

Notification no 668 dated 10th February, 2003

S.O.668(E) In exercise of the powers conferred by section 17 of the Export (Quality Control and Inspection) Act, 1963 (22 of 1963), the Central Government hereby makes the following rules, namely:-

1. Short Title and commencement –

(1) These rules may be called the Export of Bivalve Molluscs (Quality Control, Inspection and Monitoring) Rules, 2003.

(2) They shall come into force on the date of their final publication in the Official Gazette;

2. In these rules, unless the context otherwise requires -

(a) “**Act**” means the Export (Quality Control and Inspection) Act 1963 (22 of 1963) ;

(b) “**Agency**” means any one of the Export Inspection Agency established at Bombay, Calcutta, Cochin, Delhi and Madras established under section 7 (1) of the Act;

(c) “**Council**” means Export Inspection Council established under the Act;

(d) “**bivalve molluscs**” means filter-feeding lamellibranch molluscs;

(e) “**batch**” means a quantity of live bivalve molluscs collected from a production area and subsequently intended for delivery to an approved dispatch centre, purification centre, relaying area or processing plant as appropriate;

(f) “**clean sea water**” means sea water or brackish water which is to be used under the conditions laid down in this rules and which is free from microbiological contamination and toxic and objectionable substances;

(g) “**conditioning**” means the storage of live bivalve molluscs, whose quality does not indicate the need for relaying or treatment in a purification plant, in tanks or any other installation containing clean sea water or in natural sites to remove sand mud or slime;

(h) “**competent authority**” means the Export Inspection Council of India (EIC) and the Export Inspection Agencies (EIAs) established at Bombay, Calcutta, Cochin and Madras competent to carry out veterinary checks or any authority to which it has delegated that competence;

(i) “**consignment**” means a quantity of live bivalve molluscs handled in a dispatch centre or treated in a purification centre and subsequently intended for one or more customers;

(j) “**despatch center**” means any approved on-shore or off-shore installation for the reception, conditioning, washing, cleaning, grading and wrapping of live bivalve molluscs fit for human consumption;

(k) “**e.coli**” means faecal coliforms which also form indole from tryptophan at 44°C +/- 0. 2°C within 24 hours.

(l) “**faecal coliform**” means facultative, aerobic, gram-negative, non spore forming, cytochrome oxidase negative, rod shaped bacteria that are able to ferment lactose with gas production in the presence of bile salts, or other surface active agents with similar growth-inhabiting properties, at 44°C +/- 0. 2°C within 24 hours at least;

(m) “**gatherer**” means any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market;

(n) “**marine biotoxins**” means poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxin;

(o) “**means of transport**” means those parts set aside for goods in automobile vehicles, rail vehicles and aircraft, the holds of vessels and containers for transport by land, sea or air;

(p) “**placing on market**” means the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market of live bivalve molluscs for human consumption either raw or for the purpose of processing.

(q) “**production area**” means any sea, estuarine or lagoon area containing natural deposits of bivalve molluscs or sites used for cultivation of bivalve molluscs from which live bivalve molluscs are taken;

(r) “**purification center**” means an approved establishment with tanks fed by naturally clean sea water or sea water that has been cleaned by appropriate treatment, in which live bivalve molluscs are placed for the time necessary to remove microbiological contamination, so making them fit for human consumption;

(s) “**relaying area**” means any sea, estuarine brackish water or lagoon area approved by the competent authority and used exclusively for the natural purification of live bivalve molluscs;

(t) “**relaying**” means an operation whereby live bivalve molluscs are transferred to approved sea or lagoon areas or approved estuarine, brackish water areas under the supervision of the competent authority for the time necessary to remove contamination, which does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening;

(u) “**wrapping**” means an operation whereby live are placed in packing material adequate for the purpose;

3. **Basis of Compliance** – It shall be the primary responsibility of the industry to ensure that the fresh and processed fishery product bivalve mollusc intended for export are handled, processed at all stages of production, storage and transport under proper hygienic conditions so as to meet the health requirements laid down under this rules and that the product conforms to the specifications prescribed by the Central Government under section 6 of the Act and the same shall be further ensured by the recognized competent authority that the producers and

manufacturers comply with the requirements, by regular monitoring of the establishments as per the control measures by the Council from time to time.

