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R E P O R T

for the Committee on the Environment, Public Health and Consumer Protection

on the Commission proposal for a Council regulation laying down the health conditions for the production and the placing on the market of live bivalve molluscs

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A Series Reports - B series Motions for Resolutions, Oral Questions, Written Declarations, etc - C Series Documents received from other Institutions (e.g. Consultations)

***** = Consultation procedure requiring a single reading

****II** = Cooperation procedure (second reading) which requires the votes of the majority of the Members of Parliament

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******* = Parliamentary assent which requires the votes of the majority of the current Members of Parliament

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By letter of 19 February 1990 the Council consulted the European Parliament, pursuant to Article 43 of the EEC Treaty, on the Commission proposal for a Council regulation laying down the health conditions for the production and the placing on the market of live bivalve molluscs.

At the sitting of 12 March 1990 the President of Parliament announced that he had referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Agriculture, Fisheries and Rural Development and the Committee on Budgets for their opinions.

At its meeting of 23 March 1990 the Committee on the Environment, Public Health and Consumer Protection appointed Mr Bombard rapporteur.

At its meetings of 26 February and 23 May 1991 it considered the Commission proposal and draft report.

At the latter meeting it adopted the draft legislative resolution unanimously.

The following took part in the vote: Collins, chairman; Schleicher and Sir James Scott-Hopkins, vice-chairmen; Bombard, rapporteur; Alavanos, Avgerinos, Florenz, Green, Guidolin, Caroline Jackson, Kuhn, Muntingh, Oomen-Ruijten, Pereira, Pimenta, Roth-Behrendt, Vernier and Vittinghoff.

The opinions of the Committee on Agriculture, Fisheries and Rural Development and Committee on Budgets are attached.

The report was tabled on 29 May 1991.

The deadline for tabling amendments will appear on the draft agenda for the part-session at which the report is to be considered.

A

Commission proposal for a Council regulation laying down the health conditions for the production and the placing on the market of live bivalve molluscs

Commission text¹

Amendments

(Amendment No. 1)

Title

COUNCIL REGULATION (EEC) LAYING DOWN THE HEALTH CONDITIONS FOR THE PRODUCTION AND THE PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS

COUNCIL REGULATION (EEC) LAYING DOWN THE HEALTH CONDITIONS FOR THE PRODUCTION AND THE PLACING ON THE MARKET OF LIVE FILTER-FEEDING BIVALVE MOLLUSCS, ECHINODERMS AND TUNICATES

(Amendment No. 2)

First recital a (new)

Whereas, with a view to the completion of the internal market, it is essential for live bivalve molluscs to be subject to the same provisions with regard to health safeguards as those which apply to other foodstuffs;

(Amendment No. 3)

First recital b (new)

Whereas, however, it is necessary to adopt Community rules which take into account the requirement and specific conditions of shellfish farming;

¹ For full text see OJ No. C 84, 2.4.1990, p. 29

Commission text

Amendments

(Amendment No. 4)
Second recital

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

Whereas Council Directive 79/923/EEC of 30 October 1979 on the quality of shellfish waters lays down that it is necessary to establish the health requirements to be observed for shellfish products; whereas it should be noted that the best way of achieving a satisfactory health standard is through the strict application of this directive; whereas, unfortunately, is too often infringed;

(Amendment No. 5)
Third recital

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;

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

(Amendment No. 6)
Fifth recital

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 the maintenance of a high level of health protection for consumers requires the introduction of very strict quality standards; whereas, therefore, it is essential to develop and harmonize precise and rapid laboratory analysis methods;

Commission text

Amendments

(Amendment No. 7)
Fifth recital a (new)

Whereas it is also necessary to ensure the collection of epidemiological information at European level and to set up a system for the rapid exchange of information in the event of epidemics;

(Amendment No. 8)
Sixth recital

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 re-laying 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 re-layed;

Whereas it is necessary, on the basis of standards set at Community level, to classify the production areas in terms of the direct consumption of live bivalve molluscs or consumption following purification or re-laying;

(Amendment No. 9)
Seventh recital

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 micro-organisms and toxic substances in quantities which are considered to be dangerous to human health;

Whereas it is the responsibility of the producers to ensure that the filter-feeding 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 production areas do not contain micro-organisms and natural or artificial substances in quantities larger than those considered harmful to human health;

Commission text

Amendments

(Amendment No. 10)
Tenth recital

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 live filter-feeding bivalve molluscs from a third country and intended to be placed on the Community market must not qualify for more favourable conditions than those applied in the Community; whereas therefore all third countries must be required to attach an identification mark to live bivalve molluscs and to enter all filter-feeding production areas and approved establishments from which the import of live filter-feeding bivalve molluscs is authorized on a list kept by the Commission;

(Amendment No. 11)
Tenth recital a (new)

Whereas provision must be made for a Community inspection procedure for the conditions for production and placing on the market in third countries in order to enable the Community to apply a common import system based on equivalent conditions;

Commission text

Amendments

(Amendment No. 12)
Eleventh recital

Whereas it is possible that, due to some particular situations, some establishments in function before 1 January 1993 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);

Whereas it is possible that, due to some particular situations, some establishments in function before 1 January 1993 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); whereas these derogations should under no circumstances be granted for more than a two-year non-renewable period;

(Amendment No. 13)
Eleventh recital a (new)

Whereas certain producers and establishments will experience severe financial problems in adjusting to the requirements of this regulation; whereas they should therefore benefit from Community aid as regions eligible for assistance under the Structural Funds;

Commission text

Amendments

(Amendment No. 14)

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.

This regulation lays down the health conditions for the production and the placing on the market of live filter-feeding bivalve molluscs which are destined for immediate human consumption or for treatment rendering them suitable for human consumption.

This Regulation applies *mutatis mutandis* also to echinoderms, tunicates and farmed scallops.

It shall apply without prejudice to the provisions of Council regulation (EEC) No. concerning the animal health conditions governing the placing on the market of aquaculture animals and products and Council Regulation (EEC) No. laying down the health conditions for the production and the placing on the market of fishery products, to which the species not covered by this Regulation, in particular salt-water gastropod molluscs (family pectinidaw), remain subject.

(Amendment No. 15)

Article 2(1)

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.

1. Filter-feeding 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.

Commission text

Amendments

(Amendment No. 16)
Article 2(3)

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 impair their taste and which is to be used under the conditions laid down in this regulation.

3. Healthy 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 filter-feeding bivalve molluscs or impair their taste and which is to be used under the conditions laid down in this Regulation.

(Amendment No. 17)
Article 2(3a) (new)

3a. Saline solution: saline solution obtained from drinking water, displaying identical properties to those of healthy seawater and fit for use in its stead for purifying, washing, or cleaning filter-feeding bivalve molluscs, echinoderms and tunicates. The drinking water used to prepare the saline solution must comply with the provisions of Council Directive 80/778/EEC.

(Amendment No. 18)
Article 2(5)

5. Conditioning: the temporary wet storage of live bivalve molluscs, whose quality does not indicate need for re-laying 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.

5. Conditioning: the temporary wet storage of live bivalve molluscs, whose quality does not indicate need for re-laying 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 wholesomeness and, if possible, product palatability.

Commission text

Amendments

(Amendment No. 19)
Article 2(6)

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.

6. Gatherer: any physical or legal person or legal entity who collects live bivalve molluscs by appropriate means from a harvesting area for the purpose of handling and the placing on the market.

(Amendment No. 20)
Article 2(7)

7. Harvesting area: sea, estuarine or lagoon areas with sites of re-laid 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.

