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

(a) For the passive level–
The building shall be pest proof against vermin such as insects, rodents and birds by proper design and controlling openings such as–

(i) Doors: When the door is closed it shall fit tightly so that no gap between door and frame is larger than 3mm across. Doors to the outside shall be closed when not in use for transporting goods in or out of the premises or people passing through.

(ii) Window: All windows that can be opened shall be covered with a tight fitting fly screen of mesh size less than or equal to 1mm. The frames with the fly-screen should be displaceable for cleaning purposes.

(iii) Ventilation: At some point on the way from where the ventilation duct opens to the outside of the premises to the point where it opens into the inside it shall be closed with a screen of mesh size no larger than 1 mm.

(iv) Drains: All drain openings shall be covered with grates of hole size not larger than 10 mm across. There shall be a water lock (gully traps) in the drain pipings somewhere on the way from the drain opening to the collecting well.

(v) Harbourage: Various trash and garbage inside or outside buildings that could be a harbourage for pests shall be removed.

(b) For the active level–

(i) Rodents, insects and any other vermin shall be systematically exterminated in the premises or on the equipment.

(ii) There should be available a documented plan for extermination of pests. This plan shall include–

(A) list of numbered traps and a map showing their location and 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 i.e. the presence of faecal droppings, runs and smears, holes and gnawing, damage to food, foot prints, gnawing and squeaking sounds and gnawing traces on baits;

(C) inspection of infestation in areas adjacent to premises;

(D) inspection of incoming material for pest infestation;

(E) there should be a responsible person within the firm knowledgeable about pest control and the pests likely to occur within the premises even if outside expertise on pest control is employed;

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

(iii) Rodent traps shall be strategically placed, with the assistance of an external expert if necessary, to exterminate rodents that may get into the premises. Traps may also be placed outside the premises to exterminate and monitor the presence of rodents.

(iv) At least one electric flytrap shall be installed at every entrance to rooms where processing takes place and where packaging material is stored–

(A) Fly killers shall not be placed over processing lines or in front of fans;

(B) Distance of electric trap from floor shall be 2.5 to 3 m.

(C) The fly killer shall be on 24 hours a day.

(D) Bulbs shall be replaced at least every year or according to manufacturers specifications.

(E) The catch basin should be cleaned regularly;

(iv) At least one electric flytrap shall be installed at every entrance to rooms where processing takes place and where packaging material is stored–

(A) fly killers shall not be placed over processing lines or in front of fans;

(B) distance of electric trap from floor shall be 2.5 to 3 m;

(C) the fly killer shall be on 24 hours a day;

(D) bulbs shall be replaced at least every year or according to manufacturers specifications;

(E) the catch basin should be cleaned regularly.

Rodenticides, insecticides and any other potentially toxic substances shall be stored in premises or cupboards, which can be locked. Their use shall not present any risk of contamination of the products.

Process control.

178. (1) A fail safe control system shall be implemented to check whether the pest-control plan is in compliance with the requirements described in this Section.

(2) Instructions shall be put in place to implement on a daily basis the principles and work methods designed in the procedures.

(3) Instructions shall be defined by management together with personnel to deal with the active and passive pest control.

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

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

(6) Food business operators are to ensure–

(a) that food handlers and staff are supervised and instructed,

(b) that training on the spot and special training programmes are implemented to ensure that personnel involved in pest control are trained in 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 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;

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

(H)–BEST MANUFACTURING PRACTICES

Scope of best manufacturing practices.

179. (1) Preparation and processing practices shall be implemented and maintained with the purpose to process a safe and high quality finished product.

(2) The activities considered are the activities done in the preparation, processing and packing rooms as weighing, sorting, washing, preparation, chilling, freezing, thawing, processing, packing, expedition and control activities.

Action Plan and quality objectives.

180. (1) Good manufacturing practices shall be implemented with the purpose–

(a) to avoid as much as possible any cross-contamination of the product (fillet) with contaminants from the fish (skin) or from the work and factory environment.

(b) to build up a logic and practical flow of the products from raw material to finished product.

(c) to build up a logical and practical flow of -

(i) waste products that leave the processing line

(ii) additives and packaging materials that join the processing line

(d) to organise a logical and practical flow of -

(i) dirty recipients and equipment that leave the processing line and

(ii) clean recipients and equipment that join the processing line

(e) to avoid temperature violence, exceeding the requirements specified for the process.

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

(3) These schedules and timetables shall be approved by the competent authority and checked on its execution on a regular basis.

Responsibilities and authority.

181. Responsibilities and authorities shall be established for the implementation, maintenance, monitoring and verification of the described best manufacturing practices.

Procedures for preparation and processing fishery product.

182. (1) Fishery products shall be processed rapidly, without delay and shall always be treated in a hygienic manner.

(2) All necessary and reasonable actions and precautions shall be taken in order to minimise the contamination of the fish.

(3) Fish shall never be placed on the floor without the protection of appropriate fish boxes. Also the fish boxes shall never be placed directly on the floor but on a pallet or stand.

(4) Fishery products from different harvests or from different fishing boats should, ideally, not be mixed together. Keeping them separate will prevent contamination between lots and enable easier identification in case of subsequent rejection.

5. (a) Raw materials, ingredients, intermediate products and finished products, likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health.

(b) The cold chain is not to be interrupted. However, limited periods outside temperature control are permitted to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health.

(c) During preparation or processing, the temperature of the fishery products shall be maintained at a temperature determined by management of the establishment and approved by the Competent Authority. The time-temperature combination shall be used as guideline.

(6) Should operation cease, the processing of fish, which has already started, should be finished or alternatively the fish should be transferred to a chill room or adequately iced.

(7) Deteriorated and damaged product and extraneous material shall be removed from the processing area immediately, in order to avoid contamination of the fish.

(8) Fishery products which have become spoilt, or which have been contaminated or which are no longer fit for human consumption shall not be admitted to the establishment. If identified during processing, such fish shall be isolated immediately and adequately disposed of without contaminating acceptable quality products.

Washing and decontamination of fish skin.

183. (1) The fishery products shall be decontaminated as soon as they arrive in the preparation area. This shall include–

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

(b) the washing of fishery products with adequate quantities of clean potable water where necessary and chilled to below 5° C.

(2) Fishery products shall be cleaned and washed always under running water. Cleaning and washing shall not be done in stagnant water or with hyper-chlorinated processing water.

(3) Procedures shall be documented and implemented to ensure that in all stages of the process the necessary preventive measures on the level of quality control are taken to process a safe and high quality product.

(4) The procedures represent the flow of the products through the factory. During this flow, special attention is emphasised to avoid contamination, cross-contamination and rise of temperature of the products (time-temperature control).

Preservation of fresh, chilled fishery products.

184. (1) The chilling of fishery products shall be carried out under following conditions:–

(a) the chilling of fishery products shall be performed with sufficient rapidity to prevent undesirable physical, chemical and microbiological deterioration;

(b) the temperature of fishery products that have been chilled shall reach at the end of the chilling cycle, the temperature of melting ice with a tolerance of ± 1° C;

(c) to control histamine formation, the internal temperature of the fishery products should be brought from ambient temperature to 10° C or below within 6 hours, and once chilled be maintained as close to the temperature of melting ice as possible. After chilling, during preparation or processing, the fishery products shall not be exposed to temperatures above 4° C for a cumulative period of more than 2 hours.

(2) Chill storage rooms shall comply with following conditions–

(a) establishments preparing fresh fish as a final product shall have a chill room for raw material and a chill storage room for finished fresh products;

(b) a chill storage room used to store chilled fish shall be operated at the temperature of melting ice.

(c) a chill storage room shall not be used for the purpose of the initial freezing of fish or fish product.

(d) chill storage rooms shall be kept clean and free from accumulation of ice. The floor and general structure of chill storage room shall be maintained in good condition.

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

(a) where chilled, unpackaged fishery products (raw material) are not dispatched, prepared or processed immediately after reaching the establishment, they shall be stored or displayed under ice in the establishment's chill storage room. Re-icing shall be carried out as often as necessary.

(b) the ice used, with or without salt, shall be made from potable water or clean sea water and be stored under hygienic conditions in containers provided for the purpose; such containers shall be kept clean and in a good state of repairs.

(4) Pre-packed fresh products shall be chilled with ice or mechanical refrigeration creating similar temperature conditions.

(5) 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 as quickly as possible after the products have been caught or landed. The products shall be washed thoroughly with potable water immediately after such operations;

(b) the quantities of fish on the worktables at any one time should be kept to a minimum. Fillets and slices must not remain on the worktables beyond the time necessary for their preparation. Fillets and slices must be wrapped and, where necessary, packaged and must be chilled as quickly as possible after their preparation;

(c) fish, which is held on the tables waiting processing, shall be protected by adequate quantities of ice. Due to the fact that the tables provide a good heat transfer medium, the fish should rest on a layer of ice, as well as being covered with it;

(d) should operation cease the process fishery products should not be left on the worktables. Processing of fish already on the tables shall be completed before the workers leave their posts;

(e) the internal temperature of the fishery products should be maintained below a limit designated by management and approved by the Competent Authority during processing and handling on the worktables;

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

(g) all equipment used for the filleting of fish should be washed and disinfected regularly during the process. This applies to knives, cutting boards, tables, etc;

(h) fillets should be rapidly rinsed immediately after filleting and prior to subsequent packing;

(i) all persons who fillet fish should wash their hands well and/or wear clean gloves before commencing their work;

(j) if the fillets are not immediately packed or frozen they shall be stored at 0° C with adequate quantities of ice, or in a chill storage room, different from the chill storage room for raw material;

(k) containers used for the dispatch or storage of fresh fishery products shall be designed in such a way as to ensure both their protection from contamination and their preservation under sufficiently hygienic conditions and, more particularly, they shall provide adequate drainage of melt water.

Freezing and storage of frozen products.

185. (1) Freezing of fishery products shall be carried out under the following conditions:–

(a) Establishments shall have freezing equipment in blast/contact/plate/tunnel or brine freezers sufficiently powerful to achieve a rapid reduction in the temperature so that the temperatures laid down in this regulation can be obtained as fast as possible in the core of the product.

(b) Fresh products to be frozen or quick-frozen shall comply with the requirements, the conditions and procedures for fresh products laid down in regulation 184.

(c) The freezing process shall be carried out in a way that minimises undesirable, chemical and microbiological changes.

Therefore–

(i) Fish shall be frozen in a room or chamber specifically designed for this purpose, kept clean and free from accumulation of ice.

(ii) Blocks of fish or fish products for freezing should not have a maximum thickness greater than 80 mm.

(iii) If the fish is not to be packed and frozen immediately it shall be stored with sufficient ice to maintain its temperature at 0° C or in a chill store at that temperature.

(iv) Any glaze water, which is added to the fish, shall first be chilled to 0° C. It is recommended that a mixture of ice and potable water be used.

(v) During the unloading of the freezer the internal temperature of the fish shall not be permitted to rise above –18° C. Ideally freezers should be unloaded and the fish packed in a chamber held at 0° C or less.

(vi) The packing of master cartons shall be done rapidly to prevent the internal temperature of fish rising above -18° C.

(2) When freezing fishery products, management shall take into account the freezing capabilities of the facilities:

(a) Freezing chambers or other freezing equipment, when utilised for the initial freezing of unfrozen fish or fishery products should reduce the product temperature through the zone of maximum crystallisation (in most products –1° C to –5° C) preferably within 4 hours but not exceeding 6 hours from the commencement of the refrigeration process.

(b) Where the refrigeration process is continued in order to reduce the thermal core temperature to –18° C or colder, the whole refrigeration process should be preferably completed within 8 hours, but not exceeding 12 hours.
Longer freezing times damage the texture and quality of the fishery products, and indicate that the capacity of the freezing plant is inadequate.

(c) The process should not be regarded as completed unless and until the product temperature has reached –18° C at the thermal centre after thermal stabilisation. An exception is brine frozen fish to be used for canning, which may be frozen at higher temperature, although not exceeding –9° C.

(3) Any blast freezer should not be overloaded with quantities of fish in excess of the designed capacity. Reference should be made to the specifications of the supplier of the refrigeration equipment; in order to determine the recommended capacity, but generally loading should not exceed 70 % of the internal volume.

(4) So as to keep fishery products in a frozen condition by proper storage of frozen fishery products, in cold storage rooms, the storage shall comply with the following requirements:–

(a) Plants must have freezing equipment sufficiently powerful to keep products in the storage rooms at a temperature not exceeding those laid down in these Regulations, whatever the ambient temperature may be.

(b) The floor and general structure of the cold storage rooms shall be maintained in good condition.

(c) All cold storage rooms should be kept clean and free from accumulation of ice.

(d) The cold storage room shall be well organised, with separation of different products and batches.

(e) In order to permit the free circulation of air within the cold storage room, product shall not be stored in contact with the walls or floor. The use of a pallet and rack system is recommended.

(f) Poultry, meat and other products which may contaminate the fishery products should not be stored in the cold storage room unless the product is packaged and physically separated from the seafood product.

(g) Cardboard shall not be placed on the floor for the purposes of keeping it clean.

(h) Whenever possible, any products which have been stored longest shall be the first to be distributed (first in, first out principle).

(i) Effective measures shall be taken to keep temperature variations to a minimum after the freezing process and during handling and transport.

(j) Cold storage rooms shall have a temperature-recording device in a place where it can easily be read. The temperature sensor of the recorder shall be located in the area furthest away from the cold source, i.e. where the temperature in the storage room is the highest.

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

Condition and procedures for thawing products.

186. (1) The thawing of fishery products are to be undertaken in such a way as to minimise the risk of growth of pathogenic micro-organisms or the formation of toxins in the foods. During thawing, fishery products are to be subjected to temperatures that would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, fishery products are to be handled in such a manner as to minimise the risk of growth of pathogenic micro-organisms or the formation of toxins.

(2) Establishments that carry out thawing operations shall comply with the following requirements:–

(a) Fishery products shall be thawed under hygienic and controlled time-temperature conditions; their contamination shall be avoided and there shall be adequate drainage for any melt water produced. During thawing, the temperature of the products shall not increase excessively and shall be monitored.

(b) Fishery products shall be brought to its thawed state as quickly as possible without causing undesirable physical, biochemical and microbial changes to the food.

(c) If water to thaw the fishery products is used, a control system shall be implemented.

(d) After thawing, fishery products shall be handled in accordance with requirements of this regulation. Where they are prepared or processed, these operations shall be carried out without delay. If they are put directly onto the market, particulars as to the thawed state of the fish shall be clearly marked on the packaging.

Procedures for mechanical recovery of fish.

187. Food business operators manufacturing mechanically separated fishery products must 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;

(ii) all raw materials must be free from guts;

(b) the manufacturing process must satisfy the following requirements:

(i) mechanical separation must take place without undue delay after filleting;

(ii) if whole fish are used, they must be gutted and washed before;

(iii) after production, mechanically separated fishery products must be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment;

(iv) the machinery shall be cleaned at frequent intervals at least every two hours.

Procedures for processed fishery products.

188. (1) Fresh, frozen and thawed products used for processing shall comply with the requirements laid down for fresh, frozen and thawed products in this chapter.

(2) Where the processing treatment is carried out to inhibit the development of pathogenic micro-organisms, or if it is a significant factor in the preservation of the product, the treatment shall be scientifically recognised by the inspection service.

(3) Contamination, cross-contamination and deterioration of fishery products shall be prevented–

(a) by design:

(i) operating practices shall be designed to avoid contamination of products, product surfaces and packaging materials.

(ii) processes in which there is risk of contamination to the final product including–

(A) prawn heading, de-veining and peeling;

(B) lobster heading, gutting and de-veining;

(C) dismembering, gutting and scaling of fish–

shall take place in areas physically separated by location or partition from where the product is further processed or packed.

(iii) pet food and fish meal preparation and packing shall take place in a building separated from that used for processing fishery products for human consumption;

(b) by operating practices:

(i) effective measures shall be taken to prevent raw material or semi processed material coming into contact with and contaminating the end product.

(ii) all steps in the production process including packaging shall be performed without unnecessary delay and under conditions, which will minimise the possibility of contamination, deterioration and growth of micro-organisms.

(iii) for the preparation and/or processing of high risk products:

(A) contaminated protective clothing worn by a person handling raw materials or partially processed foods shall be discarded before the person comes in contact with high risk processed food;

(B) if there is a likelihood of contamination, hands shall be washed thoroughly between handling processed food at different stages of processing;

(C) all equipment which has been in contact with raw materials or contaminated material shall be thoroughly cleaned and sanitised prior to being used in contact with processed food.

Conditions and procedures for smoking.

189. (1) The chemical composition of smoke is complex and depends among other things on the types of wood used, the method used for developing smoke, the water content of the wood and the temperature and oxygen concentration during smoke generation. Smoked foods in general give rise to health concerns, especially with respect to the possible presence of polycyclic aromatic hydrocarbons (PAH).

The following conditions and procedures shall be implemented to smoke fishery products in a conventional way -

(a) smoking shall be carried out in separate premises or a special place equipped, if necessary, with a ventilation system to prevent the smoke and heat from the combustion from affecting other premises or places where fishery products are prepared, processed or stored;

(b) materials used for the smoking of fish shall be stored away from the place of smoking and shall be used in such a way that they do not contaminate the products;

(c) materials used to produce smoke, that had been painted, varnished, glued, or has undergone preservation treatment or any other chemical treatment shall be prohibited;

(d) after smoking, products shall be cooled rapidly to the temperature required for their preservation before being packaged.

(2) Smoke flavourings are produces from smoke, subjected to fractionation and purification processes. The use of smoke flavourings is generally considered to be of less health concern than the traditional smoking process. However, the possibility of wider applications of smoke flavourings in comparison to conventional smoking has to be taken into account in safety assessments.

The following conditions and procedures shall be implemented for the application of smoke flavourings -

(a) (i) the use of smoke flavourings in or on foods shall only be authorised if it is sufficiently demonstrated that:

– it does not present risks to human health;

– it does not mislead consumers.

Each authorisation may be subject to specific conditions of use.

(ii) no person shall place on the market a smoke flavouring or any food in or on which such a smoke flavouring is present if the smoke flavouring is not a primary product authorised by the Food Unit, or if it is not derived therefrom,

and if the conditions of use laid down in the authorisation in accordance with this Regulation are not adhered to.

(b) (i) before an authorisation is given by the Competent Authority of Sierra Leone, the Competent Authority shall consult the list of the primary products authorised to the exclusion of all others in the Sierra Leone of importation for use as such in or on foods (fishery products) and/or for the production of derived smoke flavourings.

