

COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 31 January 1990

Proposal for a
COUNCIL REGULATION (EEC)

laying down the health conditions for the production and
the placing on the market of live bivalve molluscs

(presented by the Commission)

EXPLANATORY MEMORANDUM

With the adoption of the Single European Act, the Community has embarked upon a programme to eliminate all controls at frontiers. The programme to achieve this undertaking is set out in the Commissions White Paper of June 1985, and includes the elimination of barriers to trade related to health problems in the fisheries sector.

This proposal aims in particular to lay down the health conditions for the production and the placing on the market of live bivalve molluscs (mussels, oysters, carpet shells etc.) which, because of their particular way of production and consumption, need special attention.

It defines therefore the obligations to be respected by both professionals and the competent authorities, and lays down the measures to be taken to ensure that the final product is safe for human consumption. This implies a surveillance of the harvesting areas, the obligation to submit the molluscs to a purification process, relaying or processing in certain circumstances, a controle of the final product etc.

Provision is made for Community checks in the Member States so as to ensure the uniform application of the said requirements. This must also allow to reinforce the confidence of the Member States in each others inspection systems which is necessary to ensure a proper functioning of an internal market without frontiers.

The proposal covers the placing on the market in the whole of the Community and lays down a procedure to ensure that products originating from third countries are produced and placed on the market under conditions which are equivalent to those applied in the Community.

For certain applicatory decisions to be taken, the Commission opted for the Regulatory Committee procedure. This choice, which is justified in this case by a desire not to disrupt the management process in the health sector, is without prejudice to the Commission's preference for the Advisory Committee procedure.

PROPOSAL FOR A
COUNCIL REGULATION

laying down the health conditions for the production
and the placing on the market of live bivalve molluscs

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and
in particular Article 43 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas, in order to ensure the smooth operation of the Common market and more
in particular the common organization of the market in products of fisheries,
it is essential that the placing on the market of live bivalve molluscs should
no longer be hindered by disparities existing in the Member States in respect
of health requirements; whereas this will enable the production and the
placing on the market to be better harmonized and bring about competition on
equal terms while assuring consumers of a quality product;

Whereas Council Directive 79/923/EEC of 30 October 1979 on the quality of
shellfish waters(1) lays down that it is necessary to establish the health
requirements to be observed for shellfish products;

Whereas requirements should be laid down for all stages during harvesting,
handling, storage, transport and distribution of live bivalve molluscs in
order to safeguard the public health of consumers; whereas these requirements
shall apply equally to echinoderms and tunicates;

(1) OJ No L 281, 10.11.1979, p. 47

Whereas it is important, would a health problem occur after the placing on the market of live bivalve molluscs to be able to trace back the establishment of dispatch and the harvesting area of origin; whereas it is therefore necessary to introduce a registration and labeling system which will enable to follow the flow of a batch after harvesting;

Whereas it is important that the public health standards for the final product must be specified; whereas, however, scientific and technological knowledge is not always advanced enough to lay down definitive solutions for certain health problems and that it is therefore necessary, in order to guarantee optimal protection of public health, to fix a Community system to ensure rapid adoption and where necessary improvement of the health standards to safeguard from virus contamination or other hazards to human health;

Whereas live bivalve molluscs obtained from harvesting areas which do not permit direct, safe consumption may be rendered safe by submitting them to a purification process or by relaying in clean water over a longer period; whereas it is therefore necessary to define harvesting areas from which molluscs can be gathered for direct human consumption, or from which they have to be purified or relayed;

Whereas it is the responsibility of the producers to ensure that the bivalve molluscs are produced and placed on the market in compliance with the health requirements prescribed; whereas the competent authorities must by carrying out checks and inspections ensure that producers comply with those health requirements; whereas the competent authorities must in particular submit harvesting areas to a regular control to ensure that molluscs from these harvesting areas do not contain microorganisms and toxic substances in quantities which are considered to be dangerous to human health;

Whereas control measures organised on a Community level must be introduced to guarantee the uniform application in all Member States of the standards laid down in this Regulation;

Whereas in the context of trade between the Member States, the rules laid down in Council Directive, concerning veterinary checks in intra-Community trade, with a view to the realisation of the internal market (1) should be applied;

Whereas live bivalve molluscs produced in a third country and intended to be placed on the market in the Community must not qualify for more favourable conditions than those applied in the Community; whereas provision must be made for a Community procedure for inspecting the conditions in third countries of the production and the placing on the market in order to allow the Community to apply a common import regime based on terms of equivalence;

Whereas it is possible that, due to some particular situations, some establishments in function before 1 January 1992 will not be able to fulfil all the rules laid down in this Regulation; whereas it is opportune to settle the matter of granting limited and temporary derogations for those establishments in the general framework laid down in Council Decision .../.../EEC [on the granting of temporary limited derogations from specific Community health rules on the production and marketing of products of animal origin] (2);

Whereas it is appropriate to emphasize that any exceptions from the health rules laid down in this Regulation are without prejudice to the submission of all operations of production and placing on the market of live bivalve molluscs to the general health rules laid down by Council Regulation (EEC) No .../... [laying down general health rules applicable to the production and placing on the market of products of animal origin and specific health rules applicable to certain products of animal origin] (3);

Whereas the Commission should be entrusted with the task of adopting certain measures for implementing this Regulation; whereas to that end, procedures should be laid down introducing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

HAS ADOPTED THIS REGULATION :

- (1) COM(88)383 Final of July 1988
(2) OJ No L
(3) OJ No L

CHAPTER I : GENERAL PROVISIONS

Article 1

This Regulation lays down the health conditions for the production and the placing on the market of live bivalve molluscs which are destined for immediate human consumption or for further processing before consumption.

