PART I : SECTION (I) – GENERAL

Government Notifications

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FISHERIES AND AQUATIC RESOURCES ACT, No. 2 OF 1996

REGULATIONS made by the Minister of Fisheries and Aquatic Resources Development, under paragraphs (1) and (m) of sub section (1) of Section 61 of the Fisheries and Aquatic Resources Act, No. 2 of 1996.

MAHINDA RAJAPAKSE,
Minister of Fisheries and
Aquatic Resources Development.

Colombo,
14th September, 1998.

Regulations

1. These regulations may be cited as the Fish Products (Export) Regulations, 1998.

2. (1) The provisions of these regulations shall be applicable in respect of —

(a) every person who is issued with a licence (hereinafter referred to as "Licensee") by the Director of Fisheries and Aquatic Resources (hereinafter referred to as the "Competent - Authority") to operate a fish processing establishment which is used for the processing of fish for export from Sri Lanka ; and

(b) fishing boats which are used for catching, taking and collecting fish products for purposes of export from Sri Lanka. (herein after referred to as " fishing boats".)

2 The licence referred to in paragraph (1) is the licence issued by the Director of Fisheries and Aquatic Resoures under the fish Processing Establishments Regulations, 1998 published in *Gazette Extraordinary* No. 1036/13 of 16th July, 1998 to operate a fish processing establishment.

3. A f .hing boat that is used for processing fish in board shall be subject to such conditions concerning its design and equipment, area to be used for preparation and processing of fish products, freezing and storing of fish products, hygiene on-board, landing of fish products, as are specified in Schedule "A" to these regulation.

4. The general hygiene conditions to be maintained in a fishing boat other than boats referred to in regulation 3 and the additional hygiene conditions to be maintained in fishing boats which are designed and equipped to preserve fish on board for more than twenty -four hours (other than those equipped for keeping fish and molluscs alive without other means of conservation on board), shall be as specified in Schedule "B" to these regulations.

5. (1) An inspector appointed under regulation 12 may, on behalf of the Competent Authority, carry out inspections of all fishing boats referred to in regulations 3 and 4, for purpose of ensuring that such fishing boats comply with the conditions specified in Shedule 'A" or 'B' as the case may be.

(2) The Competent Authority shall maintain a register of all fishing boats that have been inspected under paragraph (1).

6. All fish products intended for export shall —

(a) be handled during and after landing in accordance with such requirements as are specified in Schedule "C" to these regulations

(b) have been handled, and where appropriate prepared, processed. frozen, defrosted or hygienically stored in establishments certified by the Competent Authority under regulation 10, in compliance with the requirements specified in Schedule "D" to these regulations ;

(c) have undergone a hygiene check and a monitoring of production in accordance with the requirements specified in Schedule "E" to these regulations ;

(d) be appropriately packaged in accordance with the requirements specified in Schedule "F" to these regulations ;

(e) be stored and transported under satisfactory hygiene conditions based on the requirements specified in Schedule "G" to these regulations ; and

(f) be given an identification mark in accordance with the requirements specified in Schedule "H" to these regulations.

7. The placing on the market of aquaculture products shall be subject to the following conditions :—

(a) they must have been slaughtered under appropriate conditions of hygiene, must not be soiled with earth, slime or faeces and if not processed immediately after being slaughtered, must be kept chilled; and

(b) they must comply with the requirements specified in schedules "D", "E", "F", "G" and "H" to these regulations.

8. Fish to be exported alive for consumption shall at all times be kept under the most suitable survival conditions until they are exported.

9. The following fish shall not be exported :-

(a) poisonous fish of the following families, namely, Tetraodontidae, Molidae, Diodontidae, Canthigasteridae ;

(b) fish containing biotoxins such as ciguatera toxins or muscle - paralysing toxins.

10. (1) All processing establishments which are intended to be used for purpose of processing fish products for export, shall, where such establishments comply with the relevant requirements specified in these regulations, be certified by the Competent Authority as being establishments that are authorized to be used for the processing of fish products for export (hereinafter referred to as "certified establishments").

(2) The Competent Authority shall, draw up a list of all certified establishments, each of which shall be allotted an official number.

11. (1) The Competent Authority shall be responsible for the inspection and monitoring of all certified establishments carried out regularly by Inspectors.

(2) The Inspectors shall have free access to and every part or section of a certified establishment, in order to ensure that such establishment comply with the requirements of these regulations.

12. (1) The Competent Authority may appoint such number of Inspectors as may be necessary for the purpose of carrying out inspections of certified establishments, from among persons who holds a degree or any other academic qualification from a recognized university or any other higher educational institution, in the field of Food Science, Food Technology, Fisheries Science, Microbiology Zoology or Chemistry.

(2) The Competent Authority shall provide all necessary facilities for training the Inspectors appointed under paragraph (1), to enable them to carry out official checks and to assess the own-checks systems set-up by a certified licensee, on the basis of the documents submitted by such licensee to the Competent Authority.

(3) Each Inspector appointed under paragraph (1) shall be furnished with a certificate of appointment as an Inspector by the Competent Authority and shall, if required, when within any certified establishment, be produced by such Inspector to any person holding a responsible position of management at the establishment.

13. (1) Where the Competent Authority is of opinion that all requirements under these regulations are not adequately being complied with by any certified licensee, he shall have the power by a notice issued in that behalf to require such licensee to take such measures, and within such period of time, as may be specified in such notice, to ensure due compliance.

(2) Where a certified licensee fails to take the measures within the time specified in the notice issued under paragraph (1), the Competent Authority may revoke the certification done under regulation 10 until such measures are taken, and such establishment shall thereafter cease to be a certified establishment for the purposes of these regulations.

(3) Where a licensee whose certification was revoked under paragraph (2) continues to use the establishment for the processing of fish products for export, the Competent Authority shall, on application being made to a Magistrate Court in that behalf, obtain an order for the closure of the certified establishment until adequate measures are taken as may be necessary in order to comply with the requirements specified by the Competent Authority, in his notice issued under paragraph (1).

14. (1) The Competent Authority shall ensure that, a certified licensee take all measures necessary at all stages of the production of fish products to comply with the conditions and requirements specified in these regulations, and for that purpose that such licensee carry out periodically their own-checks based on the following principles :-

(*a*) identification of critical points in their establishment on the basis of the manufacturing processes used ;

(*b*) establishment and implementation of methods for monitoring and checking such critical points based on the guidelines specified in Schedule "I" to these regulations ;

(*c*) taking samples for analysis in a laboratory approved by the Competent Authority for the purpose of checking cleaning and disinfection methods, and for the purpose of checking due compliance with the standards established by these regulations ; and

(*d*) maintaining a written record of the preceding points for the purpose of submitting such records to the Competent Authority.

(2) The results of the different checks and tests carried out by a certified licensee shall be kept for a period of at least two years.

(3) The identification of critical points as referred to in paragraph (1)(a) of this regulation, (which shall be specific to each individual establishment depending on the raw material it uses, its manufacturing process, structures and equipment, end product and its marketing system), shall be based on the guidelines specified in Schedule "J" to these regulations.

(4) Every certified licensee should adopt a sampling programme (as referred to in paragraph (1)(c) of this regulation), which, though not concerning systematically every production batch, allows –

(*a*) validation of the own-checks system when it was initially set up ;

(*b*) revalidation where necessary of the system in the event of any change in the characteristics of the product or to its manufacturing process ; and

(*c*) verification at specific intervals of the own-checks system based on the guidelines specified in Schedule "K" to these regulations

(5) In carrying out their own-checks under paragraph (1) of this regulation, a certified licensee shall make use of good manufacturing practices formulated by appropriate professional organizations or persons approved by the Competent Authority.

(6) The certified licensee shall ensure that the members of the staff working at the establishment entrusted with the task of carrying out their own-checks referred to in paragraph (1), receive adequate training in that regard to effectively participate in the proper implementation and assessment of their own checks system.