7. Production area: sea, estuarine or lagoon areas with sites of re-laid beds or natural deposits of filter-feeding bivalve molluscs, or those sites used for cultivation of filter-feeding bivalve molluscs from which live filter-feeding bivalve molluscs are taken for their placing on the market and which are subject to approval under Chapter I of the Annex and Article 5 of this Regulation.

(Amendment No. 21)
Article 2(7a) (new)

7a. Classification of a production area: statement of the conditions of placing on the market of filter-feeding bivalve molluscs originating from a production area defined on the basis of the text of Chapter I, point 1, of the Annex.

Commission text

Amendments

(Amendment No. 22)
Article 2(7b) (new)

7b. Re-laying area: sea, estuarine, or lagoon areas approved by the competent authority, clearly defined and marked by buoys, posts or any other fixed material and used exclusively for the re-laying of filter-feeding bivalve molluscs with a view to their natural purification.

(Amendment No. 23)
Article 2(9)

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.

9. Purification: the process of holding live bivalve molluscs, which are initially unfit for human consumption, for a defined period under controlled conditions in natural or artificial sea-water, whether or not treated, in order to make the live bivalve molluscs suitable for human consumption without subsequent treatment;

(Amendment No. 24)
Article 2(11)

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 micro-organisms to an acceptable level.

11. Purification plant: an establishment where live filter-feeding bivalve molluscs are kept for purification under suitable conditions using healthy seawater or seawater which is treated to remove contamination so causing the reduction of harmful micro-organisms to an acceptable level.

Commission text

Amendments

(Amendment No. 25)
Article 2(17)

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.

17. Placing on the market: the holding or displaying for sale, tasting or distribution, whether or not in return for payment, offering for sale, selling, delivering, or any other form of placing on the market of live filter-feeding bivalve molluscs for human consumption either raw or after processing in the Community.

(Amendment No. 26)
Article 3(1)(b)

(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;

(b) they must have been collected and transported from the production area to an expedition centre or purification plant under the conditions laid down in Chapter II of the Annex or undergone the specific operations carried out by expedition centres on board an offshore establishment;

(Amendment No. 27)
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 handling live bivalve molluscs from production until 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:

Persons who operate establishments shall carry out regular and frequent voluntary controls in particular to ensure that:

- adequate numbers of samples for laboratory examination are taken and analyzed in order to establish an historical record of the sanitary quality of the live bivalve molluscs both before and after handling at an expedition centre or at a purification plant,

- unchanged

Commission text

- a register is kept for the permanent record of the results of the various health checks and kept for presentation to the competent authority.

Amendments

- unchanged
- the health standards provided for in the annex are respected at all stages of the handling of live bivalve molluscs.

The nature and the frequency of the voluntary controls to be carried out are laid down in the Annex, Chapter Xa, which may be modified pursuant to the procedure in Article 15.

(Amendment No. 28)

Article 5(1)(b)

- (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.
- (b) The inspection and monitoring of these establishments shall be carried out regularly and frequently 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.

(Amendment No. 29)

Article 5(2)(a)

- 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.
- 2.(a) The competent authorities shall establish a list of production areas on the basis of Directive 79/923/EEC with indication of their location and boundaries and their classification or their designation for re-laying and from which live filter-feeding bivalve molluscs may be taken in conformity with this Regulation and, in particular, with Chapter I of the Annex.

Commission text

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

Amendments

This list must be communicated to those affected by this Regulation such as producers and operators of purification centres and expedition centres.

(Amendment No. 30)

Article 5(2)(b)

(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.

(b) The monitoring of the production 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 the Regulation are not being met, or that the production area in question is failing to satisfy the requirements of its classification, the competent authority may downgrade the production area and ultimately close it until the situation has been restored.

(Amendment No. 31)

Article 5(2)(b) a (new)

(b)a The competent authority must prohibit the production of live filter-feeding bivalve molluscs in any area which does not satisfy the conditions provided for in Chapter I of the Annex, taking into account the topography of the area, the sewage systems and their quality, the sources of pollution and the hydrographic and climatic conditions.

Commission text

Amendments

(Amendment No. 31)
Article 5(2)(ba) (new)

- (ba) The competent authority must prohibit the production of live filter-feeding bivalve molluscs in any area which does not satisfy the conditions provided for in Chapter I of the Annex, taking into account the topography of the area, the sewage systems and their quality, the sources of pollution and the hydrographic and climatic conditions.

(Amendment No. 32)
Article 5(2a) (new)

- 2a. The lists drawn up pursuant to paragraphs 1(a) and 2(a) of this article shall be communicated to the Commission and the other Member States.

(Amendment No. 33)
Article 5 (3)

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

3. The competent authorities concerned shall take all measures necessary within an appropriate time-limit to take account of the results referred to in Article 6 (1).

If the competent authorities fail to take the necessary measures within the appropriate time-limit, the Commission may, as a precautionary measure, where the protection of public health so requires, suspend the approved status of an establishment or downgrade or ultimately close a production area after notifying its intention to the competent authorities of the Member States concerned.

Commission text

Amendments

The Commission shall immediately inform the Member States of its decision. This decision may be amended by the procedure set out in Article 15. In case of need, the Commission may give notice of its decision by means of publication in the Official Journal or by any other means appropriate to the circumstances.

(Amendment No. 34)

Article 6 (1)

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.

1. Experts from the Commission shall be required to make on-the-spot checks to ensure the uniform application of this Regulation. They shall 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 on the basis of the regular reports drawn up by the experts, of the results of such checks.

(Amendment No. 35)

Article 6(3)

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.

3. The Commission, in accordance with the procedure laid down in Article 16, must draw up guidelines on good manufacturing practices applicable at the different stages of production and placing on the market.

Commission text

Amendments

(Amendment No. 36)
Article 9(3)(b)

(b) for each third country, the conditions for the importation of live bivalve molluscs. These conditions may include in particular:

(b) for each third country, the conditions for the importation of live filter-feeding bivalve molluscs. These conditions must include in particular:

(Amendment No. 37)
Article 9(3)(b)(i)

(i) the supplying of a health certificate which must accompany consignments when forwarded to the Community;

(i) the supplying of a health certificate which must accompany consignments when forwarded to the Community; this certificate must be drawn up in one of the official languages of the Community;

(Amendment No. 38)
Article 9(3)(b)(iv)

(iv) possibly the mandatory purification after arrival at the territory of the Community.

(iv) where this seems necessary in application of the provisions of Chapter I of the Annex, purification after arrival at the territory of the Community.

(Amendment No. 39)
Article 12a (new)

Small and medium-sized undertakings in the shellfish sector situated in regions eligible for aid under the Structural Funds may obtain funding to enable them to adapt their structures to meet the health requirements laid down in this Regulation.

(Amendment No. 40)
Article 14(2) second and third subparagraphs

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

The Commission shall adopt measures which are applicable immediately. However if they are not in accordance with the opinion delivered by the Committee these measures shall be communicated forthwith by the Commission to the Council. In this case:

Commission text

Amendments

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.

The Commission shall defer application of the measures it has decided on by a time-limit set in each act to be adopted by the Council, but not exceeding three months from the date of the communication.

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.

The Council, acting by a qualified majority, may take a different decision within the time-limit referred to in the previous subparagraph.

(Amendment No. 41)

Article 15(2) second and third subparagraphs

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

The Commission shall adopt measures which are applicable immediately. However if they are not in accordance with the opinion delivered by the Committee these measures shall be communicated forthwith by the Commission to the Council. In this case:

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.

The Commission may defer application of the measures it has decided on by a maximum period of fifteen days from the date of this communication.

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.

The Council, acting by a qualified majority, may take a different decision within the period referred to in the previous subparagraph.