This Regulation applies mutatis mutandis also to echinoderms and tunicates.

Article 2

For the purpose of this Regulation, the following definitions shall apply :

- 1) Bivalve molluscs : Lamellibranch molluscs which are filter-feeders and may be eaten raw or partially cooked, and are normally consumed whole including the viscera or after removal of selected parts of the viscera.
- 2) Marine biotoxins : poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxin.
- 3) Clean seawater : seawater or estuary water which is free from microbiological contamination and toxic and objectionable substances occurring naturally or after discharge in the environment such as those listed in the Annex to Directive 79/923/EEC, in such quantities as may adversely affect the health quality of bivalve molluscs or to impair their taste and which is to be used under the conditions laid down in this Regulation.
- 4) Competent authority : the department designated by the Member State concerned to monitor the implementation of this Regulation.
- 5) Conditioning : the temporary wet storage of live bivalve molluscs, whose quality does not indicate need for relaying or treatment in a purification plant, in tanks or any other installation containing clean seawater or in natural sites to remove sand, mud or slime and to improve product palatability.
- 6) Gatherer : any physical or legal person or legal entity who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and the placing on the market.

- 7) Harvesting area : sea, estuarine or lagoon areas with sites of relaid beds or natural deposits of bivalve molluscs, or those sites used for cultivation of bivalve molluscs from which live bivalve molluscs are taken for their placing on the market.
- 8) Establishment : any on shore or off-shore construction or area in which live bivalve molluscs are handled and stored after harvesting and before placing on the market.
- 9) Purification : the process of holding contaminated live bivalve molluscs in clean seawater for a time sufficient to permit removal of microbiological contamination through normal filter-feeding processes so making them suitable for human consumption.
- 10) Expedition center : an establishment for the reception, conditioning, washing, cleaning, calibration and wrapping of live bivalve molluscs which conform to the requirements of this Regulation.
- 11) Purification plant : an establishment where live bivalve molluscs are kept for purification under suitable conditions using clean seawater or seawater which is treated to remove contamination so causing the reduction of harmful microorganisms to an acceptable level.
- 12) Relaying : transfer of live bivalve molluscs to suitable natural sea or estuarine areas under the supervision of the competent authority in order for purification to occur. It does not include the specific operation of transferring bivalve molluscs to more suitable areas for further growth or fattening.
- 13) Means of transport : 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.
- 14) Wrapping : an operation whereby live bivalve molluscs are protected from shock and desiccation by placing them in packaging material adequate for that purpose.

- 15) Consignment : quantity of live bivalve molluscs handled in an expedition center or treated in a purification plant and subsequently bound for one or more customers.
- 16) Batch : quantity of live bivalve molluscs collected from a harvesting area and subsequently destined for delivery to an approved expedition center, purification plant, relaying area or processing establishment as appropriate.
- 17) Placing on the market : 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 after processing in the Community.
- 18) Importation : the introduction of live bivalve molluscs into the territory of the Community from third countries.
- 19) Faecal coliform : facultative, aerobic, gram-negative, non-sporeforming, 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-inhibiting properties, at $44^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$ within 24h at least.
- 20) E. coli : faecal coliforms which also form indole from tryptophan at $44^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$ within 24h.

CHAPTER II : PROVISIONS FOR COMMUNITY PRODUCTION

Article 3

1. The placing on the market of live bivalve molluscs for immediate human consumption shall be subject to the following conditions:
 - a) they must originate from harvesting areas which comply with the requirements laid down in Chapter I of the Annex;
 - b) they must have been collected and transported from the harvesting area to an expedition centre or purification plant under the conditions laid down in Chapter II of the Annex;

- c) where provided for in this Regulation, they must have been relayed in suitable sites approved for that purpose and complying with the conditions laid down in Chapter III of the Annex;
 - d) they must have been handled hygienically, and where appropriate, they must have been purified in establishments approved for that purpose and complying with the requirements of Chapter IV;
 - e) they must comply with the criteria set out in Chapter V of the Annex;
 - f) health controls must have been carried out in accordance with Chapter VI of the Annex;
 - g) they must have been appropriately wrapped in accordance with Chapter VII of the Annex;
 - h) they must have been stored and transported under satisfactory hygiene conditions in accordance with Chapters VIII and IX of the Annex;
 - i) they must bear a health mark as provided for in Chapter X of the Annex.
2. Live bivalve molluscs intended for further processing must comply with the relevant requirements of paragraph 1, and be processed in conformity with the requirements of Council Regulation (EEC) No laying down the health conditions for the production and the placing on the market of fishery products (1).