15. (1) In maintaining the written record referred to in paragraph (1)(d) of regulation 13, the certified licensee should document all information relating to the implementation of the own-checks system and their verification and in particular the said documentation shall include the following :-

(*a*) a detailed and comprehensive document which includes a –

(i) description of the product;

(ii) decription of the manufacturing process indicating critical points ;

(iii) for each critical point, identified hazards, assessment of risks and control measures taken;

(iv) procedures for monitoring and checking at each such critical point, with indication of critical limits for parameters that need to be controlled and corrective action to be taken in case of loss of control ; and

(v) procedures for verification and review; and

(*b*) records of the observations and/or measurements necessary to ensure that critical points are kept under control results of the verification activities referred to paragraph (4) of regulation 13, reports and written accounts of decisions relating to corrective action when taken.

(2) The document management system must also provide, for the easy retrieval of all documents relating to an identified production batch.

16. (1) Experts from any specified country may, with the co-operation of the Competent Authority, make on the spot checks in so far as it may be necessary to ensure and verify that provisions of these regulations and of agreements entered into are being properly given effect to by a certified licensee.

(2) It shall be the duty of the Competent Authority and the person in charge of the establishment to give all necessary assistance to the experts in carrying out their duties under paragraph (1).

(3) For the purpose of this regulation "specified country" means any country, (including the European Commission and its Member States) with which Sri Lanka has entered into any bi-lateral agreement pertaining to the export of fish products from Sri Lanka to such country.

17. (1) The competent Authority may, in performing his monitoring and inspection duties under these regulations, obtain the assistance of any statutory authority or any accredited inspection body, and shall have the power to delegate to such authority or body any of his powers pertaining to the performance of his monitoring and inspection duties, where the delegation of such powers becomes necessary to enable the authority or body whose assistance is being sought, to carry out their duties in granting such assistance.

(2) Where the Competent Authority seek assistance in carrying out laboratory testing of fish products, such test shall be carried out only by any accredited laboratory that fulfil the requirements of ISO Guide 25.

(3) The Competent Authority may, notwithstanding any delegation under paragraph (1), perform himself such duty delegated, and may also at any time revoke such delegation.

(4) Notwithstanding any delegation done under paragraph (1) and (2), the Competent Authority shall take responsibility for all acts done and duties performed by any authority, body or laboratory to which such power was delegated.

18. In these Regulations —

"Accredited Inspection Body" means any institution accredited by any statutory authority established for the purpose of Accreditation ;

"aquaculture product" means a product obtained from the husbanding of aquatic plants and organisms ranging from the propagation of aquatic organisms under human control to the manipulation of at least one stage of an aquatic organisms life for the purpose of increasing production ;

"certified licensee" means a licensee of a certified establishment ;

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

"critical point" means any point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels ;

"drinking water" means water which is used for human consumption and which comply with the physical and chemical requirements for portable water specified by the Sri Lanka Standards Institution established by the Sri Lanka Standards Institution Act, No. 6 of 1984 ;

"establishment" means a fish processing establishment where fish are prepared, processed, packaged, frozen or stored ;

"fish products" means any aquatic organism whether piscine or not, and includes any shellfish, crustacean, pearl oyster, mollusc, holothurian, and its young, fry, egg or spawn ;

"monitoring and checking critical points" includes observations and measurements necessary to ensure that critical points are kept under control, but does not include verifying that the end product conform to the herein standards laid down;

"own checks" means all those actions aimed at ensuring and demonstrating that a fish product satisfies the requirement specified in these regulations, and such action.

(a) must correspond to an approach internal to the establishment ;

(b) must be developed and implemented by persons responsible for each production unit or under their management, in accordance with the requirements specified in Schedules "I", "J", and "K" to these regulations.

"packaged" means the protecting of fish products by a wrapper, a container or any other suitable device ; and

"placing on the market" means the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market excluding retail sales and direct transfers on local markets of small quantities by fishermen to retailers or consumers.

(Regulation 3).

SCHEDULE " A "

CONDITIONS APPLICABLE TO FISHING BOATS USED FOR PROCESSING FISH ON BOARD

(A) Conditions concerning design and equipment – 1. *The Minimum requirements for fishing boats.*– (a) there shall be an exclusive reception area for taking fish on board, designed and arranged insuch manner as to allow each successive catch to be separated

(b) the reception area and its plant, machinery and equipment should be easy to clean ;

(c) the reception area should be designed in such a manner that it adequately protects the fish products from the sun or any other natural elements and from dirt or other source of contamination ;

(d) there shall be a system for conveying fish products from the reception area to the work area that conforms to rules of hygiene, preventing any contamination ;

(e) there shall be work areas large enough for the preparation and processing of fish products in proper conditions of hygiene. They must be designed and arranged in such a way as to prevent any contamination of the products;

(f) there shall be storage areas for the finished products that are large enough and designed in a manner that is easy to clean. If a waste processing unit operates on board the fishing boat, a seperate hold must be designed for the storage of these by -products;

(g) there shall be a place for storing packing material, separate from the cold room and the reception area ;

(h) the boat should be equipped with special equipment for pumping waste or fish products that are unfit for human consumption, into a watertight tank reserved for that purpose ;

(i) if the boat has a facility to store and process waste on board with a view to cleaning, separate areas should be allocated for that purpose ;

(j) there shall be equipment providing a supply of drinking water or pressurized clean sea water ;

(k) if the boat is supplied with any form of sea water, the sea water inlet should be separated away from the discharge outlets of waste water and engine coolant ; and

(l) the boat should contain a suitable number of changing rooms, wash basins and toilets. The toilets should not open directly on to areas where fish products are prepared, processed or stored. The wash basins must be equipped with appliances for washing and drying hands and comply with hygiene requirements. The wash basin taps must not be hand operable.

2. Areas used for the preparation and processing or freezing/quick-freezing of fish products should have –

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

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

(c) the hydraulic circuits must be arranged or proceed in such a way as to ensure that it is not possible for any leakage of oil to contaminate fish products ;

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

(e) adequate lighting ;

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

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

3. Equipment and tools, containers, conveyors etc. shall be resistant to sea water corrosion, easy to clean and disinfect and well maintained.

4. Fishing boat which provides for the freezing of fish products should have -

(a) a refrigeration plant sufficiently powerful to lower the temperature rapidly so as to achieve a core temperature , reaching -18^{0} C at the most after sixteen hours;

(b) refrigeration plants sufficiently powerful to keep fish products in the storage holds at a temperature of -18^{0} C. The storage holds must be equipped with a temperature recording system placed so that it can be consulted.

(B) Hyg*ienic conditions relating to on-board handling and storage of fish.*- *(a)* there shall be a person on board the vessel responsible to ensure, that the provisions of these regulations are complied with and where necessary he should make available documents and registers to relevant authorities for inspection ;

(b) the general conditions of hygiene laid down in Schedule D Part I item A shall be complied with in relation to areas and equipment and in relation to the staff ;

(c) heading, gutting and filleting should be carried out in compliance with hygiene conditions laid down in Schedule D Part IIA, items 2, 3 and 4;

(d) on-board processing of fish products must be carried out in compliance with hygiene conditions laid down in Schedule D Part II C, D and E;

(e) fish products must be wrapped and packaged in compliance with the conditions laid down in Schedule F; and

(f) storage of fish on board should be carried out in compliance with the conditions laid down in Schedule "G" items 1 and 2.

(Regulation 4).

SCHEDULE " B "

Part I

GENERAL HYGIENE CONDITIONS APPLICABLE TO FISH PRODUCTS ON BOARD FISHING BOATS

1. The sections of the boat or container reserved for the storage of fish products should be completely clean.

2. The sections of the boat or the container reserved for the storage of fish products should not contain objects or products liable to transmit harmful properties or abnormal characteristics.