(Amendment No. 42)

Annex, Chapter I, title

CONDITIONS FOR HARVESTING AREAS

CONDITIONS FOR PRODUCTION AREAS

Commission text

Amendments

(Amendment No. 43)
Annex, Chapter I, paragraph 1

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;

1. The competent authority shall determine the location and the boundaries of production areas, taking into account the topographic, hydrographic and climatic conditions and the existence of sources of pollution (waste water, sewage treatment plants, intensive farming). It shall then classify these areas as follows:

(a) 'A' zone: live filter-feeding bivalve molluscs can be collected for direct human consumption; they shall meet the requirements set out in Chapter V; from 1 January 1992 Member States may classify as A zones only those harvesting areas: (i) which have been designated as shellfish waters pursuant to Articles 1 and 4 of Directive 79/923/EEC on the quality of shellfish waters; (ii) which meet the quality standards for water pursuant to Articles 3 and 6 of the Annex of that directive.

Commission text

(b) can be collected but only placed on the market after treatment in a purification system, after re-laying 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 6000 faecal coliforms per 100 grams of flesh or 4600 E. Coli per 100 grams of flesh in 95% of samples. After purification, re-laying or processing, the requirements set out in Chapter V shall be met;

(c) can be collected but only placed on the market after re-laying over a long period or after re-laying 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.

Amendments

(b) 'B' zone: live filter-feeding bivalve molluscs can be collected but only placed on the market after treatment in a purification system, after re-laying 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 filter-feeding bivalve molluscs from these areas must not exceed the limits of a 5-tube-3-dilution MPN-test of 3 000 faecal coliforms per 100 grams of flesh or 2 400 E. Coli per 100 grams of flesh in 95% of samples. After purification, re-laying or processing, the requirements set out in Chapter V shall be met;

(c) 'C' zone: live filter-feeding bivalve molluscs can be collected but only placed on the market after re-laying over a period which shall depend on the contaminants and the level of contamination or after re-laying 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.

Commission text

Amendments

Live bivalve molluscs exceeding the maximum limits of 20 000 faecal coliforms per 100 grams of flesh or 15 000 E.coli per 100 grams of flesh in 95% of samples shall be excluded from any re-laying and purification and thus from any placing on the market.

(Amendment No. 44)
Annex, Chapter I, point 2

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 centres.

2. Any change in the delimitation and classification of production areas and the downgrading or 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 centres.

(Amendment No. 45)
Annex, Chapter II, title

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

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

(Amendment No. 46)
Annex, Chapter II, point 2

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.

2. Live filter-feeding 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 or to significant fluctuations in temperature.

Commission text

Amendments

(Amendment No. 47)
Annex, Chapter II, point 6

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, re-laying 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:

6. A registration document for the identification of batches of live filter-feeding bivalve molluscs during transport from the production area to an approved expedition centre, purification centre, re-laying area or processing plant shall be issued by the competent authority. For each batch, the competent authority shall require this registration document, the relevant sections of which have been completed by the producer legibly and indelibly, and which must contain the following information:

(Amendment No. 48)
Annex, Chapter III, throughout the chapter

re-laying site

re-laying area

(Amendment No. 49)
Annex, Chapter IV, section I, introductory paragraph

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 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 and must not be near a waste water outlet.

(Amendment No. 50)
Annex, Chapter IV, section I, point 2a (new)

2a. If the facilities are not connected to the mains drainage system they must have a waste disposal system which meets the legal requirements.

Commission text

Amendments

(Amendment No. 51)

Annex, Chapter IV, section I point 5a (new)

5a. If harvesting, conditioning and expedition are carried out on boats intended for this purpose, the conditions laid down in this chapter shall apply, modified in line with the circumstances.

(Amendment No. 52)

Annex, Chapter IV, section II, points 4 and 5

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.

4. Premises, equipment and instruments used for handling of live filter-feeding 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.

5. Premises, instruments and equipment must not be used for purposes other than handling live filter-feeding bivalve molluscs, unless authorization by the competent authority.

(Amendment No. 53)

Annex, Chapter IV, section III, point 3

3. The purification system must be supplied with sufficient seawater or flow of seawater per hour and per tonne of live bivalve molluscs treated.

3. The purification system must be supplied with sufficient seawater or saline solution or flow of seawater or saline solution per hour and per tonne of filter-feeding bivalve molluscs treated.

Commission text

Amendments

(Amendment No. 54)

Annex, Chapter IV, section III, point 4

4. Clean seawater must be used for purifying live bivalve molluscs; the distance between the seawater intake point and the waste water outlets must be sufficient to avoid contamination; the procedure for sanitizing the seawater 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.

4. Healthy seawater or a saline solution within the meaning of Article 2(3a) of this Regulation must be used for purifying live filter-feeding bivalve molluscs; the distance between the seawater intake point and the waste water outlets must be sufficient to avoid contamination; the procedure for sanitizing the seawater shall be authorized once its effectiveness has been verified by the competent authority.

(Amendment No. 55)

Annex, Chapter IV, section IV, point 1(a),

(a) conditioning must not cause any d e l e t e r i o u s microbiological contamination of the product;

(a) conditioning must not cause any microbiological contamination leading to deterioration of the product and therefore liable to affect the human metabolism;

(Amendment No. 56)

Annex, Chapter V, point 3

3. Absence of salmonella in 25 grams mollusc flesh;

3. Absence of salmonella in 100 grams mollusc flesh;

(Amendment No. 57)

Annex, Chapter V, point 6

6. The total Paralytic Shellfish Poison (PSP) content shall not exceed 80 micrograms per 100 grams of mollusc flesh;

6. The total Paralytic Shellfish Poison (PSP) content shall not exceed 40 micrograms per 100 grams of mollusc flesh;

Commission text

Amendments

(Amendment No. 58)
Annex, Chapter V, point 7

7. The Diarrhetic Shellfish Poison (DSP) content of the flesh shall not exceed levels which may be considered dangerous to human health.

7. The Diarrhetic Shellfish Poison (DSP) content of the soft parts shall be below levels likely to affect the human metabolism, to be established by the Community authorities.

(Amendment No. 59)
Annex, Chapter V, first paragraph after point 8

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

Laboratory analyses for checking the compliance with the requirements of this Chapter must be carried out in accordance with proven methods which are scientifically recognized and harmonized as a matter of urgency, so that the quality standards given in this chapter can be supplemented and revised on the basis of comparable date.

(Amendment No. 60)
Annex, Chapter V, second paragraph after point 8

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.

For the uniform application of this Regulation and taking into account developments in scientific knowledge, 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.

(Amendment No. 61)
Annex, Chapter VI, point 1(b)

(b) to check the microbiological quality of the live bivalve molluscs in relation to the area of harvesting as laid down in Chapter I;

(b) to check the microbiological quality of and presence of any other abiotic contaminants in the live filter-feeding bivalve molluscs in relation to the area of production as laid down in Chapter I;

Commission text

Amendments

(Amendment No. 62)
Annex, Chapter VI(1)(ca) (new)

(ca) to monitor the level of contamination derived from oil-based hydrocarbons, organohalogens and heavy metals. Because of the risks of accumulation, sampling plans should make provision to increase the frequency of sampling laid down in Directive 79/923/EEC, namely every month for hydrocarbons and every three months for organohalogens and heavy metals. Where a health risk exists, checks should cover any pathogen likely to be present in the environment or which could come from a human or animal source.

(Amendment No. 63)
Annex, Chapter VI, paragraph 2 a (new)

The collection at European level of epidemiological data with a view to setting up a system for the rapid exchange of information to operate in the event of epidemics.

(Amendment No. 64)
Annex, Chapter IX, point 1

1. Consignments of live bivalve molluscs destined for human consumption must be transported wrapped as a sealed parcel from the expedition centre up to the time of being offered for immediate sale to the consumer or retailer.