Article 4

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 Regulation.

Persons who operate establishments shall in particular ensure that :

- adequate numbers of samples for laboratory examination are taken and analysed in order to establish an historical record of the sanitary quality of the live bivalve molluscs both before and after handling at an expedition center or at a purification plant;
- a register is kept for the permanent record of the results of the various health checks and kept for presentation to the competent authority.

(1)

Article 5

1. a) The competent authorities shall draw up a list of their approved expedition centers and purification plants, each of which shall have an official number.

The competent authority shall approve such centers or plants only where they can be sure that they meet the requirements of this Regulation. Member States shall withdraw approval if the requirements cease to be met.

- b) The inspection and monitoring of these establishments shall be carried out regularly on the responsibility of the competent authority, which shall at all times have free access to all parts of the establishments, in order to ensure compliance with the requirements of this Regulation.

If such inspections reveal that not all the requirements of this Regulation are being met, the competent authority shall take the appropriate action.

2. a) The competent authorities shall establish a list of harvesting areas with indication of their location and boundaries from which live bivalve molluscs may be taken in conformity with this Regulation, and in particular, with Chapter I of the Annex.

This list must be communicated to those affected by this Regulation such as harvesters and operators of purification plants and expedition centers.

- b) The monitoring of the harvesting areas shall be carried out on the responsibility of the competent authority in accordance with the requirements of this Regulation.

If such monitoring reveals that the requirements of this Regulation are not being met, the competent authority shall close the harvesting area concerned until the situation has been restored.

3. The competent authorities concerned shall take all measures necessary to take account of the results referred to in Article 6(1).

Article 6

1. Experts from the Commission may make on-the-spot checks in so far as is necessary to ensure the uniform application of this Regulation. They may check whether establishments and harvesting sites are in effect complying with the requirements of this Regulation. A Member State in whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the Member States of the results of such checks.
2. The general provisions for implementing paragraph 1 shall be determined in accordance with the procedure laid down in Article 16. If necessary, and in accordance with the same procedure, a code shall be established containing the rules to be followed for the purpose of the checks provided for in paragraph 1.
3. The Commission, in accordance with the procedure laid down in Article 16, may draw up recommendations containing guidelines on good manufacturing practices applicable at the different stages of production and placing on the market.

Article 7

The rules laid down in Directive, [concerning veterinary controls in intra-Community trade, with a view to the realisation of the internal market], shall apply, in particular with respect to the organisation of the checks carried out by the Member State of destination, and the subsequent action and the safeguard measures to be applied.

However, the definitions to be applied are the ones laid down in this Regulation.

CHAPTER III : IMPORTS FROM THIRD COUNTRIES

Article 8

Provisions applied to imports of live bivalve molluscs from third countries shall be equivalent to those governing the placing on the market of Community products.

Article 9

In order to ensure the uniform application of the provision laid down in Article 8, the following procedure shall apply :

1. Inspections shall be carried out on the spot by experts of the Commission and the Member States to verify whether the conditions of production and placing on the market can be considered as being equivalent to those applied in the Community.

The experts from the Member States who are to be entrusted with these inspections shall be appointed by the Commission, acting on a proposal from the Member States.

These inspections shall be made on behalf of the Community, which shall bear the cost of any expenditure in this connection.

The frequency and the procedure for these inspections shall be determined in accordance with the procedure laid down in Article 16.

2. In deciding whether the conditions of production and placing on the market of live bivalve molluscs in a third country can be deemed equivalent to those of the Community, particular account shall be taken of :

- a) the legislation of the third country;
- b) the organisation of the competent authority of the third country and of its inspection services, the powers of such services and the supervision to which they are subject, as well as their facilities for monitoring the implementation of their legislation;
- c) the actual health conditions during the production and placing on the market of live bivalve molluscs and in particular the surveillance of harvesting areas in relation to microbiological and environmental contamination, and to the presence of marine biotoxins;

- d) the regularity and the rapidity of the information by the third country on the presence of plankton containing toxin in the harvesting areas;
 - e) the assurances a third country can give on the compliance of the molluscs with the standards laid down in Chapter V of the Annex.
3. The Commission, following the procedure laid down in Article 14 shall decide on :
- a) the third countries fulfilling the conditions of equivalence referred to in paragraph 2;
 - b) for each third country, the conditions for the importation of live bivalve molluscs. These conditions may include in particular :
 - i) the supplying of a health certificate which must accompany consignments when forwarded to the Community.
 - ii) the definition of the harvesting areas from which live bivalve molluscs may be collected and imported.
 - iii) the obligation of immediate information to the Community on every possible change of the approval of harvesting areas.
 - iv) possibly the mandatory purification after arrival at the territory of the Community.
 - c) a list of establishments from which the importation of live bivalve molluscs is authorized. For that purpose, one or more lists of such establishments shall be established. An establishment may not appear on a list unless it is officially approved by the competent authority of the third country exporting to the Community. Such approval shall be subject to observance of the following requirements :
 - compliance with requirements equivalent to those laid down in this Regulation,
 - supervision by an official inspection service of the third country.

4. The Decisions referred to in point 3 may be modified or supplemented in accordance with the procedure laid down in Article 15.