3. The section of boat or container should be so designed to be cleaned easily and to ensure that melt water cannot remain in contact with the fish products.

4. Sections of boat or the container should not be capable of being contaminated by the fuel used for the propulsion of the boat or by bilge water.

5. As soon as the fish products are taken on board, they should be protected from the effects of the sun or any other source of heat.

6. When the fish products are washed, the water used should be either drinking water or clean sea water, so as not to impair their quality or wholesomeness.

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

8. Fish products other than those kept alive should undergo cold treatments as soon as possible after loading. However in the case of fishing boats where cooling is not possible from a practical point of view, the fish products must not be kept on board for more than eight hours.

9. Ice used for the chilling of products should be made from drinking water or clean sea water. Before use, it must be stored under conditions which prevent its contamination.

10. After the fish products have been unloaded, the containers. Equipment and sections of the boat which are directly in contact with the fish products should be cleaned with drinking water or clean sea water.

11. Where fish is headed and/or gutted on board, such operations should be carried out hygienically and the products should be washed immediately and throughly with drinking water or clean sea water. The viscera and parts which may pose a threat to public health must be removed and set apart from products intended for human consumption. Livers and roes intended for human consumption must be refrigerated or frozen.

12. Equipment used for gutting, heading and the removal of fins, and containers and equipment in contact with the fish products, should be made of or coated with a material which is waterproof, resistant to decay, smooth and easy to clean and disinfect. When used they must be completely clean.

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

PART II

ADDITIONAL HYGIENE CONDITIONS APPLICABLE TO FISHING BOATS

1. Fishing boats must be equipped with holds, tanks or containers for the storage of refrigerated or frozen fish products at a temperature of - 18° C or lower after temperature stabilization. These holds shall be separated from the machinery space and the quarters reserved for the crew by partitions which are sufficiently impervious to prevent any contamination of the stored fish products.

2. The inside surface of the holds, tanks or containers shall be waterproof and easy to wash and disinfect. It shall consist of a smooth material or, failing that, smooth paint maintained in good conditions, not being capable of transmitting to the fish products substances harmful to human health.

3. The holds shall be designed to ensure that melt water cannot remain in contact with the fish products.

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

5. The working decks, the equipment and the holds, tanks and containers shall be cleaned each time they are used. Drinking water or clean sea water shall be used for this purpose. Disinfection, the removal of insects or rat extermination shall be carried out whenever necessary.

6. Cleaning products, disinfectants, and all potentially toxic substances shall be stored in locked premises or cupboards. Their use must not present any risk of contamination of the fish products.

7. If fish products are frozen on board, this operation must be carried out in accordance with the conditions laid down in Schedule "D" Part II item 1 and 3 of II. Where freezing in brine is used, the brine shall not be a source of contamination for the fish.

8. Boats equipped for chilling of fish products in cooled sea water, either chilled by ice (CSW) or refrigerated by mechanical means (RSW) shall comply with the following requirements :-

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

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

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

(*d*) after each unloading the tanks circulation systems and containers must be completely emptied and thoroughly cleaned using drinking water or clean sea water. They should only be filled with clean sea water;

(*e*) the date and the number of the tank must be clearly indicated on the temperature recordings which must be kept available for the control authorities.

9. The Competent Authority shall keep up to date for control purposes, a list of the boats equipped in accordance with items 7 or 8 above with the exemption however of boats equipped with removable containers which, without prejudice to item 8 of Part I of this Schedule, are not engaged regularly in preserving fish in chilled sea water.

10. Boat owners or their representatives shall take all the measures necessary to prevent persons liable to contaminate fish products from working on hand handling them, until there is evidence that such persons can do so without risk.

(Regulation 6(a)).

SCHEDULE "C"

REQUIREMENTS DURING AND AFTER LANDING

1. All unloading and landing equipment should be constructed of material which are easy to clean, and disinfect and should be kept in a good state of repair and cleanliness.

2. Any contamination of fish should be prevented during unloading and loading and in particular it should conform to the following requirements:-

(*a*) unloading and loading operations should proceed fast ;

(*b*) fish are placed without unnecessary delay in a conducive environment at a temperature required on the basis of the nature of the product and where necessary placed in ice during transport, storage, or in an establishment; and

(*c*) to take care of unnecessary damage to the edible parts of the fish during handling practices.

3. All places of sale, auctions, wholesale or retail markets where fish are for sale, should comply with the following requirements:-

(*a*) It should have an enclosed area, with walls which are easy to clean ;

(*b*) It should have water proof flooring which facilitates easy washing, disinfection, and proper drainage of waste water including a suitable hygienic waste water disposal system ;

(*c*) It should possess proper sanitary facilities equipped with an appropriate number of wash basins and flush lavatories. The wash basins should be supplied with single use hand towels and disinfectants for cleaning the hands.

(*d*) The area should be well lit to facilitate the inspection and monitoring of fish products in compliance with provisions of Schedule E ;

(*e*) All areas used for display or storage of fish products, not be used for other purposes ;

(*f*) Vehicles emitting exhaust fumes and undesirable animals which may impair the quality of fish should not be allowed in the areas used ;

(*g*) Be cleaned regularly and at least after each sale; crates must, after each sale, be cleaned and rinsed inside and outside with drinking water or clean sea water; where required, they must be disinfected ;

(*h*) Signs prohibiting smoking, spitting, eating and drinking; should be displayed in a prominent place and position ;

(*i*) Areas should be able to be closed when the Competent Authority consider it necessary ;

(*j*) Should have facilities to provide adequate water supply satisfying the conditions laid down in Schedule D Part I Item 1 (g) ;

(*k*) Should provide special watertight receptacles made of corrosion resistant materials for fish products which are unfit for human consumption ;

(*l*) In the absence of own premises on-the-spot or in the immediate vicinity on the basis of the quantities displayed for sale, provisions should be made for the purposes of the Competent Authority, an adequately equipped lockable room and the equipment necessary for carrying out inspections.

4. After landing or, where appropriate, after first sale, fish products should be transported without delay, under the conditions laid down in Schedule G, to their place of destination.

5. However, if the conditions laid down in items 4 are not fulfilled, the markets in which fish products may be stored before being displayed for sale or after being sold and pending transport to their place of destination must have sufficiently large cold rooms which satisfy the conditions laid down in Schedule D Part I item I (c). In such cases, fish products must be stored at a temperature approaching that of melting ice.

6. The general conditions of hygiene laid down in Schedule D Part II with the exception of item B 1 (*a*), of Part II of Schedule D, should apply mutatis mutandis to the markets in which fish products are displayed for sale or stored.

7. The wholesale markets in which fish products are displayed for sale or stored should be subject to the same conditions as those laid down in item 3 and 5 of this Schedule and to those set out in items (*d*), (*j*) and (*k*) of Part I, (i) of Schedule D.

The general conditions of hygiene laid down in Part I, (ii) of Schedule "D" shall apply *mutatis mutandis* to wholesale markets.

(Regulation 6(b)).