4. **Approval-** Live bivalve molluscs shall be exported subject to the approval by the competent authority or all or any of the following conditions, namely:-

(a) Originate from production areas which comply with the requirements laid down in chapter I.

(b) Have been harvested and transported from the production area to a dispatch centre, purification centre, relaying area or processing plant under the requirements laid down in Chapter II.

(c) Have been relayed in suitable areas as approved for the purpose of standards and complying with the conditions laid down in Chapter III.

(d) Have been handled hygienically, and where appropriate, have been purified in establishments approved for that purpose and complying with the requirements of chapter IV.

(e) Comply with the criteria set out in Chapter V.

(f) Have been subjected to health controls in accordance with Chapter VI.

(g) Have been appropriately wrapped in accordance with Chapter VII.

(h) Have been stored and transported under satisfactory conditions of hygiene in accordance with Chapters VIII and IX.

(i) Bear a health mark as provided for in Chapter X

5. **Handing and processing** - It shall be ensured that persons handling live bivalve molluscs during their production and placing on the market shall adopt all measures necessary to comply with the requirements of this standard. The persons responsible for dispatch and purification centre shall in particular ensure that representative numbers of samples for laboratory examination are regularly taken and analysed in order to establish an historical record on the basis of the areas where batches come from and of the health quality of the live bivalve molluscs both before and after handling at a dispatch centre or purification center. A register shall be kept for the permanent record of the results of the various checks and kept for presentation to the competent authority.

6. **Functions of competent authority** -

(1) The competent authority shall approve dispatch centres and purification centres once it is satisfied that they meet the requirements of this standard. The competent authority shall take the necessary measures if the requirements cease to be met.

(2) The Competent Authority shall draw up a list of approved dispatch centres and purification centres, each of which shall have an official number.

(3) The list of approved despatch centres and purification centres, and any subsequent amendments thereto, shall be communicated by the competent authority to the Commission.

(4) The inspection and monitoring of these shall be carried out regularly under the responsibility of the competent authority, which shall have free access to all parts of the centre, in order to ensure compliance with the provision of this standard.

(5) If such inspection and monitoring reveal that the requirements of these standards are not being met, the competent authority shall take appropriate action.

(6) The competent authority shall establish a list of production and relaying areas, with an indication of their location and boundaries, from which live bivalve molluscs may be taken in accordance with the requirements of the standards and, in particular, with Chapter I of the Annexure of these rules.

(7) This list shall be communicated to those affected by the standards, such as

gatherers and operators of purification centres and despatch centres

(8) The monitoring of the production and relaying areas shall be carried out under the responsibility of the competent authority in accordance with the requirements of the standards.

(9) If such monitoring reveals that the requirements of the standards are no longer being met, the competent authority shall close the production or relaying area concerned until the situation has been restored to normal.

(10) The competent authority may prohibit any production and harvesting of bivalve molluscs in area considered unsuitable for these activities for health reasons.

(11) Having satisfied that the establishment or factory vessel meet the requirements with regard to the nature of the activities they carry out, the competent authority shall accord approval to such establishments or factory vessel. If the establishment or factory vessel decides to carry out activities other than those for which it has received approval, specific approval from competent authority shall be obtained for that purpose.

(12) The competent authority may seek the advice of the experts from Marine Products Export Development Authority (MPEDA) and Central Institute of Fishery Technology (CIFT) in the manner of approval of establishment.

(13) The competent authority shall take necessary measures including withdrawal of approval, if the requirements cease to be met.

(14) The inspection and monitoring of establishments or factory vessels shall be carried out regularly under the responsibility of the recognized competent authority which shall at all times have a free access to all parts of the establishments or factory vessels and records pertaining application of these rules to ensure compliance with the requirements under the rules.

(15) If such inspections and monitoring reveal that the requirements of these rules are not being met, the competent authority shall take appropriate action.