These Decisions and the amendments thereto shall be published in the Official Journal of the European Communities, series L.

Article 10

Should an inspection as referred to in Article 9(1) bring to light serious facts which may render the placing on the market of live bivalve molluscs unsafe for human consumption, the Commission shall immediately inform the Member States and forthwith adopt a decision to change the import conditions or to suspend the importation from a particular establishment, harvesting area or from a part or the whole of the third country concerned.

A final decision shall be taken in accordance with the procedure provided for in Article 15.

Article 11

1. The rules laid down in Council Regulation (EEC) No, laying down the principles relating to the organisation of health controls for products arising from third countries with a view to the completion of the internal market (1) will apply.

2. The importation of live bivalve molluscs shall be prohibited if the conditions laid down in this Regulation have not been observed, and in particular when it is ascertained that :

- the consignment does not comply with the conditions for importation laid down for the third country concerned;
- the consignment constitutes a hazard to human health.

(1)

Article 12

1. If a disease capable of being conveyed to humans by live bivalve molluscs and therefore liable to be a serious hazard to public health, breaks out or spreads in a third country or if other considerations of public health so warrant, the Commission acting in accordance with the procedure laid down in Article 15, or a Member State may prohibit or subject to specific conditions the importation of those live bivalve molluscs directly or indirectly from the whole or part of the territory of the third country.
2. Measures taken by the Member States under paragraph 1 and withdrawal of such measures, shall be notified immediately to the other Member States and the Commission, together with the reasons therefor.
3. The Commission shall as soon as possible appraise the situation and take the requisite decisions in accordance with the procedure laid down in Article 15.
4. The Commission shall monitor the situation and, in accordance with the procedure laid down in Article 15, shall amend or repeal the decisions referred to in paragraphs 1 and 3, having regard to such situation.

CHAPTER IV : FINAL PROVISIONS

Article 13

The Annex to this Regulation shall be amended in accordance with the procedure laid down in Article 14.

Article 14

1. Where the procedure laid down in this Article is to be applied, the matter shall be referred forthwith to the Standing Veterinary Committee set up by the Council Decision 68/361/EEC(1) (hereinafter called "the Committee") by its chairman on his initiative or at the request of a Member State.

(1)

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measure envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 15

1. Where the procedure laid down in this Article is to be applied, the chairman shall refer the matter without delay on his own initiative or at the request of a Member State to the Committee.
2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within two days. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of fifteen working days from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 16

Where the procedure laid down in this Article is to be applied, the following rules shall apply.

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time-limit which the Chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account.

Article 17

This Regulation shall enter into force on 1 January 1993.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Council

A N N E X

CHAPTER I

CONDITIONS FOR HARVESTING AREAS

1. The location and the boundaries of harvesting areas must 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 direct human consumption; live bivalve molluscs taken from these areas shall meet the requirements set out in Chapter V;
 - b) can be collected but only placed on the market after treatment in a purification system, after relaying or after processing by a heat treatment sufficient to kill microorganisms as described in Chapter III, Section III, 4 of the Annex to Regulation (EEC) No concerning the health conditions governing the production and the placing on the market of fishery products. Live bivalve molluscs from these areas must not exceed the limits of a 5-tube-3-dilution MPN-test of 6.000 faecal coliforms per 100 g of flesh or 4.600 E. Coli per 100 g of flesh in 95 % of samples. After purification, relaying or processing, the requirements set out in Chapter V shall be met.
 - c) can be collected but only placed on the market after relaying over a long period or after relaying combined with purification to meet the requirements under (a). Processing of these molluscs by a heat treatment sufficient to kill micro organisms as described in Chapter III, Section III, 4 of the Annex to Regulation (EEC) No concerning the health conditions governing the production and the placing on the market of fishery products may be carried out if the limits laid down under (b) are met.
2. Any change in the delimitation of harvesting areas and the temporary or definite closure thereof shall be immediately announced by the competent authorities to those affected by this Regulation and in particular to producers and operators of purification plants and expedition centers.

CHAPTER II

REQUIREMENTS FOR HARVESTING AND TRANSPORTATION
OF BATCHES TO AN EXPEDITION CENTER OR PURIFICATION PLANT

1. Harvesting techniques must not cause excessive damage to the shells or tissues of live bivalve molluscs.
2. Live bivalve molluscs must be adequately protected from excessive crushing, abrasion or vibration after harvesting and must not be exposed to extremes of hot or cold temperature.
3. Techniques for harvesting, transporting, landing and handling live bivalve molluscs must not result in additional contamination of the product, nor in a significant reduction of the keeping quality of the product, nor in any changes significantly affecting the ability to be treated by purification or processing or relaying.
4. Live bivalve molluscs must not be reimmersed in water which could have additional contamination between harvesting and landing onshore.
5. Means of transport used for transporting live bivalve molluscs must be used under conditions which protect against additional contamination and crushing of shells. They must permit adequate drainage and cleaning. In the event of bulk transport over long distances of live bivalve molluscs to an expedition center, purification plant or relaying site, the means of transport must be equiped in such a way as to ensure the best survival conditions possible, and in particular must they comply with the requirements laid down in Chapter IX, point 2.