SCHEDULE "D"
Part I
GENERAL CONDITIONS FOR CERTIFIED PROCESSING ESTABLISHMENTS

1. *General conditions relating to premises and equipment.*- Establishment should afford at least the following facilities: -

(*a*) working areas of sufficient size for work to be carried out under adequate hygienic conditions. Their design and layout should be such so as to preclude contamination of the product and keep the clean and contaminated parts of the building separated;

(*b*) areas where products are handled, prepared and processed, should have —

(i) waterproof flooring which is easy to clean and disinfect and laid down in such manner, to facilitate the drainage of the water or with availability of equipment to remove water;

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

(iii) ceilings or rooflinings which are easy to clean;

(iv) doors made out of material which are easy to clean;

(v) adequate ventilation and where necessary, efficient steam and water vapour extraction facilities;

(vi) adequate natural or artificial lighting;

(vii) an adequate number of facilities for cleaning and disinfecting hands. In work rooms and lavatories taps must not be hand operable. These facilities must be provided with single use hand towels; and

(viii) facilities for cleaning plant, equipment and utensils

(*c*) In cold rooms where fish products are stored

(i) the provisions set out under item (b), (i) (ii), (iii), (iv) and (vi);

(ii) where necessary, a sufficiently powerful refrigeration plant should be made available to keep products at temperatures specified in these regulations;

(*d*) appropriate facilities should be provided for protection against pests such as insects, rodents, birds, etc.;

(*e*) Instruments and working equipment such as cutting tables, containers, conveyor belts and knives should made of corrosion resistant material, and be easy to clean and disinfect;

(*f*) availability of special watertight, corrosion resistant containers for fish products not intended for human consumption and premises for the storage of such containers if they are not emptied at least at the end of each working day;

(*g*) facilities to provide adequate supply of drinking water or alternatively of clean sea water or sea water treated by an appropriate system, under pressure and in sufficient quantity. However, by way of exception, a supply of non drinking water is permissible for the production of steam, fire fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products. Non drinking water pipes must be clearly distinguished from those used for drinking water or clean sea water;

(*h*) be equipped with a hygienic waste water disposal system;

(*i*) contain an adequate number of changing rooms with smooth, water proof, washable walls and floors, wash basins and flush lavatories. The lavatories may not open directly onto the work rooms. The wash basins must have material for cleaning the hands and disposable towels and the wash basin taps must not be hand operable;

(*j*) if the volume of products treated requires regular or permanent presence of the Competent Authority an adequately equipped lockable room for the exclusive use of the inspection service;

(*k*) availability of adequate facilities for cleaning and disinfecting means of transport. However, such facilities are not compulsory if there is a requirement for the means of transport to be cleaned and disinfected at facilities officially authorised by the Competent Authority; and

(*l*) establishments keeping live animals such as crustaceans and fish must have appropriate fittings ensuring the best survival conditions, provided with water of a quality so that no harmful organism or substances are transferred to the animals.

2. *General conditions relating to hygiene.*– A. *General conditions of hygiene applicable to premises and equipment* :

1. Floor, walls and partitions, ceilings or roof linings, equipment and instruments used for working on fish products should be kept in a satisfactory state of cleanliness and repair, so that they do not become a source of contamination for the products.

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

3. Working areas, instruments and working equipment should be used only for work on fish products. However, following authorisation by the Competent Authority, they may be used at the same time or other times for work on other foodstuff.

4. Drinking water, or clean sea water must be used for all purposes. However, by way of an exception, non drinking water may be used for steam production, fire fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products. Non drinking water pipes shall be clearly distinguished from drinking water pipes.

5. Detergents, disinfectants and similar substances used should be approved by the Competent Authority and be used in a manner that they do not have adverse effects on the machinery, equipment and products.

B. *General conditions of hygiene applicable to staff.* – 1. The highest possible standards of cleanliness is required of staff. More specifically :

(*a*) staff should wear suitable clean working clothes and headgear which completely encloses the hair. This applies particularly to persons handling exposed fish products ;

(*b*) staff assigned to the handling and preparation of fish products should be required to wash their hand at least each time work is resumed ; wounds to the hands must be covered by a waterproof dressing ;

(*c*) smoking, spitting, eating and drinking within work and storage premises of fish products should be prohibited.

2. The employer should take all the requisite measures to prevent persons liable to contaminate fish products from working and handling them, until there is evidence that such persons can do so without risk.

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

4. The provisions contained in Part V and Part VI of Food Regulations, 1988, published in *Gazette* Extraordinary No.560/13 of June 2, 1989 relating to personal cleanliness and clothing for persons handling exposed food, shall *mutatis mutandis* apply to and in respect of staff assigned to the handling and preparation of fish products.

Part II

SPECIAL CONDITIONS FOR HANDLING FISH PRODUCTS ON SHORE

A. *Conditions for fresh products.*- 1. Where chilled, unpackaged products are not dispatched, prepared or processed immediately after reaching the establishment, they must be stored or displayed under ice in the establishment's cold room. Re-icing should be carried out as often as is necessary. The ice used, with or without salt, should be made from drinking water or clean sea water and be stored under hygienic conditions in receptacles provided for the purpose. Such receptacles should be kept clean and in a good state of repair. Prepacked fresh products should be chilled with ice or mechanical refrigeration plant creating similar temperature conditions.

2. Operations such as heading and gutting should be carried out hygienically. The products should be washed thoroughly with drinking water or clean sea water immediately after such operations.

3. Operations such as filleting and slicing should 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 must not remain on work tables any longer than is necessary for their preparation, and must be protected from contamination by appropriate packaging.

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

5. Containers used for the dispatch or storage of fresh fish products must 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 should provide adequate drainage of melt water.

6. Special facilities should be provided for the continuous disposal of waste. If not there should be leakproof, covered containers which are easy to clean and disinfect. The waste should be removed either continuously or as soon as the containers are full and at least at the end of each working day in the containers or to the premises referred to in item I(f) of Part I of this Schedule. The containers, receptacles and or premises set aside for waste should always be thoroughly cleaned and, if appropriate, disinfected after use. Waste stored there must not constitute a source of contamination for the establishment or of pollution of its surroundings.

B. *Conditions for frozen products.*- 1. Plants should have :-

(*a*) freezing equipment sufficiently powerful to achive a rapid reduction in the temperature so that the temperatures laid down in these regulations can be obtained in the product ;

(*b*) freezing equipment sufficiently powerful to keep products in storage rooms at a temperature not exceeding those laid down in these regulations, whatever the ambient temperature may be ;

(*c*) for technical reasons related to the method of freezing and to the handling of such products, for whole fish frozen in brine and intended for canning, higher temperatures than those laid down in these regulations are acceptable although they may not exceed - 9°C.

2. Fresh products to be frozen or quick frozen must comply with the requirements of item A of this Part of this Schedule.

3. Storage rooms should have a temperature recording device in a place where it can easily be read. The temperature sensor of the recorder must be located in the area furthest away from the cold source, i.e. where the temperature in the storage room is the highest.

4. The temperature charts should be available for inspection by the supervisory authorities at least during the period in which the products are stored.

C. *Conditions for thawing products.*- Establishments that carry out thawing operations should comply with the following requirements :-

1. Fish products must be thawed under hygienic conditions ; their contamination must be avoided and there should be adequate drainage for any melt water produced.
2. During thawing, the temperature of the products should not increase excessively.
3. After thawing, fish products must be handled in accordance with the requirements of these regulations. When they are prepared or processed, these operations should be carried out without delay. If they are put directly into the market, particulars as to the thawed state of the fish must be clearly marked on the packaging.

D. *Conditions for processed products.*- 1. Fresh, frozen and thawed products used for processing should comply with the requirements of items A, B or C of this Part of this Schedule.

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 should be scientifically recognised by the laws in force.

3. The certified licensee should keep a register of the processing carried out. Depending on the type of process employed, heating time and temperature, salt content, pH, water content, etc., should be monitored and controlled. Records should be kept at least for the expected storage life of the products and be available to the Competent Authority.

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

Canning.- In the case of fish products which have been subjected to sterilisation in hermetically sealed containers:-

(*a*) the water used for the preparation of cans should be drinking water ;

(*b*) the process used for the heat treatment should be appropriate, having emphasis on major criteria such as the heating time temperature, filling, size of containers, etc. and these details should be recorded. Heat treatment should be capable of destroying or inactivating pathogenic organisms and the spores of pathogenic micro-organisms. The heating equipment should be fitted with devices for verifying whether the containers have in fact undergone appropriate heat treatment. Drinking water should be used to cool containers after heat treatment, without prejudice to the presence of any chemical additives used in accordance with good technological practice to prevent corrosion of the equipment and containers;

(*c*) further checks should be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat, treatment,*viz.* -

(i) incubation tests: incubation should be carried out at 37°C for seven days or at 35°C for ten days, or at any other equivalent combination;

(ii) the contents and containers should undergo micro-biological examination in the establishments laboratory or in an approved laboratory.