(ii) in respect of each authorised primary product, the list referred to in paragraph (i) shall give a unique code for that product, the name of the product, the name and address of the authorisation holder, a clear description and characterisation of the product, the conditions of its use in or on specific foods or food categories and the date from which the product is authorised.

(c) after an authorisation has been issued in accordance with this regulation, the authorisation holder or any other food business operator using the authorised primary product or derived smoke flavourings shall comply with any condition or restriction attached to such authorisation;

(d) the granting of an authorisation shall not diminish the general civil and criminal liability of any food business operator in respect of the authorised primary product, derived smoke flavouring or food containing the authorised primary product or derived smoke flavouring;

(e) at the first stage 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 (b) (i), the Food Unit of Sierra Leone shall ensure that the following information is transmitted to the food business operator receiving the product:

(i) the code of the authorised product as given in the list referred to in paragraph (b) (i);

(ii) the conditions of use of the authorised product as set out in the list referred to in paragraph (b) (i);

(iii) 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 food business operator can use the derived smoke flavouring in compliance with the conditions of use set out in the list referred to in paragraph (b) (i).

Polycyclic aromatic hydrocarbons (PAH).

190. A number of Polycyclic Aromatic Hydrocarbons (PAH) are genotoxic carcinogens:

(a) Benzo(a)pyrene can be used as a marker for the occurrence and effect of carcinogenic PAH in food, including also benzo (a) anthracene, benzo (b) fluoranthene, benzo (j) fluoranthene, benzo (k) fluoranthene, benzo (g, h, i) perylene, chrysene, cyclopenta (c) pyrene, dibenzo (a, h) anthracene, dibenzo (a, e) pyrene, dibenzo (a, h) anthracene, dibenzo (a, e) pyrene, dibenzo (a, h) pyrene, bibenzo (a, i) pyrene, dibenzo (a, l) pyrene, indene (1,2,3-cd) pyrene and 5 methylchrysene.

PAH can contaminate foods and especially fishery products during direct heating and fire-drying processes that allow combustion products to come in direct contact.

In order to protect public health, maximum levels are necessary for benzo(a pyrene in fishery products, where smoking or drying processes might cause high levels of contamination.

(b) Maximum levels are also necessary in foods where environmental pollution may cause high levels of contamination, in particular in fish and fishery products, for example resulting from oil spills caused by shipping.

(c) The maximum level (ìg/kg wet weight) of benzo(a) pyrene in:

(i) muscle meat of smoked fish and smoked fishery products, excluding bivalve molluscs is 5 ppb;

(ii) muscle meat of fish, other than smoked fish is 2 ppb;

(iii) crustaceans cephalopods, other than smoked is 5 ppb;

(iv) bivalve molluscs is 10 ppb.

(d) Methods available to test for multiple PAH are HPLC –fluorescence and GC-MS quadruple;

Sierra Leone 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, sub-Schedule c, Part I;

(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, sub-Schedule c, Part II.

Conditions and procedures for salting.

191. (1) Salting operations shall take place in different premises and sufficiently removed from the premises where the other operations are carried out.

(2) Salt used in the treatment of fishery products shall be clean and stored in such a way as to preclude contamination. It shall not be re-used.

(3) Any container used for salting or brining shall be constructed in such a way as to preclude contamination during the salting or brining process.

(4) Containers or areas used for salting or brining shall be cleaned before use.

Conditions and procedures for cooking crustaceans and molluscan shell fish products.

192. (1) Where products are being heated in any way such as blanching, retorting, there shall be adequate control to ensure the correct temperature/time regime is used to ensure the product achieves the desired functionality and shelf life without jeopardising human health.

(2) Any cooking shall be followed by rapid cooling. Water used for this purpose shall be potable water or on board vessels clean seawater. If no other method of preservation is used, cooling shall continue until a temperature approaching that of melting ice is reached.

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

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

(5) Every manufacturer shall carry out microbiological checks on his production at regular intervals, complying with the standards set forth in the Third Schedule.

Conditions and procedures for processing shrimps.

193. (1) All tanks or sinks used for the washing of shrimp shall be supplied with a constant flow of water, sufficient to replace the contents of the tank every ½ hour.

(2) Tanks used for the washing of shrimp should be emptied completely and washed and disinfected during every cessation in the process and between different batches of shrimp.

(3) All product which is stored for more than one day before processing should be de-headed. The priority should be to de-head the shrimp as soon as possible after arrival at the plant (if not done previously).

(4) If shrimp intended for peeling and de-veining is not to be processed immediately, it should be stored with sufficient quantity of ice to maintain its temperature at 0° C.

(5) The shrimp should be peeled and de-veined rapidly in order to minimise the rise in temperature.

(6) If the peeled and de-veined shrimp is not to be frozen immediately it should be stored at 0° C with adequate quantities of ice.

(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) If the final product is to be head-on shrimp, the processing of the raw material should commence as soon as possible after arrival at the plant. The nature of the product demands rapid processing with rigorous temperature control.

(9) Chilled water shall be used for the washing of head-on shrimp, at all stages of the process.

(10) Any areas in which cooked or head-on shrimp is processed should be air-conditioned, in order to maintain an air temperature of less than 25° C.

Conditions and procedures for cooked shrimps.

194. (1) Cooked shrimp shall only be handled in an area separate to that in which the raw product is processed. There shall be no direct access for personnel between the two areas.

(2) All personnel who handle cooked shrimp, or who work in or enter the area in which it is processed, shall wear coats, boots, hats and aprons which are used exclusively by such personnel, and which are kept separate from the protective clothing used in the processing of raw shrimp. In order to avoid confusion it is recommended that the uniforms, boots, etc. should be of a different colour.

(3) All persons entering the cooked products area shall wash their hands and boots.

(4) No equipment or other articles (including fish boxes, knives etc.) shall be transferred from an area in which raw shrimp is handled to the cooked product area, without first receiving a thorough cleaning and disinfecting.

(5) If the final product is to be head-on shrimp, this should be processed immediately, and without a period of storage.

Conditions and procedures for canning.

195. (1) The following requirements apply, only to food placed on the market in hermetically sealed containers:

(a) any heat treatment process used to process an unprocessed product or to process further a processed product is -

(i) to raise every part of the product treated to a given temperature for a given period of time; and

(ii) to prevent the product from becoming contaminated during the process;

(b) to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including the use of automatic devices;

(c) the process used should conform to an internationally recognised standard (for example, 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.

A "Standard Operating Procedure" Manual shall be compiled specifying–

(a) the establishment of the thermal process with

(i) heat penetration and

(ii) heat distribution study

(b) the process control system with–

(i) equipment description

(ii) monitoring system

(iii) general operations in thermal process room

(c) the container integrity checks–

(i) incoming containers

(ii) seaming machines

(iii) evaluation of double seam integrity

(iv) cooling water monitoring

(v) cooling of containers

(vi) post-process handling of containers

(d) the documentation and records–

(i) processing and production records;

(ii) management review of records;

(iii) process deviation records;

and shall be approved by the Food Unit.

(3) Canning conditions shall comply with following requirements –

(a) the water used for the preparation of cans shall be potable water;

(b) the process used for the heat treatment shall be appropriate, having regard to such major criteria as the heating time, temperature, filling, size of containers, etc., a record of which shall be kept;

(c) the heat treatment shall be capable of destroying or inactivating pathogenic organisms and the spores of pathogenic micro-organisms;

(d) the heating equipment shall be fitted with devices for verifying whether the containers have in fact undergone appropriate heat treatment;

(e) potable water shall be used to cool containers after heat treatment, without prejudice to the presence of any chemical additives used in accordance with good technological practice to prevent corrosion of the equipment and container.

(f) the maximum level (mg/kg net weight) for inorganic tin–

– in canned fishery products, is 200ppm (mg/kg);

– in canned foods for infants, young children and babies is 50ppm (mg/kg).

Sierra Leone shall take all measures necessary to ensure that -

(i) 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, sub-Schedule D, Part I;

(ii) 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, sub-schedule D, Part II.

(4) The following checks shall be carried out to verify the canning process:

(a) Further checks shall be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat treatment:

(i) incubation test: incubation shall be carried at 37° C for seven days or at 35° C for ten days, or at any other equivalent combination.

(ii) microbiological examination of the content of the containers in the establishment's laboratory or in another approved laboratory.

(b) Samples shall be taken of production each day at predetermined intervals, to ensure the efficiency of sealing or of any other method of hermetic closure. For that purpose, appropriate equipment shall be available for the examination of cross-sections of the can-seams.

(c) Checks carried out in order to ensure that containers are not damaged.

(d) All containers which have undergone that treatment under practically identical conditions during a same period of time shall be given a batch identification mark.

Conditions and procedures against parasites.

196. (1) The general conditions for the visual inspection shall be implemented as follows:

(a) During production, and before they are released for human consumption fish and fish products shall be subject to a visual inspection for the purpose of detecting and removing any parasites that are visible.

(b) Visual inspection shall be performed on a representative number of samples.

(c) The persons in charge of on shore plants and qualified persons on board factory vessels shall determine the scale and frequency of the inspections required in paragraph (b) 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. According to the system of gutting used, the visual inspection shall be carried out.

(i) in case of manual evisceration in a continuous manner by the operative at the time of evisceration and washing.

(ii) in the case of mechanical evisceration by sampling carried out on a representative number of samples being not less than 10 fish per batch.

(b) The visual inspection of fish fillets or fish slices shall be carried out by qualified persons during trimming after filleting or slicing. Where an individual examination is not possible because of the size of the fillets or the filleting operations, a sampling plan shall be drawn up and kept available for the Competent Authority. Where candling of

fillets is possible from a technical viewpoint, it shall be included in the sampling plan.

(3) Measures to take before release for consumption are :

(a) Fish or parts of fish which are obviously infested with parasites, and which are removed, shall not be placed on the market for human consumption.

(b) The fish and fish products referred to in paragraph (c) which are to be consumed as they are, shall, in addition be subjected to freezing at a temperature of not more than – 20° C in all parts of the product for no less than 24 hours. Products subjected to this freezing process shall be either raw or finished.

(c) Fish and products subjected to the condition in sub-paragraph (b) are:–

(i) fish to be consumed raw or almost raw.

(ii) the following species if they are to undergo a cold smoking process at which the internal temperature of the fish is less than 60° C.

- herring
- mackerel
- sprat
- (wild) Atlantic and
- Pacific salmon

(iii) marinated and/or salted herring where this process is insufficient to destroy the larvae of the nematodes.

(d) Manufacturers shall ensure that fish and fish products listed in sub-paragraph (c) or the raw materials for use in their manufacture are subject to the treatment described in sub-paragraph (b) prior to their release for consumption.

(e) The fishery products listed in sub-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) Food business operators need not carry out the treatment under sub regulation (3) if–

(a) epidemiological data are available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites; and

(b) the Food Unit so authorises.

Wrapping and packaging.

197. (1) The time that elapses between processing and packaging shall not cause the food to suffer any undesirable physical, chemical or microbiological deterioration.

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

(a) Labels, tags and adhesives used in packaging shall not contaminate food

(b) A container of food for export shall not contain any foreign objects except the food.

(3) Material used for wrapping and packaging are not to be a source of contamination.

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

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

(b) they shall not be capable of transmitting to the fishery products substances harmful to human health, and

(i) the ink used to apply description markings, inks and colorants applied to food shall not contaminate the food and shall be non-toxic.

(ii) inks applied to food or packaging shall not contain any of the following substances:-

(A) antimony

(B) arsenic

(C) cadmium

(D) chromium

(E) lead

(F) mercury

(G) other toxic metals.

(iii) fluorescent brighteners or carcinogens, mutagens and teratogens shall not be used in inks applied to food or packaging;

(iv) a lacquer applied to the inner surface or part of the inner surface of covering shall-

(A) cover the inner surface in a continuous film

(B) be uniform in thickness

(C) leave no area of the surface uncoated

(D) firmly adhere to the covering

(E) be compatible and non-toxic with the food being packed

(c) They shall be strong enough to protect the fishery products adequately:

(i) The first envelope (wrapping), which is in direct contact with the food can be plastic food packaging materials, a foam box or a can.

(ii) The second envelope (packaging), which is not in direct contact with the food, is a cardboard box or a master carton.

(d) Fishery products shall not be transported unless they are packed and covered in such a way that will enable the goods to reach their destination in a satisfactory and wholesome condition.

(e) With the exception of certain containers made of impervious, smooth and corrosion-resistant materials which are easy to clean and disinfect, which may be re-used after

cleaning and disinfecting, packaging materials may not be re-used;

(f) 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.

(g) Packaging materials used for fresh products held under ice shall provide adequate drainage for melt water.

(h) 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 88. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.

(i) Frozen blocks prepared on board vessels must be adequately wrapped before landing;

(j) When fishery products are wrapped on board fishing vessels, fish business operators must ensure that wrapping material:

(i) is not a source of contamination;

(ii) is stored in such a manner that it is not exposed to a risk of contamination;

(iii) intended for re-use is easy to clean and, where necessary, to disinfect.

(4) Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.

Traceability, origin and labelling.

198. (1) It must be possible to trace the fishery products by means of the labelling or packaging of the product, or by means of a commercial document or invoice accompanying the fishery products and to be informed about:

(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);

(c) the catch area. The indication of catch area shall consist of the following:–

(i) in the case of products caught at sea, a reference has to 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

Operators may indicate a more precise catch area.
(1)Excluding the Black Sea

(ii) in the case of products caught in freshwater a reference has to be made to the country;

(iii) in the case of farmed products a reference has to be made to the country in which the product undergoes the final development stage.

(d) In the case of combinations offered for sale–

(i) Where a combination of different species is offered for sale, the following indications shall be provided for each species:

	CN code	*Description of goods*
(a)	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.
(b)	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.
(c)	0306	Crustaceans, whether in shell or not, live, fresh, chilled, frozen, dried, salted 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.

(d) 0307 ..... Molluscs, whether in shell 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.

(ii) 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.

(iii) Where a combination is offered for sale consisting the "same species" but derived from a variety of catch areas or fish farming countries, at least the area of the batch which is most representative in terms of quantity must be stated, together with an indication that the products also came from different catch or fish farming areas.

(2) It shall be possible to trace for inspection purposes the plant of dispatch of consignments of fishery products, by means of labelling and by the accompanying documents. For that purpose, without prejudice to the provisions concerning labelling of food products laid down in these Regulations, and the provision in sub-regulation (1), at least the following information shall appear on the packaging or, in the case of non-packaged products in the accompanying documents:

(a) country of dispatch which may be written out in full or shown as an abbreviation using capitals

(b) identification of the establishment or factory vessel by its official approval number

(c) identification of the freezer vessel, in case of marketing from a freezer vessel, by its official registration number.

(3) 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.

199. (1) A fail-safe pre-control system, as part of the auto-control system, shall be implemented 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 food shall be graduated so as to be read easily and calibrated so as to be accurate.
A calibration system shall be applied either in-house or by an external authority and results of the calibration kept for 2 years unless otherwise specified in these Regulations.

(5) The following instructions shall be documented and implemented in detail for every specific case:–

(a) Work instructions, for e.g.

(i) chilling, freezing, thawing fishery products

(ii) preparation of fishery products as rinsing, filleting, skinning, trimming, grading, packing, mechanical recovery of fish

(iii) processing of fishery products as canning, smoking, salting and cooking

(iv) to prevent cross contamination, temperature abuse

(v) use of sweeteners, colours and food additives other than colours and sweeteners.

(b) Control instructions for e.g.
- controlling time-temperature conditions
- candling
- visual checks

(6) Product quality specifications as process description (nature of the packing – unit packing – volume/weight per unit packing) shelf life and storage conditions, transport conditions, distribution conditions, label information shall be in place if applicable.

(7) Product safety specifications for

(a) potential chemical hazards as:

(i) environmental chemical and pesticides

(ii) sweeteners, colours and food additives other than colours and sweeteners

(iii) ichthyotoxins

(iv) scombrotoxins

(v) ciguatera;

(b) potential biological hazards as microbes and parasites; and

(c) potential physical hazards;

shall be in place, if applicable.

(8) All procedures, instructions and specifications, control and monitoring activities shall be thoroughly documented and recorded.

(9) Food business operators are to ensure–

(a) that food handlers and staff are supervised and instructed,

(b) that training on the spot and special training programmes are implemented to ensure that food handlers and staff are trained in food hygiene matters commensurate with their work activity, and

(c) that staff are continually reminded of the risks and their responsibility within the fish industry especially concerning the 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;

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

(I)–BEST STORAGE PRACTICES

Scope of best storage practices.

200. (1) The storage of fishery products (raw materials and finished products), packaging material, cleaned recipients, tubs, baskets and equipment and other products as ingredients, additives, chemicals, has to be organised in accordance to the requirements with respect to temperature, humidity, quality and safety of the products, imposed by customers but at least to the requirements stipulated by this Section.

(2) Storage shall be under conditions that will protect materials against physical, chemical and microbiological contamination as well as against deterioration of the materials and the containers.

(3) Raw materials and all ingredients stored in a fish business are to be kept in appropriate conditions designed to prevent deterioration and protect them from contamination.

(4) Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt 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 are not to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of fishery products, provided that it does not result in a risk to health. Fish businesses manufacturing, handling and wrapping processed fishery products are to have suitable rooms, large enough for the storage of all materials. Raw materials, processed products and products already packed in cardboard shall be stored in separate storage rooms.

Action plan and quality objectives.

201. (1) Procedures and instructions shall be implemented and maintained by the fish business operators:

(a) For storage of raw materials and finished products

(i) to avoid decrease of shelf life of the products and deterioration

(ii) to avoid decomposition of fishery products

(iii) to eliminate or minimise possible occurrence of contamination and proliferation of micro-organisms.

(b) For storage of packaging material to prohibit the chance of spoilage, damage or contamination of packaging materials.

(c) For storage of chemicals:

(i) to identify hold, use and store toxic compounds in a manner that protects against contamination of food, contact surfaces of food-packaging materials

(ii) to identify, hold and store toxic cleaning compounds, disinfecting agents and pesticide chemicals in a manner that protects against contamination of fish, fish-contact surfaces or fish-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;

are allowed to be used and stored in the plant.

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

(4) These schedules and timetables shall be approved by the Competent Authority and checked on its execution on a regular basis

Responsibilities and authority.

202. (1) Responsibilities and authorities have to be established for the implementation, maintenance, monitoring and verification of the described Best Storage Practices.

(2) 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 storage.

203. (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 approaching that of melting ice–

(i) fresh or thawed unprocessed fishery products shall always be chilled with ice, whether or not completed with mechanical refrigeration.