6. A registration document for the identification of batches of live bivalve molluscs during transport from the harvesting area to an approved expedition centre, purification plant, relaying site or processing plant is issued by the competent authority upon request of the gatherer. For each batch, the gatherer must complete the relevant sections of the registration document legibly and indelibly and which must contain the following information :

- the gatherer's identity and signature,
- the date of harvesting,
- the location of the harvesting area in as precise detail as is practicable,
- the shellfish species and quantity in as precise detail as is practicable,
- the approval number and place of destination for wrapping, relaying or purification or processing.

The registration documents must be permanently and sequentially numbered. The competent authority shall keep a register indicating the number of the registration documents together with the names of the persons collecting live bivalve molluscs to whom they have been issued. The registration document for each batch of live bivalve molluscs must be date-stamped upon delivery of a batch to an expedition center, purification plant relaying site or processing plant and must be kept available by operators of these sites or establishments for at least 60 days.

However, if the gathering is carried out by the same person operating the expedition center, purification plant, relaying site or processing plant of destination, the registration document may be replaced by a permanent derogation granted by the competent authority.

7. In case any harvesting area is closed temporarily, the competent authority shall refrain from issuing registration documents for that area and immediately suspend the validity of all registration documents already issued.

CHAPTER III

CONDITIONS FOR RELAYING LIVE BIVALVE MOLLUSCS

The following conditions must be met :

1. live bivalve molluscs must be gathered and transported in accordance with the requirements of Chapter II;
2. techniques for handling live bivalve molluscs destined for relaying must permit the resumption of filter-feeding activity after immersion in natural waters;
3. live bivalve molluscs must not be relaid at a density which does not permit purification;
4. live bivalve molluscs must be immersed in seawater at the relaying site for an appropriate period which must exceed the time taken for levels of faecal bacteria to become reduced to the levels permitted in this Regulation, and taking into account that the standards of Chapter V have to be complied with;
5. the minimum water temperature for effective relaying must, where necessary, be determined and announced by the competent authority for each species of live bivalve mollusc and approved relay site;
6. sites for relaying live bivalve molluscs must be approved by the competent authority. The boundaries of the sites must be clearly identified;
7. sites within a relaying area must be well separated to prevent mixing of batches;
8. permanent records of the source of live bivalve molluscs, relaying period, relaying site and subsequent destination of the batch after relaying must be maintained by the operators of relaying sites for inspection by the competent authority;

9. after harvesting from the relaying site, the batches must during transport from the relaying site to the approved expedition center, purification plant or processing plant be accompanied by the registration document referred to in Chapter II, point 6, except in the case where the same staff is operating both the relaying site and the expedition center, purification plant or processing plant.

CHAPTER IV

CONDITIONS FOR THE APPROVAL OF ESTABLISHMENTS

I. GENERAL CONDITIONS RELATING TO PREMISES AND EQUIPMENT

Establishments must be located in areas which are free from objectionable odours, smoke, dust and other contaminants. The location must not be subject to flooding by ordinary high tides or run-off from surrounding areas.

Establishments must have at least :

1. in areas where live bivalve molluscs are handled or stored :
 - a) buildings or facilities of sound construction and designed and maintained adequately for the purpose of preventing contamination of live bivalve molluscs with 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 adequate 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.
2. Access to an appropriate number of changing rooms, wash basins and lavatories; there must be a sufficient number of hand wash basins close to the lavatories.
 3. Adequate equipment for washing tools, containers and equipment.
 4. Facilities for the supply and, where appropriate, adequate storage and distribution of exclusively potable water within the meaning of Council Directive 80/778/EEC of 15 July 1980 relating the quality of water intended for human consumption (1) or facilities for the supply of clean sea water.

Facilities supplying non-potable water may be authorized. The water concerned may not come into contact with live bivalve molluscs or be used for cleaning or disinfecting containers, plant or equipment which come into contact with the live bivalve molluscs. Pipes and outlets carrying non-potable water must be clearly distinguished from those carrying potable water.

5. Equipment and instruments or their surfaces which are intended to come into contact with live bivalve molluscs must be made of material which is easy to wash and clean repeatedly and resists corrosion.

(1) OJ No L 229, 30.08.1980, p 11.

II. GENERAL HYGIENE REQUIREMENTS

A high degree of cleanliness and hygiene shall be required of staff, premises, equipment and working conditions :

1. Staff who treat or handle live bivalve molluscs must in particular wear clean working clothes and, where appropriate, clean gloves which are suitable for the work in which the person is engaged.
2. It is forbidden for staff to apply types of personal behaviour, 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 must be temporarily prohibited, until recovery, from working with or handling products.
3. Any rodents, insects or other vermin found must be destroyed and further infestation prevented. Domestic animals must not enter the facilities.
4. Premises, equipment and instruments used for production of live bivalve molluscs shall be kept clean and in a good state of repair; equipment and instruments must be thoroughly cleaned at the end of the day's work or at such other times as may be appropriate.
5. Premises, instruments and equipment must not be used for purposes other than the production of live bivalve molluscs unless authorization by the competent authority.
6. Waste products must be stored hygienically in a separate area and, where appropriate, in covered receptacles suitable for the purpose intended. Waste material must be removed from the vicinity of the establishment at suitable periods.
7. The finished products must be stored under cover and must be kept away from the areas where animals other than live bivalve molluscs, such as crustaceans are handled.