(*d*) samples should be taken of production daily at predetermined intervals, to ensure the efficiency, sealing or any other method of hermetic closure.

(*e*) checks should be carried out in order to ensure that containers are not damaged; and

(*f*) all containers which have undergone heat treatment under practically identical conditions should given a batch identification mark.

Smoking.- (*a*) Smoking must be carried out in a separate premises or a special place equipped, if necessary, with a ventilation system to prevent the smoke and heat from the combustion affecting other premises or places where fish products are prepared, processed or stored.

(*b*) Material used to produce smoke for the smoking fish must be stored away from the place of smoking and must be used in such manner that they do not contaminate the products.

(*c*) Production of smoke by burning and using wood that has been painted, varnished, glued or had undergone any chemical preservation treatment should be prohibited.

(*d*) On completion of smoking products should be cooled rapidly to the temperature required for their preservation before being packed.

Salting.- (*a*) salting operations must take place in different premises and sufficiently away from the premises where the other operations are carried out.

(*b*) Salt used in the treatment of fish products should be clean and stored in such manner as to preclude contamination. It should not be re-used.

(*c*) Any container, used for salting or brining should be constructed in such a manner as to preclude contamination during the salting or brining process.

(*d*) Containers or areas used for salting or bringing should be cleaned before use.

Cooked crustacean and molluscan shellfish products.- Crustaceans and molluscan shellfish should be cooked as follows:-

(*a*) Any cooking should be followed by rapid cooling. Water used for this purpose should be drinking water or clean sea water. If no other method of preservation is used, cooking must continue until the temperature approchig that is melting ice is reached.

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

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

(*d*) Every manufacturer should carry out microbiological checks on his production at regular intervals, complying with the standards to be fixed in accordance with the provisions of Schedule "E";

Mechanically recovered fish flesh.- The mechanical recovery of fish flesh should be carried out under the following conditions :-

(*a*) mechanical recovery of gutted fish should take place without undue delay after filleting, using raw material free of guts. Where whole fish are used, they should be gutted and washed beforehand ;

(*b*) the machinery used should be cleaned at frequent intervals and at least every two hours ;

(*c*) after recovery, mechanically recovered flesh should be frozen as quickly as possible or incorporated in a product intended for freezing or stabilizing treatment.

E. *Conditions concerning parasites.*- (1) During production and prior to they being released for human consumption, fish and fish product should be subject to a visual inspection for the purpose of detecting and removing any parasites that are visible. Fish or parts of fish which are obviously infested with parasites, and which are removed free of parasites should not be placed on the market for human consumption.

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

(3) The persons in charge of certified establishments and qualified persons on board fishing boats shall determine the scale and frequency of the inspections by reference to the nature of the fishery products, their geographical origin and their use.

(4) During production the visual inspection of eviscerated fish must be carried out by qualified persons on the abdominal cavity and livers and rose intended for human consumption. According to the system of gutting used the visual inspection must be carried out -

(*a*) in the case of manual evisceration, in a continuous manner by the operative at the time of evisceration and washing ;

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

(5) The visual inspection of fish fillets or fish slices must be carried out by qualified persons during trimming after filleting or slicing where an individual examination is not possible, because of the size of the fillets or the filleting operations, a sampling plan must be drawn up and kept available for the competent authority in accordance with the provisions laid down in Regulation 13 where candling of fillets is possible from a technical viewpoint, it must be included in the sampling plan.

(6) For the purpose of item (1), (2), (3), (4) and (5) above :-

"parasites that are visible" means a parasites which has a dimension, colour or texture which is clearly distinguishable from fish tissues ; and

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

7. The fish and fish products referred to in item 8 of these conditions, which are to be consumed as they are should in addition, be subjected to freezing at a tepmerature of not more than –20° C in all parts of the products for not less that 24 hours. Products subjected to this freezing process should be either raw or finished.

8. Fish and products subject to the conditions in item 7 are as follows:–

(*a*) fish to be consumed raw or almost raw, e.g. raw herring 'maatje';

(*b*) the following species, if they are to undergo cold smoking process at which the internal temperature of the fish is less than 60° C :–

(i) Herring ;
(ii) Mackerel ;
(iii) Sprat ;
(iv) (Wild) Atlantic and Pacific salmon,

(*c*) marinated and / or salted herring where this process is insufficient to kill the larvae of nematodes.

9. Manufacturers should ensure that fish and fish products listed in Item 8 above or the raw material used in their manufacture are subjected to the treatment described in item 7 above, prior to their release for consumption.

10. The fish products listed in item 8 above should at the time they are placed on the market, be accompanied by a document from the manufacturer stating the type of process they have undergone.

(Regulation 6(c)).

SCHEDULE "E"

HEALTH CONTROL AND MONITORING OF PRODUCTION CONDITIONS

A. *General Monitoring*.– Arrangements for checking and monitoring should be made by the Competent Authority in order to ensure the compliance of requirements laid down in these regulations. Such arrangements should include, in particular :–

(*a*) a check on the fishing boats on the understanding that such a check may be carried out during the stay in port ;

(*b*) a check on the conditions of landing and first sale ;

(*c*) an inspection at regular intervals of establishments to check, in particular :

(i) whether the conditions for approval are continued to be fulfilled ;

(ii) whether the fish products are handled correctly ;

(iii) whether the cleanliness of the premises, facilities and instruments and staff hygiene are in compliance with regulations ;

(iv) whether identification marks are put on correctly.

(*d*) an inspection of the wholesale and auction markets ;

(*e*) a check on storage and transport conditions.

B. *Special checks.*-

1. *Organoleptic checks.*- 1. Each batch of fish products should be submitted for inspection by the Competent Authority at the time of landing or before first sale to check whether they are fit for human consumption. This inspection comprises an organoleptic check carried out by sampling.

2. Fish products complying, as far as the freshness criteria are concerned, with the criteria laid down in the Annex I to this Schedule, are considered to fulfil the organoleptic requirements necessary for compliance with the provisions of these regulations.

3. The organoleptic examination should be repeated after the first sale of fish products, if it is found that the requirements of these regulations have not been complied with or when considered necessary. After the first sale, fish products should at least comply with the minumum freshness requirements of the aforementioned regulations.

4. If the organoleptic examination reveals that the fish products are not fit for human consumption, measures should be taken to withdraw them from the market and denature in such a way that they cannot be re-used for human consumption.

5. Organoleptice examination reveals any doubt as to the freshness of the fish products, use may be made of chemical checks or micro-biological analyses.

2. *Parasite checks.*- 1. Before they are released for human consumption, fish and fish products must be subject to a visual inspection, by way of sam le, for the purpose of detecting any parasites that are visible.

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

3. *Chemicals checks.*- 1. Samples should be taken and subject to laboratory analysis for the control of the following parameters :-

(*A*) TVB-N (Total Volatile Basic Nitrogen) and TMA-N (Trimethylamine-Nitrogen) :

(i) Unprocessed fish products belonging to the species of -

(*a*) *Sebastes* spp, *Helicolenus dactylopterus, Sebastichthys capensis;*

(*b*) Species belonging to the Pleuronectidae family (with the exception of halibut: *Hippoglossus* spp); and

(*c*) *Salmo salar* - Species belonging to the Merluceudae family Species belonging to the Gadidac family

shall be regarded as unfit for human consumption where, organoleptic assessment having raised doubts as to their freshness, chemical checks reveal that the follwoing TVB.N limits are exceeded:-

- 25milligrams of nitrogen/100 grams of flesh for the species referred to in A; and
- 30 milligrams of nitrogen/100 grams of flesh for the species referred to in B; and
- 35 milligrams of nitrogen/100 grams of flesh for the species referred to in C.