(ii) prepacked fishery products may be chilled with ice or with mechanical refrigeration.

(b) Frozen fishery products with the exception of frozen fish in brine intended for the manufacture of canned foods shall be kept at an even temperature of –18° C or less in all parts of the product.

To prevent to histamine formation in scombrotoxin fish species that has first been chilled and then frozen for a long time, fish should not be exposed to a temperature rise above 4.4 ° C from the time it is frozen for a cumulative period of more than 12 hours. An uninterrupted period of exposure should not exceed 6 hours.

(c) Processed products shall be kept at the temperature specified by the manufacturer.

(d) Fishery product kept alive must 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.

204. (1) Fresh fishery products shall be–

(a) maintained under conditions that will prevent spoilage;

(b) protected against damage;

(c) protected against contamination;

(d) not processed or used unless inspected for contamination, decomposition and parasites and found to be in a sound condition. The nature and frequency of such inspections shall be set by the exporter and approved by the Competent Authority.

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

(3) No materials other than those used for immediate processing shall be stored in an area in use or in processing.

Storage conditions for frozen fishery products.

205. (1) The freezing of fish shall not be carried out in a cold store.

(2) Frozen fish shall be protected from dehydration and freezer burn by–

(a) the application of a glaze or

(b) by enclosure in an impervious wrap.

(3) (a) 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.

(b) All measuring instruments used for the purpose of monitoring the temperature, as provided for in paragraph (a), shall comply with EN 12830, EN 13485 and EN 13486 standards.
Food operators shall keep all relevant documents permitting verification that the instruments referred to above conform to the relevant EN standards.

(c) Temperature recording shall be dated and stored by the food operator for a period of at least one year, or for a longer period taking into account the nature and the shelf-life of the frozen fishery products.

(4) The air velocity in cold store rooms shall be moderate and no higher than necessary to achieve uniform temperatures within the rooms.

(5) Products should be stacked so that air circulation within the storage room is not impaired. Except in jacketed rooms no direct contact with ceilings and floors shall be allowed.

(6) A system of controlled stock rotation shall be employed in cold stores and chill rooms.

Storage conditions for dry ingredients.

206. (1) Dry ingredients shall be stored in a closed, good ventilated, pest proof and clean area with the required room temperature and humidity. The products shall be protected against spoilage, damage and contamination.

Storage for packaging materials.

207. (1) Packaging materials shall be stored in a closed, good ventilated, pest proof, dust-free and clean area with the required room temperature and humidity.

(2) Packaging materials shall be protected by poly-sheets in a way that the inside of the boxes are protected against contamination.

(3) Empty cans shall not be exposed at ambient conditions without protection.

Storage for conditions for hazardous substances.

208. (1) Pesticides, cleaning agents or other substances which could represent a hazard to health shall be suitably labelled with a warning about their toxicity and use and extreme care taken to avoid the chemicals contaminating food, food contact surfaces and ingredients.

(2) Hazardous substances shall be stored in rooms or cabinets used only for that purpose and handled only by authorised and properly trained persons.

(3) Except when necessary for hygienic or preparation purposes no substances which could contaminate food may be used or stored in food handling areas or be stored with any product, ingredients or product packaging material.

Process control.

209. (1) A fail-safe control system shall be implemented–

(a) To control temperatures of chill rooms and cold rooms. Cold rooms (storage rooms for frozen products) shall have a temperature

recording device in place and temperature charts shall be available for inspection by the supervisory authorities at least during the period in which the products are stored.

(b) To control the compliance with the requirements for–

(i) chemicals;

(ii) packaging materials;

(A) first envelope (poly-bags and poly-styrene boxes);

(B) second envelope (cartons);

laid down in the Supplier Quality Assurance Agreement for chemicals, ingredients and packaging materials.

(2) 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.

(3) Temperature standards and tolerances shall be implemented in every establishment.

(4) The temperature conditions, the hygienic conditions and the piling practices in chill storage rooms, cold storage rooms and other storage facilities shall be recorded.

(5) Food business operators are to ensure–

(a) that food handlers and staff are supervised and instructed,

(b) that training on the spot and special training programmes are implemented to ensure that food handlers and staff are trained in food hygiene matters commensurate with their work activity, and

(c) that staff are continually reminded of the risks and their responsibility within the fish industry especially concerning the 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 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.

(J) - BEST TRANSPORT PRACTICES

Scope of best transport practices.

210. (1) The transport of fishery products (raw materials and finished products) has to be organised in accordance with the requirements with respect to temperature, humidity, quality and safety of the products, imposed by customers but at least to the requirements imposed by this regulation, including–

(a) 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.

(b) all measuring instruments used for the purpose of monitoring the temperature, as provided for in paragraph (1) (a) of this regulation, shall comply with EN 12830, EN 13485 and EN 13486 standards.
Food operators shall keep all relevant documents permitting verification that the instruments referred to above conform to the relevant EN standards.

(c) temperature recording shall be dated and stored by the food operator for a period of at least one year, or for a longer period taking into account the nature and the shelf-life of the frozen fishery products.

(2) Transport shall be done under conditions that will protect materials against physical, chemical and microbiological contamination as well as against deterioration of the materials and containers.

Quality objectives and action plan.

211. (1) Procedures and instructions shall be implemented and maintained by the fish business operators–

(a) for transport of raw materials and finished products, so as–

(i) to avoid decrease of shelf life of the products

(ii) to avoid decomposition of fishery products

(iii) to eliminate possible occurrence of contamination;

(b) for transport of packaging material, to prohibit the chance of spoilage, damage or contamination

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

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

Responsibilies and authority for transport practices.

212. (1) Responsibilities and authorities have to be established for the implementation, maintenance, monitoring and verification of the described transport practices.

(2) It shall be the responsibility of the owner of the vehicle to comply with the provisions of this Section. However, the management of the establishment shall supervise the unloading of vehicles and shall communicate to its owner the existence of any infractions.

(3) Procedures shall be defined to ensure that the hygienic requirements for contamination prevention, temperature maintenance with respect to transport of raw materials, finished products and packaging materials are met.

Temperature conditions during transport.

213. Fishery products shall, during transport, be kept at the temperature laid down in this Section and, in particular–

(a) fresh or thawed fishery products and cooked and chilled crustacean and molluscan shellfish products shall be kept at the temperature of melting ice–

(i) fresh or thawed fishery products shall always be chilled with ice whether or not completed with mechanical refrigeration.

(ii) prepared fishery products may be chilled with ice or with mechanical refrigeration;

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

Fish business operators do not need to comply with the first paragraph, when frozen fishery products are transported from a cold storage plant to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing and if the journey is short and the Food Unit so permits;

(c) processed products shall be kept at the temperature specified by manufacturer;

(d) whole and gutted fresh fishery products may be transported and stored in cooled water on board vessels. They may also continue to be transported in cooled water after landing, and be transported from the aquaculture establishments, until they arrive at the first establishment on land carrying out any activity other than transport or sorting.

Hygienic conditions for vehicles transporting fishery products.

214. (1) The parts of the vehicle, in which chilled or frozen fish is transported shall–

(a) be clean and in good state of repair

(b) be covered during transport of the product in order to prevent exposure to dust, birds, insects and sunlight;

(c) be of adequate size, shall have sections or containers designed specifically for storage of fishery products;

(d) be constructed and equipped in such a way that the temperature laid down in this regulation can be maintained throughout the period of transport;

(e) be equipped with internal surfaces of the cargo area constructed from smooth, corrosion resistant impervious materials, free from cracks and crevices, which are easy to clean. The use of wood is not permitted unless it is painted with gloss paint of a light colour and the fish are carried in fish boxes;

(f) have internal surface joints that are smooth or flush and sealed to prevent the entry of moisture and shall be finished in such a way that they do not adversely affect the fishery products and shall be easy to clean and disinfect;

(g) have adequate drainage, if ice is used to chill the products, in order to ensure that water from melted ice does not stay in contact with the products;

(h) if lighting is supplied, have light sources covered by a shatterproof shield.

(2) The hygiene conditions on construction level for vessels transporting fishery products are laid down in regulation 66.

General transport conditions for fishery products.

215. (1) Means of transport used for fishery products may not be used for transporting other products likely to impair, transmit harmful properties or abnormal characteristics, or contaminate fishery products, except where the fishery products can be guaranteed uncontaminated as a result of such transport being thoroughly cleaned and disinfected.

(2) The fishery products shall not be impaired by the smell or odour of the mechanical cooling system.

(3) Animals shall never be carried in the cargo area.

(4) Ramps, if provided, shall not be stowed in the cargo area.

(5) Fishery products shall not be transported in a vehicle or container which is not clean or which should have been disinfected.

(6) Vehicles may transport only fishery products, which are fit for human consumption. The transport of wastes and by-products in fish vehicles is prohibited.

(7) After each journey the vehicle and any fish boxes used should be washed with water and detergent, followed by a disinfecting.

Requirements for specific types of transport.

216. (1) The transport of raw fishery products fresh on ice by road shall be done–

(a) in closed insulated containers (whereby is agreed that the different layers of raw materials are completely covered with ice) in open means of transport, or,

(b) in open not insulated containers stored in insulated and dust free means of transport, provided with mechanical refrigeration where the distance to be covered or the journey is so long that melting of ice cannot be avoided without mechanical refrigeration.
Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water does not remain in contact with the products.

(2) Raw fresh frozen fishery products shall be transported in clean closed pre-cooled containers, holds or other means of transport on the appropriate temperature laid down in this regulation, provided with a thermometer to be able to control temperature.

(3) Fishery products to be placed on the market live must be transported in such a way as not adversely to affect food safety or their viability.

(4) Packed frozen finished products in cartons and packed fresh on ice finished products in polystyrene packaging material are transported in clean closed pre-cooled containers or other means of transport, on the appropriate temperature, laid down in this regulation, provided with a thermometer to be able to control temperature.

(5) Fishery products which have been subjected to sterilisation in hermetically sealed containers shall be transported in clean closed containers or other means of transport on ambient temperature in a way that cartons and the cans are not damaged during loading, transport and off loading.

(6) The shipment containers used to transport frozen products shall be made of easy to clean material, and are checked and pre-cooled before loading. After stuffing, the container is again cooled down to –18° C before leaving the establishment for the harbour.

(7) A Fail Safe Control system shall be implemented whereby the transport activities of raw materials and finished products are checked and controlled on their compliance with the activities described in the procedures and the instructions.

(8) Instructions shall be put in place by food business operators for–

(a) 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.

(9) Specifications shall be defined for all means of transport and their use.

(10) All procedures, instructions, specifications, control and check activities shall be thoroughly documented and recorded.

Training of transportation staff, etc.

217. (1) 1. Food business operators are to ensure–

(a) that food handlers and staff are supervised and instructed,

(b) that training on the spot and special training programmes are implemented to ensure that food handlers and staff are trained in food hygiene matters commensurate with their work activity, and

(c) that staff are continually reminded of the risks and their responsibility within the fish industry 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;

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

(K) BEST WASTE DISPOSAL PRACTICES

Scope of best waste disposal practices.

218 The establishment shall have appropriate facilities–

(a) to treat the by-products on an appropriate way, in case these by-products are products destined for human consumption,

(b) to separate guts, parts, non edible by-products and other waste that may constitute a danger to public health and remove from the vicinity of product intended for human consumption,

(c) to drain the liquid waste water and treat the sewage.

Quality objectives and action plan.

219. (1) Procedures and instructions shall be implemented and maintained:

(a) to treat the by-products, if applicable,

(b) to prevent the contamination of fishery products with bacteria from residues and wastes,

(c) to deal with wastewater drainage and sewage treatment.

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

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

(4) Responsibilities and authorities shall be established for the implementation, maintaining, monitoring and verification of regulations described in Best Waste Disposal Practices.

Procedures

220. (1) Procedures shall be defined to ensure that the hygienic requirements with respect to by-products, solid and liquid waste disposal are met.

(2) Waste containers and their use shall comply with the following hygienic requirements:–
Unless special facilities are provided, for the continuous disposal of waste, the latter shall be placed in leak-proof, impermeable containers–

(a) which are provided with tight fitting lids to prevent the entry of insects, rodents and other animals;

(b) which are designed to facilitate cleaning and disinfecting;

(c) which are clearly marked for that purpose only or be of a different colour to boxes used for fish for human consumption;

(d) which, when used for temporary storage of viscera and offal in the work room, should be kept below the level of the work tables to avoid splashing and contamination of the product;

(e) which shall be always thoroughly cleaned and disinfected after use.

(3) Disposal of waste shall comply with the following hygienic requirements:–

(a) waste shall not be allowed to accumulate in working areas but shall be removed either continuously or regularly, as soon as the

containers are full, but at least at the end of each working day, from the main work room to the premises allocated for the storage of such containers;

(b) waste shall be removed from the vicinity of the establishment at regular intervals in a hygienic and environmentally friendly way in order to ensure that the waste not constitute a source of contamination for the establishment or of pollution of its surroundings by the development of smells and the presence of insects and rodents;

(c) the room in which residues and wastes are stored shall–

(i) have a permanent water supply and adequate drainage;

(ii) be kept clean and free of animals and pests;

(iii) be regularly inspected to ensure that this requirement is met.

(4) A Fail Safe Control System shall be installed to control the compliance with the requirements laid down in regulations 219 (2) and 219 (4) .

(5) Instructions shall be documented and implemented on how to–

(a) treat the by-products if applicable;

(b) dispose of guts, offal and waste;

(c) deal with waste water and sewage;

(d) store and remove waste; and

(e) organise the cleaning and disinfecting of containers, waste storage rooms, waste water drainage channels, solid mesh traps, gully traps and manholes.

(6) Specifications shall be in place concerning identifications and the use of the waste containers.

. (7) All procedures and instructions, control and check activities shall be thoroughly documented and recorded.

Training for waste disposal staff.

221 Food business operators are to ensure:–

(a) that food handlers and staff are supervised and instructed,

(b) that training on the spot and special training programmes are implemented to ensure that food handlers and staff are trained in food hygiene matters commensurate with their work activity, and

(c) that staff are continually reminded of the risks and their responsibility within the fish industry especially concerning the hygienic handling of by-products or waste products or both;

(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.

PART XIII –CONDITIONS FOR THE USE OF FOOD ADDITIVES

Food additives in general.

222. (1) Fishery products, intended to be placed on the market shall not contain sweeteners, colours or food additives other than sweeteners and colours–

(a) included in these Regulations, or

(b) in excess of any maximum quantity or proportion permitted by the regulations of Part XIV.

(2) In the context of these Regulations, “quantum satis” means that no maximum level is specified. However, colouring matters shall be used according to best manufacturing practices at a level not higher than is necessary to achieve the intended purpose and provided that they do not mislead the consumer.

(3) Maximum levels indicated in these Regulations refer to fishery products as marketed unless otherwise stated.

Sweeteners.

223. (1) Sweeteners within the meaning of these Regulations are food additives, which are used to impart a sweet taste to processed fishery products.

(2) Only the following sweeteners at the mentioned concentrations may be used in the manufacture of sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs:–

E950 Acesulfame K at 200 mg/kg
E951 Aspartame at 300 mg/kg
E954 Saccharine and its Na, K and Ca salts at 160 mg/kg
E959 Neohesperidine DC at 30 mg/kg

Colours.

224. (1) "Colours" within the meaning of these Regulations are–

(a) substances, which add or restore colour in a food, and include natural constituents of foodstuffs and natural sources which are normally not consumed as foodstuffs as such and not normally used as characteristic ingredients of food.

(b) preparations obtained from foodstuffs and other natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents.

(2) However, the following substances shall not be considered colours for the purposes of these Regulations–

(a) foodstuffs, whether dried or in concentrated form and flavourings incorporated during the manufacturing of compound foodstuffs, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect, such as paprika, turmeric and saffron

(b) colours used for the colouring of the inedible external parts of foodstuffs.

(3) The colour, E160 b Annatto, Bixin, Norbixin may be used at 10 mg/kg in smoked fishery products.

(4) In following processed fishery products–

(a) fish paste and crustacean paste;

(b) precooked crustaceans;

(c) salmon substitutes;

(d) surimi;

(e) fish roe;

(f) smoked fish;

under-mentioned colours may be used at quantum satis:

E101	(i)	Riboflavin
	(ii)	Riboflavin-5'-phosphate
E140		Chlorophylls and chlorophyllins
E141		Copper complexes of chlorophylls and chlorophyllins
E150a		Plain caramel
E150b		Caustic sulphite caramel
E150c		Ammonia caramel
E150d		Sulphite ammonia caramel
E153		Vegetable carbon
E160a		Carotenes
E160c		Paprika extract, capsanthin, capsorubin
E162		Beetroot red, betanin
E163		Anthocyanins
E170		Calcium carbonate
E171		Titanium dioxide
E172		Iron oxides and hydroxides

(5) Following colours:–

E100	Curcumin
E102	Tartrazine
E104	Quinoline Yellow
E110	Sunset Yellow FCF
	Orange Yellow S
E120	Cochineal, Carminic acid, Carmines
E122	Azorubine, Carmoisine
E124	Ponceau 4R, Cochneal Red A
E129	Allura Red AC

E131	Patent Blue V
E132	Indigotine, Indigo carmine
E133	Brilliant Blue FCF
E142	Green S
E151	Brillant Black BN, Black PN
E155	Brown HT
E160d	Lycopene
E160c	Beta-apo-8'-carotenal (C30)
E160f	Ethyl ester of Beta-apo-8'-carotenic acid (C30)
E161b	Lutein

may be used single or in combination in–

(a) fish paste and crustacean paste up to the maximum level of 100 mg/kg

(b) precooked crustaceans up to the maximum level of 250 mg/kg

(c) salmon substitutes up to the maximum level of 500 mg/kg

(d) surimi up to the maximum level of 500 mg/kg

(e) fish roe up to the maximum level of 300 mg/kg

(f) smoked fish up to the maximum level of 100 mg/kg.

Food additives other than colours and sweeteners.