III. REQUIREMENTS FOR PURIFICATION PLANTS

In addition to the requirements under I and II, the following conditions must be met:

1. The floors and walls of the purification system and any water storage containers must have a smooth, hard and impermeable surface and be easy to clean by scrubbing or use of pressurised water. The base of the purification system must be sufficiently sloped and be equipped with drains sufficient for the volume of work.
2. Live bivalve molluscs must be washed free of mud with pressurized clean sea water or potable water before purification. The initial washing may also be carried out in the purification system 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 system must be supplied with sufficient seawater or flow of sea water per hour and per tonne of live bivalve molluscs treated.
4. Clean sea water must be used for purifying live bivalve molluscs; the distance between the sea water intake point and the waste water outlets must be sufficient to avoid contamination; the procedure for sanitizing the sea water shall be authorized once its effectiveness has been verified by the competent authority; potable water used to prepare seawater from its major constituent chemicals shall conform to the meaning of Council Directive 80/778/EEC.
5. Operation of the purification system must be in accordance with instructions issued by the competent authority to ensure that live bivalve molluscs rapidly resume filter-feeding activity, remove sewage contamination, do not become recontaminated and are able to remain alive in a suitable condition after purification for wrapping, storage and transport before placing on the market.

6. The quantity of live bivalve molluscs shall not exceed the capacity of the purification system; the live bivalve molluscs must be continuously purified for a period sufficient to allow the microbiological standards laid down in Chapter V to be met. This period starts from the moment at which the live bivalve molluscs in the purification system are adequately covered by the water until the moment when water is drained away before removal from the said system. The establishment operator must take account of the data relating to the raw materials (the type of bivalve mollusc, 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 shall not contain more than one batch of molluscs during the period of purification.
8. Containers used to hold live bivalve molluscs in purification system must have a mesh-type construction which allows seawater to flow through; the depth of layers of live bivalve molluscs should not impair the opening of shells during purification; containers of live bivalve molluscs should be placed at densities recommended by the competent authorities.
9. No crustaceans, fish or other marine species must be kept in a purification system in which live bivalve molluscs are undergoing purification.
10. After completion of purification, the shells of live bivalve molluscs can be washed thoroughly by hosing with potable water or clean seawater, this may take place in the purification system if necessary, the washing water must not be recirculated.
11. The purification plants must have their own laboratory or secure the services, or access to data of, a laboratory equipped with the necessary facilities for checking the efficiency of purification by use of microbiological specifications. Laboratory facilities must be approved by the competent authority.

12. Purification plants must regularly keep record of the following data :

- Results of microbiological tests on purification system water entering the purification tanks.
- Results of microbiological tests on unpurified live bivalve molluscs.
- Results of microbiological tests on purified live bivalve molluscs.
- Date and quantity of live bivalve molluscs delivered to the purification plant and appropriate registration document number.
- The times of filling and emptying of purification systems (purification times).
- Dispatch details of consignments after purification.

These records must be complete and accurate, legible and recorded in a permanent ledger book which must be available for inspection by the competent authority.

13. Purification plants must only accept batches of live molluscs which are accompanied by the registration document referred to in Chapter II;

Purification establishments dispatching batches of live bivalve molluscs to expedition centers must provide for the registration document referred to in Chapter II, point 6.

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

IV. REQUIREMENTS FOR EXPEDITION CENTERS

1. In addition to meeting the requirements under I and II, the following conditions must be met :
 - a) conditioning must not cause any deleterious microbiological contamination of the product;
 - b) instructions for the use of conditioning facilities shall be issued by the competent authority and will have special regard to the bacteriological and chemical quality of the seawater used in the facilities;
 - c) equipment and containers in the conditioning facilities do not constitute a source of contamination;
 - d) procedures for calibration of live shellfish must 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.
 - e) any washing or cleaning of live bivalve molluscs must be carried out using pressurised clean seawater or potable water - cleaning water may not be recycled.
2. Expedition centers must only accept batches of live shellfish which are accompanied by the registration of documents referred to in Chapter II, point 6 and coming from an approved harvesting area, relaying site or purification plant.
3. The expedition centers must have their own laboratory or secure the services of a laboratory equipped with the necessary facilities for checking if the molluscs comply with the microbiological standards of Chapter V. Laboratory facilities must be approved by the competent authority.

However, this requirements is invalid if the expedition centers get their molluscs from a purification plant where they have been examined after purification.