7. Functions of the Industry –

(1) The industry shall ensure that persons responsible for the establishment take all necessary measures so that at all stages of production of bivalve molluscs the specifications are complied with and to that end the said persons shall carry out their own checks based on the following principles namely :-

(a) Identification of critical points in their establishment on the basis of the manufacturing process used;

(b) Establishment and implementation of methods for monitoring and checking such critical points.

(c) Taking samples for analysis in an approved laboratory by the recognized competent authority for the purpose of checking the cleaning and disinfection methods and for the purpose of checking compliance with the standards established in this rules;

(d) Keeping a written record or record registered in indelible manner of the preceding points with a view to submitting them to the competent authority. The results of the different checks and tests shall in particular be kept for a period of at least two years.

(e) The establishment shall have competent and qualified technologists duly approved by the competent authority to conduct own checks and tests;

(f) The technologists shall possess one of the qualifications and experience or training, as the case may be:-

(1) Graduation/Post Graduation in Fishery Science, Fishery Management, Industrial Fishery or Fish Processing, or graduation/Post Graduation in Marine Biology, Fishery Biology, Microbiology, Chemistry, Biochemistry, Bioscience or Food Processing Technology; Degree in Pharmacy and

Agricultural Science (B.Sc. Agriculture /M.Sc. Agriculture) and one year experience in Fish Processing and Quality Control or Training for minimum six months duration in a Government recognized institute in Fish Processing and Quality Control

(2) If the results of own checks or any information at the disposal of the technologists referred to above reveal the risk of health or suggest that one might exist, appropriate measures shall be taken under the official supervision of the recognised competent authority.

8. Certification – (1) On request from the processors or exporter the competent authority shall issue Health or Veterinary Certificate in the prescribed proforma after satisfying that the bivalve molluscs are processed in approved establishment or factory vessels having valid approval number and after satisfying that the consignments comply with the requirements of these rules.

(2) The competent authority may also issue such other certificates on request after satisfying that the requirements of the relevant standards are met.

9. Inspection Fee – (1) A fee of Rs. 2000/- shall be paid by the processor along with the application for approval of the establishment or factory vessel as per these rules.

(2) A monitoring fee @ 0.2 percent of FOB value shall be paid by the processor or the exporters to the concerned Export inspection Agency.

10. Appeal – (1) Any person aggrieved by a –

- i) Decision of the competent authority not to accord approval under sub-rule (11) of rule 6; or
- ii) Decision of the competent authority to withdraw the approval under sub-rule (13) of rule 6; or
- iii) Refusal of the competent authority to issue Health or Veterinary Certificate under sub-rule (1) of rule 8; may prefer an appeal within ten days of receipt of such communication to an Appellate Authority appointed by the Central Government.

(2) At least two-thirds of the total membership of the Appellate Authority shall consist of non-officials.

(3) The quorum of Panel shall be three.

(4) The appeal shall be disposed of within fifteen days of receipt.

CHAPTER – I

REQUIREMENTS FOR PRODUCTION AREAS

1. The location and the boundaries of production areas shall be fixed by the competent authority in such a way as to identify the areas from which live bivalve molluscs:-

- a) Can be collected for human consumption. Live bivalve molluscs taken from these

areas shall meet the requirements set out in Chapter V of the rules;

b) Can be collected but only placed on the market for human consumption after treatment in a purification centre. Live bivalve molluscs from these areas shall not exceed the limits of a five-tube, three-dilution MPN-test of 6000 faecal coliforms per 100g of flesh or 4600 E.Coli per 100g of flesh in 90% of samples. After purification, all the requirements set out in Chapter V of this rule shall be met;

c) Can be collected but placed on the market only after relaying over a long period (at least two months), whether or not combined with purification, or after intensive purification for a period to be fixed, so as to meet the requirements under (a).

2. Any change in the demarcation of production areas and the temporary or definitive closure thereof shall be immediately announced by the competent authority to those affected by this standard and in particular, to producers and operators of purification and despatch centres.

