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II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 15 July 1991

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

(91/492/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas, with a view to achieving the internal market and more especially to ensure the smooth operation of the common organization of the market in fishery products established by Regulation (EEC) No 3796/81 ⁽⁴⁾ as last amended by Regulation (EEC) No 2886/89 ⁽⁵⁾, it is essential that the placing on the market of live bivalve molluscs should no longer be hindered by disparities existing in the Member States in respect of health requirements; whereas this will enable production and placing on the market to be better harmonized and bring about competition on equal terms while ensuring quality products for the consumer.

Whereas Council Directive 79/923/EEC of 30 October 1979 on the quality required of shellfish waters ⁽⁶⁾ lays down that it is necessary to establish the health requirements to be observed for shellfish products;

⁽¹⁾ OJ No C 84, 2. 4. 1990, p. 29.

⁽²⁾ OJ No C 183, 15. 7. 1991.

⁽³⁾ OJ No C 332, 31. 12. 1990, p. 1.

⁽⁴⁾ OJ No L 379, 31. 12. 1981, p. 1.

⁽⁵⁾ OJ No L 282, 2. 10. 1989, p. 1.

⁽⁶⁾ OJ No L 281, 10. 11. 1979, p. 47.

Whereas these 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, tunicates and marine gastropods;

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

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 whereas it is therefore necessary, in order to guarantee optimal protection of public health, to set up a Community system to ensure rapid adoption and where necessary reinforcement of the health standards to safeguard human health from virus contamination or other hazards;

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

Whereas it is primarily 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 requirements; whereas the competent authorities must in particular submit harvesting areas to a regular control to ensure that molluscs from these harvesting areas do not contain microorganisms and toxic substances in quantities which are considered to be dangerous to human health;

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

Whereas the rules, principles and safeguard measures established by Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries ⁽¹⁾, should apply to the case in question;

Whereas in the context of trade between the Member States, the rules laid down in Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade, with a view to the completion of the internal market ⁽²⁾ as amended by Directive 90/675/EEC should also be applied;

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

Whereas, so that account may be taken of particular circumstances, derogations should be granted to certain establishments already operating before 1 January 1993 so as to allow them to adapt to all the requirements laid down in this Directive;

Whereas, in the case of living animals that are edible whilst they are alive, a derogation should be made, with regard to the durability date, to the rules of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale ⁽³⁾ as last amended by Directive 91/72/EEC ⁽⁴⁾;

Whereas provision should be made for the possibility of adopting transitional measures in order to cover the absence of certain implementing rules;

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

⁽¹⁾ OJ No L 373, 31. 12. 1990, p. 1.

⁽²⁾ OJ No L 395, 30. 12. 1989, p. 13.

⁽³⁾ OJ No L 33, 8. 2. 1979, p. 1.

⁽⁴⁾ OJ No L 42, 16. 1. 1991, p. 27.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

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

With the exception of the provisions on purification, this Directive applies to echinoderms, tunicates and marine gastropods.

Article 2

For the purposes of this Directive, the following definitions shall apply:

1. 'bivalve molluscs' means filter-feeding lamellibranch molluscs;
2. 'marine biotoxins' means poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxin;
3. 'clean sea water' means sea water or brackish water which is to be used under the conditions laid down in this Directive and which is free from microbiological contamination and toxic and objectionable substances occurring naturally or after discharge in the environment such as those listed in the Annex to Directive 79/923/EEC, in such quantities as may adversely affect the health quality of bivalve molluscs or to impair their taste;
4. 'competent authority' means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence;
5. 'conditioning' means the storage of live bivalve molluscs, whose quality does not indicate the need for relaying or treatment in a purification plant, in tanks or any other installation containing clean sea water or in natural sites to remove sand, mud or slime;
6. 'gatherer' means any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market;
7. 'production area' means any sea, estuarine or lagoon area containing natural deposits of bivalve molluscs or sites used for cultivation of bivalve molluscs from which live bivalve molluscs are taken;
8. 'relaying area' means any sea, estuarine or lagoon area approved by the competent authority, with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs;

9. *'dispatch centre'* means any approved on-shore or off-shore installation for the reception, conditioning, washing, cleaning, grading and wrapping of live bivalve molluscs fit for human consumption;
10. *'purification centre'* means an approved establishment with tanks fed by naturally clean sea water or sea water that has been cleaned by appropriate treatment, in which live bivalve molluscs are placed for the time necessary to remove microbiological contamination, so making them fit for human consumption;
11. *'relaying'* means an operation whereby live bivalve molluscs are transferred to approved sea or lagoon areas or approved estuarine areas under the supervision of the competent authority for the time necessary to remove contamination. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening;
12. *'means of transport'* means those parts set aside for goods in automobile vehicles, rail vehicles and aircraft, the holds of vessels and containers for transport by land, sea or air;
13. *'wrapping'* means an operation whereby live bivalve molluscs are placed in packaging material adequate for the purpose;
14. *'consignment'* means a quantity of live bivalve molluscs handled in a dispatch centre or treated in a purification centre and subsequently intended for one or more customers;
15. *'batch'* means a quantity of live bivalve molluscs collected from a production area and subsequently intended for delivery to an approved dispatch centre, purification centre, relaying area or processing plant as appropriate;
16. *'placing on the market'* means the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market of live bivalve molluscs for human consumption either raw or for the purpose of processing in the Community, excluding the direct transfer on the local market in small quantities by the coastal fisherman to the retailer or the consumer which must be subject to the health checks laid down by national rules for checking on retail business;
17. *'importation'* means the introduction of live bivalve molluscs into the territory of the Community from third countries;
18. *'faecal coliform'* means facultative, aerobic, gram-negative, non-sporeforming, cytochrome oxidase negative, rod-shaped bacteria that are able to ferment lactose with gas production in the presence of bile salts, or other surface active agents with similar growth-inhibiting properties, at $44\text{ }^{\circ}\text{C} \pm 0,2\text{ }^{\circ}\text{C}$ within 24 hours at least;
19. *'E. coli'* means faecal coliforms which also form indole from tryptophan at $44\text{ }^{\circ}\text{C} \pm 0,2\text{ }^{\circ}\text{C}$ within 24 hours.

CHAPTER II

Provisions for Community production

Article 3

1. The placing on the market of live bivalve molluscs for immediate human consumption shall be subject to the following conditions:

- (a) they must originate from production areas which comply with the requirements laid down in Chapter I of the Annex; however, in the case of pectinidae, this provision shall apply only to aquaculture products as defined in Article 2 (2) of Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and placing on the market of fishery products ⁽¹⁾;
- (b) they must have been harvested and transported from the production area to a dispatch centre, purification centre, relaying area or processing plant under the conditions laid down in Chapter II of the Annex;
- (c) where provided for in this Directive, they must have been relaid in suitable areas approved for that purpose and complying with the conditions laid down in Chapter III of the Annex;
- (d) they must have been handled hygienically, and where appropriate, they must have been purified in establishments approved for that purpose and complying with the requirements of Chapter IV of the Annex;
- (e) they must comply with the criteria set out in Chapter V of the Annex;
- (f) health controls must have been carried out in accordance with Chapter VI of the Annex;
- (g) they must have been appropriately wrapped in accordance with Chapter VII of the Annex;
- (h) they must have been stored and transported under satisfactory conditions of hygiene in accordance with Chapters VIII and IX of the Annex;
- (i) they must bear a health mark as provided for in Chapter X of the Annex.

2. Live bivalve molluscs intended for further processing must comply with the relevant requirements of paragraph 1 and be processed in accordance with the requirements of Council Directive 91/493/EEC.

Article 4

Member States shall ensure that persons handling live bivalve molluscs during their production and placing on the market shall adopt all measures necessary to comply with the requirements of this Directive.

Persons responsible for dispatch and purification centres shall in particular ensure that:

⁽¹⁾ See page 15 of this Official Journal.

- representative numbers of samples for laboratory examination are regularly taken and analysed in order to establish an historical record on the basis of the areas where batches come from and of the health quality of the live bivalve molluscs both before and after handling at a dispatch centre or purification centre.
- a register is kept for the permanent record of the results of the various checks and kept for presentation to the competent authority.

Article 5

1. (a) The competent authority shall approve dispatch centres and purification centres once it is satisfied that they meet the requirements of this Directive. The competent authority shall take the necessary measures if the requirements cease to be met. In so doing, it shall take account of, in particular, the outcome of any check carried out in accordance with Article 6 (1).

However, subject to the express condition that live molluscs coming from such centres meet the hygiene standards set by this Directive, Member States may, for the requirements relating to equipment and structures laid down in Chapter IV of the Annex, to be specified before 1 October 1991 in accordance with the procedure laid down in Article 12, grant to dispatch and purification centres, a further period expiring on 31 December 1995 within which to comply with the conditions of the approval set out in the abovementioned Chapter. Such derogations may be granted only to establishments, already operating on 31 December 1991, which have, before 1 July 1992, submitted a duly substantiated application for derogation to the competent national authority. This application must be accompanied by a work plan and programme indicating the period within which it would be possible for the establishments to comply with the requirements in question. Where financial assistance is requested from the Community, only requests in respect of projects complying with the requirements of this Directive can be accepted.

The competent authority shall draw up a list of approved dispatch centres and purification centres, each of which shall have an official number.

The list of approved dispatch centres and purification centres, and any subsequent amendments thereto, must be communicated by each Member State to the Commission, which shall pass such information on to the other Member States.

- (b) The inspection and monitoring of these centres shall be carried out regularly under the responsibility of the competent authority, which shall have free access to all parts of the centres, in order to ensure compliance with the provisions of this Directive.

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

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

This list must be communicated to those affected by this Directive, such as gatherers and operators of purification centres and dispatch centres.

- (b) The monitoring of the production and relaying areas shall be carried out under the responsibility of the competent authority in accordance with the requirements of this Directive.

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

3. The competent authority may prohibit any production and harvesting of bivalve molluscs in areas considered unsuitable for these activities for health reasons.

Article 6

1. Experts from the Commission may, in cooperation with the competent authorities of the Member States, make on-the-spot checks insofar as is necessary to ensure the uniform application of this Directive. They may, in particular, check whether centres, production and relaying areas are in effect complying with the requirements of this Directive. A Member State in whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the Member States of the results of such checks.

2. The arrangements for implementing paragraph 1 shall be adopted in accordance with the procedure laid down in Article 12.

3. The Commission, may draw up recommendations containing guidelines on good manufacturing practices applicable at the different stages of production and placing on the market.

Article 7

1. The rules laid down in Directive 89/662/EEC as regards live bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption, shall apply, in particular as regards the organization of and the action to be taken following the checks to be carried out by the Member State of destination, and the safeguard measures to be implemented.

2. Directive 89/662/EEC shall be amended as follows:

(a) In Annex A, the following indent shall be added:

‘— Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and placing on the market of live bivalve molluscs, (OJ No L 268, 24. 9. 1991, p. 1.);

(b) in Annex B, the following indent shall be deleted:

‘— live bivalve molluscs intended for human consumption’.

(c) the actual health conditions during the production and placing on the market of live bivalve molluscs and in particular the monitoring of production areas in relation to microbiological and environmental contamination, and to the presence of marine biotoxins;

(d) the regularity and the rapidity of the information provided by the third country on the presence of plankton containing toxin in the production areas and, in particular, of species not occurring in Community waters, and risks that such presence may signify for the Community;

(e) the assurances which a third country can give on the compliance with the standards laid down in Chapter V of the Annex;

CHAPTER III

Imports from third countries

Article 8

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

Article 9

In order to ensure the uniform application of the requirement imposed in Article 8, the following procedure shall apply:

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

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

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

The frequency and the procedure for these inspections shall be determined in accordance with the procedure laid down in Article 12;

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

(a) the legislation of the third country;

(b) the organization of the competent authority of the third country and of its inspection services, the powers of such services and the supervision to which they are subject, as well as their facilities for monitoring the implementation of their legislation in force;

3. the Commission, following the procedure laid down in Article 12, shall decide on:

(a) the list of third countries fulfilling the conditions of equivalence referred to in paragraph 2;

(b) for each third country, the specific conditions for the importation of live bivalve molluscs. These conditions must include:

(i) the procedure for obtaining a health certificate which must accompany consignments when forwarded to the Community;

(ii) the demarcation of the production areas from which live bivalve molluscs may be harvested and imported;

(iii) the obligation to notify the Community of any possible change in the approval of production areas;

(iv) any purification after arrival in the territory of the Community;

(c) a list of establishments from which the importation of live bivalve molluscs is authorized. For that purpose, one or more lists of such establishments shall be established. An establishment may not appear on a list unless it is officially approved by the competent authority of the third country exporting to the Community. Such approval shall be subject to observance of the following requirements:

— compliance with requirements equivalent to those laid down in this Directive,

— monitoring by an official inspection service of the third country;

4. the decisions referred to in paragraph 3 may be amended in accordance with the procedure laid down in Article 12.

These decisions and the amendments thereto shall be published in the *Official Journal of the European Communities*, L series;

5. pending the decisions referred to in paragraph 3, the conditions which Member States shall apply to imports

of live bivalve molluscs from third countries shall be at least equivalent to those governing the production and placing on the market of Community products.

Article 10

The rules and principles laid down in Directive 90/675/EEC shall apply, with particular reference to the organization of and follow up to the inspections to be carried out by the Member States and the safeguard measures to be implemented.

