A**	**B**	**Not permit-ted** (1)
Skin	Bright, iridescent pigment (save for redfish) or opalescent. No discoloration	Pigmentation bright but not lustrous	Pigmentation in the process of becoming discoloured and dull	Dull pigmenta-tion
Skin mucus	Aqueous transparent	Slightly cloudy	Milky	Yellowish grey, opaque
Eye	Convex (bulging), black, bright pupil, transparent cornea	Convex and slightly sunken, black dull pupil, slightly opalescent cornea	Flat, opalescent cornea, opaque pupil	Concave in the center, grey pupil, milky cornea (2)
Gills	Bright colour, no mucus	Less coloured, transparent mucus	Brow/grey, be-coming discoloured thick opaque mucus	Yellowish, milky mucus[2]
Peritoneum (gutted fish)	Smooth, bright, difficult to detach from flesh	Slightly dull, can be detached from flesh	Speckled, comes away easily from flesh	Does not stick[2]
Smell of gills and abdominal cavity	Seaweedy	Not smell of seaweed	Fermented, slightly sour	Sour[2]
Flesh	Firm and elastic, smooth surface[3]	Less elastic	Slightly soft (flaccid), less elastic waxy (velvety) and dull surface	Soft (flaccid) 2, scales easily de-tached from skin, surface rather wrinkled

(2) Bluefish, Albacore or Long-finned tuna, Big-eye tuna, Mackerel

	Freshness category			
Criteria	**Extra**	**A**	**B**	**Not permit-ted[1]**
Skin	Bright pigmentation, bright shining iridescent colours, Clear distinction between dorsal and central surfaces	Loss of lustre and shine, duller colours, less difference between surface	Dull, lustreless, insipid colours, skin creased when fish curved	Very dull pigmentation[5]
Skin mucus	Aqueous transparent	Slightly cloudy	Milky	Yellowish grey, opaque[5]
Consi-stency of flesh	Very firm, rigid	Fairly rigid, firm	Slightly soft	Soft (flaccid)[5]
Gills covers	Silvery	Silvery, slightly red or brown	Brownish and extensive seepage of blood from vessels	Yellowish[5]
Eye	Convex (bulging), blue, black, bright Pupil transparent "eyelid"	Convex and slightly sunken, dark pupil, slightly opalescent cornea	Flat, blurred pupil, blood seepage around the eye	Concave in the center, grey pupil, milky cornea[5]
Smell of gills and abdominal cavity	Fresh sea-weedy, pungent, iodine	Not smell of seaweed, neutral smell	Slightly sulphurous fatty smell, rancid bacon cuttings, or rotten fruit	Rotten sour[5]

1 Unfit for human consumption

2 Or in a more advanced state of decay

3 Fresh fish prior to the onset of rigor mortis will not be firm and elastic but will still be graded in category Extra

4 Unfit for human consumption

5 Or in a more advanced state of decay

(3) Selachii

	Freshness category			
Criteria	**Extra**	**A**	**B**	**Not permitted[1]**
Eye	Convex, and iridescent, small pupils	Convex and slightly sunken, loss of brightness and iridescent oval pupils	Flat, dull	Concave yellowish
Appearance	In rigor mortis or partially in rigor, small quantity of clear mucus present on skin	Beyond rigor stage, no mucus on skin and especially in mouth and gill openings	Some mucus in mouth and on gill openings, slightly flattened jaw	Large quantity of mucus in mouth and gill openings (2)
Smell	Seaweed smell	No smell or very slight stale but not ammonia smell	Slight ammonia, sour	Pungent ammonia smell (2)

[1] Unfit for human consumption [2] Or in a more advanced state of decay

(4) Cephalopods

	Freshness category		
Criteria	**Extra**	**A**	**B**
Skin	Bright pigmentation skin sticks to flesh	Dull pigmentation, skin sticks to flesh	Discoloured, easily detached from flesh
Flesh	Very firm, pearly White	Firm, chalky white	Slightly soft, pinkie white or slightly yellowish
Tentacles	Resistant to Removal	Resistant to removal	More easily removed
Smell	Fresh, seaweed	Slightly or no smell	Ink smell

(5) Crustaceans

(a) shrimps

	Freshness category	
Criteria	**Extra**	**A**
Minimum requirements	Surface of the shell- moist and shiny, flesh must be free from any foreign odour, shrimp must be free from sand, mucus or other foreign matter. Cephalo-thorax must stay attached to the body	The same as for extra
Shell	No melanosis, no red legs, Hepato-pancreas intact	Red legs, hepato-pancreas opened
Smell	Fresh seaweed, slightly sweet smell	No smell of seaweed, acidulous

(b) Lobster

	Freshness category		
Criteria	**Extra**	**A**	**B**
Shell	Bright pigmentation, no discoloration, Cephalo-thorax holds on the body	Dull pigmentation	Discoloured, Cephalo-thorax easily detached from tail
Flesh	Translucide	No longer translucent but not discoloured	Opaque and dull in appearance
Eye and gills	Shiny black eyes, pink gills	Eyes dull and grey/black, gills greyish	Gill dark grey
Smell	Characteristic mild shellfish smell	Loss of characteristic shell fish smell. No ammonia smell	Slightly sour

SCHEDULE 7 (regulation 154)

This Schedule lays down the reference procedure for the determination of the concentration of volatile nitrogenous bases (TVB-N) in fish and fishery products provided for in regulation 154.