CHAPTER – II

REQUIREMENTS FOR HARVESTING AND TRANSPORTATION OF BATCHES TO A DISPATCH OR PURIFICATION CENTRE, RELAYING AREA OR PROCESSING PLANT.

1. Harvesting techniques shall not cause excessive damage to the shells or tissues of live bivalve molluscs.

2. Live bivalve molluscs shall be adequately protected from crushing, abrasion or vibration after harvesting and shall not be exposed to extremes of hot or cold temperature.

3. Techniques for harvesting, transporting, landing and handling live bivalve molluscs shall not result in additional contamination of the product, nor in a significant reduction in the quality of the product, nor in changes significantly affecting their ability to be treated by purification, processing or relaying.

4. Live bivalve molluscs shall not be reimmersed in water which could cause additional contamination between harvesting and landing.

5. The means of transport used for transporting live bivalve molluscs shall be used under condition which protect the latter from additional contamination and crushing of shells. They shall permit adequate drainage and cleaning. In the event of bulk transport over long distances of live bivalve molluscs to a despatch centre, purification centre, relaying area or processing plant, the means of transport shall be equipped in such a way as to ensure the best survival conditions possible, and in particular shall comply with the requirements laid down in Chapter IX.

6. (1) A traceability document for the identification of batches of live bivalve molluscs during transport from the production area to a despatch centre, purification centre relaying area or processing plant must be issued by the competent authority upon request by the gatherer. The traceability document shall contain the following information, namely:-

(a) The gatherer's identity and address,

- (b) The date of harvesting,
- (c) The location of the production area described in as precise detail as is practicable or by a code number,
- (d) The shellfish species and quantity indicated in as precise detail as is practicable,
- (e) The approval number and place of destination for wrapping, relaying, purification or processing,
- (f) The traceability document shall be dated and signed by the gatherer,

(2) The traceability documents shall be numbered regularly and in sequence.

(3) The competent authority shall keep a register indicating numbers of traceability documents together with the names of the persons collecting live bivalve molluscs and to whom the documents have been issued. The traceability document for each batch of live bivalve molluscs shall be date-stamped upon delivery of a batch to a despatch centre, purification centre, relaying area or processing plant and shall be kept by the operators of such centres, areas or plants and the gatherer, if any, for at least twelve months.

CHAPTER – III

REQUIREMENTS FOR RELAYING LIVE BIVALVE MOLLUSCS

- 1 Live bivalve molluscs shall be gathered and transported in accordance with the requirements of Chapter II of these rules;
- 2 Techniques for handling live bivalve molluscs intended for relaying shall permit the resumption of filter feeding activity after immersion in natural waters;
- 3 Live bivalve molluscs shall not be re-laid at a density which does not permit purification;
- 4 Live bivalve molluscs shall be immersed in seawater at the relaying area for an appropriate period which shall exceed the time taken for levels of faecal bacteria to become reduced to the levels permitted by this rule taking into account of the fact that the Standards of Chapter V shall be met;
- 5 The minimum water temperature for effective relaying shall, where necessary, be determined and announced by the competent authority for each species of live bivalve molluscs and approved relaying area;
- 6 Areas for relaying live bivalve molluscs shall be approved by the competent authority. The boundaries of the sites must be clearly identified by buoys or other fixed means; there shall be a minimum distance of three hundred between relaying areas, and also between relaying areas and production areas;
- 7 Sites within a relaying area shall be well separated to prevent mixing of batches; the 'all in, all out' system shall be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed;

- 8 Permanent record of the source of live bivalve molluscs, relaying periods, relaying areas and subsequent destination of the batch after relaying shall be kept by the operators of relaying areas for inspection by the competent authority;
- 9 After harvesting from the relaying area, batches shall, during transport from the relaying area to the approved despatch centre, purification centre or processing plant, be accompanied by a traceability document, setting out, in addition to the information specified in point 6 of Chapter II, inter alia the location and approval number of the relaying area and the duration of relaying, together with any other information needed to identify and trace the product.