1. Consignments of live filter-feeding bivalve molluscs destined for human consumption must be transported wrapped as a sealed package from the expedition centre up to the time of being offered for immediate sale to the consumer or retailer.

Commission text

Amendments

(Amendment No. 65)
Annex, Chapter X, point 1

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 centre. 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, as last amended by Directive 89/395/EEC, the mark must contain the following information:

- the country of dispatch,
- species of bivalve mollusc (common name and scientific name),
- the identification of the expedition centre by the approval number granted by the competent authority,
- the date of wrapping.

1. All parcels in a consignment of live filter-feeding 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 production area. 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, as last amended by Directive 89/395/EEC, the mark must contain the following information:

- the country of dispatch, or export in the case of non-member countries,
- species of filter-feeding bivalve mollusc (common name and scientific name),
- the identification of the production area and the expedition centre by the approval numbers granted by the competent authority,
- the date of production and wrapping and the origin of the product.

(Amendment No. 66)
Annex, Chapter X, paragraph 1, fourth indent a

- the 'use by' date

DRAFT LEGISLATIVE RESOLUTION

embodying the opinion of the European Parliament on the Commission proposal for a Council regulation laying down the health conditions for the production and the placing on the market of live bivalve molluscs

The European Parliament,

- having regard to the Commission proposal to the Council (COM(89) 0648 final)²,
 - having been consulted by the Council pursuant to Article 43 of the EEC Treaty (C3-0054/90),
 - having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinions of Committee on Agriculture, Fisheries and Rural Development and the Committee on Budgets (A3-0151/91),
1. Approves the Commission proposal subject to Parliament's amendments and in accordance with the vote thereon;
 2. Calls on the Commission to amend its proposal accordingly, pursuant to Article 149(3) of the EEC Treaty;
 3. Asks to be consulted again should the Council intend to make substantial modifications to the Commission proposal;
 6. Instructs its President to forward this opinion to the Council and Commission.

² OJ No. C 84, 2.2.1990, p. 29

EXPLANATORY STATEMENT

Oysters, mussels and other bivalve molluscs are great delicacies and have considerable nutritional value as proteins. However they also have a bad reputation as regards the risk of food poisoning. They are held responsible by an undiscerning public for all cases of diarrhoea, gastroenteritis, typhoid, hepatitis, poliomyelitis, cholera, respiratory paralysis, amnesia, quite apart from urticaria.

Oysters and mussels are basically excellent. However, since bivalve molluscs filter large amounts of water and retain the suspended particles which provide them with food in their branchiae they also retain all the pathogens in the water. Eaten raw or, in particular lightly cooked (inadequate cooking encourages the microbes to multiply), bivalve molluscs inevitably pass on to man what man originally dumped in the sea. Molluscs have the misfortune to live and grow along the coasts, in the estuaries and generally near inhabited, industrialized or intensively farmed areas. Oysters and mussels grow in waters which mankind has polluted by discharges of waste water, heavy metals, industrial waste, agricultural nitrates and animal wastes from intensive farming.

In fact, even though this seems contradictory, it is less dangerous to eat oysters now than at the beginning of the century. Firstly, certain serious illnesses such as typhoid and poliomyelitis have virtually disappeared as a result of vaccinations. Secondly, all Community countries have adopted health measures. However, dangers to human health still exist and certain types of poisoning can cause death or, at the very least, serious problems. Furthermore, risks are increasing as the consumption of bivalve molluscs is rising (250 000 tonnes of shellfish are eaten in France each year³).

The occurrence of poisoning caused by oysters and mussels in one region also causes an immediate drop in consumption of these animals in the region concerned and in regions which are not affected. Shellfish farming is an extremely important if not vital economic activity for certain maritime regions.

Lastly, oysters and mussels form part of an expanding international trade. At present it is thought that about 40% of the shellfish produced in Europe cross at least one frontier before reaching the market⁴.

Any proposal for a Community regulation in this area is therefore welcome, but the rapporteur considers that it must have three objectives:

- to provide maximum safety for consumers;
- to maintain a significant branch of the economy;
- to achieve the free movement of foodstuffs within the single market.

³ see Ch. VIVARES: 'Consommer des coquillages est-il dangereux? contamination, surveillance et santé publique'.

La Recherche No. 228, vol 22, p. 122

⁴ idem p. 126

The provision of a wholesome product is the prerequisite for achieving the other two objectives.

I. Conditions necessary to ensure health quality

To ensure maximum protection against poisoning transmitted by eating raw bivalve molluscs, action must be taken at various levels. First, action with regard to the waters, then relating to the chain from harvesting to placing on the market (especially during transport) and lastly the identification of the products.

A. The health of shellfish waters

This aspect is fundamental. If the waters where bivalve molluscs live and grow are not clean, any number of expensive treatments and processes can be carried out but the oysters and mussels will inevitably not have all the necessary qualities of wholesomeness and will also lose palatability.

In October 1979 the Council adopted a directive (79/923/EEC) on the quality of shellfish waters⁵. It sets the values for various parameters listed in the annex and refers to Directive 76/464/EEC of 4 May 1976⁶ as regards discharges of organohalogenated substances and heavy metals. The last recital of Directive 79/923/EEC states that it 'cannot, by itself, ensure protection of consumers of shellfish products and that proposals to this end should therefore be submitted by the Commission as soon as possible.'

The proposal for a regulation under consideration is thus closely linked to this directive. It would therefore seem necessary, even if this is going beyond the framework provided by the regulation under consideration, to examine the implementation of the directive on shellfish waters by the Member States and whether, because of scientific and technical developments, it has not become essential to revise that directive, or at least to inform the European Parliament of any modifications which may have been adopted by the committee provided for in its Article 13.

Thus, even if, strictly speaking, this directive does not come within the framework of the proposal for a regulation concerning the health conditions applicable to bivalve molluscs, it is nevertheless of fundamental importance and the essential reference point for the definition of the production areas, as provided for in chapter I of the Annex 'Conditions for production areas'. If the basic principle is that the health of oysters and mussels depends on the quality of the waters in which they live, the first stage must be to apply the directive on shellfish waters (if this has not yet been done), to monitor its application and, if necessary, to strengthen it.

B. Health standards applicable to molluscs

Assuming that the Member States have applied the directive on shellfish waters, the fact remains that the mussels and oysters harvested in these waters cannot necessarily be eaten immediately either raw or lightly cooked. In the proposal for a regulation (Chapter I of the Annex) the Commission

⁵ OJ No. L281, 10.11.1979, p. 47

⁶ OJ No. L129, 18.5.1976, p. 23

therefore defines the harvesting areas in terms of the level of bacteria contained in the flesh of the animal.

Thus, molluscs harvested in 'A' areas and deemed fit for immediate human consumption must meet standards which take into account the parameters on the presence of bacteria, levels of radionuclides, toxic plankton and toxic elements (levels fixed by Directive 79/923/EEC - shellfish waters).

There are as yet unfortunately no standards and no sure methods of detection for viruses.

In the recitals the Commission explains the absence of standards in the body of the proposal for a regulation on grounds of the lack of scientific knowledge. However it would seem inadequate merely to undertake 'to fix a Community system to ensure rapid adoption and where necessary improvement of health standards'. In plain language it means leaving a management or regulatory committee to set the standards.

The problem of standards is even more acute for the 'B' and 'C' areas set up under the proposal for a regulation. In particular the 'C' area has no set maximum level above which the harvesting and rearing of live bivalve molluscs should be absolutely prohibited.

C. Purification processes

Molluscs harvested in 'B' and 'C' areas are, by definition, polluted and must therefore be purified using various processes to render them suitable for consumption.