Without prejudice to compliance with the rule and principles referred to in the first subparagraph of this Article and pending implementation of the decisions provided for in Article 8 (3) and Article 30 of Directive 90/675/EEC, the relevant national rules for applying Article 8 (1) and (2) of the said Directive shall continue to apply.

CHAPTER IV

Final provisions

Article 11

The chapters of the Annex may be amended by the Council, acting by a qualified majority on a proposal from the Commission.

The Commission shall, before 1 January 1994, submit to the Council, after receiving the opinion of the Scientific Veterinary Committee, a report on Chapters I and V of the Annex, accompanied by any proposed amendments to those Chapters.

Article 12

1. Where the procedure laid down in this Article is to be followed, the Chairman shall refer the matter to the Standing Veterinary Committee hereafter referred to as the committee, either on his own initiative or at the request of a Member State.

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

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

(b) If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay,

submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission save where the Council has decided against the said measures by a simple majority.

Article 13

In order to take into account the possible failure to take a decision on the detailed rules for applying this Directive by 1 January 1993, necessary transitional measures may be adopted in accordance with the procedure laid down in Article 12 for a period of two years.

Article 14

The Commission shall, after consulting the Member States, submit, before 1 July 1992, a report to the Council on the minimum requirements to be met with regard to structure and equipment by small dispatch centres or by small establishments ensuring distribution on the local market and situated in areas subject to particular constraints with respect to their supply, possibly accompanied by proposals, on which the Council will take a decision, acting in accordance with the voting procedure laid down in Article 43 of the Treaty, before 31 December 1992.

The provisions of this Directive shall be re-examined before 1 January 1998 by the Council, acting on a Commission proposal, in the light of the experience gained.

Article 15

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1993. They shall notify the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 16

This Directive is addressed to the Member States.

Done at Brussels, 15 July 1991.

For the Council
The President
P. BUKMAN

ANNEX

CHAPTER I

CONDITIONS FOR PRODUCTION AREAS

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 from which live bivalve molluscs:
 - (a) can be collected for direct human consumption. Live bivalve molluscs taken from these areas must meet the requirements set out in Chapter V of this Directive;
 - (b) can be collected but only placed on the market for human consumption after treatment in a purification centre, after relaying. Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three-dilution MPN-test of 6 000 faecal coliforms per 100 g of flesh or 4 600 *E. Coli* per 100 g of flesh in 90 % of samples.

After purification or relaying, all the requirements set out in Chapter V of this Annex must be met;
 - (c) can be collected but placed on the market only after relaying over a long period (at least two months), whether or not combined with purification, or after intensive purification for a period to be fixed in accordance with the procedure provided for in Article 12 of this Directive, so as to meet the requirements under (a). Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three-dilution MPN-test of 60 000 faecal coliforms per 100 g of flesh.
2. Any change in the demarcation of production areas and the temporary or definitive closure thereof must be immediately announced by the competent authority to those affected by this Directive and in particular to producers and operators of purification and dispatch centres.

CHAPTER II

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

1. Harvesting techniques must not cause excessive damage to the shells or tissues of live bivalve molluscs.
2. Live bivalve molluscs must be adequately protected from crushing, abrasion or vibration after harvesting and must not be exposed to extremes of hot or cold temperature.
3. Techniques for harvesting, transporting, landing and handling live bivalve molluscs must not result in additional contamination of the product, nor in a significant reduction in the quality of the product, nor in any changes significantly affecting their ability to be treated by purification, processing or relaying.
4. Live bivalve molluscs must not be re-immersed in water which could cause additional contamination between harvesting and landing.
5. The means of transport used for transporting live bivalve molluscs must be used under conditions which protect the latter from additional contamination and crushing of shells. They must permit adequate drainage and cleaning.

In the event of bulk transport over long distances of live bivalve molluscs to a dispatch centre, purification centre, relaying area or processing plant, the means of transport must be equipped in such a way as to ensure the best survival conditions possible, and in particular must comply with the requirements laid down in Chapter IX, Section 2 of this Annex.

6. A registration document for the identification of batches of live bivalve molluscs during transport from the production area to a dispatch centre, purification centre, relaying area or processing plant is issued by the competent authority upon request by the gatherer. For each batch, the gatherer must complete legibly and indelibly the relevant sections of the registration document which must contain the following information:
 - the gatherer's identity and signature,
 - the date of harvesting,
 - the location of the production area in as precise detail as is practicable,

- the shellfish species and quantity indicated in as precise detail as is practicable,
- the approval number and place of destination for wrapping, relaying, purification or processing.

The registration documents must be numbered permanently in sequence. The competent authority must keep a register indicating numbers of registration documents together with the names of the persons collecting live bivalve molluscs and to whom the documents were issued. The registration document for each batch of live bivalve molluscs must be date-stamped upon delivery of a batch to a dispatch centre, purification centre, relaying area or processing plant and must be kept by operators of such centres, areas or establishments for at least 60 days.

However, if gathering is carried out by the same staff operating the dispatch centre, purification centre, relaying area or processing plant of destination, the registration document may be replaced by a permanent transport authorization granted by the competent authority.

7. If a production or relaying area is closed temporarily, the competent authority must refrain from issuing registration documents for that area and immediately suspend the validity of all registration documents already issued.

CHAPTER III

CONDITIONS FOR RELAYING LIVE BIVALVE MOLLUSCS

The following conditions must be met:

1. live bivalve molluscs must be gathered and transported in accordance with the requirements of Chapter II of this Annex;
2. techniques for handling live bivalve molluscs intended for relaying must permit the resumption of filter-feeding activity after immersion in natural waters;
3. live bivalve molluscs must not be relaid at a density which does not permit purification;
4. live bivalve molluscs must be immersed in seawater at the relaying area for an appropriate period which must exceed the time taken for levels of faecal bacteria to become reduced to the levels permitted by this Directive taking account of the fact that the standards of Chapter V of this Annex must be met;
5. the minimum water temperature for effective relaying must, where necessary, be determined and announced by the competent authority for each species of live bivalve mollusc and approved relaying area;
6. areas for relaying live bivalve molluscs must be approved by the competent authority. The boundaries of the sites must be clearly identified by buoys, poles or other fixed means; there must be a minimum distance of 300 metres between relaying areas, and also between relaying areas and production areas;
7. sites within a relaying area must be well separated to prevent mixing of batches; the 'all in, all out' system must be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed;
8. permanent records of the source of live bivalve molluscs, relaying periods, relaying areas and subsequent destination of the batch after relaying must be kept by the operators of relaying areas for inspection by the competent authority;
9. after harvesting from the relaying area, batches must, during transport from the relaying area to the approved dispatch centre, purification centre or processing plant, be accompanied by the registration document referred to in Chapter II, section 6 of this Annex, except in the case where the same staff operates both the relaying area and the dispatch centre, purification centre or processing plant.

CHAPTER IV

CONDITIONS FOR THE APPROVAL OF DISPATCH OR PURIFICATION CENTRES

I. General conditions relating to premises and equipment

Centres must not be located in areas which are close to 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.

Centres must have at least:

1. on premises where live bivalve molluscs are handled or stored:
 - (a) buildings or facilities of sound construction, designed and maintained adequately for the purpose of preventing contamination of live bivalve molluscs by any type of waste, dirty water, fumes, dirt or by the presence of rodents or other animals;
 - (b) flooring which is easy to keep clean and is laid in such a way as to facilitate drainage;
 - (c) adequate working space to allow for satisfactory performance of all operations;
 - (d) durable walls which are easy to clean;
 - (e) adequate natural or artificial lighting;
2. access to an appropriate number of changing rooms, wash basins and lavatories; there must be a sufficient number of wash basins close to the lavatories;
3. adequate equipment for washing tools, containers and equipment;
4. facilities for the supply and, where appropriate, storage of exclusively potable water within the meaning of Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption ⁽¹⁾ or facilities for the supply of clean sea water.

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

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

II. General hygiene requirements

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

1. staff who treat or handle live bivalve molluscs must in particular wear clean working clothes and, where appropriate, gloves which are suitable for the work in which the person is engaged;
2. staff are obliged to refrain from personal behaviour, such as spitting, which could result in contamination of live bivalve molluscs; any person suffering from an illness which can be transmitted by live bivalve molluscs must be temporarily prohibited, until recovery, from working with or handling these products;
3. any rodents, insects or other vermin found must be destroyed and further infestation prevented. Domestic animals must not enter the facilities;
4. premises, equipment and instruments used for handling live bivalve molluscs must 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 and at such other times as may be appropriate;
5. premises, instruments and equipment must not be used for purposes other than the handling of live bivalve molluscs without authorization by the competent authority;
6. waste products must be stored hygienically in a separate area and, where appropriate, in covered containers suitable for the purpose intended. Waste material must be removed from the vicinity of the establishment at appropriate intervals;
7. the finished products must be stored under cover and must be kept away from the areas where animals other than live bivalve molluscs, such as crustaceans, are handled.

III. Requirements for purification centres

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

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

⁽¹⁾ OJ No L 229, 30. 8. 1980, p. 11. Directive last amended by the 1985 Act of Accession (OJ No L 302, 15. 11. 1985, p. 218).

2. live bivalve molluscs must be washed free of mud with pressurized clean sea water or potable water before purification. The initial washing may also be carried out in the purification tanks before purification commences, the drainage pipes being kept open during the entire initial washing and sufficient time being allowed thereafter for the system to be flushed clean before the purification process begins;
3. the purification tanks must be supplied with a sufficient flow of sea water per hour and per tonne of live bivalve molluscs treated;
4. clean sea water or sea water cleaned by treatment must be used for purifying live bivalve molluscs; the distance between the sea water intake point and the waste water outlets must be sufficient to avoid contamination; if treatment of the sea water is necessary, the process shall be authorized once its effectiveness has been verified by the competent authority; potable water used to prepare sea water from its major constituent chemicals must comply with the requirements laid down in Directive 80/778/EEC;
5. operation of the purification system must allow live bivalve molluscs to rapidly resume filter feeding activity, remove sewage contamination, not to become recontaminated and be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market;
6. the quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre; the live bivalve molluscs must be continuously purified for a period sufficient to allow the microbiological standards laid down in Chapter V of this Annex to be met. This period starts from the moment at which the live bivalve molluscs in the purification tanks are adequately covered by the water until the moment when they are removed.

The purification centre must take account of the data relating to the raw materials (the type of bivalve mollusc, its area of origin, microbe content, etc.) in case it is necessary to extend the purification period so as to ensure that the live bivalve molluscs meet the bacteriological requirements of Chapter V of this Annex;

7. should a purification tank contain several batches of molluscs, they must be of the same species and come from the same production area or different areas conforming to the same health conditions. The length of the treatment must be based on the time required by the batch needing the longest period of purification;
8. containers used to hold live bivalve molluscs in purification systems must have a construction which allows sea water to flow through; the depth of layers of live bivalve molluscs should not impede the opening of shells during purification;
9. no crustaceans, fish or other marine species must be kept in a purification tank in which live bivalve molluscs are undergoing purification;
10. after completion of purification, the shells of live bivalve molluscs must be washed thoroughly by hosing with potable water or clean sea water; this may take place in the purification tank if necessary; the washing water must not be recirculated;
11. purification centres must have their own laboratories or secure the services of a laboratory equipped with the necessary facilities for checking the efficiency of purification by use of microbiological specifications. Laboratory facilities outside the centres must be recognized by the competent authority;
12. purification centres must regularly keep a record of the following data:
 - results of microbiological tests on purification system water entering the purification tanks;
 - results of microbiological tests on unpurified live bivalve molluscs;
 - results of microbiological tests on purified live bivalve molluscs;
 - dates and quantities of live bivalve molluscs delivered to the purification centre and corresponding registration document numbers;
 - the times of filling and emptying of purification systems (purification times);
 - dispatch details of consignments after purification.

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

13. purification centres must accept only those batches of live molluscs which are accompanied by the registration document referred to in Chapter II of this Annex;
Purification centres dispatching batches of live bivalve molluscs to dispatch centres must provide the registration document referred to in Chapter II, section 6 of this Annex.
14. every package containing purified live bivalve molluscs must be provided with a label certifying that all molluscs have been purified.

IV. Requirements for dispatch centres

1. In addition to the requirements under Sections I and II, the following conditions must be met:
 - (a) conditioning must not cause any contamination of the product; conditioning facilities must be used in accordance with procedures recognized by the competent authorities, with special regard to the bacteriological and chemical quality of the sea water used in those facilities;
 - (b) equipment and containers in the conditioning facilities must not constitute a source of contamination;
 - (c) procedures for calibration of live bivalve molluscs must not result in additional contamination of the product or in any changes affecting the ability of the product to be transported and stored after wrapping;
 - (d) any washing or cleaning of live bivalve molluscs must be carried out using pressurized clean sea water or potable water; cleaning water may not be recycled.
2. Dispatch centres must accept only those batches of live bivalve molluscs which are accompanied by the registration document referred to in Chapter II, section 6 of this Annex and coming from an approved production area, relaying area or purification centre.
3. Dispatch centres must have their own laboratories or secure the services of a laboratory equipped with the necessary facilities for checking, *inter alia*, whether the molluscs comply with the microbiological standards of Chapter V of this Annex. Laboratory facilities outside the centres must be recognized by the competent authority.

However, these requirements do not apply to dispatch centres obtaining their molluscs exclusively and directly from a purification centre where they have been examined after purification.