CHAPTER – IV

REQUIREMENTS FOR THE APPROVAL OF DESPATCH OR PURIFICATION CENTRES

- I. **General conditions relating to premises and equipment-** The despatch or purification centres shall not be located in areas which are close to objectionable odours, smoke, dust and other contaminants. The location shall not be subject to flooding by ordinary high tides or run off from surrounding areas.

The premises of the despatch or purification centers shall have-

- a) Facilities of sound construction, designed and maintained adequately for the purpose of preventing contamination of live bivalve molluscs by any type of waste, dirty water, fumes, dirt or by the presence of rodents or other animals;
- b) Flooring, which is easy to keep clean and is laid in such a way as to facilitate drainage;
- c) Adequate working space to allow for satisfactory performance of all operations;
- d) Durable walls, which are easy to clean;
- e) Adequate natural or artificial lighting;
- f) An appropriate number of changing rooms, wash basins and lavatories for the workers;
- g) Adequate equipment for washing tools, containers and equipment;
- h) Facilities for the supply and, where appropriate, storage of exclusively potable water within the meaning of EC Directive 778/80/EEC of 15 July 1980 relating to the quality of water intended for human consumption or facilities for the supply of clean sea water;
- i) Facilities for supplying non-potable water may be authorized. The water concerned

shall not come into direct contact with live bivalve molluscs or be used for cleaning or disinfecting containers, plant or equipment which come into contact with live bivalve molluscs. Pipes and outlets carrying non-potable water shall be clearly distinguished from those carrying potable water;

j) Equipment and instruments made of corrosion-resistant material, which come into contact with the live bivalve molluscs;

II General Hygiene Requirements-A high degree of cleanliness and hygiene shall be required of staff, premises, equipments and working conditions namely:-

1. Staff, who treat or handled live bivalve molluscs, shall in particular wear clean working clothes and, where appropriate, gloves, which are suitable for work in which the person, is engaged;

2. Staff are obliged to refrain from personal behavior, such as spitting, which could result in contamination of live bivalve molluscs; any person suffering from an illness, which can be transmitted by live bivalve molluscs, shall be temporarily prohibited, until recovery, from working with or handling these products;

3. Any rodents, insects or other vermin found shall be destroyed and further infestation prevented. Domestic animals shall not be permitted to enter the facilities;

4. Premises, equipment and instruments used for handling live bivalve molluscs shall be kept clean and in good state of repair; equipment and instruments shall be thoroughly cleaned at the end of the day's work and at such times as may be appropriate;

5. Premises, instruments and equipment shall not be used for purpose other than the handling of live bivalve molluscs without authorization by the competent authority.

6. Waste products shall be stored hygienically in a separate area and, where appropriate, in covered containers suitable for the purpose intended. Waste material shall be removed from the vicinity of the establishment at appropriate intervals;

7. The finished product shall be stored under cover and shall be kept away from the areas, where animals other than live bivalve molluscs, such as crustaceans, are handled.

III Special requirements for purification centers-

(a) The purification centers shall have the following special requirements namely:-

1. The floors and walls of the purification tanks and any water storage containers shall have a smooth, hard and impermeable surface and be easy to clean scrubbing or use of pressurized water. The base of the purification tanks shall be sufficiently sloped and equipped with drainage sufficient for the volume of work;

2. Live bivalve molluscs shall be washed free of mud with pressurized clean sea water or potable water before purification. The initial washing shall also be carried out in the purification tanks before purification commences, the drainage pipes being kept open during

the entire initial washing and sufficient time being allowed thereafter for the system to be flushed clean before the purification process begins;

3. The purification tanks shall be supplied with a sufficient flow of sea water per hour and per tonne of live bivalve molluscs treated;

4. Clean sea water or sea water cleaned by treatment shall be used for purifying live bivalve molluscs; the distance between the sea water intake point and the waste water outlets shall be sufficient to avoid contamination; if treatment of the sea water is necessary, the process shall be authorized once its effectiveness has been verified by the competent authority; potable water used to prepare sea water from its major constituent chemicals must comply with the requirements laid down in EC Directive 778/80/EEC;