The first recognized and most simple process is relaying in clean sea water (which still has to be defined precisely). The other processes involve chemical procedures (chlorine, ozone) or ionization or ultra-violet rays. Whilst the conditions for relaying are given in chapter 3 of the Annex, there is no mention of the actual purification processes.

The lack of detail on purification processes is doubtless related to the fact that the processes known and used up to now have sometimes proved inadequate. Furthermore each country has traditionally had preference for one or other of the processes and has the installations required for the purpose. Lastly, scientific research in this field is progressing and the Commission does not wish to restrict the possibilities for development.

Thus even though the proposal for a regulation does not deal with the quality of waters (subject of the 1979 directive), does not set precise standards on pollution levels in shellfish and does not specify the purification processes, it does provide for various measures to monitor the health qualities of oysters and mussels.

II. Content of the proposal for a regulation

A. Control measures

As in the proposal for a Council regulation laying down the health conditions governing the production and placing on the market of fishery products

(COM(89) 645⁷, the Commission makes provision in the regulation on molluscs for setting up a voluntary control system (HACCP - Hazard Analysis Critical Control Point). This system is being used increasingly in the food industry and implies that in their own interest industrialists will assure the quality of their products by carrying out checks themselves. However this principle involves specific obligations and does not replace inspections by the competent health authorities.

The setting-up of a voluntary control system implies the drawing up of monitoring guidelines for various stages during the handling of molluscs and also the training and education of staff. It is not apparent that the current shellfish farming structures which are dominated in many Community countries by small operations (4000 undertakings in France) and the demands of seasonal production (the highest consumption of mussels and in particular oysters is over the Christmas and New Year period) would be particularly suited to the application of this voluntary control system.

The proposal for a regulation also makes provision for checks and inspections. The competent authorities in the Member States are responsible for approving and drawing up a list of each expedition centre and purification plant and a list of harvesting areas. They are also responsible for carrying out regular inspections and monitoring. These authorities are required to impose penalties should inspections reveal that the requirements of this regulation are not being met. For the production areas, the penalty specified is the closure of the area concerned until the normal situation has been restored.

Lastly, the proposal provides for possible checks by experts from the Commission (Article 6). In this proposal, as in the proposal on fishery products, it would seem essential that there should be a Community inspection and that the Commission should be provided with the necessary funds and staff for this purpose.

B. Conditions applicable to imports from third countries

The countries of the Community are not self-sufficient in the production of live bivalve molluscs. Products must therefore be imported from third countries and the same health rules must be applied to these products. Apart from the on-the-spot checks carried out by Commission experts, the remaining provisions, and especially the decision on whether the conditions for the production and placing on the market in third countries are equivalent are dealt with by a committee under the regulatory committee procedure (procedure IIIa).

C. Contents of the Annex

The annex to the proposal for a regulation is extremely important as its different chapters set out the health rules to be observed for production areas, transport, re-laying, general hygiene conditions in the various establishments and labelling.

Only chapter V of the Annex, dealing with the quality standards for bivalve molluscs, may be modified using the regulatory committee procedure.

⁷ OJ C84, 2.4.1990, p. 58

III. Comments on the amendments

While stressing that the quality of the water provides the best guarantee of a wholesome product and that it is essential to revise or even amend the 1979 directive on shellfish waters, it seemed necessary to strengthen the text submitted by means of amendments in order to ensure better protection for the health of gourmets.

Amendments 2 and 3 state that live bivalve molluscs are foodstuffs and that they must therefore be subject to provisions similar to those which apply to other foodstuffs. However it is also necessary to take account of the specific conditions of shellfish farming. Equivalent amendments were adopted by the European Parliament and accepted by the Commission during the vote on the report on health conditions concerning nematodes⁸.

Amendments 5 and 14 extend the application of the regulation to farmed scallops. Wild scallops are not gathered from a harvesting area like other live bivalve molluscs and are therefore covered by the proposal for a regulation laying down the health conditions for the production and the placing on the market of fishery products (COM(89) 645).

Amendment 6 highlights the weaknesses of the proposal for a regulation. It shows clearly that it will be impossible to introduce strict quality standards until the laboratory analysis methods have been harmonized and developed.

Similarly Amendment 7 points to the need to collect epidemiological data and to provide a system for the rapid exchange of information.

These two points, which the rapporteur considers essential, are included in the body of the text in Amendments 59 and 60.

Amendment 8 introduces a clearer classification of production areas.

Amendment 43 also makes this classification explicit, which enables graduated penalties to be imposed if live bivalve molluscs no longer meet the requirements of this regulation. Thus, Amendment 33 makes provision for the possibility of downgrading a harvesting area before closing it.

Although not convinced that the voluntary control system can apply to shellfish farming, the obligations associated with this system must be strengthened. Amendment 27 thus specifies that the system must apply throughout the production process until the placing on the market and also to checks for compliance with the health standards provided for in the Annex.

Amendment 31 provides for a ban on the production of live filter-feeding bivalve molluscs in areas which not only do not comply with the requirements of chapter I of the Annex but also do not meet the environmental conditions. In other words, there must be an absolute ban on the production of these animals, for example at a sewage outfall, which would seem to be obvious, but unfortunately is not always the case. At certain levels of water pollution even the best purification processes will not make live bivalve molluscs wholesome and suitable for consumption.

⁸ OJ No. C96, 17.4.1989, p. 194

Similarly, Amendment 43 seeks to specify the conditions which must be observed by the competent authorities in establishing the location and boundaries of harvesting areas. A harvesting area may not be established unless there has first been a proper analysis of the topographic, hydrographic (tides, currents) and climatic conditions and in particular its position in relation to sources of pollution such as waste water, sewage treatment plants, intensive farming areas, etc.

The last part of the amendment sets the limits above which it is prohibited to gather live bivalve molluscs.

Lastly, Amendments 65 and 66 seek to strengthen consumer protection by listing the date of harvest and the 'use by' date. It is necessary to ensure the health guarantees for live bivalve molluscs right to the end of the process. It is not unusual to see oysters and mussels on the market which have arrived in a shop on 22 December, for example, and are still on the shelves on 31 December.

Conclusions

Without wanting to underestimate the problems encountered by the Commission in its attempt to harmonize the very diverse health rules in the Member States on live bivalve molluscs, the rapporteur feels that the proposal for a regulation is not adequate to the task of providing optimum protection for the health of the consumer.

It is true that scientific knowledge on screening methods for pathogens is very uncertain, if not non-existent as far as viruses are concerned. For this reason attention should be focused on the quality of shellfish waters. To some extent the problem must be dealt with at source rather than attempting merely to limit the damage caused by pollution.

We therefore expect the Commission to produce a detailed report on the application of the directive on shellfish waters.

OPINION
of the Committee on Budgets

Letter from the chairman of the committee to Mr COLLINS, chairman of the Committee on the Environment, Public Health and Consumer Protection.

Brussels, 26 April 1990

Subject: proposal for a regulation laying down the health conditions for the production and placing on the market of live bivalve molluscs (COM(89) 648 - C3-0054/90)

Dear Mr Collins,

The Committee on Budgets considered the above proposal at its meeting of 25 April 1990. After considering the proposal, the Committee on Budgets contests the entering of administrative appropriations in Part B of the budget, reserved for operating appropriations.

The Committee on Budgets calls on the Commission to propose a more appropriate budgetary allocation when drawing up the preliminary draft budget.

Furthermore, the Committee on Budgets noted that, for the implementation of this decision, the Commission proposes that it should be assisted by a regulatory committee. Pursuant to Article 205 of the EEC Treaty and the conclusions of the working party set up by the Bureau of the European Parliament in March 1989 on the problems of commitology, the Committee on Budgets has adopted the amendments attached to this letter.