4. Dispatch centres must keep the following data at the disposal of the competent authority:
 - results of microbiological tests on live bivalve molluscs from an approved production area or relaying area;
 - dates and quantities of live bivalve molluscs delivered to the dispatch centre and corresponding registration document numbers;
 - dispatch details.

These data must be classified chronologically and preserved for a period to be laid down by the competent authority, but not less than three months.

5. Dispatch centres situated aboard vessels shall be subject to the conditions laid down in point 1 (b), (c) and (d) and in points 3 and 4. The conditions laid down in I and II shall apply *mutatis mutandis* to such dispatch centres although special conditions may be laid down in accordance with the procedure laid down in Article 12 of this Directive.

CHAPTER V

REQUIREMENTS CONCERNING LIVE BIVALVE MOLLUSCS

Live bivalve molluscs intended for immediate human consumption must comply with the following requirements:

1. The possession of visual characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion, and normal amounts of intravalvular liquid.
2. They must contain less than 300 faecal coliforms or less than 230 *E. Coli* per 100 g of mollusc flesh and intravalvular liquid based on a five-tube, three-dilution MPN-test or any other bacteriological procedure shown to be of equivalent accuracy.
3. They must not contain salmonella in 25 g of mollusc flesh.
4. They must not contain toxic or objectionable compounds occurring naturally or added to the environment such as those listed in the Annex to Directive 79/923/EEC in such quantities that the calculated dietary intake exceeds the permissible daily intake (PDI), or that the taste of the molluscs may be impaired.

In accordance with the procedure laid down in Article 12 of this Directive, the Commission shall determine the testing methods for checking the chemical criteria and the limit values applicable.

5. The upper limits as regards the radionuclide contents must not exceed the limits for foodstuffs as laid down by the Community.
6. The total Paralytic Shellfish Poison (PSP) content in the edible parts of molluscs (the whole body or any part edible separately) must not exceed 80 microgrammes per 100 g of mollusc flesh in accordance with the biological testing method — in association if necessary with a chemical method for detection of Saxitoxin — or any other method recognized in accordance with the procedure laid down in Article 12 of this Directive.

If the results are challenged, the reference method shall be the biological method.
7. The customary biological testing methods must not give a positive result to the presence of Diarrhetic Shellfish Poison (DSP) in the edible parts of molluscs (the whole body or any part edible separately).
8. In the absence of routine virus testing procedures and the establishment of virological standards, health checks must be based on faecal bacteria counts.

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

For the uniform application of this Directive sampling plans as well as the methods and analytical tolerances to be applied in order to check compliance with the requirements of this Chapter must be established in accordance with the procedure laid down in Article 12 of this Directive.

The effectiveness of the faecal indicator bacteria and their numerical limits as well as the other parameters laid down in this Chapter must be kept under constant review and, where scientific evidence proves the need to do so, be revised following the procedure laid down in Article 12 of this Directive.

When there is scientific evidence indicating the need to introduce other health checks or to amend the parameters in this Chapter for the purpose of protecting public health, such measures must be adopted in accordance with the procedure laid down in Article 12.

CHAPTER VI

PUBLIC HEALTH CONTROL AND MONITORING OF PRODUCTION

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

1. periodic monitoring of live bivalve mollusc relaying and production areas in order to:
 - (a) avoid any malpractice with regard to the origin and destination of the live bivalve molluscs;
 - (b) check the microbiological quality of the live bivalve molluscs in relation to the production and relaying areas;
 - (c) check the possible presence of toxin-producing plankton in production and relaying waters and biotoxins in live bivalve molluscs;
 - (d) check the possible presence of chemical contaminants, the maximum authorized level of which will be fixed, in accordance with the procedure laid down in Article 12 of this Directive, by 31 December 1992.

For the purposes of points (c) and (d), sampling plans must be established by the competent authorities for checking such possible presence at regular intervals or on a case-by-case basis in the event of irregular periods of harvesting.

2. Sampling plans as provided for in point 1, must in particular take account of:
 - (a) likely variations in faecal contamination at each production and relaying area;
 - (b) possible variations in production at relaying areas in the presence of plankton containing marine biotoxins. The sampling must be carried out as follows:
 - (i) monitoring: periodic sampling organized to detect changes in the composition of the plankton containing toxins and the geographical distribution thereof. Information leading to a suspicion of accumulation of toxins in mollusc flesh must be followed by intensive sampling;

(ii) intensive sampling:

- monitoring plankton in the growing and fishing waters by increasing the number of sampling points and the number of samples, and
- toxicity tests using the molluscs from the affected area which are most susceptible to contamination.

Placing on the market of molluscs from that area may not be re-authorized until new sampling has provided satisfactory toxicity test results;

(c) possible contamination of the molluscs in the production and relaying area;

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

3. Laboratory tests in order to check compliance with the requirements for the end product as laid down in Chapter V of this Annex. A control system must be established to verify that the level of marine biotoxins does not exceed safety limits.
4. An inspection of establishments at regular intervals. These inspections must include in particular checks:
 - (a) to verify whether the approval conditions are still being complied with;
 - (b) on the cleanliness of the premises, facilities, equipment and on staff hygiene;
 - (c) to verify whether the live bivalve molluscs are handled and treated correctly;
 - (d) on the correct application and functioning of purification or conditioning systems;
 - (e) on the ledger books referred to in Chapter IV section III, 12 of this Annex,
 - (f) on the correct use of health marks.

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

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

CHAPTER VII

WRAPPING

1. Live bivalve molluscs must be wrapped under satisfactory conditions of hygiene.

The wrapping material or container must:

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

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

CHAPTER VIII

PRESERVATION AND STORAGE

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

CHAPTER IX

TRANSPORT FROM THE DISPATCH CENTRE

1. Consignments of live bivalve molluscs intended for human consumption must be transported wrapped as sealed parcels from the dispatch centre until offered for sale to the consumer or retailer.
2. The means of transport used for consignments of live bivalve molluscs must have the following characteristics:
 - (a) their interior walls and any other parts which might come into contact with the live bivalve molluscs must be made of corrosion-resistant materials; the walls must be smooth and easy to clean;
 - (b) they must be suitably equipped to provide efficient protection of the live bivalve molluscs against extremes of hot and cold, contamination with dirt or dust, and damage to the shells from vibration and abrasion;
 - (c) the live bivalve molluscs must not be transported with other products which might contaminate them.
3. Live bivalve molluscs must be transported and distributed using closed vehicles or containers which maintain the product at a temperature which does not adversely affect their quality and viability.

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

Where ice is used in transporting consignments of live bivalve molluscs, it must have been made from potable water or clean sea water.

CHAPTER X

MARKING OF CONSIGNMENTS

1. All parcels in a consignment of live bivalve molluscs must be provided with a health mark so that the original dispatch centre may be identified at all times during transport and distribution until retail sale. Without prejudice to Directive 79/112/EEC, the mark must contain the following information:
 - the country of dispatch,
 - the species of bivalve mollusc (common name and scientific name),
 - the identification of the dispatch centre by the approval number issued by the competent authority,
 - the date of wrapping, comprising at least the day and the month.

By way of derogation from Directive 79/112/EEC the date of durability may be replaced by the entry 'these animals must be alive when sold'.

2. The health mark may be printed on the wrapping material or be put on a separate label which is then affixed to the wrapping material or put inside the wrapping. It may also be of a twist-tie or staple design; self-adhesive health marks must not be used, unless they are not detachable. All types of health mark must be for single use only and may not be transferred.
3. The health mark must be durable and waterproof, and the information presented must be legible, indelible and in easily decipherable characters.
4. The health mark attached to consignments of live bivalve molluscs which are not wrapped in individual consumer-size parcels must be kept for at least 60 days by the retailer after splitting up the contents of the consignment.

COUNCIL DIRECTIVE

of 22 July 1991

laying down the health conditions for the production and the placing on the market of fishery products

(91/493/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposals from the Commission ⁽¹⁾,

Having regard to the opinions of the European Parliament ⁽²⁾,

Having regard to the opinions of the Economic and Social Committee ⁽³⁾,

Whereas, with a view to achieving the internal market and more especially to ensuring the smooth operation of the common organization of the market in fishery products established by Regulation (EEC) No 3796/81 ⁽⁴⁾, as last amended by Regulation (EEC) No 2886/89 ⁽⁵⁾, it is essential that the marketing of fish and fish products should no longer be hindered by disparities existing in the Member States in respect of health requirements; whereas this will enable production and placing on the market to be better harmonized and bring about competition on equal terms, whilst ensuring quality products for the consumer;

Whereas the European Parliament in its legislative resolution of 17 March 1989 ⁽⁶⁾ requested the Commission to come forward with comprehensive proposals on the hygienic production and placing on the market of fishery products, including solutions for the problem of nematodes;

Whereas fishery products freshly caught are in principle free of contamination with micro-organisms; whereas however contamination and subsequent decomposition may occur when handled and treated unhygienically;

Whereas therefore the essential requirements should be laid down for the correct hygienic handling of fresh and processed fishery products at all stages of production and during storage and transport;

Whereas it is appropriate to apply by analogy certain marketing standards which are laid down pursuant to Article 2 of Regulation (EEC) No 3796/81, in order to fix the health quality of these products;

Whereas it is the responsibility primarily of the fisheries industry to ensure that fishery products meet the health requirements laid down in this Directive;

Whereas the competent authorities of the Member States must, by carrying out checks and inspections, ensure that producers and manufacturers comply with the said requirements;

Whereas Community control measures should be introduced to guarantee the uniform application in all Member States of the standards laid down in this Directive;

Whereas, in order to ensure the smooth operation of the internal market, the measures should apply in an identical manner to trade within the Member States and to trade between the Member States;

Whereas in the context of intra-Community trade, the rules laid down in Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽⁷⁾ as amended by Directive 90/675/EEC ⁽⁸⁾ apply to fishery products;

Whereas fishery products from third countries intended to be placed on the market of the Community must not qualify for more favourable arrangements than those applied in the Community; whereas provision should therefore be made for a Community procedure for the inspection in third countries of the conditions of production and placing on the market in order to permit the application of a common import system based on conditions of equivalence;

Whereas the products in question are subject to the rules concerning checks and to safeguard measures covered by Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries;

Whereas, so that account may be taken of particular circumstances, derogations should be granted to some establishments already operating before 1 January 1993 so as to allow them to adapt to all the requirements laid down in this Directive;

⁽¹⁾ OJ No C 66, 11. 3. 1988, p. 2;

OJ No C 282, 8. 11. 1989, p. 7 and OJ No C 84, 2. 4. 1990, p. 56.

⁽²⁾ OJ No C 96, 17. 4. 1989, p. 29 and OJ No C 183, 15. 7. 1991.

⁽³⁾ OJ No C 134, 24. 5. 1988, p. 31 and OJ No C 332, 31. 12. 1990, p. 59.

⁽⁴⁾ OJ No L 379, 31. 12. 1981, p. 1.

⁽⁵⁾ OJ No L 282, 2. 10. 1989, p. 1.

⁽⁶⁾ OJ No C 96, 17. 4. 1989, p. 199.

⁽⁷⁾ OJ No L 395, 30. 12. 1989, p. 13.

⁽⁸⁾ OJ No L 373, 31. 12. 1990, p. 1.

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

Whereas the essential requirements laid down in this Directive may need further specification,

HAS ADOPTED THIS DIRECTIVE

CHAPTER I

General provisions

Article 1

This Directive lays down the health conditions for the production and the placing on the market of fishery products for human consumption.

Article 2

For the purposes of this Directive, the following definitions shall apply:

1. *'fishery products'* means all seawater or freshwater animals or parts thereof, including their roes, excluding aquatic mammals, frogs and aquatic animals covered by other Community acts;
2. *'aquaculture products'* means all fishery products born and raised in controlled conditions until placed on the market as a foodstuff. However seawater or freshwater fish or crustaceans caught in their natural environment when juvenile and kept until they reach the desired commercial size for human consumption are also considered to be aquaculture products. Fish and crustaceans of commercial size caught in their natural environment and kept alive to be sold at a later date are not considered to be aquaculture products if they are merely kept alive without any attempt being made to increase their size or weight;
3. *'chilling'* means the process of cooling fishery products to a temperature approaching that of melting ice;
4. *'fresh products'* means any fishery product whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, which have not undergone any treatment to ensure preservation other than chilling;
5. *'prepared products'* means any fishery product which has undergone an operation affecting its anatomical wholeness, such as gutting, heading, slicing, filleting, chopping, etc.;
6. *'processed products'* means any fishery product which has undergone a chemical or physical process such as the heating, smoking, salting, dehydration or marinating, etc., of chilled or frozen products, whether or not associated with other foodstuffs, or a combination of these various processes;
7. *'preserve'* means the process whereby products are packaged in hermetically sealed containers and subjected to heat treatment to the extent that any micro-organisms that might proliferate are destroyed or inactivated, irrespective of the temperature at which the product is to be stored;
8. *'frozen products'* means any fishery product which has undergone a freezing process to reach a core temperature of -18°C or lower after temperature stabilization;
9. *'packaging'* means the procedure of protecting fishery products by a wrapper, a container or any other suitable device;
10. *'batch'* means the quantity of fishery products obtained under practically identical circumstances;
11. *'consignment'* means the quantity of fishery products bound for one or more customers in the country of destination and conveyed by one means of transport only;
12. *'means of transport'* means those parts set aside for goods in automobile vehicles, rail vehicles and aircraft, the holds of vessels, and containers for transport by land, sea or air;
13. *'competent authority'* means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence;
14. *'establishment'* means any premises where fishery products are prepared, processed, chilled, frozen, packaged or stored. Auction and wholesale markets in which only display and sale by wholesale takes place are not deemed to be establishments;
15. *'placing on the market'* means the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market in the Community, excluding retail sales and direct transfers on local markets of small quantities by fishermen to retailers or consumers, which must be subject to the health checks laid down by national rules for checking the retail trade;
16. *'importation'* means the introduction into the territory of the Community of fishery products from third countries;

17. 'clean seawater' means seawater or briny water which is free from microbiological contamination, harmful substances and/or toxic marine plankton in such quantities as may affect the health quality of fishery products and which is used under the conditions laid down in this Directive;
18. 'factory vessel' means any vessel on which fishery products undergo one or more of the following operations followed by packaging: filleting, slicing, skinning, mincing, freezing or processing.