(ii) The reference method to be used for checking the TVB.N limit is the method involving distillation of an extract deprotenized by perchloric acid set out in the Annex II to this Schedule.

(iii) Distillation as referred to in item (ii) above must be performed using apparatus which complies with the principles of the diagram specified in Annex III to this Schedule.

(iv) The routine methods which may be used to check the TVB. N. limit are as follows:

- microdiffusion method described by Conway and Byrne (1933).
- direct distillation method described by Antonacopoulos (1968).
- distillation of an extract deproteinized by trichloracetic acid (Codex Almentarius Committee on Fish and Fishery Products (1968).

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

(*B*) Histamine - nine samples should be taken from each batch. These should fulfil the following requirements:-

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

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

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

The limits apply only to fish species of the following families: Scombridae, Clupeidae, engraulidae and coryphaenidae. However, fish belonging to these families which have undergone enzyme ripening treatment in brine may have higher histamine levels but not more than twice the above values. Examinations must be carried out in accordance with reliable, scientifically recognised methods, such as high performance liquid chromatography (HPLC).

4. *Contaminants present in the aquatic environment.*- Fish products must not contain in their edible parts contaminants present in the aquatic environment such as heavy metals and organochlorinated substances at such a level that the calculated dietary intake exceeds the acceptable daily or weekly intake for humans.

5. *Maximum limits for mercury in Fish Products.*- 1. The mean total mercury content of the edible Parts of Fish products must not exceed 0.5 ppm of Fresh product (0.5 miligrams per kilogram of fresh weight). This average limit is, however, increase to 1 ppm of fish product (1 miligrams per kilogram of fresh weight) for the edible parts of the species listed below:-

Sharks (all species);
Tunas (*Thunnus* spp.);
Little tuna (*Euthynnus* spp.)
Bonito (*Sarda* spp);
Plain bonito *(Orcynopsts unicolor)* ;
Swordfish (*Xiphias gladius*);
Sailfish *(Istiophorus platyptetus)* ;
Marlin (*Makaira* spp.);
Eel (Anguilla spp.);
Bass (*Dicentrarchus labrax*);
Sturgeon (*Acipenser* spp.);
Halibut (*Hippoglossus hipporlossus*);
Redfish (*Sebastes marinus, S. meniella*);
Blue ling (*Molva dipterygia*);
Atlantic catfish (*Anarbubas lupus*);
Pike (*Eaux douces*);
Portuguese dogfish (*Centroseymnes coelulepts*);
Rays (*Raja* spp.);
Scabbardfishes (*Lepidopus caudatus, Aphanopus carbo*);
Anglerfish (*Lophius* spp).

2. Sampling plans should be laid down for fresh and frozen fish products by the Competent Authority. These shall take account of the results obtained from national checks and within the frame work of the monitoring system carried out in accordance with item B (4) of this Schedule and of the following facts:-

(*a*) product type ;

(i) species listed in paragraph 1;

(ii) other species

(*b*) The minimum number of samples to be taken per lot for each product type shall be:

(i) type *(i)*, Ten samples taken from ten different individuals;

(ii) type *(ii)*, Five Samples taken from five different individuals;

3. The analysis shall be carried out on the finely homogenized mixture of the samples so as to obtain the mean valve of the mercury content. In particular, in the case of species listed in paragraph one, which are of various sizes, the samples taken must represent composition of the lot.

Annex 1.

FRESHNESS RATINGS

The ratings established in this Annex apply to the following fish products or groups of fish products, by reference to appraisal cariteria specific to each of them:

A. Whitefish:
Haddock, cod, saithe, pollack, redfish, whiting, ling, hake, Ray's bream, anglerfish, pouting and poor code, bogue, picarel, conger, gurnard, mullet, plaice, megrim, sole, dab, lemon sole, flounder, scabbard fish.

B. Bluefish :
Albacore or longfinned tuna, bluefin tuna, bigeye tuna, blue whiting, herring, sardines, mackerel, horse mackerel, anchovy.

C. Selachii :
Dogfish, skate.

D. Caphalopods :
Cuttlefish.

E. Crustaceans :
1. Shrimps,
2. Norway lobster.

(A) Whitefish :

	Criteria			
	Freshness Category			*Not admitted*
	Extra	*A*	*B*	
Skin	Bright, iridescent pigment (save for redfish) or opalescent; no discolouration	Pigmentation bright but not lustrous	Pigmentation in the process of becoming discoloured and dull	Dull pigmentation ( )
Skin Mucus	Aqueous, transparent	Slightly cloudy	Milky	Yellowish grey, opaque mucus
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 centre ; grey pupil; milky cornea (2)
Gills	Bright colour; no mucus	Less colured; transparent mucus	Brown/grey becoming discoloured; thick, opaque mucus	Yellowish; milky mucus (2)

Peritoneum (in 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- whitefish other than plaice	Seaweedy Fresh oily; peppery; earthy smell	No smell of seaweed; neutral smell Oily; seaweedy or slightly sweetish	Fermented; slightly sour	(2) sour
-plaice			Oily; fermented; stale, slightly rancid	Sour
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
Extra criteria for headed anglefish :				
Blood vessels (vental muscles)	Sharp outline and bright red	Sharp outline; darkening of the blood	Diffuse and brown	Totally (2) diffuse, brown and yellowing of the flesh.

(B) Bluefish :

	Criteria			
	Freshness Category			*Not admitted (1)*
	Extra	*A*	*B*	
Skin (2)	Bright pigmentation bright shining iridescent colours; clear distinction between dorsal and central surfaces	loss of lustre and shine, duller colours less difference between dorsal and ventral surfaces	Dull, lustreless, insipid colours; skin creased when fish curved	Very dull pigmentation; skin coming away from flesh (3)
Skin mucus	Aqueous, transparent	Slightly cloudy	Milky	Yellowish grey, opaque mucus (3)
Consistency of flesh (2)	very firm, rigid	Fairly rigid, Firm	Slightly soft	Soft (flaccid) (3)
Gill covers	Silvery	Silvery, slightly red or brown	Brownish and extensive seepage of blood from vessels	Yellowish (3)
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 centre; grey pupil; milky cornea (3)

Gills (2)	Uniformly dark red to purple, no mucus	Less bright colour, paler at edges transparent mucus	Becoming thick discoloured opaque mucus	Yellowish; milky mucus (1)
Smell of gills	Fresh seaweed; pungent; iodine	No smell or seaweed, Neutral smell	Slightly sulphureous (4) fatty smell, rancid bacon cuttings or rotten fruit	*Rotten shour* (3)

(C.) *Selachii:*

	Criteria			
	Freshness category			Not admitted (1)
	Extra	A	B	
Eye	Convex, very bright and iridescent ; small pupils	Convex and slightly sunken ; loss of brightness and iridescence, oval pupils	Flat, dull	Concave yellowish (2)
Appearance	In rigor mortis or partially in rigor ; small quantity of clear mucus present on skin	Beyond rigor stage ; no mucus on skin and especially in mouth and gill openings	Some mucus in mount and on gill openings ; slightly flattened jaw	Large quantities of mucus in mouth and on gill openings (2)
Smell	Seaweed smell	no smell or very slight stale but not an ammonia smell	Slight ammonia ; sour	Pungent ammonia smell (2)

Specific or additional criteria for skate

Skin	Bright, iridescent and shiny pigmentation, aqueous mucus	Bright pigmentation, aqueous mucus	pigmentation in the process of becoming discoloured and dull, opaque mucus	Discolouration, skin creased, thick mucus
Texture of the flesh	Firm and elastic	Firm	Soft	Flaccid
Aspect	Edge or the fins translucent and curved	stiff fins	Soft	Drooping
Belly	White and shiny with a mauvish edge around the fins	White and shiny with red patches limited to around the fins	White and dull, with numerous red or yellow patches	Yellow to greenish bellies red patches in the flish itself