Yours sincerely,

(sgd) Thomas von der VRING

The following were present: von der Vring, chairman; Arias Canete, Böge, Cochet, Colom I Naval, Fitzgerald (for Pasty), Kellett-Bowman, Lamassoure, Langes, McCartin (for Lo Giudice), Napoletano (for Colajanni), Onur (for Lüttge), Papoutsis, Samland and Theato

AMENDMENTS SUBMITTED BY THE COMMITTEE ON BUDGETS

to the proposal for a Council Regulation (EEC)
laying down the health conditions for the production
and placing on the market of live bivalve molluscs
(COM(89) 648 final - C3-0054/90)

Amendment No. 1

Article 14

Replace the second and third subparagraphs of paragraph 2 with the following:

'The Commission shall adopt measures which are applicable immediately. However if they are not in accordance with the opinion delivered by the Committee these measures shall be communicated forthwith by the Commission to the Council. In this case:

The Commission shall defer application of the measures it has decided on by a time-limit set in each act to be adopted by the Council, but not exceeding three months from the date of the communication.

The Council, acting by a qualified majority, may take a different decision within the time-limit referred to in the previous subparagraph.'

Amendment No. 2

Article 15

Replace the second and third subparagraphs of paragraph 2 with the following:

'The Commission shall adopt measures which are applicable immediately. However if they are not in accordance with the opinion delivered by the Committee these measures shall be communicated forthwith by the Commission to the Council. In this case:

The Commission may defer application of the measures it has decided on by a maximum period of fifteen days from the date of this communication.

The Council, acting by a qualified majority, may take a different decision within the period referred to in the previous subparagraph.'

OPINION

(Rule 120 of the Rules of Procedure)

of the Committee on Agriculture, Fisheries and Rural Development
for the Committee on the Environment, Public Health and Consumer Protection

Draftsman: Mrs Nicole PERY

At its meeting of 3 April 1990 the Committee on Agriculture, Fisheries and Rural Development appointed Mrs Pery draftsman of the opinion.

At its meetings of 28/29 May 1990, 18/19 March 1991 and 24/25 April 1991 it considered the draft opinion.

At its meeting of 25/26 April 1991 the Committee on Agriculture, Fisheries and Rural Development, on the recommendation of its Fisheries Subcommittee, adopted the opinion unanimously.

The following Members were present: Colino Salamanca, chairman; Borgo, vice-chairman; Ainardi, Bocklet, Dessylas, Domingo Segarra, Funk, Görlach, Howell, Kofoed, Lane, Lataillade (for Guillaume), Maher (for Vohrer), Marck, Newens, Pasty (for Killilea), N. Pisoni, Plumb, Sierra Bardaji, Stevenson, Verbeek and Woltjer.

INTRODUCTION

1. To protect public health, it is essential for completion of the internal market and the abolition of frontier checks on goods moving within the Community to be accompanied by uniform rules governing the production of foodstuffs and their placing on the market. In the specific area of products of the sea, the Commission has already submitted provisions on fishery and aquaculture products.
2. Following on from the two general proposals for regulations, the proposal dealt with in this opinion is a more specific text relating to live bivalve molluscs - however produced - and other species of seafood (sea urchins, sea squirts). In fact, the exact definition of the scope of the regulation raises certain difficulties which the draftsman has sought to remedy in some of her amendments.

I. The Commission proposal

3. The proposal is intended to replace the often contradictory, and indeed incompatible, national laws (the incompatibility resulting from specific local production practices and opposing views on the purpose of, and the resources to be allocated to, health checks). The proposal seeks to regulate three areas:

- A. **Environment** (on the basis of analyses of animals taken from their environment). The classification breaks down into three categories of environments:

- (a) the cleanest environments, the products of which can be consumed in their present condition or after a low degree of conditioning;
- (b) environments whose products must be treated at a purification plant, where animals naturally excrete their bacteriological contamination when kept in clean water for about 48 hours;
- (c) environments whose animals first have to be re-laid in special areas before being purified.

Seafood from environments that fail to satisfy the minimum requirements as laid down in class (c) is considered totally unfit for human consumption.

- B. **Products placed on the market:** products ready for consumption must comply with health standards comparable to those governing other foodstuffs as well as with the microbiological standards more specific to this type of foodstuff.
- C. **Preparation, handling, wrapping, and expedition requirements:** stringent hygiene standards are laid down to avoid any additional source of contamination. The highest proportion of financial charges is likely to be incurred by producers in complying with this section.

II. Critical assessment

The substance of the Commission proposal, which seeks to unify the rules over the whole of Community territory in such a way as to ensure that all consumers in the Community enjoy standards of hygiene comparable to the best national provisions currently in force, can be described as satisfactory.

Attention should be drawn to the Commission's efforts given that national animal health rules and the traditions from which they stem are not only at variance, but very often diametrically opposed, and a major harmonization operation was required in order to unify the rules while respecting the diversity of practices.

The draftsman consequently has virtually no criticisms to make about the health standards laid down (rules governing environments and products, limit of not more than 300 faecal coliforms in the finished product, salmonella-free flesh, inclusion of the biotoxin PSP, and tie-in with the directive on shellfish waters regarding miscellaneous other pollutants). She also approves, in the main, the procedures for monitoring, improving or adapting the rules set out in the proposal.

However, it must not be forgotten that, to attain the desired result, producer undertakings will in many cases have to make a considerable effort in order to adapt.

Financial outlay will often be entailed, especially since a considerable number of the smallest undertakings are lagging a long way behind. In many cases, the adjustments will relate purely to the organizational level, but even then, the difficulty should not be underestimated, not least because, as occupations go, shellfish farming is very much a case apart: small and often highly specialized undertakings scattered over very diverse coastal regions where the opportunities afforded by other economic activities are frequently meagre.

The distinguishing characteristics are made still more pronounced by the considerable variations in structures from one country, or indeed region, to the next. For example, production on the one hand and purification and marketing on the other are generally organized separately in Spain or Italy (70 purification plants in Spain, which also deal with expedition). By contrast, the tasks of production and expedition are carried out by the same undertakings in Scotland and on most of the French coast (3058 establishments in France).

That is why, and although the point is not strictly relevant to a regulation concerned solely with health standards, the Subcommittee on Fisheries considers it essential that the investments which undertakings will have to make in order to bring themselves into line with requirements should be allowed to benefit from Structural Fund aid within the brief time-span necessitated by the early date of entry into force of the text (1 January 1993).

The investments involved are considerable: according to information supplied to the Commission by the Member States, they total:

ECU 9.5 m in the case of
the United Kingdom

ECU 6.4 m for 404 expedition centres
ECU 3.1 m for 51 purification plants

ECU 11.9 m in the case of
Spain

for 70 purification plants. The concept of
an 'expedition centre' does not exist at
present.

ECU 66.9 m in the case of
France

ECU 58.6 m for 3058 expedition centres
ECU 3.1 m for 28 purification plants
ECU 5.2 m for other operators (producers,
reforwarding agents, etc.)

A system of rules entailing such costly investment should not enter into force before the necessary funding has been granted, subject to the provisions of Regulations (EEC) Nos. 4028/86 (producers' investments linked to production and marketing) and 4042/89 (investment undertaken at specialist wrapping and marketing establishments).

The occupations of oyster farmer, mussel breeder, etc. draw on a considerable fund of 'rule-of-thumb' expertise as well as on numerous local characteristics that must be respected. The Commission text has the merit of taking most of those characteristics into account. Your draftsman, however, firmly believes that everything possible should be done - especially in connection with the investments (considerable in themselves) necessitated by the text - to ensure the survival of these diversified modes of production.