5. Operation of the purification system shall allow live bivalve molluscs to rapidly resume filter feeding activity, remove sewage contamination, not to become re-contaminated and able to transport before being placed on the market;

6. The quantity of live bivalve molluscs to be purified shall not exceed the capacity of the purification centres; the live bivalve molluscs shall be continuously purified for a this rule to be met. This period starts from the moment at which the live bivalve molluscs in the purification tanks are adequately covered by the water until the moment, when they are removed. The purification centre shall take account of the data relating to the raw materials (the type of bivalve molluscs, its area of origin, microbe content, etc.), in case it is necessary to extend the purification period, so as to ensure that the live bivalve molluscs meet the bacteriological requirements of Chapter V.

7. A purification tank contained several batches of molluscs, shall be of the same species and come from the same production area or different areas conforming to the same health conditions. The length of the treatment shall be based on the time required by the batch needing the longest period of purification;

8. Containers used to hold live bivalve molluscs in purification systems shall have a construction which allows sea water to flow through; the depth of layers of live bivalve molluscs should not impede the opening of shells during purification;

9. No crustaceans, fish or other marine species shall be kept in a purification tank in which live bivalve molluscs are undergoing purification;

10. After completion of purification, the shell of live bivalve molluscs shall be washed thoroughly by with potable water or clean sea water; this shall take place in the purification tank if necessary; the washing water shall not be re-circulated;

11. Purification centres shall have their own laboratories or secure the services of a laboratory equipped with the necessary facilities for checking the efficiency of purification by use of microbiological specifications. Laboratory facilities outside the centres shall be recognized by the competent authority;

(b) Purification centres shall regularly keep a record of the following data, namely:-

- results of microbiological tests on water entering the purification tanks;
- § results of microbiological tests on unpurified live bivalve molluscs;

- § results of microbiological tests on purified live bivalve molluscs;
- § dates and quantities of live bivalve molluscs delivered to the purification centre and corresponding traceability document numbers;
- § the times of filling and emptying of purification systems (purification times);
- § despatch details of consignments after purification.

The above records shall be complete and accurate and recorded in a permanent ledger book, which shall be available for inspection by the competent authority;

(c) 1. Purification centres shall accept only those batches of live molluscs, which are accompanied by the traceability document referred to in Chapter II.

2. Purification centres despatching batches of live bivalve molluscs to dispatch centres shall provide a traceability document, as per the specimen drawn up by the competent authority, setting out, in addition to the information specified in point 6 of Chapter II, inter alia the approval number and address of the purification plant and the duration of purification, the dates of entering and leaving the purification centre, together with any other information needed to identify and trace the product.

3. Every package containing purified live bivalve molluscs shall be provided with a label certifying that all molluscs have been purified.

IV Special requirements for despatch centers -

(a) The despatch centers shall have the following special requirements, namely:-

1. Conditioning shall not cause any contamination of the product; conditioning facilities shall be used in accordance with procedure recognized by the competent authorities, with special regard to the bacteriological and chemical quality of the sea water used in those facilities;

2. Equipment and containers in the conditioning facilities shall not constitute a source of contamination;

3. Procedures for calibration of live bivalve molluscs shall not result in additional contamination of the product or in any changes affecting the ability of the product to be transported and stored after wrapping;

4. Any washing or cleaning of live bivalve molluscs shall be carried out using pressurized clean sea water or potable water; cleaning water may not be recycled.

(b) 1. Despatch centres shall accept only those batches of live bivalve molluscs, which are accompanied by the traceability document referred to in section 6 of Chapter II and coming from an approved production area, relaying area or purification centre.

2. Despatch centres shall have their own laboratories or secure the services of a

laboratory equipped with necessary facilities for checking, inter alia, whether the molluscs comply with the micro-biological standards of Chapter V. Laboratory facilities outside the centres shall be recognized by the competent authority. These requirements do not apply to despatch centres obtaining their molluscs exclusively and directly from a purification centre, where they have been examined after purification.