225 (1) Food additives other than colours and sweeteners within the meaning of these Regulations are–

(a) "preservatives" are substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by micro-organisms;

(b) "antioxidants" are substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes;

(c) "carriers", including carrier solvents, are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive without altering its technological function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;

(d) "acids" are substances which increase the acidity of a foodstuff or impart a sour taste to it or both;

(e) "acidity regulators" are substances which alter or control the acidity or alkalinity of a foodstuff;

(f) "anti-caking agents" are substances which reduce the tendency of individual particles of a foodstuff to adhere to one another;

(g) "anti-foaming agents" are substances which prevent or reduce foaming;

(h) "bulking agents" are substances which contribute to the volume of a foodstuff without contributing significantly to its available energy value;

(i) "emulsifiers" are substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff;

(j) "emulsifying salts" are substances which convert proteins contained in cheese into a dispersed form and thereby bring about homogenous distribution of fat and other components;

(k) "firming agents" are substances which make or keep tissues of fruit or vegetables firm or crisps, or interact with gelling agents to produce or strengthen a gel;

(l) "flavour enhancers" are substances which enhance the existing taste or odour or both of a foodstuff;

(m) "foaming agents" are substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff;

(n) "gelling agents" are substances which give a foodstuff texture through formation of a gel;

(o) "glazing agents" (including lubricants) are substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating;

(p) "Humectants" are substances which prevent foodstuffs from drying out by counteracting the effect of an atmosphere having a low degree of humidity, or promote the dissolution of a powder in an aqueous medium;

(q) "Modified starches" are substances obtained by one or more chemical treatments of edible starches, which may have undergone a physical or enzymatic treatment, and may be acid or alkali thinned or bleached;

(r) "packaging gases" are gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container;

(s) "propellants" are gases other than air which expel a foodstuff from a container

(t) "raising agents" are substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter

(u) "sequestrants " are substances which form chemical complexes with metallic ions

(v) "stabilizers" are substances which make it possible to maintain the physico-chemical state of a foodstuff; stabilizers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a food, substances which stabilize, retain or intensify an existing colour of a foodstuff; and substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into reconstituted food;

(w) "thickeners" are substances, which increase the viscosity of a foodstuff.

(2) For the purpose of these Regulations the following are not considered as food additives:–

(a) substances used for treatment of potable water

(b) products containing pectin and derived from dried apple pomace or peel of citrus fruits, or from a mixture of both, by the action of dilute acid followed by partial neutralisation with sodium or potassium salts ("liquid pectin");

(c) chewing gum bases;

(d) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolitic enzymes;

(e) ammonium chloride;

(f) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten;

(g) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts and having no additive function;

(h) caseinates and casein;

(i) inulin.

(3) (a) the presence of a food additive is permissible–

(i) 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;

(ii) 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; or

(iii) if the foodstuff is destined to be used solely in the preparation of a compound fish foodstuff;

(b) 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. Furthermore, the presence of additives in flavourings must not mislead consumers or present a hazard to their health. 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.

(4) In processed fishery products, the under mentioned food additives may be used at quantum satis:

E170 Calcium carbonate
- (i) Calcium carbonates
- (ii) Calcium hydrogen carbonate

E260 Acetic acid
E261 Potassium acetate
E262 Sodium acetates
- (i) Sodium acetate
- (ii) Sodium hydrogen acetate (diacetate)

E263 Calcium acetate
E270 Lactic acid
E290 Carbon dioxide
E296 Malic acid
E300 Ascorbic acid
E301 Sodium ascorbate
E302 Calcium ascorbate
E304 Fatty acid esters of ascorbic acid
- (i) Ascorbyl palitate
- (ii) Ascorbyl stearate

E306 Tocopherol-rich extract
E307 Alpha-tocopherol
E308 Gamma-tocopherol
E309 Delta-tocopherol
E322 Lecithins
E325 Sodium lactate
E326 Potassium lactate
E327 Calcium lactate
E330 Citric acid
E331 Sodium citrates
- (i) Monosodium citrate
- (ii) Disodium citrate
- (iii) Trisodium citrate

E332 Potassium citrates
- (i) Monopotassium citrate
- (ii) Tripotassium citrate

E333 Calcium citrates
- (i) Monocalcium citrate

(ii) Dicalcium citrate
(iii) Tricalcium citrate

E334 Tartaric acid

E335 Sodium tartrates
(i) Monosodium tartrate
(ii) Disodium tartrate

E336 Potassium tartrates
(i) Monopotassium tartrate
(ii) Dipotassium tartrate

E337 Sodium malates
(i) Sodium malate
(ii) Sodium hydrogen malate

E351 Potassium malate

E352 Calcium malate
(i) Calcium malate
(ii) Calcium hydrogen malate

E354 Calcium tartrate

E380 Triammonium citrate

E400 Alginic acid

E3401 Sodium alginate

E402 Potassium alginate

E403 Ammonium alginate

E404 Calcium alginate

E406 Agar

E407 Carrageenan

E410 Locust bean gum

E412 Guar gum

E413 Tragacanth

E414 Acacia gum (gum arabic)

E415 Xanthan gum

E417 Tara gum

E418 Gellan gum

E422 Glycerol

E440 Pectins
(i) pectin
(ii) amidated pectin

E460 Cellulose
(i) microcrystalline cellulose
(ii) powdered cellulose

E461 Methyl cellulose

E463 Hydroxpropyl cellulose

E464 Hydroxpropyl methyl cellulose

E466 Carboxy methyl cellulose, cellulose gum
Sodium carboxy methyl cellulose

E470a Sodium, potassium and calcium salts of fatty acids

E470b Magnesium salts of fatty acids

E471 Mono- and diglycerides of fatty acids

E472a Acetic acid esters of mono- and diglycerides of fatty acids

E472b Lactic acid esters of mono-and diglycerides of fatty acids

E472c Citric acid esters of mono- and diglycerides of fatty acids

E472d Tartaric acid esters of mono- and diglycerides of fatty acids

E472e Mono- and diacetyl tartaric acid esters of mono- and diglycerids of fatty acids

E472f Mixed acetic and tartaric acid esters of mono and diglycerides of fatty acids.

E500 Sodium carbonates
(i) Sodium carbonate
(ii) Sodium hydrogen carbonate
(iii) Sodium sesquicarbonate

E501 Potassium carbonates
(i) Potassium carbonate
(ii) Potassium hydrogen arbonate

E503 Ammonium carbonates
(I) Ammonium carbonate
(II) Ammonium hydrogen carbonate

E504 Magnesium carbonates
(i) Magnesium carbonate
(ii) Magnesium hydroxide carbonate (syn. Magnesium hydrogen carbonate)

E507 Hydrochloric acid

E508 Potassium chloride

E509 Calcium chloride

E511 Magnesium chloride

E513 Sulphuric acid
E514 Sodium sulphates
(i) Sodium sulphate
(ii) Sodium hydrogen sulphate
E515 Potassium sulphates
(i) Potassium sulphate
(ii) Potassium hydrogen sulphate
E516 Calcium sulphate
E524 Sodium hydroxide
E525 Potassium hydroxide
E526 Calcium hydroxide
E527 Ammonium hydroxide
E528 Magnesium hydroxide
E529 Calcium oxide
E530 Magnesium oxide
E570 Fatty acids
E574 Gluconic acid
E575 Glucono-delta-lactone
E576 Sodium gluconate
E577 Potassium gluconate
E578 Calcium gluconate
E640 Glycine and its sodium salt
E938 Argon*
E939 Helium*
E941 Nitrogen*
E942 Nitrous oxide*
E948 Oxygen*
E1200 Polydextrose
E1404 Oxidised starch
E1410 Monostarch phosphate
E1412 Distarch phosphate
E1413 Phosphated distarch phosphate
E1414 Acetylated distarch phosphate
E1420 Acetylated starch
E1422 Acetylated distarch adipate
E1440 Hydroxy propyl starch
E1442 Hydroxy propyl distarch phosphate
E1450 Starch sodium octenyl succinate
E420 Sorbitol

(i) Sorbitol
(i) Sorbitol syrup
E421 Mannitol
E953 Isomalt
(i) Maltitol
(ii) Maltitol syrup
E966 Lactitol
E967 Xylitol

(5) In processed fishery products–
(a) under mentioned food additives
E620 Glutamic acid
E621 Monosodium glutamate
E622 Monopotassium glutamate
E623 Calcium diglutamate
E624 Monoammonium glutamate
E625 Magnesium diglutamate;
may be used individually or in combination up to the maximum level of 10 g/kg
(b) undermentioned food additives
E626 Guanylic acid
E627 Disodium guanylate
E628 Dipotassium guanylate
E629 Calcium guanylate
E630 Inosinic acid
E631 Disodium inosinate
E632 Dipotassium inosinate
E633 Calcium mesinate
E634 Calcium 5'-ribonucleotides
E635 Disodium 5'-ribonucleotides
may be used individually or in combination expressed as guanylic acid up to the maximum level of 500 mg/kg.

(6) In raw or prepared fishery products following food additive:–
E290 Carbon dioxide
E938 Argon
E939 Helium
E941 Nitrogen
E948 Oxygen

E331 Sodium citrates
E332 Potassium citrates
E333 Calcium citrates
E420 Sorbitol
(i) Sorbitol syrup
E421 Mannitol
E953 Isomalt
E965 Maltiol
(i) Maltiol
(ii) Maltiol syrup
E966 Lactitol
E967 Xylitol

may be used at quantum satis.

(7) In frozen, raw, prepared or processed fish, crustaceans, molluscs and cephalopods undermentioned food additives may be used at quantum satis:

E420 Sorbitol
(i) Sorbitol
(i) Sorbitol syrup
E421 Mannitol
E953 Isomalt
(i) Maltitol
(ii) Maltitol syrup
E966 Lactitol
E967 Xylitol

Preservatives.

226 (1) Following groups of preservatives mentioned in this regulation can be used to prolong the shelf-life of fishery products–

(2) Following sorbates:–

E200 Sorbic acid
E202 Potassium sorbate
E203 Calcium sorbate and

following benzoates:–

E210 Benzoic acid
E211 Sodium benzoate
E212 Potassium benzoate
E213 Calcium benzoate

may be used singly or in combination in

(a) semi preserved fish products including fish roe products up to the maximum level of 2000 mg/kg or mg/l

(b) salted dried fish up to the maximum level of 200 mg/kg

(c) cooked shrimps up to the maximum level of 2000 mg/kg

(d) cooked Crangon crangon and Crangon vulgaris up to maximum level of 6000 mg/kg

(e) cooked crayfish tails up to maximum level of 2000mg.kg

whereby the levels of all substances mentioned above are expressed as the free acid.

(3) The following preservative food additives described as sulphur dioxide and sulphites:–

E220 Sulphur dioxide
E221 Sodium sulphite
E222 Sodium hydrogen sulphite
E223 Sodium metabisulphite
E224 Potassium metabisulphite
E226 Calcium sulphite
E277 Calcium hydrogen sulphite
E228 Potassium hydrogen sulphite

may be used singly or in combination in–

(a) fresh and frozen crustaceans and cephalopods up to the maximum level of 150 mg/kg in the edible parts

(b) crustaceans, family of penaeidae, solenoceridae, aristeidae

(i) up to 80 units/per kg, up to the maximum level of 150 mg/kg in the edible parts

(ii) between 80 and 120 units/per kg, up to the maximum level of 200 mg/kg in the edible parts

(iii) over 120 units/per kg, up to the maximum level of 300 mg/kg in the edible parts

(iv) cooked, up to maximum level of 50 mg/kg in the edible parts

(c) whereby–

(i) maximum levels are expressed as SO_2 in mg/kg and relate to the total quantity, available from all sources

(ii) an SO_2 content of not more than 10 mg/kg is not considered to be present.

(4) 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 $NaNO_2$.

(5) 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 storage and use of flavourings.

227. (1) Flavourings fall within the definition of food. "Flavouring" means flavouring substances, flavouring preparations, process flavourings, smoke flavourings or mixtures thereof.

(2) 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. However, if under certain circumstances the additive does have a technological function in the compound foodstuff, it should 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

should apply, including the labelling rules relating to the labelling, presentation and advertising of foodstuffs.

(3) The following additives can be added to the flavourings–

(i) Sorbates, benzoates and p-hydroxy benzoates can be used singly or in combination in flavourings up to the maximum level of 1500mg/kg;

(ii) E310 (propylgallate)

E311 (octylgallate)
E312 (dodecylgallate)
E320 (butylated)
hydroxyanisole (BHA) can be used in flavourings other than essential oils up to a maximum of 100mg/kg (gallates individually or in combination) or 200mg/kg (BHA);

(iii) E338 to E452 can be used in flavourings up to the maximum of 40g/kg;

(iv) E416 can be used in flavourings up to the maximum of 50g/kg;

(v) E432 to E436 (polysorbates) can be used in flavourings, except liquid smoke flavourings and flavourings based on spice and oleoresins (defined as extracts of spices from which the extraction solvent has been evaporated leaving a mixture of the volatile oil and resinous material from the spice), up to the maximum of 10g/kg;

(vi) E432 to 436 (polysorbates) can be used to foodstuffs containing liquid smoke flavourings and flavourings based on spice oleoresins up to the maximum of 1g/kg;

(vii) E551, silicon dioxide can be used in flavourings up to the maximum of 50g/kg;

(viii) E900, dimethylpoly-siloxane can be used in flavourings up to the maximum of 10mg/kg;

(ix) E1505 triethyl citrate

E1517 glyceryl diacetate (diacetin)
E1518 glyceryl triacetate (triacetin)
E1520 propane 1,2 diol (propylene glycol), and

can be used in flavourings up to the 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.

228. (1) The antioxidants E315 Erythorbic acid and E316 Sodium erythorbate may be used at 1500 mg/kg, expressed as erythorbic acid, in–

(a) preserved and semi-preserved fish products

(b) frozen fish with red skin

(2) The antioxidant E385 Calcium disodium ethylene diamine tetra-acetate (Calcium disodium EDTA) may be used up to the maximum level of 75 mg/kg in:

(a) canned and bottled crustaceans and molluscs

(b) canned and bottled fish

Polyphosphates.

229. The following polyphosphates (E452) especially–

(a) Sodium polyphosphate;

(b) Potassium polyphosphate;

(c) Sodium calcium polyphosphate;

(d) Calcium polyphosphates;

may be used in–

(i) Surimi up to the maximum level of 1g/kg;

(ii) Fish and crustacean paste up to the maximum level of 5g/kg;

(iii) Frozen fillets of unprocessed fishery products up to the maximum level of 5g/kg; and

(iv) Frozen crustacean products up to the maximum level of 5g/kg.

PART XIV –SAFETY ASSURANCE FOR PREPARATION AND PROCESSING

(HAZARD ANALYSIS CRITICAL CONTROL POINTS) (HACCP)

Introduction.

230. (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) has to be implemented if the hazard analysis reveals that processors have food safety hazards that they might control.

(3) The implementation of the HACCP system is laid down in regulations 231 to 238.

Seven principles.

231. (1) It is recommended that a model of a logical approach be followed of which the following principles form the essential components–

(a) identification of hazards, analysis of risks and determination of measures necessary to control them;

(b) identification of critical points;

(c) establishment of critical limits for each critical point;

(d) establishment of monitoring and checking procedures;

(e) establishment of corrective action to be taken when necessary;

(f) establishment of verification and review procedures; and

(g) establishment of documentation concerning all procedures and records.

(2) Such a model or the principles on which it is based should be issued with the flexibility appropriate to each situation.

Hazards.

232. (1) A hazard is a biological, chemical or physical property that may cause a food to be unsafe for consumption, and to be considered as a real hazard, a hazard must be of a nature such that their elimination or reduction to acceptable levels is essential to the production of safe food.

(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 can be–

(a) Biological hazard–

(i) Pathogenic micro-organisms (e.g. bacteria, viruses)

(ii) Parasites

(b) Chemical hazards–

(i) Natural toxins

(ii) Chemicals

(iii) Pesticides

(iv) Drug residues

(v) Unapproved food and colour additives

(vi) Decomposition (safety only, e.g. histamine)

(c) Physical hazards: metal, glass, etc. …

(5) Hazards can be–

(a) unacceptable contamination (or recontamination) of a biological (micro-organisms, parasites), chemical or physical nature of raw materials, intermediate or final products;

(b) unacceptable survival or multiplication of pathogenic micro-organism/s and unacceptable generation of chemicals in intermediate products, final products, production line or environment, and

(c) unacceptable production or persistence of toxins or other undesirable products of microbial metabolism.

(6) Species related hazards are potential hazards that are associated with specific species of fishery products. Species related hazards are–

(a) Chemical contamination;

(b) Heavy metals (Mercury,Cadmium, Lead…);

(c) Natural toxins -

(i) Paralytic Shellfish Poisoning (PSP)

(ii) Neurotoxic Shellfish Poisoning (NSP)

(iii) Diarrheic Shellfish Poisoning (DSP)

(iv) Amnesic Shellfish Poisoning (ASP)

(v) Ciguatera Food Poisoning (CFP)

(vi) Clupeotoxin

(vii) Chondrichthytoxin

(viii) Tetrodotoxin (Puffer fish)

(ix) Gempylotoxin (Escolar)

(7) Primary production related hazards are–

(a) Parasites (safety hazard);

(b) Aquaculture drugs;

(c) Histamine;

(8) Process related hazards are potential hazards that are associated with inadequate food handling, preparation or processing. Process related hazards are–

(a) inadequate drying, pathogen growth, toxin formation as a result of inadequate salt, sugar, or nitrite concentration or a combination of all;

(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;

(l) food and colour additives.

Seven preliminary steps.

233. (1) Preliminary steps shall be included to consolidate the implementation of the HACCP plan.

Preliminary step 1:

Define the terms of reference/scope of the plan
To know the scope of the Plan following questions have to be answered–

(a) will the study cover a whole process or one specific part?

(b) will the study cover one product or a group of products?

(c) will all types of hazard categories initially (i.e. microbiological, chemical and physical) be covered?

(d) should the HACCP study stop at the end of the production line or continue through distribution, retail and consumer handling ?

(2) Preliminary step 2:
Select and assemble a multidisciplinary team–

(a) The team which involves all parts of the enterprise concerned with the product, needs to include the whole range of specific knowledge and expertises appropriate to the product under consideration, its production (manufacture, storage and distribution), its consumption and the associated potential hazards.

(b) Where necessary, the team will be assisted by specialists who will help it to solve its difficulties as regards assessment control of critical points.

(c) The team may consist of–

(i) a quality control specialist who understands the biological, chemical or physical hazards connected with a particular product group.

(ii) a production specialist who has responsibility for, or is closely involved with the technical process of manufacturing the product under study.

(iii) a technician who has a working knowledge of the hygiene and operation of the process plant and equipment.

(iv) any other person with specialist knowledge of microbiology, hygiene and food technology.