(D) *Cephalopod* :

	Criteria		
	Freshness category		
	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 ; pinky white or slightly yellowing
Tentacles	Resistant to removal	Resistant to removal	More easily removed
Smell	*Fresh ; seaweed*	*slightly or no smell*	*Ink smell*

(E) *Crustaceans – 1. Shrimps :*

	Criteria	
	Freshness category	
	Extra	
Minimum requirements	Surface of shell ; moist and shiny Shrimps must fall out separately when transferred from one container to another Flesh must be free from any foreign odour Shrimps must be free from sand, mucus and other foreign bodies	The same as for extra category
Appearance of :		
1. shrimp with shell	Clear reddish-pink in colour with small white flecks; pectoral part of shell predominantly light in colour	Ranging in colour from slightly washed-out reddish-pink to bluish-red with white flecks; pectoral part of shell should be light coloured tending towards grey
2. deep-water prawn	Uniformly pink	Pink with possibility of start of blackening of head
Condition of flesh during and after shelling	Shells easily with only technically unavoidable losses of flesh Firm but not tough	Shells less easily with small losses of flesh Less firm, slightly tough
Fragments	Occasional fragments of shrimp allowed	Small quantity of fragments of shrimp allowed
Smell	Fresh seaweed, slightly sweet smell	Acidulour; no smell of seaweed

(2) *Norway lobster* :

	Criteria		
	Freshness category		
	Extra	*A*	*B*
Shell	Pale pink or pink to orange red	Pale pink or pink to orange red, no black spots	Slight discolouration, some black spots and greyish colour, particularly on shell and between tail segments
Eye and gills	Shiny black eyes; pink gills	Eyes dull and grey/black; gills greyish	Gills dark grey or some greenish colour on dorsal surface of shell
Smell	Characteristic mild shellfish smell	Loss of characteristic shellfish smell. No ammonia smell	Slightly sour
Flesh (tail)	Translucent and blue in colour tending towards white	No longer translucent but not discoloured	Opaque and dull in appearance

Annex II.

DETERMINATION OF THE CONCENTRATION OF VOLATILE NITROGENOUS BASES(TVB-N) IN FISH AND FISH 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 5mg/100g to at least 100 mg/100g.

2. *Definition.*- The TVB. N concentration is here understood to mean the nitrogen content of volatile nitrogenous bases determined by the procedure described. The concentration is stated in terms of mg/100g.

3. *Brief description.*- The volatile nitrogenous bases are extracted from a sample by a solution of 0.6 M perchloric acid. After alkahanization 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 nitration of the absorbed bases.

4. *Chemicals.*- Unless otherwise indicated, reagent-grade chemicals should be used. The water used must be either distilled or demineralized and of at least the same part unless indicated otherwise, a "solution" is to be understood as an aqueous solution:

4.1 Perchlric acid solution - 6 g/100 ml;
4.2 Sodium hydroxide solution - 20 g/100 ml;
4.3 Hydrochlric acid standard solution 0.05 mol/1 (0.05 N);
4.4 Boric acid solution - 3g/100 ml;
4.5 Silicone anti-foaming agent;
4.6 Phenolphtalin solution - 1 g/100 ml 95% ethanol;
4.7 Indicator solution (Tashiro mixed Indicator) 2 g Methyl-red and 1g 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 8000 min⁻ and 45,000 min
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 constant amount of steam over a given period of time. It must ensure that during the addition of alkalizing substances the resulting free bases cannot escape.

6. *Execution.*- Warning; when working with perchloric acid, which is strongly corrosive, necessary caution and preventive measures should be taken.

The samples should, if at all possible, be prepared according to paragraph 6.1 as soon as possible after their arrival.

6.1. *Preparation of the sample.*- The sample to be 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 perchloric acid solution as stated in section 4.1, homogenized for two minutes with a blender as described in section 5.2 and then filtered.

The extract thereby obtained can be kept for atleast seven days at a temperature between approximately 2°C and 6°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 alkalinization 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 the 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. Alter 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 hydroclioric solution as specified in section 4.3. The pH of the end point should be 5.0 +/- 0.1.

6.3. *Titration.*- Duplicate analyses are required. The applied method is correct if of the difference of the duplicates is not higher than 2 mg/100 g.

6.4. *Blank.*- A blind test carried out as described in section 6.2. Instead of the extract. 50.0 ml perchloric acid solution as specified in section 4.1. 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 :

TVB.N (expressed in mg/100 g sample)

$$\frac{(V_1 - V_0) \times 0.14 \times 2 \times 100}{M}$$

V_1 - Volume of 0.01 M hydrochloric acid solution in ml for sample.
V_0 - Volume of 0.01 M hydrochloric acid solution in ml for blank.
M. - Weight of sample in g

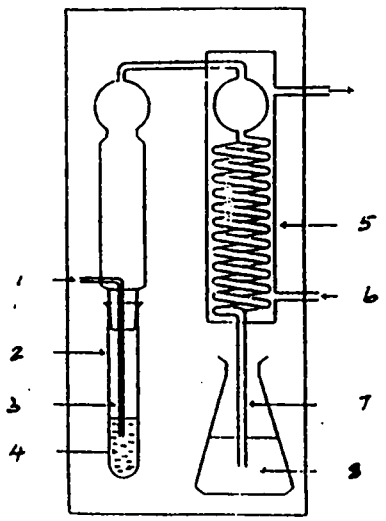
Remarks :

1. Duplicate analyses are required. The applied method is correct if the difference between duplicates is not higher than 2mg/100g.;
2. Check the equipment by distilling solutions of NH_4Cl, equivalent to 50 mg. TVB/100g.;
3. Standard deviation of reproducibility S_1 = 1.20mg/100g.;
   standard deviation of comparability S_2 = 2.50mg/100;

Annex III.

TVB.N STEAM DISTILLATION APPARATUS

1. Steam generator
2. Distillation tube
3. Steam injection tube
4. Sample extract
5. Cooler
6. Cool water
7. End of condenser
8. Flask or beaker (Boric Acid)



(Regulation 6 (d)).

SCHEDULE "F"

PACKAGING

1. Packaging must be carried out under satisfactory conditions of hygiene, to preclude contamination of fish product.

2. Packaging materials and products liable to enter into contact with fish products must comply with all rules of hygiene, and in particular they must -

(a) not be such as to impair the organoleptic characteristics of the fish products ;
(b) not be capable of transmitting to the fish products substances harmful to human health ; and
(c) be strong enough to protect the fish products adequately.

3. With the exception of certain containers made of impervious, smooth and corrosion - resistant material which are easy to clean and disinfect and which may be re-used after cleaning and disinfecting, packaging materials may not be re-used. Packaging materials used for fresh products held under ice, must provide adequate drainage for melt water.

4. Unused packaging materials must be stored in premises away from the production area and be protected from dust and contamination.

(Regulation 6(e)).

SCHEDULE " G "

STORAGE AND TRANSPORT

1. Fish products must, during storage and transport, be kept at the temperatures laid down in these regulations and in particular :-

(a) fresh or thawed fish products and cooked and chilled crustacean and molluscan shellfish products must be kept at the temperature of melting ice ;

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

(c) Processed products must be kept at the temperature specified by the manufacturer, when the circumstances so require.

2. Where frozen fish products are transported from a cold storage plant to an approved establishment to be thawed on arrival for the purposes of preparation and / or processing and where the distance to be covered is short, not exceeding 50km. or one hour's journey, the Competent Authority may grant a derogation from the conditions laid down in item I (b) of this Schedule.