In particular, she has thought fit to define certain terms more explicitly and add some details concerning the conduct of harvesting and handling operations in order to prevent a situation in which, by some mishap quite contrary to the original intentions, entirely conscientious producers were found to be out of step with a system of rules that made no allowance for their working methods.

That is why, without detracting from its approval of the Commission proposal, the Committee on Agriculture, Fisheries and Rural Development calls on the Committee on the Environment, Public Health and Consumer Protection to adopt the amendments set out below:

Commission proposal for a Council regulation (EEC)
laying down the health conditions for the production
and the placing on the market of live bivalve molluscs

Commission text¹

Amendments

(Amendment No. 1)
Title

COUNCIL REGULATION (EEC) LAYING DOWN
THE HEALTH CONDITIONS FOR THE
PRODUCTION AND THE PLACING ON THE
MARKET OF LIVE BIVALVE MOLLUSCS

COUNCIL REGULATION (EEC) LAYING DOWN
THE HEALTH CONDITIONS FOR THE
PRODUCTION AND THE PLACING ON THE
MARKET OF LIVE FILTER-FEEDING
BIVALVE MOLLUSCS, ECHINODERMS AND
TUNICATES

(NB: throughout the text, replace
the words 'live bivalve molluscs'
with 'live filter-feeding bivalve
molluscs, echinoderms and tunicates'

(Amendment No. 2)
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 lays down the health
conditions for the production and
the placing on the market of live
filter-feeding bivalve molluscs,
echinoderms, and tunicates which
are destined for immediate human
consumption or for further
processing before consumption.

It shall apply without prejudice to
the provisions of Council Regulation
(EEC) No. _____ concerning the animal
health conditions governing the
placing on the market of aquaculture
animals and products and Council
Regulation (EEC) No. _____ laying
down the health conditions for the
production and the placing on the
market of fishery products, to which
the species not covered by this
Regulation, in particular salt-water
gastropod molluscs and bivalve
molluscs (family pectinidae), remain
subject.

¹ For full text see COM(89) 0648 final - OJ No. C 84, 2.4.1990, p. 29

(Amendment No. 3)
Article 2(1)

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.

1. Filter-feeding 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.

(Amendment No. 4)
Article 2(2)

Marine biotoxins: poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxin.

Marine biotoxins: poisonous substances of biological origin accumulated by filter-feeding bivalve molluscs, echinoderms and tunicates feeding on plankton containing toxin.

(Amendment No. 5)
Article 2(3)

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 impair their taste and which is to be used under the conditions laid down in this Regulation.

3. Healthy seawater: seawater or estuary water in which the density of the pathogenic microorganisms and toxic substances of natural or artificial origin listed in the Annex to Directive 79/923/EEC present in the marine environment is such that it cannot adversely affect the health quality of filter-feeding bivalve molluscs, echinoderms and tunicates or public health in respect of consumers.

(NB: throughout the text, replace the words 'clean seawater' with 'healthy seawater')

(Amendment No. 6)
Article 2(3a) (new)

3a. Saline solution: saline solution obtained from drinking water, displaying identical properties to those of healthy seawater and fit for use in its stead for purifying, washing, or cleaning filter-feeding bivalve molluscs, echinoderms and tunicates. The drinking water used to prepare the saline solution must comply with the provisions of Council Directive 80/778/EEC.

(Amendment No. 7)
Article 2(7)

7. Harvesting area: sea, estuarine or lagoon areas with sites of re-laid 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.

7. Production area: sea, estuarine or lagoon areas with sites of re-laid beds or natural deposits of filter-feeding bivalve molluscs, echinoderms or tunicates or those sites used for cultivation of filter-feeding bivalve molluscs, echinoderms or tunicates from which live filter-feeding bivalve molluscs, echinoderms and tunicates are taken for their placing on the market and which are subject to approval under Chapter I of the Annex and Article 5 of this Regulation.

(NB: throughout the text replace the word 'harvest' with 'production')

(Amendment No. 8)
Article 2(7a) (new)

7a. Classification of a production area: statement of the conditions of placing on the market of filter-feeding bivalve molluscs, echinoderms or tunicates originating from a production area defined on the basis of the text of Chapter I, point 1, of the Annex.

(Amendment No. 9)
Article 2(7b) (new)

Re-laying area: sea, estuarine, or lagoon areas approved by the competent authority, clearly defined and marked by buoys, posts or any other fixed material and used exclusively for the re-laying of filter-feeding bivalve molluscs, echinoderms and tunicates with a view to their natural purification .

(Amendment No. 10)
Article 2(9)

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.

9. Purification: the process of removing microbiological contamination from live filter-feeding bivalve molluscs, echinoderms and tunicates with a view to making them suitable for human consumption by holding them for a sufficient time in healthy seawater.

(Amendment No. 11)
Article 2(10)

10. Expedition centre: an establishment for the reception, conditioning, washing, cleaning, calibration and wrapping of live bivalve molluscs which conform to the requirements of this Regulation.

10. Expedition centre: an establishment carrying out the operations of reception, conditioning, washing, cleaning, calibration and wrapping of live filter-feeding bivalve molluscs, echinoderms and tunicates which conform to the requirements of this Regulation.

The quantity of live bivalve molluscs handled in its conditioning installations shall not exceed the capacity of such a centre.

(Amendment No. 12)
Article 2(11)

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 micro-organisms to an acceptable level.

11. Purification plant: an establishment where live filter-feeding bivalve molluscs, echinoderms and tunicates are kept for purification and which may, when this process is completed, also serve as an expedition centre.

(Amendment No. 13)
Article 2(17)

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.

17. Placing on the market: the holding or displaying for sale, tasting or distribution, whether or not in return for payment, offering for sale, selling, delivering, or any other form of placing on the market of live filter-feeding bivalve molluscs, echinoderms and tunicates for human consumption either raw or after processing in the Community.

(Amendment No. 14)
Article 3(1)(b)

(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;

(b) they must have been collected and transported from the production area to an expedition centre or purification plant under the conditions laid down in Chapter II of the Annex or undergone the specific operations carried out by expedition centres on board an offshore establishment;

(Amendment No. 15)
Article 3(1)(a) and (b)

1. The placing on the market of 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;

1. The placing on the market of live filter-feeding bivalve molluscs, echinoderms and tunicates for immediate human consumption shall be subject to the following conditions:

(a) they must originate from production areas which comply with the requirements laid down in Chapter I of the annex and Directive 79/923/EEC;

(b) they must have been collected and transported from the production area to an expedition centre or purification centre under the conditions laid down in Chapter II of the Annex and Directive 79/923/EEC;

(Amendment No. 16)
Article 5(2)(a)

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 centres.

2.(a) The competent authorities shall establish a list of production areas on the basis of Directive 79/923/EEC with indication of their location and boundaries and their classification or their designation for re-laying and from which live filter-feeding bivalve molluscs, echinoderms and tunicates 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 producers and operators of purification centres and expedition centres.

Commission text

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(Amendment No. 17)

Article 5(2)(6)

(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.

(b) The monitoring of the production or re-laying 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, or that the production area is failing to satisfy the requirements of its classification, the competent authority shall close or downgrade the production area concerned until the situation as regards health conditions has been restored.

However, where several species of filter-feeding bivalve molluscs, echinoderms and tunicates are bred in the same production area, the closing or downgrading of the production area shall apply only to those species of bivalve molluscs, echinoderms and tunicates which no longer meet the requirements of this Regulation.

(Amendment No. 18)

Article 5(2)a (new)

2a. The lists drawn up pursuant to paragraphs 1(a) and 2(a) of this article shall be communicated to the Commission and the other Member States.