DETERMINATION OF THE CONCENTRATION OF VOLATILE NITROGENOUS BASES (TVB-N) IN FISH AND FISHERY PRODUCTS : A REFERENCE PROCEDURE

1. Purpose and area of application

This method describes a reference procedure for identifying the nitrogen concentration of volatile nitrogenous bases (Total – Volatile – Base N: TVB-N) in fish and fish products. This procedure is applicable to TVB-N concentrations from 5 mg/100 g at least 100 mg/100 g.

2. Definition

The TVB-N concentration means the nitrogen content of volatile nitrogenous bases determined by the procedure described. The concentration is stated in terms of mg/100 g.

3. Brief description

(1) The volatile nitrogenous bases are extracted from a sample by a solution of 0.6 M per-chloric acid.

(2) After alcalinsation, the extract is submitted to steam distillation, and the volatile base components are absorbed by an acid receiver.

(3) The TVB-N concentration is determined by titration of the absorbed bases.

4. Chemicals

(1) Unless otherwise indicated, reagent-grade chemicals shall be used.

(2) The water used shall be either distilled or demineralised and of at least the same purity.

(3) Unless indicated otherwise, a “solution” is to be understood as an aqueous solution.

Note 1: Perchloric acid solution = 6 g/100 ml

Note 2: Sodium hydroxide solution = 20 g/100 ml

Note 3: Hydrochloric acid standard solution 0.05 mol/1 (0.05N)

Note : when using an automatic distillation apparatus, titration should take place with a hydrochloric acid standard solution 0.01 mol/0 (0.01 N)

Note 4: Boric acid solution = 3 g/100 ml

Note 5: Silicone anti-foaming agent

Note 6: Phenolphtalein solution = 1 g/100 ml 95 % ethanol

Note 7: Indicator solution (Tashiro Mixed Indicator)

2 g Methyl – red and 1 g Methylene – blue are dissolved in 1,000 ml 95 % ethanol

5. Instruments and accessories

(1) These include -

(a) a meat grinder to produce a sufficiently homogenous fish mince;

(b) high-speed blender with revolutions of between 8,000 min –1 and 45,000 min –1;

(c) fluted filter, diameter 150 mm, quick filtering;

(d) burette, 5 ml, graduated to 0.01 ml; and

(e) apparatus for steam distillation.

(2) The apparatus shall be able to regulate various amounts of steam and produce a constant amount of steam over a given period of time.

(3) It shall ensure that during the addition of alkalising substances the resulting free bases cannot escape.

6. Execution

(1) When working with per-chloric acid, which is strongly corrosive, the necessary caution and preventive measures shall be taken.

(2) The samples shall, if at all possible, be prepared according to paragraph 7 as soon as possible after their arrival.

7. Preparation of the sample

(1) The sample to be analysed should be ground carefully by a meat grinder as described in paragraph 5 (1) (a) of this schedule.

(2) Exactly 10 g +-0.1 g of the ground sample are weighed in a suitable container, mixed with 90.0 ml perchloric acid solution as stated in paragrph 4 (1), homogenised for two minutes with a blender as described in paragraph 5 (2) and then filtered.

(3) The extract thereby obtained can be kept for at least seven days at a temperature between approximately two degrees celcius and six degrees celcius.

8. Steam distillation

(1) 50.0 ml of the extract obtained according to paragraph 7 is put in an apparatus for steam distillation as described in paragraph 5 (1) (e).

(2) For a later check on sufficient alcalinisation of the extract, several drops of phenolphtalein as specified in paragraph 4 are added.

(3) After adding a few drops silicone anti foaming agent 6.5 ml of sodium hydroxide solution as specified in paragraph 4 (2) are added to extract and steam distillation begins immediately.

(4) The steam distillation is regulated so that around 100 ml of distillate are produced within ten minutes.

(5) The distillation outflow tube is submerged in a receiver with 100 ml boric acid solution as specified in paragraph 4, to which three to five drops of the indicator solution as described in paragraph 4 have been added.

(6) After exactly ten minutes, the distillation is ended, the distilla-tion outflow tube is removed from the receiver and washed out with water.

(7) The volatile bases contained in the receiver solution are determined by titration with standard hydrochloric solution as specified in paragraph 4.

(8) The pH of the endpoint shall be 5.0+/-0.1.

9. Titration

(1) Duplicate analyses are required.