(3) Preliminary step 3:
Describe the food, distribution and storage
The product shall be described in terms of–

(a) composition (e.g. raw material ingredients, additives, etc.);

(b) structure and physico-chemical characteristics (e.g. solid, liquid, gel emulsion, pH, Aw, etc.);

(c) processing (e.g. heating, freezing, drying, salting, smoking, etc., and to what extent);

(d) packaging (e.g. hermetic, vacuum, modified atmosphere);

(e) storage and distribution conditions;

(f) required shelf life (e.g. sell by date and best before date);

(g) instruction for use; and

(h) any microbiological or chemical criteria applicable.

(4) Preliminary step 4:
Identify the intended use of the product

The multidisciplinary team shall define the normal or expected use of the product by the customer.

(5) Preliminary step 5:
Identify the intended consumer.

The multidisciplinary team shall define the normal or expected consumer target groups for which the product is intended. In specific cases, the suitability of the product for particular groups of consumers such as institutional caterers, travellers, etc., and for vulnerable groups of the population may have to be considered.

(6) Preliminary step 6:
Develop and construct flow diagram (description of manufacturing process)

(a) Whatever the format chosen all steps involved in the process, including delays during or between steps, from receiving the raw materials to placing the end product on the market, through preparation, processing, packaging, storage and distribution shall be studied in sequence in a detailed flow diagram with sufficient technical data.

(b) Types of data may include but are not limited to:

(i) plan of working premises and adjacent or adjoining premises

(ii) equipment layout and characteristics

(iii) sequence of all process steps (including the incorporation of raw materials, ingredients or additives and delays during or between steps)

(iv) technical parameters of operations (in particular time and temperature including delays)

(v) flow of products (including potential cross-contamination)

(vi) segregation of clean and dirty areas (or high/low risk areas),

(vii) personnel routes.

(7) Preliminary step 7:

Verify and confirm the flow diagram on-site.
After the flow diagram has been drawn up, the multidisciplinary team should confirm it on site during operating hours. Any observed deviation must result in an amendment to original flow diagram to make it accurate.

Seven hazard analysis steps (principle 1).

234. (1) Hazard analysis step 1: Set up a hazard analysis worksheet (column 1 – column 6) and record each processing step in column 1:

(a) Column 1: processing step

(b) Column 2: potential hazard at this step

(c) Column 3: significance of the potential food safety hazard (risk assessment)

(d) Column 4: justification of this decision

(e) Column 5: preventive (control) measures

(f) Column 6: is this step a critical control point (Yes or No)

The hazard analysis worksheet is set forth in the Eighth Schedule.

(2) Hazard analysis step 2: Identify the potential species related hazards and record in column 2

List all potential species related biological, chemical or physical hazards that may be reasonably expected to occur (including acquisition and storage of raw materials and ingredients and delay during manufacture).

(3) Hazard analysis step 3: Identify the potential process related hazards and record in column 3

Using the confirmed flow diagram as a guide, the team should list all potential process related hazards that may be reasonably expected to occur at each process step (including acquisition and storage of raw materials and ingredients and delay) during manufacture.

(4) Hazard analysis step 4: Understand the potential hazards

Hazard analysis requires two essential ingredients:

(a) First is an appreciation of the hazard e.g. pathogenic organism or any disease agent that could harm the consumer, and,

(b) Second is a detailed understanding of how these hazards could arise.

Thus the hazard analysis requires thorough microbiological, toxicological knowledge in combination with epidemiological and technical information.

(5) Hazard analysis step 5: Determine if the potential hazard is significant (risk assessment) and record in column 3 and 4.

A hazard is significant if the hazard is:

(a) reasonably likely to occur and

(b) if not properly controlled, it is likely to result as an unacceptable health risk to consumers.

(6) Hazard analysis step 6: Identify preventive measures, record in column 5:

Consider and describe what preventive measures, if any, exist which can be applied for each hazard.

(a) Preventive measures are those actions and activities that can be used to prevent hazards, eliminate them or reduce their impact or occurrence to acceptable levels.

(b) More than one preventive measure may be required to control an identified hazard and more than one hazard may be controlled by one control measure. For instance, pasteurisation or controlled heat treatment may provide sufficient assurance of reduction of the level of both Salmonella and Listeria.

(c) Preventive measures need to be supported by detailed procedures and specifications to ensure their effective implementation. For instance, precise heat treatment specifications, maximum concentrations of preservatives used in compliance with the applicable legislation on additives.

(7) Hazard analysis step 7: (= principle 2) Identify the critical control point (CCP) and record in column 6

(a) A CCP may be a location, a point, a procedure or processing step in the process flow where by taking preventive measures, effective

control can be installed and a food safety hazard can be prevented, eliminated or reduced to an acceptable level.

(b) The identification of a critical point for the control of a hazard requires a logical approach. Such approach can be facilitated by the use of the decision tree set forth in the Ninth Schedule (other methods can be used by the team, according to their knowledge and experience).

(c) For the application of the decision tree, each process step identified in the flow diagram should be considered in sequence. At each step, the decision tree must be applied to each hazard that may be reasonably expected to occur or be introduced and each control measure identified.

(d) Application of the decision tree should be flexible and requires common sense, having consideration for the whole manufacturing process in order to avoid, whenever possible, unnecessary critical points.

(e) Examples of CCP's are: a specific heat process, chilling, specific sanitation procedures, adjustment of food to a given pH or salt content.

Actions after hazard analysis step 7.

235. (1) If no CCP's are detected or identified in Hazard Analysis Step 7, HACCP analysis is finished and there is no need to implement a HACCP Plan.

(2) The identification of critical control points has two consequences for the multidisciplinary team, which should then -

(a) ensure that appropriate preventive measures are effectively designed and implemented. In particular, if a hazard has been identified at a step where control is necessary for product safety and no control measure exists at that step or at any other, then the product or process should be modified at that step, or later stage, to include a control measure.
If the hazard analysis reveals that processors have food safety hazards that they might control a safety assurance plan (HACCP Plan has to be implemented).

(b) establish and implement an appropriate monitoring and checking system at each critical point to ensure effective control thereof and proceed to the activities specified in the HACCP Plan steps.

Seven HACCP plan form steps.

236. (1) HACCP plan step 1: Set up the HACCP plan form
The HACCP plan form has 10 columns as follows:–

(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)

(j) Verification (column 10)

The HACCP plan form is set forth in the Tenth Schedule.

(2) HACCP plan step 2: Start the implementation of HACCP plan form (column 1).

(a) Find the processing steps, which we have identified as CCP in column 6 of the Hazard Analysis Worksheet. Record the names of these processing steps in column 1 of the HACCP plan form.

(b) Enter the significant hazard(s) for which these processing steps were identified as CCP's in column 2 of the HACCP plan form. This information can be found in column 2 of the Hazard Analysis Worksheet.

(c) Enter the preventive measures in column 3 of the HACCP plan form.

(3) HACCP plan step 3: Set up the critical factors (parameters) and critical limits for each preventive measure associated with each CCP (principle 3).

(a) Each control measure associated with critical control points should give rise to the specification of critical limits.

(b) Those critical limits correspond to the extreme values acceptable with regard to product safety. They separate acceptability from unacceptability. They are set for observable or measurable parameters that can readily demonstrate that the critical point is under control; they should be based on substantiated evidence that chosen values will result in process control.

(c) Examples of such parameters include temperature, time, pH, moisture level, additive, preservative or salt level, sensory parameters such as visual appearance or texture, etc.

(d) In some cases, to reduce the risk of exceeding a critical limit due to process variations, it may be necessary to specify more stringent levels (i.e. target levels) to assure that critical limits are observed.

(e) Critical limits may be derived from a variety of sources. When not taken from regulatory standards (e.g. frozen storage temperature) or from existing and validated guides of best practices, the team should ascertain their validity relative to the control of identified hazard and critical points.

(4) HACCP plan step 4: Establish a monitoring procedure (principle 4)

(a) An essential part of own-checks is a programme of observations or measurements performed at each critical point to ensure compliance with specified critical limits. The programme should describe the methods, the frequency of observations or measurements and the recording procedure.

(b) Observations or measurements must be able to detect loss of control at critical points and provide information in time for corrective action to be taken.

(c) Observations or measurements can be made continuously or discontinuously. When observations or measurements are not

continuous, it is necessary to establish a frequency of observations or measurements, which provides reliable information.

(d) The programme of observations or measurements should properly identify for each critical point :

(i) what will be monitored (column 4).

(ii) how monitoring and checking is performed (column 5)

(iii) when monitoring and checking is performed, and (column 6)

(iv) who is to perform monitoring and checking (column 7)

(5) HACCP plan step 5: Establish a corrective action plan (principle 5)

Establish corrective actions in case a deviation from a critical limit occurs.

(a) Observations or measurements may indicate:

(i) that the parameter monitored tends to deviate its specified critical limits, indicating a trend toward loss of control. Appropriate corrective action to maintain control must be taken before the occurrence of hazard, and

(ii) that the parameter monitored has deviated from its specified critical limits, indicating a loss of control. It is necessary to take appropriate corrective action to regain control.

(b) Corrective action has to be planned in advance by the multidisciplinary team, for each critical point so that it can be taken without hesitation when a deviation is observed.

(c) Such corrective action should include

(i) proper identification of the person(s) responsible for the implementation of the corrective action;

(ii) description of means and action required to correct the observed deviation;

(iii) action to be taken with regard to products that have been manufactured during the period when the process was out of control; and

(iv) written record of measures taken.

(d) Corrective actions shall be entered in column 8 of the HACCP plan form.

(6) HACCP plan step 6: Establish record keeping (principle 6)

(a) The approved HACCP plan and associated documentation and records shall be in file and available for inspection by regulatory agencies.

Who is responsible for keeping the records should be clear at all times.

(b) Three kinds of records are kept as part of the HACCP system:

HACCP plan support documentation used in developing the plan

(a) Records of CCP monitoring

(b) Records of corrective actions

(c) Records of verification activities

(c) Type of records shall be entered in column 9 of the HACCP plan form

(7) HACCP plan step 7: Verification procedures (principle)

HACCP own checks system verification is necessary to ensure that the system is working effectively. The multidisciplinary team shall specify the methods and procedures to be used:

(a) Usable methods may include in particular random sampling and analysis, reinforced analysis or tests at selected critical points, intensified analysis of intermediate or final products, surveys on actual conditions during storage, distribution and sale and on actual use of the product.

(b) Verification procedures may include: inspection of operations, validation of critical limits, review of deviations, corrective action and measures taken with regard to the product, audits of the HACCP own checks system and its records.

(c) Verification should provide for confirmation of the suitability of the own check system established and ensure, afterwards, with an appropriate frequency, that the provisions laid down are still being properly applied.

(d) Any change to the HACCP auto-control system arising should be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is available.

(e) Where criteria are specified in regulations, such criteria are to be used as reference values for the verification process.

(f) Verification shall enter in column 10 of the HACCP plan form.

Review of HACCP own checks system.

237. (1) A review of the HACCP plan is necessary to determine whether the plan is still appropriate and valid in case of change and is additional to the process of verification.

(2) When necessary such a review must result in the amendment of the provision stipulated.

(3) A HACCP review is undertaken in at least the following situations of change–

(a) factory lay-out and environment

(b) change in raw material or finished product

(c) processing system and conditions (packaging, storage or distribution conditions, etc.)

(d) process equipment

(e) cleaning and disinfecting programme

(f) health or spoilage risk associated with the product

(g) new information on e.g. hazard/risks/ intended use and/or consumers

(4) Every version of the HACCP plan shall be dated and signed by the responsible person, highest in degree in the establishment and has to be approved by the head of the Competent Authority. Only once the HACCP plan is signed management committed himself to implement the plan and take the consequences of the implementation.

Documentation and records.

238. (1) All procedures, instructions, specifications control and check activities shall be thoroughly documented.

(2) The person responsible for the establishment shall take all necessary measures to comply with these regulations. To this end the following must be done:–

(a) The person responsible for an establishment shall keep records of each lot of fish processed and shall keep a register of the processing carried out.

(b) The person responsible shall keep a written record or a record registered in an indelible fashion concerning the auto control systems, laid down in Part VI and concerning the checks (HACCP) laid down in Part XIV, with a view to submitting them to the Food Unit.

(c) Records shall show processing details including records of quantities, and depending on the type of process employed, processing temperatures and time, salt content, pH, water content, details of sampling and other records relevant to show that fishery products have been processed in accordance with this regulation.

(d) Records of the different checks and tests must be kept at least for the expected storage life of the products and for a period of two years be available to the inspection service.

(3) For products, which are preserved for a limited period by a treatment such as salting, drying or marinating, the appropriate conditions for storage must be clearly marked on the packaging.

Staff training.

239 1. Food business operators are to ensure–

(a) that food handlers and staff are supervised and instructed,

(b) that training on the spot and special training programmes are implemented to ensure that food handlers and staff are trained in food hygiene matters commensurate with their work activity, and

(c) that staff are continually reminded of the risks and their responsibility within the fish industry especially concerning the 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;

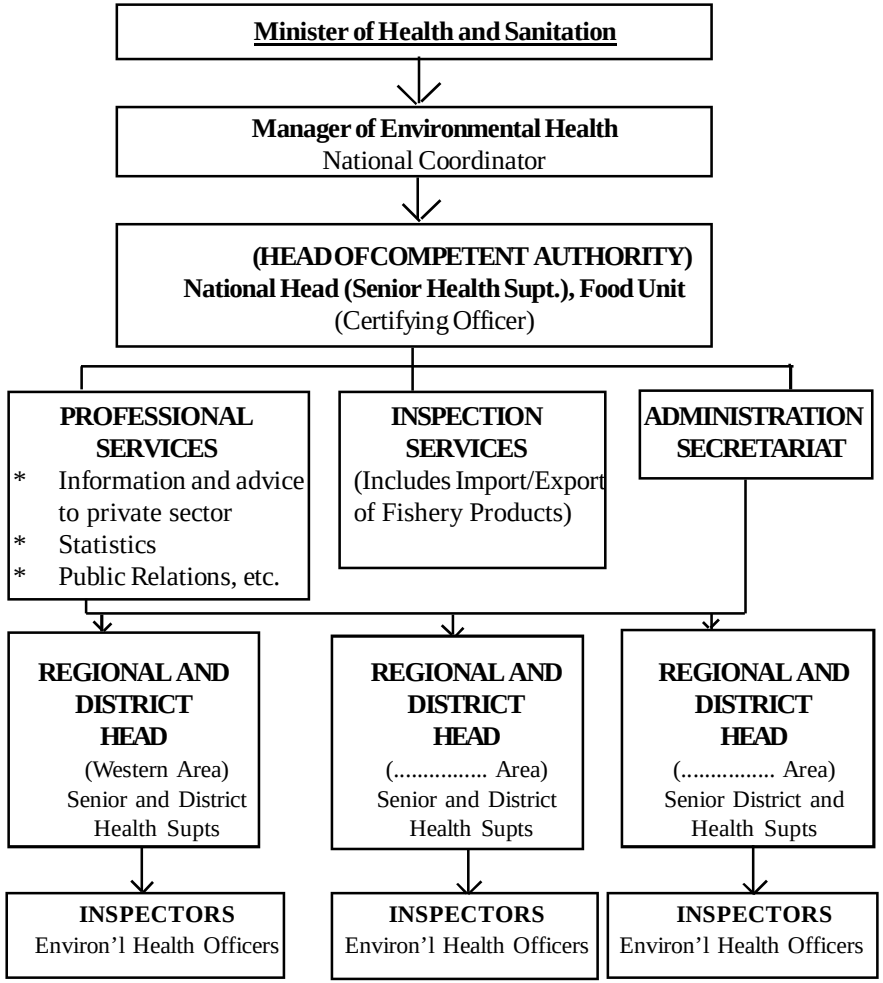
(e) compliance with any requirements of national law concerning training programmes for persons working in certain food sectors;

(f) that records of courses and training sessions attendance are kept for inspection and evaluation.

FIRST SCHEDULE (Regulation 2)

ORGANISATIONAL CHART OF THE
COMPETENT AUTHORITY FOR SIERRA LEONE

This Schedule lays down the organisational chart of the Food Unit, under the Environmental Health Division of the Ministry of Health, being the Inspection Service incorporated in the Competent Authority.



SECOND SCHEDULE Regulation 24

Export Health Certificate

The Export Health Certificate referred to in regulation 24 shall be in accordance with the requirements in regulation 25 and shall take the form determined by the importing country.

THIRD SCHEDULE (Regulations 69(5) and 192(5))

This Schedule lays down the microbiological standards applicable to the production of cooked crustaceans and molluscan shellfish provided for in regulation 69 (6) and regulation 192 (5).

1. Pathogens

Type of pathogen	Standard
Salmonella spp.	Absent in 25 g n = 5 c = 0

In addition, pathogens and toxins thereof which are to be sought according to the risk evaluation, must not be present in quantities such as to affect the health of consumers.

2. Organisms indicating poor hygiene (shelled or shucked products)

Type of organism	Standard (per g)
Staphylococcus aureus	m = 100 M = 1000 n = 5 c = 2
either: Thermotolerant coliform (44° C on solid medium)	m = 10 M = 100 n = 5 c = 2
or Escherichia coli (on solid medium)	m = 10 M = 100 n = 5 c = 1

Where parameters n, m, M and c are defined as follows:

n = number of units comprising the samples
m = limit below which all results are considered satisfactory
M = acceptability limit beyond which the results are considered satisfactory
c = number of sampling units giving bacterial counts between m and M.

The quality of a batch is considered to be:

(a) satisfactory where all the values observed are 3m or less
(b) acceptable where the values observed are between 3m and 10m (= M) and where c/n is 2/5 or less

The quality of a batch is considered to be unsatisfactory

– in all cases where the values are above M
– 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 operators are operating satisfactorily and to assist them in implementing the production monitoring procedures.

FOURTH SCHEDULE (Regulation 45)
Sub-schedule A

This Schedule lays down definitions, methods of sampling, sample preparations, 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 45.

PART I
DEFINITIONS

(1) A number of the most commonly used definitions in describing methods of sampling are given below:

(a) Lot: an identifiable quantity of food delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packaging, packer, consignor or markings. In the case of fish, also the size of fish shall be comparable.

(b) Sub-lot: designated part of a large lot in order to apply the sampling method on that designated part. Each sub-lot must be physically separated and identifiable.

(c) Incremental sample: a quantity of material taken from a single place in the lot or sub-lot.

(d) Aggregate sample: the combined total of all the incremental samples taken from the lot or sub-lot.

(e) Laboratory sample: sample intended for the laboratory

(2) A number of the most commonly used definitions that the laboratory will be required to use in establishing procedures for sample preparation and criteria for methods of analysis are given below:

(a) r — repeatability, the value below which the absolute difference between two single test results obtained under repeatability conditions (i.e. same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95%) and hence $r = 2,8 \times S_r$.