(c) Despatch centres shall keep the following at the disposal of the competent authority

1. The results of microbiological tests on live bivalve molluscs from an approved production area or relaying area or from a purification plant;
2. The dates and quantities of live bivalve molluscs delivered to the despatch centre, together with the corresponding traceability documents, despatch details including the names and addresses of consignees, the dates and quantities of live bivalve molluscs despatched, together with the corresponding entry traceability document number(s).
3. The data shall be classified chronologically and preserved for a period of twelve months.

CHAPTER – V

REQUIREMENTS OF LIVE BIVALVE MOLLUSCS

Live bivalve molluscs intended for immediate human consumption shall comply with the following requirements namely:-

1. The possession of visual characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion, and normal amounts of intravalvular liquid.
2. They shall contain less than 300 faecal coliforms or less than 230 E.Coli per 100 g of mollusc flesh and intravalvular liquid based on a five-tube, three-dilution Most Probable Numbwe-test or any other bacteriological procedure shown to be equivalent accuracy.
3. They shall not contain salmonella in 25 g of mollusc flesh.
4. They shall not contain toxic or objectionable compounds occurring naturally or added to the environment. The competent authority shall determine the testing methods for checking the chemical criteria and the limit values applicable.
5. The upper limits as regards the radionuclide contents shall not exceed the specified limits for foodstuffs.
6. The total Paralytic Shellfish Poison (PSP) content in the edible parts of molluscs (the whole body or any part edible separately) shall not exceed 80 micrograms per 100 g of molluscs flesh in accordance with the biological testing method.

7. The customary biological testing methods shall not give a positive result to the presence of Diarrhetic Shellfish Poison (DSP) in the edible parts of molluscs (the whole body or any part edible separately).

8. The total Amnesic Shellfish Poison (ASP) content in the edible parts of molluscs (the entire body or any part edible separately) shall not exceed 20 micrograms of domoic acid per gram using the High Performance Liquid Chromatography method.

9. In the absence of routine virus testing procedures and the establishment of virological Standards, health checks shall be based on faecal bacteria counts.

Note:

(a) Examination for checking compliance with the requirements of this Chapter shall be carried out in accordance with proven methods, which are scientifically recognized.

(b) For the uniform application of this Standard sampling plans as well as the methods and analytical tolerance to be applied in order to check compliance with the requirements of this chapter shall be established by the competent authority.

(c) The effectiveness of the faecal indicator bacteria and their numerical limits as well as the other parameters laid down in this Chapter shall be kept under constant review and, where scientific evidence proves the need to do so, that shall be revised.

(d) When there is scientific evidence indicating the need to introduce other health checks or to amend the parameters in this Chapter for the purpose of protecting public health, such measures shall be adopted by the competent authority.

CHAPTER – VI

PUBLIC HEALTH CONTROL AND MONITORING OF PRODUCTION

The competent authority shall establish a public health control and monitoring of production which shall include:-

- a) Periodic monitoring of live bivalve molluscs relaying and production areas in order to
 - i. Avoid any malpractice with regard to the origin and destination of the live bivalve molluscs;
 - ii. Check the microbiological quality of the live bivalve molluscs in relation to the production and relaying areas;
 - iii. Check the possible presence of toxin producing plankton in production and relaying water and biotoxins in live bivalve molluscs;
 - iv. Check the possible presence of chemical contaminants.

b) For the purpose of clauses (iii) and (iv), sampling plans shall be established by the competent authority.

c) The competent authority shall provide for the following sampling methods, namely:-

1. a) where variations in faecal contamination, at each production and relaying areas;

b) where variations in production at relaying areas, in the presence of plankton containing marine biotoxins. The sampling shall be carried out as follows:-

i) **Monitoring** : periodic sampling organized to detect changes in the composition of the plankton containing toxins and the geographical distribution thereof. Information leading to a suspicion of accumulation of toxins in mollusc flesh must be followed by intensive sampling;

ii) **Intensive sampling** : monitoring plankton in the growing and fishing water by increasing the number of sampling point and the number of samples, and toxicity tests using the molluscs from the affected area which are most susceptible to contamination. Placing on the market of molluscs from that area may not be reauthorized until new sampling has provided satisfactory toxicity test results;

2. If the result of a sampling plan shows that export of live bivalve molluscs shall constitute a hazard to human health, the competent authority shall close the production area, as regards molluscs concerned, until the situation has been restored.