The following are not deemed to be 'factory vessels':

- fishing vessels in which only shrimps and molluscs are cooked on board;
- fishing vessels on board which only freezing is carried out.

Article 3

1. The placing on the market of fishery products caught in their natural environment shall be subject to the following conditions:

- (a) they must have:
- (i) been caught and where appropriate handled for bleeding, heading, gutting and the removal of fins, chilled or frozen, on board vessels in accordance with hygiene rules to be established by the Council acting by a qualified majority on a proposal from the Commission. The Commission shall submit proposals to that effect before 1 October 1992;
 - (ii) where appropriate, been handled in factory vessels approved in accordance with Article 7, and in accordance with the requirements of Chapter I of the Annex.

The cooking of shrimps and molluscs on board must comply with the provisions of Chapter III, section I(5), or Chapter IV, section IV(7), of the Annex. Such vessels shall be specifically registered by the competent authorities;

- (b) during and after landing they must have been handled in accordance with Chapter II of the Annex;
- (c) they must have been handled and, where appropriate, packaged, prepared, processed, frozen, defrosted or stored hygienically in establishments approved in accordance with Article 7, in compliance with the requirements of Chapters III and IV of the Annex.

The competent authority may, notwithstanding Chapter II, section 2 of the Annex, authorize the transfer of fishery products *ex quay* into containers for immediate delivery to an approved establishment or registered auction or wholesale market to be checked there;

- (d) they must have undergone a health check in accordance with Chapter V of the Annex;
- (e) they must have been appropriately packaged in accordance with Chapter VI of the Annex;
- (f) they must have been given an identification mark in accordance with Chapter VII of the Annex;
- (g) they must have been stored and transported under satisfactory conditions of hygiene, in accordance with Chapter VIII of the Annex.

2. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed.

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

- (a) they must have been slaughtered under appropriate conditions of hygiene. They must not be soiled with earth, slime or faeces. If not processed immediately after having been slaughtered, they must be kept chilled;
- (b) they must, in addition, comply with the requirements laid down under 1 (c) to (g).

4. (a) The placing on the market of live bivalve molluscs shall be subject to the requirements laid down in Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs ⁽¹⁾.

- (b) When processed, bivalve molluscs must, in addition to the requirements in point (a), satisfy those of paragraph 1 (c) to (g).

Article 4

Fishery products to be placed on the market alive shall at all times be kept under the most suitable survival conditions.

Article 5

The placing on the market of the following products shall be forbidden:

- poisonous fish of the following families: *Tetraodontidae*, *Molidae*, *Diodontidae*, *Canthigasteridae*,
- fishery products containing biotoxins such as ciguatera toxins or muscle-paralysing toxins.

Detailed requirements concerning the species covered by this Article and concerning methods of analysis shall be laid down in accordance with the procedure prescribed in Article 15.

⁽¹⁾ See page 1 of this Official Journal.

Article 6

1. Member States shall ensure that persons responsible for establishment take all necessary measures, so that, at all stages of the production of fishery products, the specifications of this Directive are complied with.

To that end, the said persons responsible must carry out their own checks based on the following principles;

- identification of critical points in their establishment on the basis of the manufacturing processes used;
- establishment and implementation of methods for monitoring and checking such critical points;
- taking samples for analysis in an approved laboratory by the competent authority for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the standards established by this Directive;
- keeping a written record or a record registered in an indelible fashion of the preceding points with a view to submitting them to the competent authority. The results of the different checks and tests will in particular be kept for a period of at least two years.

2. If the results of own checks or any information at the disposal of the persons responsible referred to in paragraph 1 reveal the risk of a health risk or suggest one might exist and without prejudice to the measures laid down in the fourth subparagraph of Article 3 (1) of Directive 89/662/EEC, the appropriate measures shall be taken, under official supervision.

3. Rules for the application of the second subparagraph of paragraph 1 shall be established in accordance with the procedure laid down in Article 15.

Article 7

1. The competent authorities shall approve establishments once they have verified that these establishments meet the requirements of this Directive, with regard to the nature of the activities they carry out. The approval must be renewed if an establishment decides to carry out activities other than those for which it has received approval.

The competent authorities shall take the necessary measures if the requirements cease to be met. To this end, they shall take particular account of the conclusions of any check carried out in accordance with Article 8.

The competent authority shall register those auction and wholesale markets which are not subject to approval after verifying that such installations comply with the provisions of this Directive.

2. However, subject to the express condition that products coming from factory-vessels and establishments,

and auction and wholesale markets meet the hygiene standards set by this Directive, Member States may, for the requirements relating to equipment and structures laid down in Chapters I to IV to the Annex, grant to factory-vessels and establishments, auction and wholesale markets a further period expiring on 31 December 1995 within which to comply with the conditions of approval set out in Chapter IX. Such derogations may be granted only to factory-vessels and establishments, auction and wholesale markets, already operating on 31 December 1991, which have, before 1 July 1992, submitted a duly justified application for derogation to the competent national authority. This application must be accompanied by a work plan and programme indicating the period within which it would be possible for them to comply with the requirements in question. Where financial assistance is requested from the Community, only requests in respect of projects complying with the requirements of this Directive can be accepted.

3. The competent authorities shall draw up a list of their approved establishments, each of which shall have an official number.

Each Member State shall notify the Commission of its list of approved establishments and of any subsequent amendment thereof. The Commission shall forward this information to the other Member States.

4. The inspection and monitoring of establishments shall be carried out regularly under the responsibility of the competent authority, which shall at all times have free access to all parts of establishments, in order to ensure compliance with the requirements of this Directive.

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

5. Paragraphs 1, 3 and 4 shall also apply in respect of factory vessels.

6. Paragraphs 3 and 4 shall also apply to wholesale and auction markets.

Article 8

1. Experts from the Commission may, in cooperation with the competent authorities of the Member States, make on-the-spot checks insofar as this is necessary to ensure the uniform application of this Directive. They may in particular verify whether establishments are in effect complying with the requirements of this Directive. 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 the investigations.

2. The arrangements for implementing paragraph 1 shall be adopted in accordance with the procedure laid down in Article 15.

Article 9

1. The rules laid down in Directive 89/662/EEC, as regards fishery products intended for human consumption, shall apply, in particular as regards the organization of and the action to be taken following the inspections to be carried out by the Member States of destination, and the protective measures to be implemented.

2. Directive 89/662/EEC shall be amended as follows:

(a) in Annex A the following indent shall be added:

‘— Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and placing on the market of fishery products (OJ No L 268, 24. 9. 1991, p. 15);’

(b) In Annex B the following indent shall be deleted:

‘— fishery products intended for human consumption’.

CHAPTER II

Imports from third countries*Article 10*

Provisions applied to imports of fishery products from third countries shall be at least equivalent to those governing the production and placing on the market of Community products.

Fishery products caught in their natural environment by a fishing vessel flying the flag of a third country must undergo the checks laid down in Article 18 (3) of Directive 90/675/EEC.

Article 11

1. For each third country or group of third countries, fishery products must fulfil the specific import conditions fixed in accordance with the procedure laid down in Article 15, depending on the health situation in the third country concerned.

2. In order to allow the import conditions to be fixed, and in order to verify the conditions of production, storage and dispatch of fishery products for consignment to the Community, inspections may be carried out on the spot by experts from the Commission and the Member States.

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

These inspections shall be made on behalf of the Community, which shall bear any expenditure incurred.

The frequency of and procedure for these inspections shall be determined in accordance with the procedure laid down in Article 15.

3. When fixing the import conditions of fishery products referred to in paragraph 1, particular account shall be taken of:

- (a) the legislation of the third country;
- (b) the organization of the competent authority of the third country and of its inspection services, the powers of such services and the supervision to which they are subject, as well as their facilities for effectively verifying the implementation of their legislation in force;
- (c) the actual health conditions during the production, storage and dispatch of fishery products intended for the Community;
- (d) the assurances which a third country can give on the compliance with the standards laid down in Chapter V of the Annex.

4. The import conditions referred to in paragraph 1 shall include:

- (a) the procedure for obtaining a health certificate which must accompany consignments when forwarded to the Community;
- (b) the placing of a mark identifying the fishery products, in particular with the approval number of the establishment of origin, except in the case of frozen fishery products, landed immediately for canning and bearing the certificate provided for under (a);
- (c) drawing up a list of approved establishments and auction or wholesale markets registered and approved by the Commission in accordance with the procedure laid down in Article 15;

For that purpose, one or more lists of such establishments shall draw up on the basis of a communication from the competent authorities of the third country to the Commission. An establishment may not appear on a list unless it is officially approved by the competent authority of the third country exporting to the Community. Such approval shall be subject to observance of the following requirements:

- compliance with requirements equivalent to those laid down in this Directive,
- monitoring by an official inspection service of the third country.

5. The conditions referred to in paragraph 4 (a) and (b) may be modified in accordance with the procedure laid down in Article 15.

The list referred to in paragraph 4 (c) may be amended by the Commission, in accordance with the rules established by Commission Decision 90/13/EEC ⁽¹⁾.

6. To deal with specific situations and in accordance with the procedure laid down in Article 15, imports may be authorized direct from an establishment or factory vessel of a third country where the latter is unable to provide the guarantees laid down in paragraph 3, provided that the establishment or factory vessel in question has received special approval following an inspection carried out in accordance with paragraph (2). The authorization decision shall fix the specific import conditions to be followed for products coming from that establishment or factory vessel.

7. Pending the fixing of the import conditions referred to in paragraph 1, the Member States shall ensure that the conditions applied to imports of fishery products from third countries shall be at least equivalent to those governing the production and placing on the market of Community products.

Article 12

1. The rules and principles laid down by Directive 90/675/EEC shall apply, notably as regards the organization of and follow up to the inspections to be carried out by the Member States.

2. Without prejudice to compliance with the rules and principles referred to in paragraph 1 of this Article and pending implementation of the decisions provided for in Article 8 (3) and Article 30 of Directive 90/675/EEC, and in Article 11 of this Directive the relevant national rules for applying Article 8 (1) and (2) of the said Directive shall continue to apply.

CHAPTER III

Final provisions

Article 13

The Annexes shall be amended by the Council, acting by a qualified majority on a proposal from the Commission.

Article 14

The Commission, after consulting the Member States, shall by 1 July 1992 submit a report to the Council concerning the minimum structural and equipment requirements to be met by small establishments which distribute on the local market and are situated in regions subject to particular supply constraints, together with any proposals, on which the

⁽¹⁾ OJ No L 8, 11. 1. 1990, p. 70.

Council, acting under the voting procedure laid down in Article 43 of the Treaty, shall act before 31 December 1992.

Article 15

1. Where the procedure laid down in this Article is to be followed, the Chairman shall refer the matter to the Standing Veterinary Committee set up by Decision 68/361/EEC ⁽²⁾ hereafter referred to as the Committee, either on his own initiative or at the request of a Member State.

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

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

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

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 16

In order to take into account the possible failure to take a decision on the detailed rules for applying this Directive by 1 January 1993, necessary transitional measures may be adopted in accordance with the procedure laid down in Article 15 for a period of two years.

Article 17

The provisions of this Directive shall be re-examined before 1 January 1998 by the Council, acting on proposals from the Commission, on the basis of experience gained.

⁽²⁾ OJ No L 255, 18. 10. 1968, p. 23.

Article 18

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1993. They shall notify the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 19

This Directive is addressed to the Member States.

Done at Brussels, 22 July 1991.

For the Council
The President
P. DANKERT

ANNEX

CHAPTER I

CONDITIONS APPLICABLE TO FACTORY VESSELS

I. Conditions concerning design and equipment

1. The minimum requirements for factory vessels are as follows:

- (a) a reception area set aside for taking fishery products on board, designed and arranged into pounds or pens that are large enough to allow each successive catch to be separated. The reception area and its movable parts must be easy to clean. It must be designed in such a way as to protect the products from the sun or the elements and from any source of dirt or contamination;
- (b) a system for conveying fishery products from the reception area to the work area that conforms with rules of hygiene;
- (c) work areas that are large enough for the preparation and processing of fishery products in proper conditions of hygiene. They must be designed and arranged in such a way as to prevent any contamination of the products;
- (d) storage areas for the finished products that are large enough and designed so that they are easy to clean. If a waste processing unit operates on board, a separate hold must be designated for the storage of these by-products;
- (e) a place for storing packaging materials that is separate from the product preparation and processing areas;
- (f) special equipment for pumping waste or fishery products that are unfit for human consumption either directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to cleaning, separate areas must be allocated for that purpose;
- (g) equipment providing a supply of potable water within the meaning of Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption ⁽¹⁾ or pressurized clean seawater. The seawater intake must be situated in a position where it is not possible for the water being taken in to be affected by discharges into the sea of waste water, waste and engine coolant outlets;
- (h) a suitable number of changing rooms, wash basins and toilets, the latter not opening directly onto areas where fishery products are prepared, processed or stored. The wash basins must be equipped with appliances for washing and drying the hands that comply with hygiene requirements; the wash-basin taps must not be hand-operable.