(b) S_r — standard deviation calculated from results generated under repeatability conditions.

(c) RSD_r — relative standard deviation, calculated from results generated under repeatability conditions $[(S_r / \bar{x}) \times 100]$, where $\bar{x}$ is the average of results over all laboratories and samples.

(d) R — reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); $R = 2,8 \times S_R$.

(e) S_R — standard deviation calculated from results under reproducibility conditions.

(f) RSD_R — relative standard deviation calculated from results generated under reproducibility conditions [(S_R / ‘x) x 100]

(g) $HORRAT_r$ — the observed RSD_r divided by the RSD_r value estimated from the Horwitz equation using the assumption r = 0,66R

(h) $HORRAT_R$ — the observed RSD_R value divided by the RSD_R value calculated from the Horwitz equation ([a]).

PART II

METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF LEAD, CADMIUM AND MERCURY IN FISHERY AND AQUACULTURE PRODUCTS

CHAPTER 1
GENERAL PROVISIONS FOR SAMPLING

1. **Personnel**
The Government of Sierra Leone shall take all measures necessary to ensure that the sampling for the official control of the levels of lead, cadmium and mercury in fishery and aquaculture products is carried out in accordance with the methods described in this part of the Regulations.

2. **Material to be sampled**
Each lot that is to be examined must be sampled separately.

3. **Precautions to be taken**
In the course of sampling and preparation of laboratory samples, precautions must be taken to avoid any changes that would affect the 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 sublot. Departure from this procedure must be recorded in the record provided for under Article 14.

5. **Preparation of the aggregate sample**
The aggregate sample is made up by uniting all incremental samples. It shall be at least 1 kg unless not practical, e.g. when a single package has been sampled.

6. **Subdivision of aggregate sample into laboratory samples for enforcement, defense and referee purposes**
The laboratory samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised aggregate sample. The size of the laboratory samples for enforcement shall be sufficient to allow at least for duplicate analyses.

7. **Packaging and transport of aggregate and laboratory samples**
Each aggregate and laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage in transit. All necessary precautions shall be taken to avoid change of composition of the aggregate and laboratory samples that might arise during transportation or storage.

8. **Sealing and labelling of aggregate and laboratory samples**
Each sample taken for official use shall be sealed at the place of sampling and identified following the national instructions. A record including the date and place of sampling together with any additional information likely to be of assistance to the analyst, must be kept for each sampling, so that each lot can be identified unambiguously.

CHAPTER 2

SAMPLING PLANS

1. **Place of sampling**
Sampling should ideally take place at the point where the commodity enters the food chain and a discrete lot becomes identifiable. The sampling method applied shall ensure that the aggregate sample is representative for the lot that is to be controlled.

2. **Number of incremental samples**
(1) In the case of liquid products for which a homogeneous distribution 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. The incremental samples shall be of similar weight. Departure from this procedure must be recorded in the record provided for under Chapter 1, Point 8 of this Part.

Table 1: 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

(3) If the lot consists of individual packages, then the number of packages that shall be taken to form the aggregate sample is given in Table 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

CHAPTER 3

COMPLIANCE OF THE LOT OR SUBLOT WITH THE SPECIFICATION

3. 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.

4. Accepted and rejected lot

The lot is accepted if the mean does not exceed the respective maximum levels as laid down in regulation 45 of these Regulations taking into account the expanded measurement uncertainty and correction for recovery (1).

The lot is rejected if the mean exceeds the respective maximum level beyond reasonable doubt, taking into account the expanded measurement uncertainty and correction for recovery.

conforms to the respective maximum level as laid down in regulation 45 of these Regulations. It is rejected if the mean exceeds the respective maximum level.

5. The present interpretation rules are of application for the analytical result obtained on the sample for official control. 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

General requirements

The Government of Sierra Leone shall take all measures necessary for sample preparation and methods of analyses used for the official control of the levels of lead, cadmium and mercury in fishery and aquaculture products to comply with the criteria described in this part of this Schedule.

CHAPTER 1

SPECIFIC SAMPLE PREPARATION PROCEDURES FOR LEAD, CADMIUM AND MERCURY

1. **Sample preparation procedures**
   There are many satisfactory specific sample preparation procedures which may be used for the products under consideration. Those described in the draft CEN Standard 'Foodstuffs — Determination of trace elements — Performance criteria and general consideration' have been found to be satisfactory but others may be equally valid.

2. **Specific sample preparation for bivalve molluscs, crustaceans and small fish**
   The following point must be noted for any procedure used where bivalve molluscs, crustaceans and small fish are normally eaten whole:
   – the viscera are to be included in the material to be analysed.

CHAPTER 2

METHOD OF ANALYSIS TO BE USED BY THE LABORATORY AND LABORATORY CONTROL REQUIREMENTS

1. **General requirements**
   Methods of analysis used for food control purposes must be in accordance with reliable, scientifically recognised methods.

2. **Specific requirements for lead, cadmium and mercury analyses**
   Laboratories shall use a validated method that fulfils the performance 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 in art. 4, 5 and 6, 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 in art. 4, 5 and 6 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.

3. **Estimation of the analytical trueness, recovery calculations and reporting of results**
   Wherever possible the trueness of the analysis shall be estimated by including suitable certified reference materials in the analysis.

   The analytical result is to be reported corrected or uncorrected for recovery. The manner of reporting and the level of recovery must be reported.

   The analyst should note the "European Commission Report on the relationship between analytical results, the measurement of uncertainty, recovery factors and the provision in EU food legislation" [(1)].

   The analytical result has to be reported as x +/- U whereby x is the analytical result and U is the measurement uncertainty.

4. **Laboratory quality standards**
   Laboratories must have implemented the Good Laboratory Practices.

5. Expression of results

The results shall be expressed in the same units as the maximum levels laid down in Regulation 23 of these Regulations, that is ppm (mg/kg).

(1) European Commission Report on the relationship between analytical results, the measurement of uncertainty, recovery factors and the provisions in EU food legislation, 2004. (http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/sampling_en.htm)

FOURTH SCHEDULE

Sub-schedule B

PART 1

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

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. Aggregate samples thus obtained shall be considered as representative of the lots or sub-lots from which they are taken. 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

Lot: 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. In the case of fish and fishery products, also the size of fish shall be comparable.

Sub-lot: designated part of a large lot in order to apply the sampling method on that designated part. Each sub-lot must be physically separated and identifiable.

Incremental sample: a quantity of material taken from a single place in the lot or sub-lot.

Aggregate sample: the combined total of all the incremental samples taken from the lot or sub-lot.

Laboratory sample: a representative part/quantity 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

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.

3.0 General provisions

3.1 Personnel
Sampling shall be performed by an authorised qualified person as specified by the Member States.

3.2 Material to be sampled
Each lot, which is to be examined, must be sampled separately.

3.3 Precautions to be taken
In the course of sampling and preparation of laboratory samples precautions must 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.

3.4 Incremental samples
As far as practical incremental samples shall be taken at various places distributed throughout the lot or sub-lot. Departure from this procedure must be recorded in the record provided for under 3.8.

3.5 Preparation of the aggregate sample
The aggregate sample is made up by uniting all incremental samples. It shall be at least 1 kg unless not practical, e.g. when a single package has been sampled.

3.6 Subdivision of aggregate sample in 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 unless this conflicts with Member States' regulations on sampling. The size of the laboratory samples for enforcement shall be sufficient to allow at least for duplicate analyses.

3.7 Packaging and transmission of aggregate and laboratory samples
Each aggregate and laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, from loss of analyses by adsorption to the internal wall of the container and against damage in transit. All necessary precautions shall be taken to avoid change of composition of the aggregate and laboratory samples, which might arise during transportation or storage.

3.8 Sealing and labelling of aggregate and laboratory samples
Each sample taken for official use shall be sealed at the place of sampling and identified following the Member States' regulations. 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.

4.0 Sampling plans
The sampling method applied shall ensure that the aggregate sample is representative for the lot that is to be controlled.

4.1 Number of incremental samples

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.

Reference to the lot number shall be given. For other products, the minimum number of incremental samples to be taken from the lot shall be as given in Table 1.

The aggregate sample uniting all incremental samples shall be at least 1 kg (see point 3.5). The incremental samples shall be of similar weight. The weight of an incremental sample should be at least 100 grams. The weight of the incremental sample is dependent on the size of the particles in the lot. Departure from this procedure must be recorded in the record provided for under 3.8.

4.2. Specific provisions for the sampling of lots containing whole fishes.

The number of incremental samples to be taken from the lot is defined in Table 1. The aggregate sample uniting all incremental samples shall be at least 1kg (see point 3.5).

- 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. In case the resulting aggregate sample weighs more than 3kg, the incremental samples can consist of the middle part, weighing each at least 100 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.

- In case the lot to be sampled contains larger fish (individual fish weighing more than 1 kg), the incremental sample consists of the middle part of the fish. Each incremental sample weighs at least 100 grams. 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 350 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

5. Compliance of the lot or sub-lot with the specification

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 20 % below or above the maximum level, and calculate the mean of the results.

The lot is accepted if the result of the first analysis is more than 20 % below the maximum level or, where duplicate analysis is necessary, if the mean conforms to the respective maximum level as laid down in regulation 44 (d).

The lot is non-compliant with the maximum level as laid down in regulation 44 (d). 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.

Taking into account of the measurement uncertainty can be done according to one of the following approaches: –

- by calculating the expanded uncertainty, using a coverage factor of 2, which gives a level of confidence of approximately 95%
- by establishing the decision limit (CC) .

The present interpretation rules apply for the analytical result obtained on the sample for official control. 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 FOODSTUFFS

1.0 Objective and field of application

These requirements should be applied where foodstuffs 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.

Monitoring for the presence of dioxins in foodstuffs 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 30-40 % below or exceed the level of interest. The concentration of dioxins in those samples with significant levels needs to be determined/ confirmed by a confirmatory method.

Screening methods are methods that are used to detect the presence of dioxins and dioxin-like PCBs at the level of interest. These methods have a capacity for a high sample throughput and are used to sift large numbers of samples for potential positives. 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.

2.0 Background

Because environmental and biological samples (including samples of foodstuffs) in general contain complex mixtures of different dioxin congeners, the concept of Toxic Equivalency Factors (TEFs) has been developed to facilitate risk assessment. 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). 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. The concept of 'upper-bound' requires using the limit of quantification for the contribution of each non-quantified congener to the TEQ.

The concept of 'lower-bound' requires using zero for the contribution of each non-quantified congener to the TEQ. The concept of 'medium-bound' requires using half of the limit of quantification calculating the contribution of each non-quantified congener to the TEQ.

For the purpose of this schedule only 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.

3.0 Quality assurance requirements to be complied with for sample preparation

* Measures must be taken to avoid cross-contamination at each stage of the sampling and analysis procedure.
* The samples must be stored and transported in glass, aluminium, polypropylene or polyethylene containers. Traces of paper dust must be removed from the sample container. Glassware should be rinsed with solvents previously controlled for the presence of dioxins.
* The sample storage and transportation has to be performed in a way that maintains the integrity of the foodstuff sample.
* Insofar as relevant, finely grind and mix thoroughly each laboratory sample using a process that has been demonstrated 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.

* Perform a blank analysis by carrying out the entire analytical procedure omitting only the sample.
* Sample weight used for the extraction must be sufficient to fulfil the requirements with respect to sensitivity.
* There are many satisfactory specific sample preparation procedures, which may be used for the products under consideration. The procedures have to be validated according to internationally accepted guidelines.

4.0 Requirements for laboratories

* 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. For details of acceptance criteria, see point 5.
* Limit of quantification for a confirmatory method should 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.
* Regular blank controls and spiking experiments or analysis of control samples (preferably, if available, certified reference material) should be performed as internal quality control measures.
* Successful participation in inter-laboratory studies that assess laboratory proficiency is the best way to prove the competence in specific analyses. However successful participation in inter-laboratory studies for, e.g. soil or sewage samples, does not necessarily prove the competence also in the field of food or feeding-stuff samples, which present lower contamination levels. Therefore, the continuous participation in inter-laboratory studies for the determination of dioxins and dioxin-like PCBs in the relevant feed/food matrices is mandatory.
* Laboratories should be accredited by a recognised body operating in accordance with ISO Guide 58 to ensure that they are applying analytical quality assurance. Laboratories should be accredited following the ISO/IEC/17025:1999 standard.

5.0 Requirements to be met by analytical procedure for dioxins and dioxin-like PCBs

Basic requirements for acceptance of analytical procedures:–

* High sensitivity and low limits of detection. For PCDDs and PCDFs, detectable quantities have to 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. However, for the measurement of the more toxic dioxin-like PCB congeners (in particular non-ortho substituted congeners), the same sensitivity must be reached as for the PCDDs and PCDFs.
* 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. 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.
* High accuracy (trueness and precision). The determination should provide a valid estimate of the true concentration in a sample. 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. Accuracy is expressed as trueness (difference between the mean value measured for an analyte in a certified material and its certified value, expressed as percentage of this value) and precision (precision is usually calculated as a standard deviation including repeatability and reproducibility, and indicates the closeness of agreement between the results obtained by applying the experimental procedure several times under prescribed conditions). Screening methods can comprise bioassays and GC/MS methods; confirmatory methods are high-resolution gas chromatography/high resolution mass spectrometry (HRGC/HRMS) methods. Following criteria have to be complied with on total TEQ value:

	Screening methods	Confirmatory methods
False negative rate	< 1 %	
Trueness		– 20 % to + 20 %
CV	< 30 % < 15 %	

6.0 Specific requirements for GC/MS methods to be complied with for screening or confirmatory purposes

* 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) must 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. At least one congener for each of the tetra to octa-chlorinated 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) must be added (alternatively, at least one congener for each mass spectrometric selected ion recording function used for monitoring PCDD/F and dioxin-like PCBs). There is a clear preference, certainly 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). Relative response factors should also be determined for those congeners for which no 13C-labelled analogue is added by using appropriate calibration solutions.
* 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. For foodstuffs of animal origin containing more than 10 % fat, the internal standards can be added either before extraction or after fat extraction. An appropriate validation of the extraction efficiency should be carried out, depending on the stage at which internal standards are introduced and on whether results are reported on product or fat basis.
* Prior to GC/MS analysis, 1 or 2 recovery (surrogate) standard(s) must be added.
* Control of recovery is necessary. For confirmatory methods, the recoveries of the individual internal standards should be in the range of 60 % to 120 %. Lower or higher recoveries for individual congeners, in particular for some hepta- and octa- chlorinated dibenzodioxins and dibenzofurans, are acceptable on the condition that their contribution to the TEQ value does not exceed 10 % of the total TEQ value (based on PCDD/F only). For screening methods, the recoveries should be in the range of 30 % to 140 %.
* Separation of dioxins from interfering chlorinated compounds such as PCBs and chlorinated diphenyl ethers should be carried out by suitable chromatographic techniques (preferably with a florisil, alumina and/or carbon column).
* Gas-chromatographic separation of isomers should be sufficient (< 25 % peak to peak between 1,2,3,4,7,8-HxCDF and 1,2,3,6,7,8-HxCDF).
* Determination should 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.
* The difference between upper-bound level and lower bound level should not exceed 20 % for foodstuffs with a dioxin contamination of about 1 pg WHO-TEQ/g fat (based on PCDD/PCDF only). For foodstuffs with a low fat content, the same requirements for contamination levels of about 1 pg WHO-TEQ/g product have to be applied. For lower contamination levels, for example 0,50 pg WHO-TEQ/g product, the difference between upper-bound and lower-bound level may be in the range of 25 to 40 %.

7.0 Screening methods of analysis

7.1. Introduction

Different analytical approaches can be performed using a screening method: a pure screening approach and a quantitative approach.

Screening approach

The response of samples is compared to that of a reference sample at the level of interest. Samples with a response less than the reference are declared negative, those with a higher response are suspected positives.

Requirements:–

* A blank and a reference sample(s) have to 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.
* Extra reference samples 0,5 × and 2 × the level of interest should be included to demonstrate the proper performance of the test in the range of interest for the control of the level of interest.

* When testing other matrices, the suitability of the reference sample(s) has to 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.
* 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 should be below 30 %.
* For bioassays, the target compounds, possible interferences and maximum tolerable blank levels should be defined.

Quantitative approach

The quantitative approach requires standard dilution series, duplicate or triplicate clean up and measuring as well as blank and recovery controls. The result may be expressed as TEQ, thereby assuming that the compounds responsible for the signal correspond to the TEQ principle. 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. This is subsequently corrected for the TEQ level calculated 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). 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.

7.2. Requirements for methods of analysis used for screening

* GC/MS methods of analysis and bioassays may be used for screening. For GC/MS methods the requirements as laid down in point 6 are to be used. For cell based bioassays specific requirements are laid down in point 7.3 and for kit-based bioassays in point 7.4.
* 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. Actual false negative rates should be under 1 %. The rate of false positive samples should be low enough to make the use of a screening tool advantageous.

* Positive results have always to be confirmed by a confirmatory method of analysis (HRGC/HRMS). In addition, samples from a wide TEQ-range should be confirmed by HRGC/HRMS (approximately 2 % to 10 % of the negative samples). Information on correspondence between bioassay and HRGC/HRMS results should be made available.

7.3. Specific requirements for cell-based bioassays

* 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). However, for screening purposes an expanded low level curve for analysing low level samples could be used.
* A TCDD reference concentration (about 3 × limit of quantification) on a quality control sheet should 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.
* Quality control (QC) charts for each type of reference material should be recorded and checked to make sure the outcome is in accordance with the stated guidelines.
* In particular for quantitative calculations, the induction of the sample dilution used must be within the linear portion of the response curve. Samples above the linear portion of the response curve must be diluted and re-tested. Therefore, at least three or more dilutions at one time are recommended to be tested.
* The percent standard deviation should not be above 15 % in a triplicate determination for each sample dilution and not above 30 % between three independent experiments.
* The limit of detection may be set as 3 × the standard deviation of the solvent blank or of the background response. 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. 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.

7.4. Specific requirements for kit-based bioassays

* Manufacturer's instructions for sample preparation and analyses have to be followed.
* Test kits should not be used after the expiration date.
* Materials or components designed for use with other kits should not be used.
* Test kits should be kept within the specified range of storage temperature and used at the specified operating temperature.
* The limit of detection for immunoassays is determined as 3 × the standard deviation, based on 10 replicate analysis of the blank, to be divided by the slope value of the linear regression equation.
* Reference standards should be used for tests at the laboratory to make sure that the responsiveness to the standard is within an acceptable range.