(2) The applied method is correct if the difference of the duplicates is not higher than 2 mg/100g.

10. Blank

(1) A blind test carried out as described in paragraph 8

(2) Instead of the extract, 50.0 ml per-chloric acid solution as specified in paragraph 4 are used.

7. Calculation of TVB-N

By titration of the receiver solution with hydrochloric acid as in paragraph 4, the TVB-N concentration is calculated with the following equation:

$$\text{TVB-N (expressed in mg/100 sample)} = \frac{(V1 - V0) \times 0.14 \times 2 \times 100}{M}$$

V1 = volume of 0.01 M hydrochloric acid solution in ml for sample

V0 = volume of 0.01 M hydrochloric acid solution in ml for blanc

M = weight of sampling.

Note-

1. Duplicate analyses are required. The applied method is correct if the difference between duplicates is not higher than 2 mg/100.

2. Check the equipment by distilling solutions of NH_4Cl equivalent to 50 mg TVB-/100 g.

3. Standard deviation of reproducibility Sr = 1.20 mg/100 g
Standard deviation of comparability SR = 2.50 mg/100 g.

SCHEDULE 8 (regulation 275)

This schedule lays down the Hazard Analysis Worksheet, provided for in regulation 275 to these Regulations.

Hazard Analysis Worksheet

Firm Name: _____

Firm Address: _____

_____

_____

_____

Product Description:

_____

_____

Method of Storage and Distribution:

_____

Intended Use and Consumer:

_____

_____

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/processing step	Identify potential hazards Introduced, controlled or enhanced at this step (1)	Are any potential food-safety hazards significant? (Yes/No)	Justify your decisions for column 3	What preventative measures can be applied to prevent the significant hazards?	Is this step a critical control point? (Yes/No)
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				

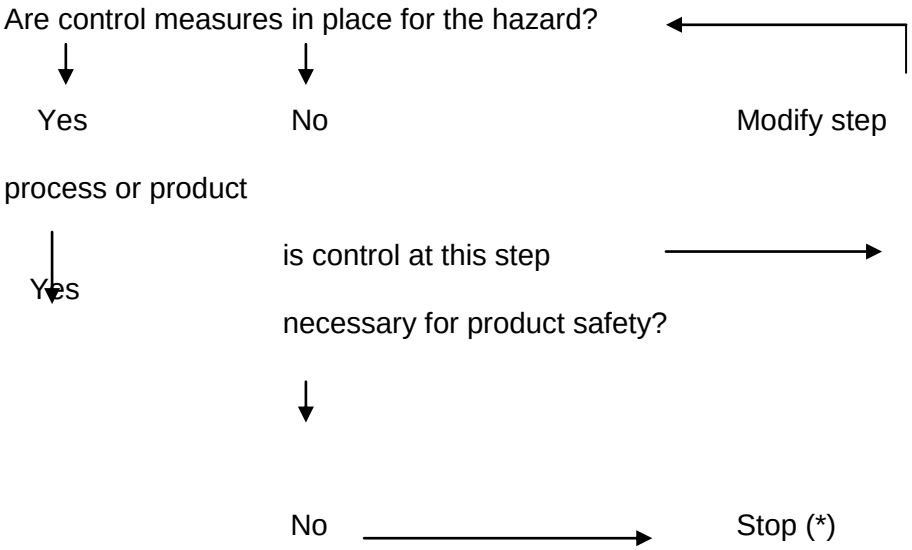
SCHEDULE 9 (regulation 275)

This Schedule lays down the decision tree for the identification of critical points, provided for in regulation 275 (7) to these Regulations.

Decision tree for the identification of critical points

Answer each question in sequence, at each step and for identification of each hazard

Question 1



Question 2

Does that step eliminate or reduce the hazard to an acceptable level?

No — Yes

Question 3

Could contamination occur at, or hazard increase to, an acceptable level?

Yes — No → Stop (*)

Question 4

Will a subsequent step eliminate or reduce the hazard to an acceptable level?

Yes → Stop (*) — No → Critical point

(*) The step is not a critical point. Proceed to next step.

SCHEDULE 10 (regulation 277)

This schedule lays down the HACCP Plan Form, provided for in regulation 277 (1) to these Regulations.

HACCP Plan Form

Firm Name:
_____

_____

Firm Address:
_____

_____

_____

_____

Product Description:
_____

_____

Method of Storage and distribution:
_____

_____

Intended Use and Consumer:
_____

_____

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	10
Critical Control Point (CCP)	Significant Hazards-(s)	Critical Limits for each Preventive measure	Monitoring				Corrective Action(s)	Records	Verification
			What	How	Frequency	Who			

Signature of Company Official: _____Date: _____

MADE THIS …… DAY OF …… 2011

……..
LAMIN KABA BAJO
MINISTER OF FISHERIES, WATER RESOURCES AND NATIONAL ASSEMBLY MATTERS