2. Areas used for the preparation and processing or freezing/quick-freezing of fishery products must have:

- (a) a non-slip floor that is also easy to clean and disinfect and equipped for easy drainage of water. Structures and fixtures must have limber holds that are large enough not to be obstructed by fish waste and to allow water to drain freely;
- (b) walls and ceilings that are easy to clean, particularly where there are pipes, chains or electricity conduits;
- (c) the hydraulic circuits must be arranged or protected in such a way as to ensure that it is not possible for any leakage of oil to contaminate fishery products;
- (d) adequate ventilation and, where necessary, proper vapour extraction;
- (e) adequate lighting;
- (f) appliances for cleaning and disinfecting tools, equipment and fittings;
- (g) appliances for cleaning and disinfecting the hands with taps that are not hand-operable and with single use towels.

⁽¹⁾ OJ No L 229, 30. 9.1980, p. 11. Directive last amended by the 1985 Act of Accession (OJ No L 302, 15. 11. 1985, p. 218).

3. Equipment and tools such as cutting benches, containers, conveyors, gutting or filleting machines, etc., must be resistant to seawater corrosion, easy to clean and disinfect and well-maintained.
4. Factory vessels which freeze fishery products must have:
 - (a) a refrigeration plant sufficiently powerful to lower the temperature rapidly so as to achieve a core temperature that complies with the specifications of this Directive;
 - (b) refrigeration plants sufficiently powerful to keep fishery products in the storage holds at a temperature that complies with the specifications of this Directive. The storage holds must be equipped with a temperature recording system placed so that it can easily be consulted.

II. Conditions of hygiene relating to on-board handling and storage of fishery products

1. A qualified person on board the factory vessel must be responsible for applying good fishery products manufacturing practices. That person shall have the authority to ensure that the provisions of this Directive are applied and shall make available to inspectors the programme for inspecting and checking critical points as applied on board, a register containing that person's comments and the temperature recordings that may be required.
2. The general conditions of hygiene applicable to areas and equipment shall be those laid down in Chapter III, section II (A), of this Annex.
3. The general conditions of hygiene applicable to staff shall be those laid down in Chapter III, section II (B), of this Annex.
4. Heading, gutting and filleting must be carried out under the conditions of hygiene laid down in Chapter IV, section I (2), (3) and (4) of this Annex.
5. On-board processing of fishery products must be carried out under the conditions of hygiene laid down in Chapter IV, sections III, IV and V of this Annex.
6. Fishery products must be wrapped and packaged under the conditions of hygiene laid down in Chapter VI of this Annex.
7. On-board storage of fishery products must be carried out under the conditions of hygiene laid down in Chapter VIII, points 1 and 2, of this Annex.

CHAPTER II

REQUIREMENTS DURING AND AFTER LANDING

1. Unloading and landing equipment must be constructed of material which is easy to clean and disinfect and must be kept in a good state of repair and cleanliness.
2. During unloading and landing, contamination of fishery products must be avoided. It must in particular be ensured that:
 - unloading and landing operations proceed rapidly;
 - fishery products are placed without unnecessary delay in a protected environment at the temperature required on the basis of the nature of the product and, where necessary, in ice in transport, storage or market facilities, or in an establishment;
 - equipment and handling practices that cause unnecessary damage to the edible parts of the fishery products are not authorized.
3. Parts of auction or wholesale markets where fishery products are displayed for sale must:
 - (a) be covered and have walls which are easy to clean;
 - (b) have waterproof flooring which is easy to wash and disinfect and laid in such a way as to facilitate the drainage of water and have a hygienic waste water disposal system;

- (c) be equipped with sanitary facilities with an appropriate number of wash basins and flush lavatories. Wash basins shall be supplied with materials for cleaning the hands and single use hand towels;
 - (d) be well lit to facilitate the inspection of fishery products provided for in Chapter V of this Annex;
 - (e) when they are used for display or storage of fishery products, not be used for other purposes; vehicles emitting exhaust fumes which may impair the quality of the fishery products not be admitted to markets; undesirable animals must not be admitted;
 - (f) be cleaned regularly and at least after each sale; crates must, after each sale, be cleaned and rinsed inside and outside with drinking water or clean seawater; where required, they must be disinfected;
 - (g) have displayed in a prominent position signs prohibiting smoking, spitting, eating and drinking;
 - (h) be closeable and be kept closed when the competent authority considers it necessary;
 - (i) have facilities to provide adequate water supplies satisfying the conditions laid down in Chapter III, section I, point 7 of this Annex;
 - (j) have special watertight receptacles made of corrosion-resistant materials for fishery products which are unfit for human consumption;
 - (k) insofar as they do not have their own premises on-the-spot or in the immediate vicinity on the basis of the quantities displayed for sale, have, for the purposes of the competent authority, an adequately equipped lockable room and the equipment necessary for carrying out inspections.
4. After landing or, where appropriate, after first sale, fishery products must be transported without delay, under the conditions laid down in Chapter VIII, of this Annex, to their place of destination.
5. However, if the conditions laid down in point 4 are not fulfilled, the markets in which fishery products may be stored before being displayed for sale or after being sold and pending transport to their place of destination must have sufficiently large cold rooms which satisfy the conditions laid down in Chapter III, section I, point 3 of this Annex. In such cases, fishery products must be stored at a temperature approaching that of melting ice.
6. The general conditions of hygiene laid down in Chapter III, section II — with the exception of point B 1(a) — of this Annex shall apply *mutatis mutandis* to the markets in which fishery products are displayed for sale or stored.
7. The wholesale markets in which fishery products are displayed for sale or stored shall be subject to the same conditions as those laid down in points 3 and 5 of this Chapter and to those set out in points 4, 10 and 11 of Chapter III, section I of this Annex.

The general conditions of hygiene laid down in Chapter III, section II of this Annex shall apply *mutatis mutandis* to wholesale markets.

CHAPTER III

GENERAL CONDITIONS FOR ESTABLISHMENTS ON LAND

I. General conditions relating to premises and equipment

Establishment shall afford at least the following facilities:

- 1. working areas of sufficient size for work to be carried out under adequate hygienic conditions. Their design and layout shall be such as to preclude contamination of the product and keep quite separate the clean and contaminated parts of the building;
- 2. in areas where products are handled, prepared and processed:
 - (a) waterproof flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of the water or provided with equipment to remove water;

- (b) walls which have smooth surfaces and are easy to clean, durable and impermeable;
 - (c) ceilings or roof linings which are easy to clean;
 - (d) doors in durable materials which are easy to clean;
 - (e) adequate ventilation and, where necessary, good steam and water-vapour extraction facilities;
 - (f) adequate natural or artificial lighting;
 - (g) an adequate number of facilities for cleaning and disinfecting hands. In work rooms and lavatories taps must not be hand-operable. These facilities must be provided with single use hand towels;
 - (h) facilities for cleaning plant, equipment and utensils;
3. in cold rooms where fishery products are stored:
 - the provisions set out under point 2 (a), (b), (c), (d) and (f);
 - where necessary, a sufficiently powerful refrigeration plant to keep products at temperatures prescribed in this Directive;
 4. appropriate facilities for protection against pests such as insects, rodents, birds, etc.;
 5. instruments and working equipment such as cutting tables, containers, conveyor belts and knives made of corrosion-resistant materials, easy to clean and disinfect;
 6. special watertight, corrosion-resistant containers for fishery products not intended for human consumption and premises for the storage of such containers if they are not emptied at least at the end of each working day;
 7. facilities to provide adequate supplies of drinking water within the meaning of Directive 80/778/EEC, or alternatively of clean seawater or seawater treated by an appropriate system, under pressure and in sufficient quantity. However, by way of exception, a supply of non-drinking water is permissible for the production of steam, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products. Non-drinking-water pipes must be clearly distinguished from those used for drinking water or clean seawater;
 8. hygienic waste water disposal system;
 9. an adequate number of changing-rooms with smooth, water-proof, washable walls and floors, wash basins and flush lavatories. The latter may not open directly onto the work rooms. The wash basins must have materials for cleaning the hands and disposable towels; the wash basin taps must not be hand-operable;
 10. if the volume of products treated requires regular or permanent presence an adequately equipped lockable room for the exclusive use of the inspection service;
 11. adequate facilities for cleaning and disinfecting means of transport. However, such facilities are not compulsory if there is a requirement for the means of transport to be cleaned and disinfected at facilities officially authorized by the competent authority;
 12. establishments keeping live animals such as crustaceans and fish must have appropriate fittings ensuring the best survival conditions provided with water of a quality such that no harmful organisms or substances are transferred to the animals.

II. General conditions of hygiene

A. *General conditions of hygiene applicable to premises and equipment*

1. Floors, walls and partitions, ceilings or roof linings, equipment and instruments used for working on fishery products must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the products.
2. Rodents, insects and any other vermin must be systematically exterminated in the premises or on the equipment; rodenticides, insecticides, disinfectants and any other potentially toxic substances must be stored in premises or cupboards which can be locked; their use must not present any risk of contamination of the products.

3. Working areas, instruments and working equipment must be used only for work on fishery products. However, following authorization by the competent authority they may be used at the same time or other times for work on other foodstuffs.
4. Drinking water, within the meaning of Directive 80/778/EEC, or clean seawater must be used for all purposes. However, by way of an exception, non-drinking water may be used for steam production, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products.
5. Detergents, disinfectants and similar substances must be approved by the competent authority and used in such a way that they do not have adverse effects on the machinery, equipment and products.

B. *General conditions of hygiene applicable to staff*

1. The highest possible standard of cleanliness is required of staff. More specifically:
 - (a) staff must wear suitable clean working clothes and headgear which completely encloses the hair. This applies particularly to persons handling exposed fishery products;
 - (b) staff assigned to the handling and preparation of fishery products must be required to wash their hand at least each time work is resumed; wounds to the hands must be covered by a waterproof dressing;
 - (c) smoking, spitting, eating and drinking in work and storage premises of fishery products must be prohibited.
2. The employer shall take all the requisite measures to prevent persons liable to contaminate fishery products from working on and handling them, until there is evidence that such persons can do so without risk.

When recruited, any person working on and handling fishery products shall be required to prove, by a medical certificate, that there is no impediment to such employment. The medical supervision of such a person shall be governed by the national legislation in force in the Member State concerned or in the case of third countries by specific guarantees to be fixed under the procedure set out in Article 15.

CHAPTER IV

SPECIAL CONDITIONS FOR HANDLING FISHERY PRODUCTS ON SHORE

I. Conditions for fresh products

1. Where chilled, unpackaged products are not dispatched, prepared or processed immediately after reaching the establishment, they must be stored or displayed under ice in the establishment's cold room. Re-icing must be carried out as often as is necessary; the ice used, with or without salt, must be made from drinking water or clean seawater and be stored under hygienic conditions in receptacles provided for the purpose; such receptacles must be kept clean and in a good state of repair. Prepacked fresh products must be chilled with ice or mechanical refrigeration plant creating similar temperature conditions.
2. If they are not carried out on board, operations such as heading and gutting must be carried out hygienically. The products must be washed thoroughly with drinking water or clean seawater immediately after such operations.
3. Operations such as filleting and slicing must be carried out in such a way as to avoid the contamination or spoilage of fillets and slices, and in a place other than that used for heading and gutting operations. Fillets and slices must not remain on work tables any longer than is necessary for their preparation. Fillets and slices to be sold fresh must be chilled as quickly as possible after preparation.
4. Guts and parts that may constitute a danger to public health must be separated from and removed from the vicinity of products intended for human consumption.
5. Containers used for the dispatch or storage of fresh fishery products must be designed in such a way as to ensure both their protection from contamination and their preservation under sufficiently hygienic conditions and, more particularly, they must provide adequate drainage of melt water.

6. Unless special facilities are provided for the continuous disposal of waste, the latter must be placed in leakproof, covered containers which are easy to clean and disinfect. Waste must not be allowed to accumulate in working areas. It must be removed either continuously or as soon as the containers are full and at least at the end of each working day in the containers or to the premises referred to in Chapter III, section I, paragraph 6 of this Annex. The containers, receptacles and/or premises set aside for waste must always be thoroughly cleaned and, if appropriate, disinfected after use. Waste stored there must not constitute a source of contamination for the establishment or of pollution of its surroundings.

II. Conditions for frozen products

1. Plants must have:

- (a) freezing equipment sufficiently powerful to achieve a rapid reduction in the temperature so that the temperatures laid down in this Directive can be obtained in the product;
- (b) freezing equipment sufficiently powerful to keep products in storage rooms at a temperature not exceeding those laid down in this Directive, whatever the ambient temperature may be.

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

2. Fresh products to be frozen or quick-frozen must comply with the requirements of section I of this Chapter.
3. Storage rooms must have a temperature recording device in a place where it can easily be read. The temperature sensor of the recorder must be located in the area furthest away from the cold source, i.e. where the temperature in the storage room is the highest.