8.0 Reporting of the result

Insofar as the used analytical procedure makes it possible, the analytical results should 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.

The report should also include the lipid content of the sample as well the method used for lipid extraction.

The recoveries of the individual internal standards must be made available in case the recoveries are outside the range mentioned in point 6, in case the maximum level is exceeded and in other cases upon request.

FOURTH SCHEDULE

Sub-schedule C

PART 1

METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF BENZO (A) PYRENE IN FOODSTUFFS

1. Purpose and scope

Samples intended for the official control of the levels of benzo(a)pyrene in foodstuffs shall be taken according to the methods described below. Aggregate samples thus obtained shall be considered as representative of the lots. 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

"Lot":	an identifiable quantity of food commodity 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":	designated part of a large lot in order to apply the sampling method on that designated part; each sub-lot must be physically separated and identifiable.
"Incremental sample":	a quantity of material taken from a single place in the lot or sublot.
"Aggregate sample":	the combined total of all the incremental samples taken from the lot or sublot.
"Laboratory sample":	a sample intended for the laboratory.

3.0 General provisions

3.1 Personnel

Sampling shall be performed by an authorised qualified person as specified by the Member States.

3.2 Material to be sampled

Each lot, which is to be examined, must be sampled separately.

3.3 Precautions to be taken

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.

3.4 Incremental samples

As far as practical incremental samples shall be taken at various places distributed throughout the lot or sublot. Departure from this procedure must be recorded in the record.

3.5 Preparation of the aggregate sample

The aggregate sample is made up by uniting all incremental samples. This aggregate sample is homogenised in the laboratory unless this is incompatible with implementation of point 3.6.

3.6 Replicate laboratory samples

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.

3.7 Packaging and transmission of samples

Each sample shall be placed in a clean, inert container offering adequate protection from contamination and against damage in transit. All necessary precautions shall be taken to avoid change in composition of the sample, which might arise during transportation or storage.

3.8 Sealing and labelling of samples

Each sample taken for official use shall be sealed at the place of sampling and identified following the Member States' rules.

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.

4.0 Sampling plans

The sampling method applied shall ensure that the aggregate sample is representative for the lot that is to be controlled.

4.1 Number of incremental samples

In the case of oils, for which a homogeneous distribution of benzo(a)pyrene can be assumed within a given lot, it is sufficient to take three incremental samples per lot to form the aggregate sample. Reference to the lot number shall be given. For olive oil and oil pomace oil further information on sampling is given in Commission Regulation (EC) no 1989/2003 ([1]).

For other products, the minimum number of incremental samples to be taken from the lot shall be as given in Table 1. 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 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

4.2 Sampling at retail stage

sampling of foodstuffs at the retail stage should be done where possible in accordance with the above sampling provisions. Where this is not possible, other effective sampling procedures at retail stage can be used provided that they ensure sufficient representativeness for the sampled lot.

([1]) OJ L 295, 13.11.2003, p. 57

5. Compliance of the lot or sub-lot with the specification

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 20 % below or above the maximum level, and calculate the mean of the results.

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.

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

1.0 Precautions and general consideration for benzo(a)pyrene in food samples

The basic requirement is to obtain a representative and homogenous laboratory sample without introducing secondary contamination.

The analyst should ensure that samples do not contaminate during sample preparation. Containers should be rinsed with high purity acetone or hexane (p.A., HLPC grade or equivalent) before use to minimise the risk on contamination. Wherever possible, apparatus coming into contact with the sample should be made of inert materials e.g. aluminium, glass or polished stainless steel. Plastics such as polypropylene, PTFE etc. should be avoided because the analyte can absorb onto these materials.

All of the sample material received by the laboratory is to be used for the preparation of test material. Only very finely homogenised samples give reproducible results.

There are many satisfactory specific sample preparation procedures which may be used.

2.0 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.

3.0 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.

4.0 Methods of analysis to be used by the laboratory and laboratory control requirements

4.1 Definitions

A number of the most commonly used definitions that the laboratory will be required to use are given below:–

r — Repeatability, the value below which the absolute difference between two single test results obtained under repeatability conditions (i.e. same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95%) and hence $r = 2{,}8 \times S_r$.

S_r — Standard deviation, calculated from results generated under repeatability conditions.

RSD_r Relative standard deviation, calculated from results generated under repeatability conditions [$(S_r / x) \times 100$].

R Reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); $R = 2,8 \times S_R$.

S_R Standard deviation calculated from results under reproducibility conditions.

RSD_R Relative standard deviation calculated from results generated under reproducibility conditions [$(S_R / x) \times 100$], where 'x is the average of results over all laboratories and samples.

$HORRAT_r$ the observed RSD_r divided by the RSD_r value estimated from the Horwitz equation using the assumption r = 0,66R

$HORRAT_R$ the observed RSD_R value divided by the RSD_R value calculated from the Horwitz equation ([a]).

U The expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95%.

4.2 General requirments

Methods of analysis used for food control purposes must comply with points 1 and 2 of the Annex to Council Directive 85/591/EEC.

4.3 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

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 Ug/kg
Limit of quantification	No more than 0,9 Ug/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

4.3.1 Performance Criteria – Uncertainty Function Approach

However, 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. The maximum standard can be calculated using the following formula:–

$$Uf = V\,[(LOD/2)^2 = (0.2C)^2]$$

(Uf is the square root of $[(LOD/2)^2 = (0.2C)^2]$)

Where:

Uf is the maximum standard uncertainty

LOD is the limit of detection of the method

C is the concentration of interest

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 the Table.

4.4 Recovery calculation and reporting of results

the analytical result is to be reported corrected or uncorrected for recovery. The manner of reporting and the level of recovery must be reported. The analytical result corrected for recovery is used for checking compliance (see Annex 1, point 5).

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).

The analytical result has to be reported as x +/- U whereby x is the analytical result and U is the measurement uncertainty.

4.5 Laboratory quality standards

laboratories must comply with Directive 93/99/EEC.

4.6 Other considerations for the analysis 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.

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).

REFERENCES

1. W. Horwitz, 'Evaluation of Analytical Methods for Regulation of Foods and Drugs', Anal. Chem., 1982, 54, 67A – 76A

2. European Commission Report on the relationship between analytical results, the measurements of uncertainty, recovery factors and the provision in EU food legislation, 2004. (http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/indexen.htm).

3. ISO/AOAC/IUPAC International Harmonised Protocol for Proficiency Testing of (chemical) Analytical Laboratories, edited by M. Thompson and R. Wood, Pure Appl. Chem., 1993, 65, 2123-2144 (Also published in J. AOAC International, 1993, 76, 929).

4. /ISO/AOAC/IUPAC International Guidelines for Internal Quality Control in Analytical Chemistry Laboratories, edited by M. Thompson and R. Wood, Pure Appl. Chem., 1995, 67, 649 – 666.

FOURTH SCHEDULE
Sub-schedule D
PART 1
METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF TIN IN FOODSTUFFS

1. Purpose and scope

Samples intended for official checking of the levels of tin in canned foodstuffs shall be taken according to the methods described below. Aggregate samples thus obtained shall be considered as representative of the lots. 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

"Lot":	an identifiable quantity of food commodity 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.
"Sublot":	designated part of a large lot in order to apply the sampling method on that designated part; each sublot must be physically separated and identifiable.
"Incremental sample":	a quantity of material taken from a single place in the lot or sublot.
"Aggregate sample":	the combined total of all the incremental samples taken from the lot or sublot.
"Laboratory sample":	a sample intended for the laboratory.

3.0 General provisions

3.1 Personnel

Sampling shall be performed by an authorised qualified person as specified by the Member States.

3.2 Material to be sampled

Each lot, which is to be examined, must be sampled separately.

3.3 Precautions to be taken

In the course of sampling and preparation of laboratory samples precautions must be taken to avoid any changes, which would affect the tin content, adversely affect the analytical determination or make the aggregate samples unrepresentative.

3.4 Incremental samples

As far as practical incremental samples shall be taken at various places distributed throughout the lot or sub-lot. Departure from this procedure must be recorded in the record.

3.5 Preparation of the aggregate sample

The aggregate sample is made up by uniting all incremental samples. This aggregate sample is homogenised in the laboratory.

3.6 Replicate laboratory samples

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.

3.7 Packaging and transmission of samples

Each sample shall be placed in a clean, inert container offering adequate protection from contamination and against damage in transit. All necessary precautions shall be taken to avoid change in composition of the sample, which might arise during transportation or storage.

3.8 Sealing and labelling of samples

Each sample taken for official use shall be sealed at the place of sampling and identified following the Member States' regulations.

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.

4.0 Sampling plans

The sampling method applied shall ensure that the aggregate sample is representative for the lot that is to be controlled.

4.1 Number of incremental samples

The minimum number of incremental samples to be taken from the lot shall be as given in Table 1. The incremental samples taken from each can 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.

4.2 Sampling at retail stage

Sampling of foodstuffs at the retail stage should be done where possible in accordance with the above sampling provisions. Where this is not possible, other effective sampling procedures at retail stage can be used provided that they ensure sufficient representativeness for the sampled lot.

5. Compliance of the lot or sub-lot with the specification

The control laboratory shall analyse the laboratory sample for enforcement in at least two independent analyses and calculate the mean of the results.

The lot is accepted 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.

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 measurement uncertainty and correction recovery.

([1]) OJ L 295, 13.11.2003, p. 57

PART II

SAMPLE PREPARATION AND CRITERIA FOR METHODS OF ANALYSIS USED IN OFFICIAL CHECKING OF THE LEVELS OF TIN IN CANNED FOODSTUFFS

1.0 Precautions and general considerations for tin

The basic requirement is to obtain a representative and homogenous laboratory sample without introducing secondary contamination.

The analyst should ensure that samples do not contaminate during sample preparation. Wherever possible, apparatus coming into contact with the sample should be made of inert materials e.g. plastics such as polypropylene, PTFE etc. and these should be acid cleaned to minimise the risk of contamination. High quality stainless steel can be used for cutting edges.

All of the sample material received by the laboratory is to be used for the preparation of test material. Only very finely homogenised samples give reproducible results.

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.

2.0 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.

3.0 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.

4.0 Methods of analysis to be used by the laboratory and laboratory control requirements

4.1 Definitions

A number of the most commonly used definitions that the laboratory will be required to use are given below:

r	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	Standard deviation, calculated from results generated under repeatability conditions.
RSD_r	Relative standard deviation, calculated from results generated under repeatability conditions $[(S_r / \bar{x}) \times 100]$.
R	Reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); $R = 2,8 \times S_R$.
S_R	Standard deviation calculated from results under reproducibility conditions.
RSD_R	Relative standard deviation calculated from results generated under reproducibility conditions $[(S_R / \bar{x}) \times 100]$.
$HORRAT_r$	the observed RSD_r divided by the RSD_r value estimated from the Horwitz equation using the assumption $r = 0,66R$
$HORRAT_R$	the observed RSD_R value divided by the RSD_R value calculated from the Horwitz equation (2).
U	The expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95%.

4.2 General requirments

Methods of analysis used for food control purposes must 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.

4.3 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

4.3.1 Performance Criteria – Uncertainty Function Approach

However, 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. The maximum standard uncertainty can be calculated using the following formula:

$$Uf = V\overline{[(LOD/2)^2 = (0.1C)^2]}$$

(Uf is the square root of $[(LOD/2)^2 = (0.2C)^2]$)

Where:

Uf is the maximum standard uncertainty

LOD is the limit of detection of the method

C is the concentration of interest

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.

4.4 Recovery calculation and reporting of results

the analytical result is to be reported corrected or uncorrected for recovery. The manner of reporting and the level of recovery must be reported. The analytical result corrected for recovery is used for checking compliance (see Annex 1, point 5).

The analyst should 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.

The analytical result has to be reported as x +/- U whereby x is the analytical result and U is the measurement uncertainty.

4.5 Laboratory quality standards

Laboratories must comply with Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs.

4.6 Other considerations for the analysis 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.

Some of these schemes specifically include the determination of tin in foods and participation in such a scheme is recommended rather than a general scheme for the determination of metals in foods.

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' (5).

REFERENCES

1. BS EN 13804:2002: Foodstuffs – Determination of trace elements – Performance criteria, general considerations and sample preparation, CEN, Rue de Stassart 36, B-1050 Brussels.

2. W. Horwitz, 'Evaluation of Analytical Methods for Regulation of Foods and Drugs', Anal. Chem., 1982, 54, 67A – 76A

3. ISO/AOAC/IUPAC Harmonised Guidelines for the Use of Recovery Information in Analytical Measurement, edited Michael Thompson, Steven L.R. Ellison, Ales Fajgelj, Paul Willetts and Roger Wood, Pure Appl. Chem., 1997, 71, 337 – 347.

4. ISO/AOAC/IUPAC International Harmonised Protocol for Proficiency Testing of (chemical) Analytical Laboratories, edited by M. Thompson and R. Wood, Pure Appl. Chem., 1993, 65, 2123-2144 (Also published in J. AOAC International, 1993, 76, 929).

5. ISO/AOAC/IUPAC International Guidelines for Internal Quality Control in Analytical Chemistry Laboratories, edited by M. Thompson and R. Wood, Pure Appl. Chem., 1995, 67, 649 – 666.

FIFTH SCHEDULE (Regulations 126 to 130)

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 regulations 126 to 130.

PART I

PARAMETERS AND PARAMETRIC VALUES

Chapter 1
Microbiological Parameters

Parameter	Parametric value (number/100 ml)
Escherichia coli (E. coli)	0
Enterococci	0

Chapter 2
Chemical Parameters

Parameter	Parametric value	Unit	Notes
Acrylamide	0,10	*ug/1*	Note 1
Antimony	5,0	*ug/1*	
Arsenic	10	*ug/1*	
Benzene	1,0	*ug/1*	
Benzo(a)pyrene	0,010	*ug/1*	
Boron	1,0	*mg/1*	
Bromate	10	*ug/1*	Note 2
Cadmium	5,0	*ug/1*	
Chromium	50	*ug/1*	
Copper	2,0	*mg/1*	Note 3
Cyanide	50	*ug/1*	
1,2-dichloroethane	3,0	*ug/1*	
Epichlorohydrin	0,10	*ug/1*	Note 1
Fluoride	1,5	*mg/1*	
Lead	10	*ug/1*	Note 3 and 4
Mercury	1,0	*ug/1*	
Nickel	20	*mg/1*	Note 3
Nitrate	50	*mg/1*	Note 5
Nitrite	0,50	*mg/1*	Note 5
Pesticides	0,10	*ug/1*	Note 6 and 7
Pesticides – Total	0,50	*ug/1*	Note 6 and 8
Polycyclic aromatic hydrocarbons	0,10	*ug/1*	Sum of concentrations of specified compounds; Note 9
Selenium	10	*ug/1*	Sum of concentrations of specified parameters
Tetrachloroethene and Trichloroethene	10	*ug/1*	Sum of concentrations of specified compounds; Note 10
Trihalomethanes– Total	100	*ug/1*	
Vinyl chloride	0,50	*ug/1*	Note 1

Note 1: The parametric value refers to the residual monomer concentration in the water as calculated according to specifications of the maximum release from the corresponding polymer in contact with the water.

Note 2: Where possible, without compromising disinfecting, The Government of Sierra Leone should strive for a lower value.

Note 3: The value applies to a sample of water intended for fishery product activities obtained by an adequate sampling method at the tap and taken so as to be representative of a weekly average value. Where appropriate the sampling and monitoring methods must be applied in a harmonised fashion. The Government of Sierra Leone must take into account the occurrence of peak levels that may cause adverse effects on human health.

Note 4: The Government of Sierra Leone must ensure that all appropriate measures are taken to reduce the concentration of lead in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value.
When implementing the measures to achieve compliance with that parametric value, The Government of Sierra Leone must progressively give priority where lead concentrations in water intended for human consumption are highest.

Note 5: The Government of Sierra Leone must ensure that the condition that [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:
- organic insecticides
- organic herbicides
- organic fungicides
- organic nematocides
- organic acaricides

- organic algicides
- organic rodenticides
- organic slimicides
- related products (*inter alia*, growth regulators)

and their relevant metabolites, degradation and reaction products.

Only those pesticides that are likely to be present in a given water supply need to be monitored.

Note 7: The parametric value applies to each individual pesticide. In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide the parameter value is 0,030 *U*g/1.

Note 8: 'Pesticides – Total' means the sum of all individual pesticides detected and quantified in the monitoring procedure.

Note 9: The specified compounds are:
- benzo(b)fluoranthene,
- benzo(k)fluoranthene
- benzo(ghi)perylene
- indeno(1,2,3-cd)pyrene

Note 10: Where possible, without compromising disinfecting, The Government of SIERRA LEONE should strive for a lower value.

The specified compounds are:–
chloroform, bromoform, dibromochloromethane, bromodichloromethane.

The Government of Sierra Leone must ensure that all appropriate measures are taken to reduce the concentration of THMs (Trihalomethanes) in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value.

When implementing the measures to achieve this value, The Government of SIERRA LEONE must progressively give priority to those areas where THM (Trihalomethane) compounds in water intended for human consumption are highest.

Chapter 3
Indicator Parameters

Parameter	Parametric value	Unit	Notes
Aluminium	200	mg/1	
Ammonium	0,50	mg/1	
Chloride	250	mg/1	Note 1
Clostridium per-fringens (including spores)	0	number/ 100 ml	Note 2
Colour	Acceptable to consumers and no abnormal change		
Conductivity	2500	mS cm^{-1} at 20°C	Note 1
Hydrogen ion concentration	[3] 6,5 and £ 9,5		Notes 1 and 3
Iron	200	mg/1	
Manganese	50	mg/1	
Odour	Acceptable to consumers and no abnormal change		
Oxidisability	5,0	mg/1 O_2	Note 4
Sulphate	250	mg/1	Note 1
Sodium	200	mg/1	
Taste	Acceptable to consumers and no abnormal change		
Colony count 22°	No abnormal change		Note 5
Coliform bacteria	0	number/ 100 ml	
Total organic carbon (TOC)	No abnormal change		Note 6
Turbidity	Acceptable to consumers and no abnormal change		Note 7

RADIOACTIVITY

Parameter	Parametric value	Unit	Notes
Tritium	100	Bq/1	Notes 8 and 10
Total indicative dose	0,10	mSv/year	Notes 9 and 10

Note 1: The water should not be aggressive.