CHAPTER V

REQUIREMENTS CONCERNING LIVE BIVALVE MOLLUSCS

Live bivalve molluscs destined for immediate human consumption shall comply with the following requirements :

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 5-tube, 3 dilution MPN-test or any other bacteriological procedure shown to be equivalent in degree of precision.
3. Absence of salmonella in 25 g mollusc flesh.
4. Live bivalve molluscs are not contaminated with toxic or objectionable compounds occurring naturally or added to the environment such as those listed in the Annex to Directive 79/923/EEC in such quantities that the calculated dietary intake exceeds the acceptable daily intake (ADI), or that the taste of the molluscs is impaired.
5. The upper limits as regards the radionuclide contents shall not exceed the limits for foodstuffs as laid down by the Community.
6. The total Paralytic Shellfish Poison (PSP) content shall not exceed 80 micrograms per 100 g of mollusc flesh.
7. The Diarrhetic Shellfish Poison (DSP) content of the flesh shall not exceed levels which may be considered dangerous to human health.
8. In the absence of routine virus testing procedures and establishment of virological standards sanitary evaluation must use counts of faecal bacteria.

Examinations for checking the compliance with the requirements of this Chapter must be carried out in accordance with proven methods which are scientifically recognised.

Where necessary for the uniform application of this Regulation, sampling plans as well as the methods and analytical tolerances to be applied in order to check compliance with the requirements of this Chapter shall be established in accordance with the procedure laid down in Article 14.

The effectiveness of the faecal indicator bacteria and their numerical limits as well as the other parameters laid down in this Chapter shall constantly be kept under review and, where scientific evidence proves the need to do so, be revised following the procedure laid down in Article 15.

When there is scientific evidence indicating the need to introduce other parameters to safeguard public health such as the possible contamination with Neurotoxin-Shellfish Poisson (NSP), this shall be done applying the same procedure.

CHAPTER VI

PUBLIC HEALTH CONTROL AND SUPERVISION OF PRODUCTION

A public health control system shall be established by the competent authorities in order to verify whether the requirements laid down in this Regulation are complied with. This control system shall include :

1. Periodic supervision of live bivalve mollusc relaying and harvesting areas in order :
 - a) to avoid any abuse of the origin and destination of the live bivalve molluscs;
 - b) to check the microbiological quality of the live bivalve molluscs in relation to the area of harvesting as laid down in Chapter I;
 - c) to check the possible presence of toxin-producing plankton.

For that purpose, sampling plans shall be established by the competent authorities for checking at regular intervals or on a case-by-case basis in the situation of irregular periods of harvesting.

Sampling plans must in particular take account of :

a) likely variations in faecal contamination at each harvesting area;

b) possible variations of the presence of plankton containing marine biotoxins; the sampling must be designed as follows :

(i) surveillance : periodic sampling organised 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 muscle flesh must be followed by

(ii) intensive sampling :

- control of the plankton in the growing and fishing waters by increasing the number of sampling points and the number of samples and
- toxicity tests on molluscs from the affected zone and most susceptible to the contamination.

This intensive sampling plan must be continued until the results of toxicity tests permit again the placing on the market of the molluscs;

c) possible contamination of the molluscs in the harvesting area.

If the result of a sampling plan shows that the placing on the market of live bivalve molluscs may constitute a hazard to human health, the competent authority shall close the harvesting area until the situation has been restored.

2. Laboratory tests in order to check the respect of the requirements for the end product as laid down in Chapter V of this Annex.

There shall in particular be established a control system to verify that the level of marine biotoxins do not exceed the safe levels required by this Regulation.

3. An inspection at regular intervals of establishments. These inspections shall include in particular checks :
 - a) to verify whether the approval conditions are still being complied with;
 - b) on the cleanliness of the premises, facilities, equipment and of 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) of the record books referred to in Chapter IV under III, 12;
 - f) the correct use of health marks.

These checks may include the taking of samples for laboratory tests; the results of these tests shall be notified to the persons responsible for the establishments.

4. Checks on the storage and transport conditions of the consignments of live bivalve molluscs.

CHAPTER VII

WRAPPING

1. Live bivalve molluscs shall be wrapped under satisfactory hygiene conditions.

The wrapping material or container must :

- not impair the organoleptic characteristics of the live bivalve molluscs;
- must not be capable of transmitting substances which are harmful to human health to the live bivalve molluscs;
- be strong enough to give adequate protection to the live bivalve molluscs.

2. Oysters must be wrapped with the concave shell downwards.
3. All wrappings of live bivalve molluscs must be sealed and remain sealed from the expedition centre until delivery to the consumer or retailer.

CHAPTER VIII

PRESERVATION AND STORAGE

1. In any storing rooms, live bivalve molluscs must be kept at a temperature which does not adversely affect their quality and viability, the wrapping must not come into contact with the floor of the store room but must be placed on a clean, raised surface.
2. Reimmersion of live bivalve molluscs in seawater must not take place after being wrapped and having left the expedition center except in the case of retail sale at the expedition centre.

CHAPTER IX

TRANSPORT FROM THE EXPEDITION CENTER

1. Consignments of live bivalve molluscs destined for human consumption must be transported wrapped as a sealed parcel from the expedition center up to the time of being offered for immediate sale to the consumer or retailer.
2. The means of transport used for consignments of live bivalve molluscs must have the following characteristics :

- a) their interior walls and any other parts which might come into contact with the live bivalve molluscs must be made of corrosion-resistant materials; the walls must be smooth and easy to clean;
 - b) they must 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 must not be transported with other products which might contaminate them.
3. Consignments of live bivalve molluscs must 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.