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

III. Conditions for thawing products

Establishments that carry out thawing operations must comply with the following requirements:

1. fishery products must be thawed under hygienic conditions; their contamination must be avoided and there must be adequate drainage for any melt water produced.
During thawing, the temperature of the products must not increase excessively;
2. after thawing, fishery products must be handled in accordance with the requirements of this Directive. When they are prepared or processed, these operations must be carried out without delay. If they are put directly onto the market, particulars as to the thawed state of the fish must be clearly marked on the packaging in accordance with Article 5 (3) of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ⁽¹⁾.

IV. Conditions for processed products

1. Fresh, frozen and thawed products used for processing must comply with the requirements of sections I or II of this Chapter.
2. Where the processing treatment is carried out to inhibit the development of pathogenic micro-organisms, or if it is a significant factor in the preservation of the product, the treatment must be scientifically recognized by the law in force, or in the case of a treatment of products referred to in Chapter I Section 1 (b) and (c) of Directive 91/492/EEC which have not been relayed or purified, such treatment must be approved, in accordance with the procedure laid down in Article 15 of this Directive, within four months of receipt of a request from a Member State.

The person responsible for an establishment must keep a register of the processing carried out. Depending on the type of process employed, heating time and temperature, salt content, pH, water content, etc., must be monitored and controlled. Records must be kept at least for the expected storage life of the products and be available to the competent authority.

⁽¹⁾ OJ No L 33, 8. 2. 1979, p. 1. Directive last amended by Directive 91/72/EEC (OJ No L 42, 16. 1. 1991, p. 22).

3. For products which are preserved for a limited period by a treatment such as salting, smoking, drying or marinating, the appropriate conditions for storage must be clearly marked on the packaging, in accordance with Directive 79/112/EEC.

In addition, the following conditions shall be complied with.

4. *Canning*

In the case of fishery products which have been subjected to sterilization in hermetically sealed containers:

- (a) the water used for the preparation of cans must be drinking water;
- (b) the process used for the heat treatment must be appropriate, having regard to such major criteria as the heating time, temperature, filling, size of containers, etc., a record of which must be kept; the heat treatment must be capable of destroying or inactivating pathogenic organisms and the spores of pathogenic micro-organisms. The heating equipment must be fitted with devices for verifying whether the containers have in fact undergone appropriate heat treatment. Drinking water must be used to cool containers after heat treatment, without prejudice to the presence of any chemical additives used in accordance with good technological practice to prevent corrosion of the equipment and containers;
- (c) further checks must be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat treatment, *viz.*:
 - incubation tests: incubation must be carried out at 37 °C for seven days or at 35 °C for ten days, or at any other equivalent combination;
 - microbiological examination of contents and containers in the establishment's laboratory or in another approved laboratory;
- (d) samples must be taken of production each day at predetermined intervals, to ensure the efficacy of sealing. For that purpose, appropriate equipment must be available for the examination of cross-sections of the can-seams;
- (e) checks are carried out in order to ensure that containers are not damaged;
- (f) all containers which have undergone heat treatment under practically identical conditions must be given a batch identification mark, in accordance with Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs ⁽¹⁾.

5. *Smoking*

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

- (a) Materials used to produce smoke for the smoking of fish must be stored away from the place of smoking and must be used in such a way that they do not contaminate the products.
- (b) Materials used to produce smoke by burning wood that has been painted, varnished, glued or has undergone any chemical preservation treatment must be prohibited.
- (c) After smoking, products must be cooled rapidly to the temperature required for their preservation before being packaged.

6. *Salting*

- (a) Salting operations must take place in different premises and sufficiently removed from the premises where the other operations are carried out.
- (b) Salt used in the treatment of fishery products must be clean and stored in such a way as to preclude contamination. It must not be re-used.
- (c) Any container used for salting or brining must be constructed in such a way as to preclude contamination during the salting or brining process.
- (d) Containers or areas used for salting or brining must be cleaned before use.

⁽¹⁾ OJ No L 186, 30. 6. 1989, p. 21.

7. *Cooked crustacean and molluscan shellfish products*

Crustaceans and molluscan shellfish must be cooked as follows:

- (a) any cooking must be followed by rapid cooling. Water used for this purpose must be drinking water or clean seawater. If no other method of preservation is used, cooling must continue until the temperature approaching that of melting ice is reached;
- (b) shelling or shucking must be carried out under hygienic conditions avoiding the contamination of the product. Where such operations are done by hand, workers must pay particular attention to the washing of their hands and all working surfaces must be cleaned thoroughly. If machines are used, they must be cleaned at frequent intervals and disinfected after each working day.

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

- (c) every manufacturer must carry out micro-biological checks on his production at regular intervals, complying with the standards to be fixed in accordance with Chapter V, Section 4 of this Annex.

8. *Mechanically recovered fish flesh*

The mechanical recovery of fish flesh must be carried out under the following conditions:

- (a) mechanical recovery of gutted fish must take place without undue delay after filleting, using raw materials free of guts. Where whole fish are used, they must be gutted and washed beforehand;
- (b) the machinery must be cleaned at frequent intervals and at least every two hours;
- (c) after recovery, mechanically recovered flesh must be frozen as quickly as possible or incorporated in a product intended for freezing or stabilizing treatment.

V. *Conditions concerning parasites*

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

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

The detailed rules for this inspection shall be adopted in accordance with the procedure laid down in Article 15 of this Directive, on a proposal from the Commission to be submitted before 1 October 1992.

2. The fish and fish products referred to in point 3 which are to be consumed as they are must, in addition, be subjected to freezing at a temperature of not more than -20°C in all parts of the product for not less than 24 hours. Products subjected to this freezing process must be either raw or finished.
3. Fish and products subject to the conditions in point 2:
 - (a) fish to be consumed raw or almost raw, e.g. raw herring 'maatje';
 - (b) the following species, if they are to undergo a cold smoking process at which the internal temperature of the fish is less than 60°C :
 - herring,
 - mackerel,
 - sprat,
 - (wild) Atlantic and Pacific salmon;
 - (c) marinated and/or salted herring where this process is insufficient to destroy the larvae of nematodes.

This list may be amended, in the light of scientific data, in accordance with the procedure laid down in Article 15 of this Directive. In accordance with the same procedure, criteria will be laid down which must enable the processes which are deemed sufficient or insufficient to destroy nematodes to be defined.

4. Manufacturers must ensure that fish and fish products listed in point 3 or the raw materials for use in their manufacture are subjected to the treatment described in point 2, prior to their release for consumption.
5. The fishery products listed in point 3 must, when they are placed on the market, be accompanied by a document from the manufacturer stating the type of process they have undergone.

CHAPTER V

HEALTH CONTROL AND MONITORING OF PRODUCTION CONDITIONS

I. General monitoring

Arrangements for checking and monitoring must be made by the competent authorities in order to establish whether the requirements laid down in this Directive are complied with.

Such arrangements will include, in particular:

1. a check on the fishing vessels, on the understanding that such a check may be carried out during the stay in port;
2. a check on the conditions of landing and first sale;
3. an inspection at regular intervals of establishments to check, in particular:
 - (a) whether the conditions for approval are still fulfilled;
 - (b) whether the fishery products are handled correctly;
 - (c) the cleanliness of the premises, facilities and instruments and staff hygiene;
 - (d) whether identification marks are put on correctly;
4. an inspection of the wholesale and auction markets;
5. a check on storage and transport conditions.

II. Special checks

1. *Organoleptic checks*

Without prejudice to the derogations provided for by Council Regulation (EEC) No 103/76 of 19 January 1976 laying down common marketing standards for certain fresh or chilled fish ⁽¹⁾, each batch of fishery products must be submitted for inspection by the competent authority at the time of landing or before first sale to check whether they are fit for human consumption. This inspection comprises an organoleptic check carried out by sampling.

Fishery products complying, as far as the freshness criteria are concerned, with the common marketing standards already laid down pursuant to Article 2 of Regulation (EEC) No 3796/81 are considered to fulfil the organoleptic requirements necessary for compliance with the provisions of this Directive.

The Commission may, where necessary, in accordance with the procedure referred to in Article 15 of this Directive, lay down specific organoleptic requirements for fishery products not harmonized under Regulation (EEC) No 3796/81.

The organoleptic examination must be repeated after the first sale of fishery products, if it is found that the requirements of this Directive have not been complied with or when considered necessary. After the first sale, fishery products must at least comply with the minimum freshness requirements of the aforementioned Regulation.

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

If the organoleptic examination reveals any doubt as to the freshness of the fishery products, use may be made of chemical checks or microbiological analyses.

2. *Parasite checks*

Before they are released for human consumption, fish and fish products must be subject to a visual inspection, by way of sample, for the purpose of detecting any parasites that are visible.

⁽¹⁾ OJ No L 20, 28. 1. 1976, p. 29. Regulation last amended by Regulation (EEC) No 33/89 (OJ No L 5, 7. 1. 1989, p. 18).

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

The detailed rules for this inspection shall be established in accordance with the procedure laid down in Article 15.

3. *Chemicals checks*

A. Samples must be taken and subjected to laboratory analysis for the control of the following parameters:

(a) TVB-N (Total Volatile Basic Nitrogen) and TMA-N (Trimethylamine-Nitrogen)

The levels of these parameters must be specified for each category of species in accordance with the procedure laid down in Article 15 of this Directive.

(b) Histamine

Nine samples must be taken from each batch. These must fulfil the following requirements:

- the mean value must not exceed 100 ppm;
- two samples may have a value of more than 100 ppm but less than 200 ppm;
- no sample may have a value exceeding 200 ppm.

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

B. Contaminants present in the aquatic environment

Without prejudice to the Community rules concerning water protection and management, and in particular those concerning pollution of the aquatic environment, fishery products must not contain in their edible parts contaminants present in the aquatic environment such as heavy metals and organochlorinated substances at such a level that the calculated dietary intake exceeds the acceptable daily or weekly intake for humans.

A monitoring system must be established by the Member States to check the level of contamination of fishery products.

C. In accordance with the procedure laid down in Article 15 of this Directive, the following shall be decided on by not later than 31 December 1992:

- (a) the methods of analysis to be used to check the chemical parameters, as well as the sampling plans;
- (b) the acceptable levels for the chemical parameters.

4. *Microbiological analyses*

In accordance with the procedure laid down in Article 15 of this Directive, microbiological criteria, including sampling plans and methods of analysis, may be laid down when there is a need to protect public health. The Commission will to this end submit appropriate proposals for measures by 1 October 1992.

CHAPTER VI

PACKAGING

1. Packaging must be carried out under satisfactory conditions of hygiene, to preclude contamination of the fishery products.
2. Packaging materials and products liable to enter into contact with fishery products must comply with all the rules of hygiene, and in particular:
 - they must not be such as to impair the organoleptic characteristics of the fishery products;
 - they must not be capable of transmitting to the fishery products substances harmful to human health;
 - they must be strong enough to protect the fishery products adequately.

3. With the exception of certain containers made of impervious, smooth and corrosion-resistant material which are easy to clean and disinfect, which may be re-used after cleaning and disinfecting, packaging materials may not be re-used. Packaging materials used for fresh products held under ice must provide adequate drainage for melt water.
4. Unused packaging materials must be stored in premises away from the production area and be protected from dust and contamination.

CHAPTER VII

IDENTIFICATION MARKS

Without prejudice to the requirements laid down in Directive 79/112/EEC, it must be possible to trace for inspection purposes the establishment of dispatch of consignments of fishery products, by means of either labelling or the accompanying documents. For that purpose, the following information must appear on the packaging or in the accompanying documents:

- the country of dispatch;
- identification of the establishment by its official approval number or, in the case of separate registering of auction or wholesale markets as laid down in Article 7 (1), third subparagraph of this Directive, the registration number of the auction or wholesale market.

CHAPTER VIII

STORAGE AND TRANSPORT

1. Fishery products must, during storage and transport, be kept at the temperatures laid down in this Directive and in particular:
 - fresh or thawed fishery products and cooked and chilled crustacean and molluscan shellfish products must be kept at the temperature of melting ice;
 - frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned foods, must be kept at an even temperature of -18°C or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than 3°C , during transport;
 - processed products must be kept at the temperatures specified by the manufacturer, when the circumstances so require, prescribed in accordance with the procedure laid down in Article 15 of this Directive.
2. Where frozen fishery products are transported from a cold-storage plant to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing and where the distance to be covered is short, not exceeding 50 km or one hour's journey, the competent authority may grant a derogation from the conditions laid down in point 1, second indent.
3. Products may not be stored or transported with other products which may contaminate them or affect their hygiene, unless they are packaged in such a way as to provide satisfactory protection.
4. Vehicles used for the transport of fishery products must be constructed and equipped in such a way that the temperatures laid down in this Directive can be maintained throughout the period of transport. If ice is used to chill the products, adequate drainage must be provided in order to ensure that water from melted ice does not stay in contact with the products. The inside surfaces of the means of transport must be finished in such a way that they do not adversely affect the fishery products. They must be smooth and easy to clean and disinfect.
5. Means of transport used for fishery products may not be used for transporting other products likely to impair or contaminate fishery products, except where the fishery products can be guaranteed uncontaminated as a result of such transport being thoroughly cleaned and disinfected.

6. Fishery products may not be transported in a vehicle or container which is not clean or which should have been disinfected.
7. The transport conditions of fishery products to be placed on the market alive must not adversely affect the products.

CHAPTER IX

POINTS OF ANNEX I WHICH MAY BE SUBJECT TO DEROGATIONS AND POSSIBLE CONDITIONS APPLICABLE IN THE CASE OF DEROGATIONS

Re Chapter I Part I of the Annex

1. *Point 1 (a)*

provided products are sheltered from the sun and the elements and from any source of dirt or contamination.