Note 2: This parameter need not be measured unless the water originates from or is influenced by surface water. In the event of non-compliance with this parametric value, SIERRA LEONE must investigate the supply to ensure that there is no potential danger to human health arising from the presence of pathogenic micro-organisms, e.g. cryptosporidium, giardia (lamblia), algae and other possible pathogenic animalcules.

Note 3: For still water put into bottles or containers, the minimum value may be reduced to 4,5 pH units.

For water put into bottles or containers which is naturally rich in or artificially enriched with carbon dioxide, the minimum value may be lower.

Note 4: This parameter need not be measured if the parameter TOC is analysed.

Note 5: For water put into bottles or containers the unit is number/250 ml.

Note 6: This parameter need not be measured for supplies of less than 10 000 m^3 a day.

Note 7: In the case of surface water treatment, Sierra Leone should strive for a parametric value not exceeding 1,0 NTU (nephelometric turbidity units) in the water ex treatment works.

Note 8: Monitoring frequencies to be set later in Annex II.

Note 9: Excluding tritium, potassium –40, radon and radon decay products; monitoring frequencies, monitoring methods and the most relevant locations for monitoring points to be set later in Annex II.

Note 10: Sierra Leone is not required to monitor drinking water for tritium or radioactivity to establish total indicative dose where it is satisfied that, on the basis of other monitoring carried out, the levels of tritium of the calculated total indicative dose are well below the parametric value.

PART II

MONITORING

TABLE 1

Parameters to be analysed

1. Check monitoring

The purpose of check monitoring is regularly to provide information on the organoleptic and microbiological quality of the water supplied for human consumption as well as information on the effectiveness of drinking-water treatment (particularly of 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.

The following parameters must be subject to check monitoring. The Competent Authority may add other parameters to this list if they deem it appropriate.

Aluminium (Note 1)
Ammonium
Clostridium perfringens (including spores) (Note 2)
Colour
Conductivity
Escherichia coli (E. coli)
Hydrogen ion concentration
Iron (Note 1)
Nitrite (Note 3)
Odour
Pseudomonas aeruginosa (Note 4)
Taste
Colony count 22 °C and 37 °C (Note 4)
Coliform bacteria
Turbidity

Note 1: Necessary only when used as flocculant (*).
Note 2: Necessary only if the water originates from or is influenced by surface water (*).
Note 3: Necessary only when chloramination is used as a disinfectant (*).
Note 4: Necessary only in the case of water offered for sale in bottles or containers.

(*) In all cases, the parameters are in the list for audit monitoring.

2. Audit monitoring

The purpose of audit monitoring is to provide the information necessary to determine whether or not all the parametric values laid down in this Schedule are being complied with. All parameters set in accordance with regulation 126 (1) and (3) must be subject to audit monitoring unless it can be established by the Food Unit, for a period of time to be determined, that a parameter is not likely to be present in a given supply in concentrations which could lead to the risk of a breach of the relevant parametric value. This paragraph does not apply to the parameters for radioactivity, which, subject to Notes 8, 9 and 10 in Part I Chapter 3 of this Schedule will be monitored in accordance with monitoring requirements adopted laid down later.

TABLE 2

Minimum frequency of sampling and analyses for water intended for human consumption supplied from a distribution network or from a tanker or used in a food-production undertaking.

The Government of Sierra Leone must take samples at the points of compliance as defined in regulation 126 (5) to ensure that water intended for human consumption meets the requirements of these Regulations. However, in the case of a distribution network, the authority may take samples within the supply zone or at the treatment works for particular parameters if it can be demonstrated that there would be no adverse change to the measured value of the parameters concerned.

Volume of water distributed or produced each day within a supply zone (Notes 1 and 2) m^3	Check monitoring 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 ≤ 1000	4	1
> 1 000 ≤ 10000	4 + 3 for each 1000 m^3/d and part thereof of the total volume	1 + 1 for each 3 300 m^3/d and part thereof of the total volume
> 10 000 ≤ 100 000		3 + 1 for each 10 000 m^3/d and part thereof of the total volume
> 100 000		10 + 1 for each 25 000 m^3/d and part thereof of the total volume

Note 1: A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and within which water quality may be considered as being approximately uniform.

Note 2: The volumes are calculated as average taken over a calendar year. The Government of Sierra Leone may use the number of inhabitants in a supply zone instead of the volume of water to determine the minimum frequency, assuming a water consumption of 200 l/day/capita.

Note 3: In the event of intermittent short-term supply the monitoring frequency of water distributed by tankers is to be decided by the Government of Sierra Leone.

Note 4: For the different parameters in Part I, The Government of Sierra Leone may reduce the number of samples specified in the table if:

(a) the values of the results obtained from samples taken during a period of at least two successive years are constant and significantly better than the limits laid down in Annex I, and

(b) no factor is likely to cause a deterioration of the quality of the water.

The lowest frequency applied must not be less than 50% of the number of samples specified in the table except in the particular case of Note 6.

Note 5: As far as possible, the number of samples should be distributed equally in time and location.

Note 6: The frequency is to be decided by the Government of Sierra Leone.

PART III
SPECIFICATIONS FOR THE ANALYSIS OF PARAMETERS

The Government of Sierra Leone must ensure that any laboratory at which samples are analysed has a system of analytical quality control that is subject from time to time to checking by a person who is not under the control of the laboratory and who is approved by the Food Unit for that purpose.

Chapter 1

1. Parameters for which methods of analysis are specified

The following principles for methods of microbiological parameters are given either for reference whenever a CEN/ISO method is given or for guidance of further CEN/ISO international methods for these parameters. The Government of Sierra Leone may use alternative methods, providing the provisions of regulation 100 are met.

Coliform bacteria and Escherichia coli (E. coli) (ISO 9308-1)
Enterococci (ISO 7899-2)

Pseudomonas aeruginosa (prEN ISO 12780)

Enumeration of culturable micro-organisms – Colony count 22 °C (prEN ISO 6222)

Enumeration of culturable micro-organisms – Colony count 37 °C (prEN ISO 6222)

Clostridium perfringens (including spores)

Membrane filtration followed by anaerobic incubation of the membrane on m-CP agar (Note 1) at 44 ± 1 °C for 21 ± 3 hours. Count opaque yellow colonies that run pink or red after exposure to ammonium hydroxide vapours for 20 to 30 seconds.

Note 1: The composition of m-CP agar is:

Basal medium

Tryptose	30g
Yeast extract	20g
Sucrose	5g
L-cysteine hydrochloride	1g
$MgSO_4 \cdot 7H_2O$ 0,1g	
Bromocresol purple	40g
Agar	1.5g
Water	1000g

Dissolve the ingredients of the basal medium; adjust pH to 7,6 and autoclave at 121 °C for 15 minutes. Allow the medium to cool and add the following supplements after being sterilised through membrane filter of pores diameter of 0.20 mm:

D-cycloserine	400mg
Polymyxine-B sulphate	25mg
Indoxyl-b-D-glucose	60mg (

to be dissolved in 8 ml sterile water before addition

Filter – sterilised 0,5% phenol-phthalein 20ml diphosphate solution

Filter – sterilised 4,5 % $FeCl_3 \cdot 6H_2O$ 1 2ml

Chapter 2

2. Parameters for which performance characteristics are specified

2.1 For the following parameters, the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness, precision and limit of detection specified. Whatever the sensitivity of the method of analysis used, the result must be expressed using at least the same number of decimals as for the parametric value considered in Annex I, Parts B and C.

Parameters	Trueness % of para-metric value	Precision % of para-metric value (Note 2)	Limit of detection % of parametric value (Note 3)	Conditions	Notes
Acrylamide				*To be con-trolled by product specification*	
Aluminium	10	10	10		
Ammonium	10	10	10		
Antimony	25	25	25		
Arsenic	10	10	10		
Benzo(a) pyrene	25	25	25		
Benzene	25	25	25		
Boron	10	10	10		
Bromate	25	25	25		
Cadmium	10	10	10		
Chloride	10	10	10		
Chromium	10	10	10		
Conducti-vity	10	10	10		
Copper	10	10	10		
Cyanide	10	10	10		Note 4
1,2-dichloro-ethane	25	25	10		

Parameters	Trueness % of parametric value	Precision % of parametric value (Note 2)	Limit of detection % of parametric value (Note 3)	Conditions	Notes
Epichlorohydrin				*To be controlled by product specification*	
Fluoride	10	10	10		
Iron	10	10	10		
Lead	10	10	10		
Manganese	10	10	10		
Mercury	20	10	20		
Nickel	10	10	10		
Nitrate	10	10	10		
Nitrite	10	10	10		
Oxidisability	25	25	10		Note 5
Pesticides	25	25	25		Note 6
Polycyclic aromatic hydrocarbons	25	25	25		Note 7
Selenium	10	10	10		
Sodium	10	10	10		
Sulphate	10	10	10		
Tetrachloroethene	25	25	10		Note 8
Trichloroethene	25	25	10		Note 8
Trihalomethanes – Total	25	25	10		Note 7
Vinyl chloride				*To be controlled by product specification*	

2.2 For hydrogen ion concentration the specified performance characteristics are that the method of analysis used must be capable of measuring concentrations equal to the parametric value with a trueness of 0,2 pH unit and a precision of 0,2 pH unit.

Note 1 (*): Trueness is the systematic error and is the difference between the mean value of the large number of repeated measurements and the true value.

Note 2 (*): Precision is the random error and is usually expressed as the standard deviation (within and between batch) of the spread of results about the mean. Acceptable precision is twice the relative standard deviation.

(*) These terms are further defined in ISO 5725

Note 3: Limit of detection is either:
- three times the relative within batch standard deviation of a natural sample containing a low concentration of the parameter, or
- five times the relative within batch standard deviation of a blank sample.

Note 4: The method should determine total cyanide in all forms.

Note 5: Oxidation should be carried out for 10 minutes at 100 °C under acid conditions using permanganate.

Note 6: The performance characteristics apply to the individual pesticide and will depend on the pesticide concerned. The limit of detection may not be achievable for all pesticides at present, but SIERRA LEONE should strive to achieve this standard.

Note 7: The performance characteristics apply to the individual substances specified at 2.5% of the parametric value in Annex I.

Note 8: The performance characteristics apply to the individual substances specified at 50% of the parametric value in Annex I.

Chapter 3

3. Parameters for which no method of analysis is specified

Colour
Odour
Taste
Total organic carbon
Turbidity (Note 1)

Note 1: For turbidity monitoring in treated surface water the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness of 2.5%, precision of 2.5% and a 2.5% limit of detection.

SIXTH SCHEDULE (Regulation 141)

This Schedule lays down Freshness Rating Tables for White Bony Fish, Bluefish, Selachii, Cephalopods, and Crustaceans provided for in regulation 141.

Freshness Rating Tables for:

(1) White Bony Fish

Criteria	Freshness category			
	Extra	**A**	**B**	**Not permitted[1]**
Skin	Bright, iridescent pigment save for redfish) or opalescent No discoloration	Pigmentation bright but not lustrous	Pigmentation in the process of becoming discoloured and dull	Dull Pigmentation
Ski mucus	Aqueous transparent	Slightly cloudy	Milky grey, opaque	Yellowish
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 detached from skin, surface rather wrinkled

(2) Bluefish, Albacore or Long-finned tuna, Big-eye tuna, Mackerel

Criteria	Freshness category			
	Extra	**A**	**B**	**Not permitted[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]
Consistency of flesh	Very firm, rigid	Fairly rigid, firm	Slightly soft	Soft (flaccid)[5]
Gills covers	Silvery	Silvery, slightly 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 seaweedy, 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 opening	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

SEVENTH SCHEDULE (Regulation 141)

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 141.

DETERMINATION OF THE CONCENTRATION OF VOLATILE NITROGENOUS BASES (TVB-N) IN FISH AND FISHERY PRODUCTS : A REFERENCE PROCEDURE

1. Purpose and area of application

This method describes a reference procedure for identifying the nitrogen concentration of volatile nitrogenous bases (Total – Volatile – Base N: TVB-N) in fish and fish products. This procedure is applicable to TVB-N concentrations from 5 mg/100 g at least 100 mg/100 g.

2. Definition

The TVB-N concentration is here understood to mean the nitrogen content of volatile nitrogenous bases determined by the procedure described. The concentration is stated in terms of mg/100 g.

3. Brief description

The volatile nitrogenous bases are extracted from a sample by a solution of 0.6 M per-chloric acid. After alcalinsation the extract is submitted to steam distillation, and the volatile base components are absorbed by an acid receiver. The TVB-N concentration is determined by titration of the absorbed bases.

4. Chemicals

Unless otherwise indicated, reagent-grade chemicals should be used. The water used must be either distilled or demineralised and of at least the same purity. Unless indicated otherwise, a "solution" is to be understood as an aqueous solution.

4.1. Perchloric acid solution = 6 g/100 ml

4.2 Sodium hydroxide solution = 20 g/100 ml

4.3. Hydrochloric acid standard solution 0.05 mol/1 (0.05N)
Note : when using an automatic distillation apparatus, titration should take place with a hydrochloric acid standard solution 0.01 mol/0 (0.01 N)

4.4. Boric acid solution = 3 g/100 ml

4.5. Silicone anti-foaming agent

4.6. Phenolphtalein solution = 1 g/100 ml 95 % ethanol

4.7. Indicator solution (Tashiro Mixed Indicator)
2 g Methyl – red and 1 g Methylene – blue are dissolved in 1,000 ml 95 % ethanol

5. Instruments and accessories

5.1. A meat grinder to produce a sufficiently homogenous fish mince

5.2. High-speed blender with revolutions between 8,000 min –1 and 45,000 min –1

5.3. Fluted filter, diameter 150 mm, quick filtering

5.4. Burette, 5 ml, graduated to 0.01 ml

5.5. Apparatus for steam distillation
The apparatus must be able to regulate various amounts of steam and produce a constant amount of steam over a given period of time. It must ensure that during the addition of alkalising substances the resulting free bases cannot escape.

6. Execution

Warning : When working with per-chloric acid, which is strongly corrosive, necessary caution and preventive measures should be taken.

The samples should; if at all possible, be prepared according to paragraph 6.1 as soon as possible after their arrival.

6.1. Preparation of the sample

The sample to be analysed should be ground carefully by a meat grinder as described in section 5.1 Exactly 10 g +-0.1 g of the ground sample are weighed in a suitable container, mixed with 90.0 ml per-chloric acid solution as stated in section 4.1, homogenised for two minutes with a blender as described in section 5.2 and then filtered.

The extract thereby obtained can be kept for at least seven days at a temperature between approximately 2 deg. C and 6 deg. C.

6.2. Steam distillation

50.0 ml of the extract obtained according to section 6.1 are put in an apparatus for steam distillation as described in section 5.5. For a later check on sufficient alcalinisation of the extract, several drops of phenolphtalein as specified in section 4.6 are added. After adding a few drops silicone anti foaming agent 6.5 ml of sodium hydroxide solution as specified in section 4.2 are added to extract, and steam distillation begins immediately.

The steam distillation is regulated so that around 100 ml of distillate are produced within 10 minutes. The distillation outflow tube is submerged in a receiver with 100 ml boric acid solution as specified in section 4.4, to which three to five drops of the indicator solution as described in 4.7 have been added. After exactly 10 minutes, the distillation is ended. The distillation outflow tube is removed from the receiver and washed out with water. The volatile bases contained in the receiver solution are determined by titration with standard hydrochloric solution as specified in section 4.3.

The pH of the endpoint should be 5.0+/-0.1.

6.3. Titration

Duplicate analyses are required. The applied method is correct if the difference of the duplicates is not higher than 2 mg/100g.

6.4. Blank

A blind test carried out as described in section 6.2
Instead of the extract, 50.0 ml per-chloric acid solution as specified in section 4.1 are used.

7. Calculation of TVB-N

By titration of the receiver solution with hydrochloric acid as in 4.3, the TVB-N concentration is calculated with the following equation :

$$\text{TVB-N (expressed in mg/100 sample)} = \frac{(V1 - V0) \times 0.14 \times 2 \times 100}{M}$$

V1 = volume of 0.01 M hydrochloric acid solution in ml for sample
V0 = volume of 0.01 M hydrochloric acid solution in ml for blanc
M = weight of sample in g.

Remarks:

1. Duplicate analyses are required. The applied method is correct if the difference between duplicates is not higher than 2 mg/100.
2. Check the equipment by distilling solutions of NH4Cl equivalent to 50 mg TVB-/100 g
3. Standard deviation of reproducibility Sr = 1.20 mg/100 g
   Standard deviation of comparability SR = 2.50 mg/100 g

EIGHTH SCHEDULE **(Regulation 234)**

This Schedule lays down the Hazard Analysis Worksheet, provided for in regulation 234

Hazard Analysis Worksheet

Firm Name:..... Product Description:.....
.....
Firm Address:..... Method of Storage and Distribution:.....
.....
..... Intended Use and Consumer:.....
.....

(1) Ingredient/ processing step	(2) Identify potential hazards Introduced, controlled or enhanced at this step (1)	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decisions for column 3	(5) What preventative measures can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				

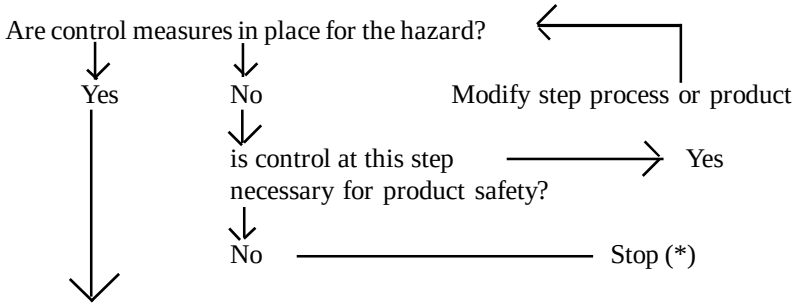
NINTH SCHEDULE (Regulation 234(7))

This Schedule lays down the decision tree for the identification of critical points, provided for in regulation 234 (7).

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.

TENTH SCHEDULE (Regulation 236)

This schedule lays down the HACCP Plan Form, provided for in regulation 236.

HACCP Plan Form

Firm Name:..... Product Description:.....
.....
Firm Address:..... Method of Storage and Distribution:.....
.....
..... Intended Use and Consumer:.....
.....

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	Signi-ficant Hazards (s)	Critical Limits for each Preven-tive measure	Monitoring				Correc-tive Action (s)	Records	Veri-fication
			What	How	Frequency	Who			

Signature of Company Official: .....Date:.....

MADE this *28th* day of *February, 2007.*

A. THOMAS,
Minister of Health and Sanitation.

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