The parcels containing live live bivalve molluscs must not be transported in direct contact with the floor of the vehicle or container but must be supported on raised surfaces or by some other means which prevents contact.

Where ice is used in transporting consignments of live bivalve molluscs, it must 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 must be provided with a health mark so enabling at all times during transport and distribution until retail, the identification of their original expedition center. Without prejudice to Council Directive 79/112/EEC on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs⁽¹⁾ as last amended by Directive 89/395/EEC (2), the mark must contain the following information :

(1) OJ No L 33, 08.02.1979, p. 1

(2) OJ No L 186, 30.06.1989, p. 17

- the country of dispatch,
 - species of bivalve mollusc (common name and scientific name)
 - the identification of the expedition center by the approval number granted by the competent authority,
 - the date of wrapping.
2. The health mark may be printed on the wrapping material or be put on a separate tag which is then fixed on the wrapping material or put inside the wrapping. They may also be of a twist-tie or staple design; self-adhesive health marks must not be used. All types of health marks must be designed for single use and be not transferable.
 3. The health mark must be durable and waterproof and the information presented as legible, indelible and in easily decipherable characters.
 4. The health mark attached to consignments of live bivalve molluscs which are not wrapped as consumer size parcels must be kept for at least 60 days by the retailer after splitting up the content of the consignment.

: F I N A N C I A L S T A T E M E N T concerning :

: Draft proposal for a Council Regulation concerning the health conditions governing
: the production and the placing on the market of live bivalve molluscs

: 1. BUDGET HEADING: Item: Title:
: III B 382 (1) Inspection in Agriculture

: 2. LEGAL BASIS: Article 43 of the Treaty

: 3. CLASSIFICATION: Non-compulsory expenditure

: 4. PURPOSE/DESCRIPTION OF THE MEASURE:
: Verification of the application of the Regulation (Art. 6 and 9)

: 5. METHOD OF CALCULATION:

: 5.1. Form of expenditure: Mission expenses

: 5.2. Community contribution: 100 %

: 5.3. Calculation:
: 300 mission days per year at ECU 170 per day (current cost of inspection) =
: ECU 51.000 per year

: 6. FINANCIAL IMPLICATION AS REGARDS OPERATING APPROPRIATIONS

: 6.1. Schedule of appropriations (m ECU):

<u>Year</u>	
1991	
1992	
1993	0,051
1994	0,051
1995	0,051
following years	---
Total	<u>0,153</u>

: 6.2. Financing during current year: NIL

: 7. OBSERVATIONS:

: (1) When the preliminary draft budget is prepared, an examination will be made to
: see where this category of expenditure is to be charged in the budget.

: This proposal also calls for 3 additional A7/6 posts.
: Staff requirements set out above must be met by redeployment within the Commission
: or by the budget procedure for the year concerned.

STATEMENT OF IMPACT ON BUSINESS

NAME OF THE PROPOSAL

Draft proposal for a Council Regulation on the health conditions affecting the production and the placing on the market of live bivalve molluscs.

OBJECTIVES

The proposal outlines the health requirements to be respected by industry and commerce, as well as by the competent authorities during production, handling, storage and distribution of live bivalve molluscs.

These requirements replace the different health conditions at present applied by the Member States and will help to bring about a single market.

IMPACT ON BUSINESS

The national rules of the Member States as regards health problems related to live bivalve molluscs are not always on an equivalent level or are conceived in a different manner.

Live bivalve molluscs are extremely sensitive as far as health risks are concerned. The creation of a single market where bivalve molluscs are allowed to be moved freely requires a harmonisation of the conditions for production and marketing, based on a high level of protection.

This will inevitably require for a certain number of mainly small enterprises an effort in order to adapt to the proposed rules as far as upgrading of premises and control procedures are concerned. It is also likely that, in order to meet the proposed standards, a number of establishments which are situated in zones where the quality of coastal waters is not satisfactory will need to provide for purification equipment.

In order to allow smooth adaptation to the proposed rules and in order to limit possible influence on business, transitional periods are proposed for certain requirements.

.../...

Member States will also be allowed, under the conditions set out in Council Decision ----- laying down the conditions for granting derogations to the Community health requirements for the production and the placing on the market of products of animal origin⁽¹⁾, to submit to the Commission requests for derogations to the proposed rules if these are well grounded and documented.

It must be further emphasized that the Community is prepared to assist the Member States in achieving higher health standards. For that purpose, the Commission has submitted to the Council a proposal for a Regulation on the improvement of the conditions under which fishery products and aquaculture products are processed and marketed [COM (89) 187 final] ⁽²⁾.

It must also be carried in mind that Member States are already bound to respect certain standards for the shellfish waters by virtue of Directive 79/923/EEC on the quality required of shellfish waters⁽³⁾. The respect of these standards will to a large extent help to achieve the product standards as envisaged in the present proposal.

Furthermore, free trade will be ensured once consignments comply with the proposed standards: this will be without doubt to the benefit of enterprises.

(1) O.J. n°

(2) O.J. n° C 143 of 09.06.89, p. 6

(3) O.J. n° L 281 of 10.11.79, p. 47

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