2. *Point 1 (c)*

provided any contamination of the products is prevented.

3. *Point 1 (d), first sentence*

provided the finished products are stored on board at the required temperature.

4. *Point 1 (g), last sentence*

provided products cannot be contaminated by waste water, waste or engine coolant.

5. *Point 1 (h)*

provided staff handling fishery products can wash their hands after using the toilet.

6. *Point 2 (a)*

provided floors are properly cleaned and disinfected.

7. *Point 2 (b), (c) and (d)*

8. *Point 2 (g) on taps and towels*

9. *Point 3*

provided equipment and tools are well maintained.

Re Chapter II of the Annex

10. *Point 3 (a)*

provided the walls are kept clean.

11. *Point 3 (b)*

provided the flooring is kept clean after every sale.

12. *Point 3 (c), first sentence*

13. *Point 3 (e): vehicles emitting exhaust fumes*

provided products contaminated by exhaust fumes are withdrawn from the market.

14. *Point 3 (j)*

provided that products which are not fit for human consumption cannot contaminate or be mixed with fishery products.

15. *Point 3 (k)*
16. *Point 7*
insofar as it refers to point 3 of the same Chapter and point 10 of Chapter III, section I.

Re Chapter III Part I of the Annex

17. *Point 1*
provided finished products cannot be contaminated by raw materials or waste.
18. *Point 2 (a)*
provided the flooring is cleaned and disinfected accordingly.
19. *Point 2 (b)*
provided the walls are kept clean.
20. *Point 2 (c)*
provided the ceiling is not a source of contamination.
21. *Point 2 (d)*
22. *Point 2 (e)*
provided products cannot be spoiled or contaminated by the steam.
23. *Point 2 (g)*
provided there are facilities available for staff to wash their hands.
24. *Point 3*
25. *Point 5*
insofar as it relates to corrosion-resistant materials provided instruments and working equipment are kept clean.
26. *Point 6*
provided products cannot be contaminated by waste or leakage therefrom.
27. *Point 10*

Re Chapter IV of the Annex

28. *Part I, point 1*
in respect of the requirement for products being held over to be put in the establishment's cold room provided the products are re-iced as often as necessary during a period not in excess of 12 hours or that a nearby cold room not belonging to the establishment can be used.
29. *Part I, point 6*
in respect of the requirement for waste to be put in leakproof covered containers provided products cannot be contaminated by waste or leakage therefrom.
30. *Part IV, point 5, first paragraph*
provided that every precaution is taken to prevent fishery products that are being prepared or stored from being affected by the smoke.
31. *Part IV, point 6 (a)*
provided fishery products that are being prepared or stored are not affected by salting operations.

COUNCIL DIRECTIVE

of 26 June 1991

on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat

(91/494/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas poultrymeat is included in the list of products in Annex II to the Treaty; whereas the breeding and rearing of poultry is included in the farming sector and constitutes a source of income for part of the farming population;

Whereas disparities between Member States should be removed by laying down rules regarding the animal health aspects of intra-Community trade in fresh poultrymeat in order to ensure the rational development of that sector and improve productivity by encouraging intra-Community trade, with a view to the completion of the internal market;

Whereas, in particular, to improve information concerning the state of health of the poultry from which fresh meat for consignment to another Member State comes, it should be stipulated that the poultry must either have been reared on the territory of the Community or have been imported from third countries in accordance with Chapter III of Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade and imports from third countries of poultry and hatching eggs ⁽⁴⁾;

Whereas, in order to prevent it from propagating epizootic diseases, fresh meat coming from a holding or area which, in accordance with Community rules, has been placed under health restrictions or from an area infected by avian influenza or Newcastle disease should be excluded from intra-Community trade;

Whereas care should be taken that fresh poultrymeat that does not comply with Community rules should not be given

the health mark provided for in Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat ⁽⁵⁾, as last amended by Directive 90/484/EEC ⁽⁶⁾; whereas, such meat may, however, be put to other uses provided that it has undergone treatment designed to destroy the germs of diseases, in which case it will bear a special mark to that effect;

Whereas, in respect of the organization of and the follow-up to the checks being carried out by the Member State of destination and the safeguard measures to be implemented, reference should be made to the general rules laid down in Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽⁷⁾;

Whereas provision should be made so that inspections may be carried out by the Commission;

Whereas, in the interests of the harmonious development of intra-Community trade; Community arrangements should be defined in respect of imports from third countries;

Whereas defining the said arrangements requires in particular that a list be drawn up of third countries or parts of third countries from which fresh poultrymeat may be imported and that a certificate be produced;

Whereas the Commission's veterinary experts should be instructed to carry out checks in third countries in order to determine whether the Community rules are complied with;

Whereas the rules and general principles governing checks on fresh poultrymeat will be determined later as part of the measures to be taken to bring about the internal market;

Whereas Directive 90/539/EEC should be amended in order to take into account the contents of this Directive, with a view in particular to ensure parallelism with regard to the date on which Member States must comply with the new health rules;

Whereas the provisions of this Directive will have to be reviewed in the context of the completion of the internal market;

⁽¹⁾ OJ No C 327, 30. 12. 1989, p. 72.

⁽²⁾ OJ No C 183, 15. 7. 1991.

⁽³⁾ OJ No C 124, 21. 5. 1990, p. 12.

⁽⁴⁾ OJ No L 303, 31. 10. 1990, p. 6.

⁽⁵⁾ OJ No L 55, 8. 3. 1971, p. 23.

⁽⁶⁾ OJ No L 267, 29. 9. 1990, p. 45.

⁽⁷⁾ OJ No L 395, 31. 12. 1989, p. 13.

Whereas provision should be made for a procedure establishing close cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas it is advisable to allow time to introduce harmonized rules concerning Newcastle disease,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

This Directive lays down animal health requirements governing intra-Community trade in and imports from third countries of fresh poultrymeat.

Article 2

For the purposes of this Directive, the definitions, and especially those for poultry, set out in Article 2 of Directive 90/539/EEC shall also apply.

Moreover:

- (a) 'meat' means any parts of poultry which are fit for human consumption;
- (b) 'fresh meat' means any meat, including meat vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any treatment other than cold treatment to ensure its preservation.

CHAPTER II

Rules governing intra-community trade

Article 3

A. In order to be traded within the Community fresh meat must have been obtained from poultry which:

1. has been held in Community territory since hatching or has been imported from third countries in accordance with the requirements of Chapter III of Directive 90/539/EEC.

Until 31 December 1992 poultrymeat intended for Member States or regions of Member States the status of which has been recognized in accordance with Article 12 (2) of that Directive must come from poultry which has not been vaccinated against Newcastle disease using an attenuated live vaccine during the 30 days preceding slaughter.

Acting before 1 January 1992 by a qualified majority on a proposal from the Commission based on a report on the risks of transmission of Newcastle disease, the Council shall adopt the rules applicable as from 1 January 1993;

2. comes from a holding:

- which has not been placed under animal health restrictions in connection with a poultry disease,
- which is not situated in an area which has been declared an avian influenza or Newcastle disease infection area;

3. during transport to the slaughterhouse did not come into contact with poultry suffering from avian influenza or Newcastle disease; such transport through an area which has been declared an avian influenza or Newcastle disease infection area shall be prohibited unless major road or rail links are used;

4. comes from slaughterhouses in which, at the time of slaughter, no case of avian influenza or Newcastle disease had been recorded.

Any fresh meat which is suspected of having been contaminated at the slaughterhouse, cutting plant or storage depot or in the course of transport must be excluded from trade;

5. is marked in accordance with Articles 4 and 5;

6. is accompanied by the health certificate provided for in Annex IV to Directive 71/118/EEC, amended in accordance with the Annex to this Directive.

B. Exempted from this chapter are national controls governing meat:

- contained in the personal luggage of travellers and intended for their personal consumption,
- in small consignments to private individuals, provided that the said consignments are not of a commercial nature,
- for consumption by the crew and passengers on board means of transport operating internationally.

Article 4

Fresh poultrymeat covered by this Directive shall be given the health mark specified in Article 3 (1) A (e) of Directive 71/118/EEC, provided that it meets the requirements laid down in Article 3 (A) of this Directive and that it comes from poultry slaughtered in accordance with the hygiene requirements laid down in Directive 71/118/EEC.

Article 5

1. Notwithstanding Article 4, and insofar as it is not intended for intra-Community trade in fresh meat, fresh poultrymeat which does not satisfy the requirements laid down in Article 3 (A) (2) (3) and the first subparagraph of (4) may carry a mark in accordance with Article 3 (1) A (e) of Directive 71/118/EEC, provided that this mark is immediately:

- (a) either overstamped in such a way that the health mark defined in point 44.1 (a) and (b) of Chapter X of Annex I to Directive 71/118/EEC is covered by a diagonal cross consisting of two straight lines crossing at right angles, with the point of intersection in the centre of the stamp and the information thereon remaining legible;
- (b) or replaced by a single special mark consisting of the health mark defined in point 44 (a) and (b) of Chapter X of Annex I to Directive 71/118/EEC, overstamped in accordance with point (a) of this paragraph.

The provisions of point 43 of Chapter X of Annex I to Directive 71/118/EEC shall apply *mutatis mutandis* to the keeping and use of marking instruments.

2. The meat referred to in paragraph 1 must be obtained, cut, transported and stored separately from, or not at the same time as, meat intended for intra-Community trade in fresh meat and must be used in such a way as to avoid it being introduced into meat products intended for intra-Community trade unless they have undergone the treatment specified in Article 4 (1) of Directive 80/215/EEC ⁽¹⁾ as last amended by Directive 89/662/EEC.

Article 6

The rules laid down in Directive 89/662/EEC shall apply, in particular as regards the organization of and the follow-up to the checks carried out by the Member State of destination and the safeguard measures to be applied.

Article 7

Commission veterinary experts may, to the extent necessary to ensure uniform application of this Directive, and in conjunction with the competent national authorities, carry out on-the spot inspections. The Commission shall inform the Member States of the outcome of such inspections.

Member States in whose territory an inspection is carried out shall give the experts all the assistance necessary for the performance of their tasks.

General rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 18. The rules to be followed for the inspections provided for in this Article shall be adopted in accordance with the same procedure.

⁽¹⁾ OJ No L 47, 21. 2. 1980, p. 4.

CHAPTER III

Rules applicable to imports from third countries

Article 8

1. Fresh poultrymeat imported into the Community must satisfy the requirements laid down in Articles 9 to 12.

2. However, this Chapter shall not apply to:

- (a) poultrymeat forming part of travellers' personal luggage and intended for their personal consumption, provided that the quantity transported does not exceed one kilogram per person and that it comes from a third country or part thereof appearing on the list drawn up in accordance with Article 9 and from which importation is not prohibited under Article 14;
- (b) poultrymeat sent as small consignments to private individuals, provided that such meat is not imported by way of trade, that the quantity does not exceed one kilogram and that it comes from a third country or part thereof appearing on the list drawn up in accordance with Article 9 and from which importation is not prohibited under Article 14;
- (c) meat for consumption by the crew and passengers on board means of transport operating internationally.

Where such meat or the resulting kitchen waste is unloaded, it must be destroyed. It is not, however, necessary to destroy meat when it is transferred, directly or after being placed provisionally under customs supervision, from one means of transport to another.

Article 9

1. Fresh poultrymeat must come from a third country or part of a third country appearing on a list drawn up by the Commission in accordance with the procedure laid down in Article 18. The list may be supplemented or amended in accordance with the procedure laid down in Article 17.

2. In deciding whether a third country or part thereof may be included in the list referred to in paragraph 1, particular account shall be taken of:

- (a) the state of health of the poultry, other domestic animals and wildlife in the third country, particular attention being paid to exotic animal diseases, and the environmental health situation in that country, where either are liable to endanger public and animal health in the Member States;
- (b) the regularity and rapidity of the supply of information by the third country relating to the existence of contagious animal diseases in its territory, in particular the diseases appearing on lists A and B of the International Office of Epizootics;

- (c) that country's rules on animal disease prevention and control;
- (d) the structure of the veterinary services in the country and their powers;
- (e) the organization and implementation of measures to prevent and control contagious animal diseases;
- (f) that country's legislation on the use of banned substances, in particular legislation concerning the prohibition or authorization of substances, their distribution, placing on the market and the rules on administering and controlling them;
- (g) the guarantees which the third country can give with regard to rules laid down by this Directive.

3. The list referred to in paragraph 1 and any amendments thereto shall be published in the *Official Journal of the European Communities*.

Article 10

1. Fresh poultrymeat must come from third countries free from avian influenza and Newcastle disease.

2. The general criteria for classifying third countries in terms of the diseases referred to in paragraph 1 shall be adopted in accordance with the procedure laid down in Article 17. These criteria must in no case be more favourable than those adopted for the Member States pursuant to Directive 90/539/EEC.

3. The Commission may, in accordance with the procedure laid down in Article 18, decide that paragraph 1 shall apply only to a part of the territory of a third country.

Article 11

1. Fresh poultrymeat must:

- (a) satisfy animal health requirements adopted in accordance with the procedure laid down in Article 17. These requirements may differ according to the species of bird;
- (b) come from flocks which, prior to consignment, have, without interruption, been held in the third country or part thereof for a period to be defined in accordance with the procedure laid down in Article 17.