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

4. Vehicles used for the transport of fish product must be constructed and equipped in such a way that the temperatures laid down in these regulations can be maintained throughout the period of transport. If ice is used; to chill the products, adequate drainage must be provided in order to ensure that water from melted ice does not stay in contact with the products. The inside surfaces of the means of transport must be finished in such a way that they do not adversely affect the fish products. They must be smooth and easy to clean and disinfect.

5. Means of transport used for fish products may not be used for transporting other products likely to impair or contaminate the fish products, except where the fish products can be guaranteed uncontaminated as a result of such transport being thoroughly cleaned and disinfected.

6. Fish products may not be transported in a vehicle or container which is not clean or which requires disinfection.

7. The transport conditions of fish products to be placed on the market alive, must not adversely affect the products.

(Regulation 6(f)).

SCHEDULE " H "

IDENTIFICATION MARKS

For the purpose of making it possible to trace for inspection purposes the establishment of dispatch of consignments of fishery products, by means either of labelling or of the accompanying documents, the following information must appear on the packaging or in the case of a non-packaged product in the accompanying documents :-

(a) the country of dispatch which may be written out in full or shown as an abbreviation, using capital letters ;
(b) identification of the establishment or fishing boat by its official certified number allotted under paragraph (2) of regulation 9 of these regulations or the identification number of the fishing boat.
(c) all letters and figures must be fully legible and grouped together on the packaging in a place where they are visible from the outside, without any need to open the packaging.

(Regulation 14(i)(b)).

SCHEDULE " I "

ESTABLISHMENT AND IMPLEMENTATION OF MONITORING AND CHECKING CRITICAL POINTS

To develop an appropriate monitoring and checking system the following guidelines may be adopted :–

1. *Establishment of critical limits for each control measure associated with each critical point.*–(a) Each control measure with a critical point, should give rise to the specification of critical limits.

(*b*) The critical limits referred to in (a) should correspond to the extreme values acceptable with regard to product safety. They separate acceptability from-un acceptability, are set for observable or measurable parameters which can readily demonstrate that the critical point is under control and 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 guidelines of good manufacturing practices, the team should ascertain their validity relative to the control of identified hazard and critical points.

2. *Establishment of a monitoring and checking system for each critical point.*–(*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*) Observation 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) who is to perform monitoring and checking; and

(ii) when monitoring and checking is to be performed.

3. *Establisment of a corrective action plan.*– (*a*) Observations or measurements may indicate that the parameters monitored :–

(i) tends to deviate from its specified critical limits, indicating a trend toward loss of control, in which case appropriate corrective action to maintain control must be taken before the occurrence of hazard ; or

(ii) has deviated from its specified critical limits, indicating a loss of control in which case it would be necessary to take appropriate corrective action to 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*) 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.

(Regulation 14(3).

SCHEDULE J "

IDENTIFICATION OF CRITICAL POINTS

1. Assembly of a multidisciplinary team.- (*a*) This team, which involves all parts of the establishment concerned with the product, needs to include the whole range of specific knowledge and expertise appropriate to the product under consideration. its production (manufacture, storage, and distribution), its consumption and the associated potential hazards. Where necessary, the team will be assisted by specialists who will help it to solve its difficulties as regards assessment and control of critical points.

(*b*) The team may consists 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 ; and

(iv) one other person with specialist knowledge of microbiology, hygiene and food techonology.

(*c*) One person may fulfil several of the roles referred to in (b) provided all relevant information is available to the team and is used to ensure that the own checks system developed is reliable. Where expertise is not available in the establishment, advice should be obtained from other sources (consultancy, guides of good manufacturing practices, etc.).

2. *Description of the product.*- The end product should be described in terms of -

(*a*) composition (e.g. raw materials, ingredients, additive, etc.) ;

(*b*) structure and physico-chemical characteristics (e.g. solid, liquid, gel, emulsion, Aw, pH, 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*) instructions for use; and
(*h*) any microbiological or chemical criteria applicable.

3. *Identification of intended use.*- The multidisciplinary team should also define the normal or expected use of the product by the customer and the 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.

4. *Construction of a flow diagram (Description of manufacturing process).*- 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, should be studied in sequence and presented in a detailed flow diagram with sufficient technical data.

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

(*a*) plan of working premises and ancillary premises;
(*b*) equipment layout and characteristics;
(*c*) sequence of all process steps (including the incorporation of raw materials, ingredients or additives and delays during or between steps);
(*d*) technical parameters of operations (in particular, time and temperature, including delays) ;
(*e*) flow of products (including potential cross contamination) ;
(*f*) segregation of clean and dirty areas (or high / low risk areas) ;
(*g*) cleaning and disinfection procedures ;
(*h*) hygienic environment of the establishment ;
(*i*) personnel routes and hygiene practices; and
(*j*) product storage and distribution conditions.

5. *On-site confirmation of the flow diagram.*- 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 of the original flow diagram to make it accurate.

6. *Listing of hazards and control measures.*- Using the confirmed flow diagram as a guide, the team should -

(a) list all potential biological, chemical or physical hazards that may be reasonably expected to occur at each process step (including acquisition and storage of raw material and ingredients and delays dring manufacture);

For purpose of paragraph (a), a hazard is a potential to cause harm to health and is anything covered by the hygiene objectives of these regulations. Specifically, it can be any of the following -

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

(ii) unacceptable survival or multiplication of pathogenic micro-organisms and unacceptable generation of chemicals in intermediate products, final products, production line or line environment;

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

For inclusion in the list, hazards must be of such nature that their elimination or reduction to acceptable levels is essential to the production of safe in food.

(b) Consider and describe what control measures, if any, exist which can be applied for each hazard.

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

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

(iii) Control measures need to be supported by detailed procedures and specifications to ensure their effective implementation. for instance, detailed cleaning schedules, precise heat treatment specifications, maximum concentrations of preservatives used in compliance with the applicable rules on additives.

7. *Methods for identification of critical points.*— (a) The identification of a critical point for the control of a hazard requires a logical approach. Such an approach can be facilitated by the use of the following "decision tree" (other methods can be used by the team, according to their knowledge and experience).

DECISION TREE FOR THE IDENTIFICATION OF CRITICAL POINTS.

Answer each question in sequence, at each step and for each identified hazard.

Question 1

Are control measures in place for the hazard ?

Yes

No

Modify step, process or product

Is control at this step necessary for product safety ?

Yes.

No ——— STOP ( )

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 unacceptable 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.

(b) 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.

(c) 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.

8. Action to be taken following identification of a critical point.— The identification of critical points has two consequences for the multidisciplinary team which should then :—

(a) ensure that appropriate control 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 at any other, or at an earlier or later stage, to include a control measure : and

(b) establish and implement a monitorig and checking system at each critical point.

(Regulation 14 (4) (c).

SCHEDULE "K"

VERIFICATION OF OWN CHECKS SYSTEM

1. Own checks system verification is necessary to ensure that they are working effectively. The multidisciplinary team referred to in Schedule J should specify the methods and procedures to be used for verification of own checks systems adopting the following guide lines :

(*a*) random sampling and analysis, reinforced analysis or tests at selected critical points, intensified analysis of intermediate or final products, surveys on actual condition during storage, distribution and sale and on actual use of the product;

(*b*) inspection of operation, validation of critical limits, review of deviations, corrective action and measures taken with regard to the product, audits of the own-check system and its records; and

(*c*) confirmation of the suitablity of the own-checks system established and ensure, afterwards, with an appropriate frequency, that the provisions laid down are still being properly applied.

2. It would be necessary to review the system, to ensure that it is (or will be) still valid in case of change. The changes envisaged may include:-

(*a*) change in raw material or in product, processing conditions (factory layout and environment, process equipment, cleaning and disinfection programme);

(*b*) change in packaging, storage or distribution conditions;

(*c*) change in consumer use; or

(*d*) receipt of any information on a new hazard associated with the product;

3. Where necessary, a review of the system must result in the amendment of the provisions laid down.

4. Any change to the own-checks system arising should be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is readily available.

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