Commission text

Amendments

(Amendment No. 19)
Article 5(3)

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

3. The competent authorities concerned shall take all measures necessary to take account within an appropriate time-limit of the results referred to in Article 6(1).

If the competent authorities fail to take the necessary measures within the appropriate time-limit, the Commission may, as a precautionary measure, where the protection of public health so requires, suspend the approved status of an establishment or close or downgrade a production or re-laying area after notifying its intention to the competent authorities of the Member States concerned.

The Commission shall immediately inform the Member States of its decision. The decision may be amended by the procedure set out in Article 15. In case of need, the Commission may give notice of its decision by means of publication in the Official Journal or by any other means appropriate to the circumstances.

Commission text

Amendments

(Amendment No. 20)
Article 6(1)

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.

1. Representatives of the Commission may make on-the-spot checks. Wherever possible, the Commission representatives shall issue a prior invitation to the competent authority of the Member State concerned to accompany them. They may check whether establishments and production or re-laying areas 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 Commission representatives in carrying out their duties.

In carrying out their duties, the Commission representatives shall enjoy the rights of access accorded to the competent authority under Article 5(1)(b).

(Amendment No. 21)
Article 6(3)

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.

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. These recommendations shall have binding force only in respect of matters which are absolutely essential for uniform and correct implementation for this Regulation and after application of Article 16 thereof.

(Amendment No. 22)
Article 12(1)a (new)

1a. If the prohibition is imposed by a Member State, the Commission shall authorize or rescind the measure in question within 30 days on the basis of appropriate tests.

(Amendment No. 23)
ANNEX
CHAPTER I, title

CONDITIONS FOR HARVESTING AREAS

CONDITIONS FOR PRODUCTION AREAS

(Amendment No. 24)
ANNEX
CHAPTER I, point 1

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 can be collected.

(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 etc ...

(c) can be collected etc ...

1. The location and the boundaries of production areas must be fixed by the competent authority in such a way as to identify the areas in which, in accordance with the provisions of Directive 79/923/EEC, live filter-feeding bivalve molluscs, echinoderms and tunicates.

(a) can be produced for direct human consumption, live filter-feeding bivalve molluscs, echinoderms and tunicates taken from these areas shall meet the requirements set out in Chapter V;

(b) can be produced etc ...

(c) can be produced etc ...

(Amendment No. 25)
ANNEX
CHAPTER I, point 1a (new)

1a. The location and the boundaries of re-laying areas as defined in Article 2(7b) of this Regulation must be laid down and physically demarcated by the competent authorities, which shall ensure that the density of the filter-feeding bivalve molluscs, echinoderms and tunicates re-laid there is compatible with the purification to be carried out.

Commission text

Amendments

(Amendment No. 26)

ANNEX

CHAPTER I, point 2

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 centres.

2. Any change in the delimitation of production areas and their temporary or definite closure or downgrading 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 centres.

(Amendment No.27)

ANNEX

CHAPTER II, title and point 6

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

REQUIREMENTS FOR THE PRODUCTION AND TRANSPORTATION OF BATCHES TO AN EXPEDITION CENTRE OR PURIFICATION CENTRE

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, re-laying 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:

6. A registration document for the identification of batches of live bivalve molluscs during transport from the production area to an approved expedition centre, purification centre, re-laying site or processing plant shall be issued by the competent authority. For each batch, the competent authority shall require this registration document, the relevant sections of which have been completed by the producer legibly and indelibly, and which must contain the following information:

(Amendment No. 28)

ANNEX

CHAPTER III, throughout the chapter

re-laying site

re-laying area

Commission text

Amendments

(Amendment No. 29)

ANNEX

CHAPTER IV, Section I, introductory paragraph

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 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 and must not be near a waste water outlet.

(Amendment No. 30)

ANNEX

CHAPTER IV, Section I, point 2a (new)

2a.If the facilities are not connected to the mains drainage system they must have a waste disposal system which meets the legal requirements.

(Amendment No. 31)

ANNEX

CHAPTER IV, Section I, point 4, second subparagraph

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.

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

Commission text

Amendments

(Amendment No. 32)

ANNEX

CHAPTER IV, Section II, points 4 and 5

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.

4. Premises, equipment and instruments used for handling of live filter-feeding bivalve molluscs, echinoderms and tunicates 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 handling live filter-feeding bivalve molluscs, echinoderms and tunicates unless authorization by the competent authority.

(Amendment No. 33)

ANNEX

CHAPTER IV, section II, point 7

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.

7. The finished products must be stored under cover and must be kept away from the areas where marine species other than those covered by this Regulation, such as crustaceans, are handled.

(Amendment No.34)

ANNEX

CHAPTER IV, section III, point 3

3. The purification system must be supplied with sufficient seawater or flow of seawater per hour and per tonne of live bivalve molluscs treated.

3. The purification system must be supplied with sufficient seawater or saline solution or flow of seawater or saline solution per hour and per tonne of filter-feeding bivalve molluscs, echinoderms and tunicates treated.

(Amendment No. 35)

ANNEX

CHAPTER IV, section III, point 4

4. Clean seawater must be used for purifying live bivalve molluscs; (...); potable water used to prepare seawater from its major constituent chemicals shall conform to the meaning of Council Directive 80/778/EEC.

4. Healthy seawater or a saline solution within the meaning of Article 2(3a) of this Regulation must be used for purifying live filter-feeding bivalve molluscs, echinoderms and tunicates; (...).

(Amendment No. 36)

ANNEX

CHAPTER IV, section IV, point 1(a),

(a) conditioning must not cause any deleterious microbiological contamination of the product;

(a) conditioning must not cause any deleterious contamination of the product liable to affect the human metabolism;

(Amendment No. 37)

ANNEX

CHAPTER V, point 7

7. The Diarrhetic Shellfish Poison (DSP) content of the flesh shall not exceed levels which may be considered dangerous to human health.

7. The Diarrhetic Shellfish Poison (DSP) content of the soft parts shall be below levels likely to affect the human metabolism, to be established by the Community authorities.

(Amendment No. 38)

ANNEX

CHAPTER VI, point 1(b)

(b) to check the microbiological quality of the live bivalve molluscs in relation to the area of harvesting as laid down in Chapter I;

(b) to check the microbiological quality of and presence of any other abiotic contaminants in the live filter-feeding bivalve molluscs, echinoderms and tunicates in relation to the area of production as laid down in Chapter I;

Commission text

Amendments

(Amendment No. 39)

ANNEX

CHAPTER IX, point 1

1. Consignments of live bivalve molluscs destined for human consumption must be transported wrapped as a sealed parcel from the expedition centre up to the time of being offered for immediate sale to the consumer or retailer.

1. Consignments of live filter-feeding bivalve molluscs, echinoderms and tunicates destined for human consumption must be transported wrapped as a sealed package from the expedition centre up to the time of being offered for immediate sale to the consumer or retailer.

(Amendment No. 40)

ANNEX

CHAPTER X, point 1

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 centre. 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, as last amended by Directive 89/395/EEC, the mark must contain the following information:

- the country of dispatch,
- species of bivalve mollusc (common name and scientific name),
- the identification of the expedition centre by the approval number granted by the competent authority,
- the date of wrapping.

1. All parcels in a consignment of live filter-feeding bivalve molluscs, echinoderms and tunicates must be provided with a health mark so enabling at all times during transport and distribution until retail, the identification of their original production area. 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, as last amended by Directive 89/395/EEC, the mark must contain the following information:

- the country of dispatch, or export in the case of non-member countries,
- species of filter-feeding bivalve mollusc, echinoderm or tunicate (common name and scientific name),
- the identification of the production area by the approval numbers granted by the competent authority,
- the date of wrapping and the origin of the product.