3. Laboratory tests in order to check compliance with the requirements for the end product as laid down in Chapter V. A control system must be established to verify that the level of marine biotoxins does not exceed safety limits.

4. An inspection of establishment at regular intervals. These inspections shall include in particular, checks, namely:-

a) To verify whether the approval conditions are still being complied with;

b) On the cleanliness of the premises, facilities, equipment and on staff hygiene;

c) To verify whether the live bivalve molluscs are handled and treated correctly;

d) On the correct application and functioning of purification or conditioning systems;

e) On the correct use of health marks.

These checks shall include the taking of samples for laboratory tests; the result of these tests are notified to the persons responsible for the establishments.

5. Checks on the storage and transport conditions for consignments of live bivalve

molluscs.

CHAPTER – VII

WRAPPING

1. Live bivalve molluscs must be wrapped under satisfactory conditions of hygiene. The wrapping material or container shall not impair the organoleptic characteristics of the live bivalve molluscs, not be capable of transmitting substances harmful to human health to the live bivalve molluscs, be strong enough to give adequate protection to the live bivalve molluscs.
2. Oysters shall be wrapped with the concave shell downwards.
3. All wrappings of live bivalve molluscs for export shall be sealed and remained sealed from the despatch centre.

CHAPTER – VIII

PRESERVATION AND STORAGE

1. In any storing rooms, live bivalve molluscs shall be kept at a temperature which does not adversely affect their quality and viability; the wrapping shall not come into contact with the floor of the store room, but shall be placed on a clean, raised surface.
2. Reimmersion in water or spraying water on live bivalve molluscs shall not take place after they have been wrapped and have left the despatch centre for export.

CHAPTER – IX

TRANSPORT FROM THE DESPATCH CENTRE

1. Consignment of live bivalve molluscs intended for human consumption shall be transported, wrapped as sealed parcels from the despatch centre for export.
2. The means of transport used for consignments of live bivalve molluscs shall have the following characteristics :
 - a) Their interior walls and any other parts which might come into contact with the live bivalve molluscs shall be made of corrosion – resistant material; the walls shall be smooth

and easy to clean;

b) They shall be suitably equipped to provide efficient protection of the live bivalve molluscs against extremes of hot and cold, contamination with dirt or dust, and damage to the shells from vibration and abrasion;

c) The live bivalve molluscs shall not be transported with other products which might contaminate them.

d) Live bivalve molluscs shall be transported and distributed using closed vehicles or containers which maintain the product at a temperature which does not adversely affect their quality and viability.

e) The parcels containing live bivalve molluscs shall not be transported in direct contact with the floor of the vehicle or container but shall be supported on raised surface or by some other means which prevent contact with the floor. Where ice is used in transporting consignments of live bivalve molluscs, it shall have been made from potable water or clean sea water.

CHAPTER – X

MARKING OF CONSIGNMENTS

1. All parcels in a consignment of live bivalve molluscs for export shall be provided with a health mark so that the original despatch centre may be identified at all times during transport. The mark shall contain the following information :

a) The country of despatch,

b) The species of bivalve molluscs (common name and scientific name),

c) The identification of the despatch centre by the approval number issued by the competent authority,

d) The date of wrapping, comprising at least the day and the month,

e) By way of expressing durability, it shall be mentioned that these animals shall be alive when exported.

2. The health mark shall be printed on the wrapping material or be put on a separate label, which is then affixed to the wrapping material or put inside the wrapping. It shall also be a twist-tie or staple design; self-adhesive health marks shall not be used, unless they are not detachable. All types of health mark must be for single use only and shall not be transferred.

3. The health mark shall be durable and waterproof, and the information presented shall be legible, indelible and in easily decipherable characters.

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