2. The animal health conditions shall be determined on the basis of the rules laid down in Chapter II and the corresponding Annexes to Directive 90/539/EEC. In accordance with the procedure laid down in Article 18, derogations may be granted on a case-by-case basis, if the third country concerned offers similar animal health guarantees which are at least of an equivalent standard.

Article 12

1. Fresh poultrymeat must be accompanied by a certificate drawn up by an official veterinarian of the exporting third country.

The certificate must:

- (a) be issued on the day of loading for consignment to the country of destination;
- (b) be drawn up in the official language or languages of the country of shipment, of the country of destination, and in one of the official languages of the country in which the import checks are to be carried out;
- (c) accompany the consignment in the original;
- (d) attest that the fresh meat satisfies the requirements of this Directive and those adopted pursuant to this Directive with regard to importation from third countries;
- (e) consist of a single sheet of paper;
- (f) be made out for a single consignee.

2. The certificate must conform with a model established in accordance with the procedure laid down in Article 18.

Article 13

On-the-spot inspections shall be carried out by veterinary experts of the Member States and the Commission to ensure that all the provisions of this Directive are effectively applied.

Member States' experts responsible for these inspections shall be designated by the Commission on proposals from the Member States.

The inspections shall be carried out on behalf of the Community, which shall bear the expenditure incurred.

The frequency of the inspections and the inspection procedure shall be determined in accordance with the procedure laid down in Article 18.

Article 14

1. The Commission may, in accordance with the procedure laid down in Article 17, decide that imports from a third country or part thereof are to be confined to fresh poultrymeat of particular species.

2. The Commission may decide, in accordance with the procedure laid down in Article 17, to apply animal health restrictions, as required, after importation.

Article 15

The rules and general principles applicable during inspections in third countries or during inspections of

imported poultrymeat from third countries and the safeguard measures to be implemented shall be those set out in Directive 90/675/EEC⁽¹⁾.

Article 16

1. Pending the implementation of Community health rules concerning imports of poultrymeat from third countries, Member States shall apply to such imports provisions which shall not be more favourable than those governing intra-Community trade in accordance with Directive 71/118/EEC and shall make trade in poultrymeat subject to the requirements laid down in the second subparagraph of Article 6(1)(b) of Directive 89/662/EEC.

2. To ensure uniform application of these provisions, inspections may be carried out on-the-spot in third countries by veterinary experts of the Member States and the Commission.

Member States' experts responsible for these inspections shall be designated by the Commission on a proposal from the Member States.

The inspections shall be carried out on behalf of the Community, which shall bear the expenditure incurred.

However, Member States shall be entitled to continue to make inspections under national arrangements of any third country establishments which have not been inspected under the Community procedure.

A list of establishments meeting the conditions referred to Annex 1 to Directive 71/118/EEC shall be drawn up in accordance with the procedure laid down in Article 18.

3. The health certificate which accompanies products on import, and the form and nature of the health mark which the products shall bear, shall correspond to a model to be determined in accordance with the procedure laid down in Article 18.

CHAPTER IV

Common provisions

Article 17

Where the procedure laid down in this Article is to be used, the Standing Veterinary Committee (hereinafter referred to as 'the Committee'), set up by Decision 68/361/EEC⁽²⁾, shall discuss the matter in accordance with the rules laid down in Article 12 of Directive 71/118/EEC.

Article 18

Where the procedure laid down in this Article is to be used, the Committee shall discuss the matter in accordance

with the rules laid down in Article 12 a of Directive 71/118/EEC.

Article 19

1. Annex A to Directive 89/662/EEC shall be supplemented by the following text:

— Council Directive 91/494/EEC of 26 June 1991, on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat (OJ No L 268, 24. 9. 1991, p. 35).'

2. Directive 90/539/EEC shall be amended as follows:

(a) In Article 12(2), first subparagraph, the phrase 'at the latest six months before the date on which the Member States must conform to this Directive' shall be deleted.

(b) In Article 36, the date '1 January 1992' shall be replaced by '1 May 1992'.

Article 20

In connection with the proposals for completing the internal market the Council shall review the provisions of this Directive before 31 December 1992, acting by a qualified majority on a proposal from the Commission.

Article 21

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 1 May 1992. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 22

This Directive is addressed to the Member States.

Done at Luxembourg, 26 June 1991.

For the Council
The President
R. STEICHEN

⁽¹⁾ OJ No L 373, 31. 12. 1990, p. 1.

⁽²⁾ OJ No L 255, 18. 10. 1968, p. 23.

ANNEX

Amendments to be made to the health certificate set out in annex IV to Directive 71/118/EEC

1. The title should be supplemented as follows:

'ANIMAL-HEALTH AND HEALTH CERTIFICATE'

2. Point IV should be replaced by the following:

IV. Attestation

I, the undersigned, official veterinarian, certify that:

- (a) the poultrymeat described above ⁽¹⁾ satisfies the requirements of Directive 90/494/EEC on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat and also the requirements of the second subparagraph of Article 3 (1) of that Directive, if such meat is destined for a Member State or region of a Member State that is recognised as being free of Newcastle disease;
- (b) — the poultrymeat described above ⁽⁴⁾,
— the packaging of the meat described above ⁽⁴⁾,
bear a mark proving that:
— the meat comes from animals slaughtered in approved slaughterhouses ⁽⁴⁾,
— the meat was cut in approved cutting premises ⁽⁴⁾;
- (c) this meat has been passed as fit for human consumption following a veterinary inspection carried out in accordance with Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat;
- (d) the transport vehicles or containers and the loading conditions of this consignment meet the hygiene requirements laid down in Directive 71/118/EEC.

3. Footnote 1 should be replaced by the following:

⁽¹⁾ fresh poultrymeat: fresh meat from the following species: live domestic hens, turkeys, guinea fowls, ducks, geese, quail, pigeons, pheasants and partridges which have not been treated to ensure their preservation'.

COUNCIL DIRECTIVE

of 27 November 1990

concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat

(91/495/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas rabbit meat and farmed game meat are included in the list of products in Annex II to the Treaty; whereas rabbit and game farming are generally included in the farming sector; whereas this farming constitutes a source of income for part of the farming population;

Whereas, in order to ensure the rational development of this sector and to improve productivity, rules concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat must be laid down at Community level;

Whereas disparities as regards animal health and public health conditions in the Member States should be eliminated in order to encourage intra-Community trade in rabbit meat and farmed game meat, with a view to the completion of the internal market;

Whereas diseases transmissible to domestic animals and humans may be spread by rabbit meat and farmed game meat; whereas it is necessary to lay down rules enabling these risks to be controlled;

Whereas the meat in question must be treated in good hygienic conditions in order to avoid food-borne infections and intoxications;

Whereas Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community ⁽⁴⁾, as last amended by Directive 89/162/EEC ⁽⁵⁾, lays down the conditions for notification of animal diseases in the Community; whereas it is opportune to have, for certain contagious diseases affecting farmed game, the same information as for other domestic animals;

Whereas Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat ⁽⁶⁾, as last amended by Directive 89/662/EEC ⁽⁷⁾ and Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat ⁽⁸⁾, as last amended by Directive 90/539/EEC ⁽⁹⁾, lay down the health requirements for, respectively, fresh meat and fresh poultrymeat; whereas farmed wildlife used for game production is similar to farmed mammals and farmed birds; whereas it is therefore opportune to extend to farmed game meat, while taking into account certain specific aspects, the health rules already applied for trade in fresh meat and poultrymeat;

Whereas it is appropriate to lay down exceptions for small quantities of rabbit meat and farmed game meat used for local trade;

Whereas, in respect of the organization of, and the follow-up to, the checks to be carried out by the Member State of destination and the safeguard measures to be implemented, reference should be made to the general rules laid down in Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zoo-technical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market ⁽¹⁰⁾;

Whereas the Commission should be entrusted with the task of adopting measures for applying this Directive; whereas, to that end, provision should be made for procedures establishing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee,

⁽¹⁾ OJ No L 378, 31. 12. 1982, p. 58.

⁽²⁾ OJ No L 61, 4. 3. 1989, p. 48.

⁽³⁾ OJ No 121, 29. 7. 1964, p. 2012/64.

⁽⁴⁾ OJ No L 395, 30. 12. 1989, p. 13.

⁽⁵⁾ OJ No L 55, 8. 3. 1971, p. 23.

⁽⁶⁾ OJ No L 303, 31. 10. 1990, p. 6.

⁽⁷⁾ OJ No L 224, 18. 9. 1990, p. 29.

⁽¹⁾ OJ No C 327, 30. 12. 1989, p. 40.

⁽²⁾ OJ No C 260, 15. 10. 1990, p. 154.

⁽³⁾ OJ No C 124, 21. 5. 1990, p. 7.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General rules

Article 1

This Directive lays down requirements concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat.

Article 2

For the purposes of this Directive, the definitions given in Article 2 of Directive 64/433/EEC and in Article 2 of Directive 71/118/EEC shall apply.

The following definitions shall also apply:

1. 'rabbit meat': all parts of domestic rabbit which are fit for human consumption;
2. 'farmed game meat': all parts of wild land mammals and wild birds — including the species referred to in Article 2 (1) of Directive 90/539/EEC — bred, reared and slaughtered in captivity which are fit for human consumption;
3. 'farmed game': land mammals, or birds, which are not considered as domestic and not referred to in Article 1 (1) of Directive 64/433/EEC or in Article 1 of Council Directive 71/118/EEC, but which are farmed as domestic animals. However, wild mammals living within an enclosed territory under conditions of freedom similar to those enjoyed by wild game shall not be deemed farmed game;
4. 'country of production': the Member State in the territory of which the farm of production is situated.

CHAPTER II

Rules applicable to the production and placing on the market of rabbit meat

Article 3

1. Member States shall see to it that rabbit meat:
 - (a) is obtained in an establishment fulfilling the general conditions of Directive 71/118/EEC and approved for the purposes of this chapter in accordance with Article 14;
 - (b) comes from animals from farms or areas in which bans have not been imposed for veterinary inspection reasons;

- (c) comes from animals which have undergone ante-mortem inspection by an official veterinarian or by assistants, in accordance with Article 4 of Directive 71/118/EEC, such inspection being in accordance with Chapter I of Annex I to this Directive and which have been deemed suitable for slaughter following such inspection;
- (d) has been treated under satisfactory hygiene conditions similar to those provided for in Chapter V of Annex I to Directive 71/118/EEC, except for those in points 28a and 28b;
- (e) has undergone, in accordance with Chapter II of Annex I to this Directive, post-mortem inspection by an official veterinarian or, pursuant to Article 4 of Directive 71/118/EEC, by assistants, and has not shown any change except for traumatic lesions which occurred shortly before slaughter or localized malformations or changes, provided that it is established, if necessary by appropriate laboratory tests, that these do not render the carcass or offal unfit for human consumption or dangerous to human health;
- (f) bears a health mark in accordance with Chapter III of Annex I to this Directive.

A decision may be taken, where appropriate, to amend or supplement the provisions of the aforementioned Chapter in accordance with the procedure provided for in Article 20, in order to take into account notably the different forms of presentation, providing they conform to the rules covering hygiene; in particular, and by way of derogation from the said Chapter, the said procedure shall determine — before 1 January 1992 for the first time — the conditions under which the marketing, in large packages, which have not been marked in accordance with section 11.3 (a) of the said Chapter, of carcasses, parts of carcasses or of offal may be authorized;

- (g) is stored in accordance with Chapter IV of Annex I to this Directive after post-mortem inspection under satisfactory hygiene conditions in establishments approved in accordance with Article 14 or in stores approved in accordance with Community rules;
- (h) has been transported under satisfactory hygiene conditions in accordance with Chapter V of Annex I to this Directive;
- (i) in the case of parts of carcasses or boned meat, has also been obtained in conditions similar to those provided for in Article 3 of Directive 71/118/EEC, in establishments specially approved for this purpose in accordance with Article 14 of this Directive.

2. Each Member State shall also see to it that fresh rabbit meat sent to the territory of another Member State is accompanied by a health certificate during its transport to the country of destination.

The original of the health certificate, which must accompany the fresh rabbit meat during its transport to the consignee,

must be issued by an official veterinarian at the moment of loading. The health certificate must correspond, in presentation and context, to the model in Annex II; it must be drawn up at least in the language or languages of the country of destination and must contain the information provided for in the model in the said Annex.

Article 4

1. By way of derogation from Article 3, Member States may authorize:

- (a) the direct supply of rabbit meat by a small producer to a private individual for his own consumption;
- (b) the supply of fresh rabbit meat in small quantities, by farmers who produce rabbits on a small scale:
 - either directly to the final consumer at those local markets which are closest to their farms,
 - or to a retailer with a view to direct sale to the final consumer, provided that such retailer conducts his business in the same locality as that of the producer or in a neighbouring locality.

The said possible derogation shall not include itinerant sales, mail order sales and, as far as the retailer is concerned, sales on a market.

2. Member States shall take the measures necessary to ensure the health control of these operations provided for in paragraph 1 and to adopt rules enabling the original holding of such meat to be traced.

3. Under the procedure laid down in Article 20, the Commission may adopt the detailed rules for applying this Article and in particular, at the request of Member State, fix the maximum limits of quantities which may be supplied pursuant to paragraph 1.

CHAPTER III

Rules applicable to the production and marketing of farmed game meat

Article 5

Member States shall ensure that intra-Community trade in farmed game meat is subject:

- (a) where farmed game birds are concerned, to the requirements of Council Directive 91/494/EEC of

26 June 1990 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat ⁽¹⁾;

- (b) where other species of farmed game are concerned, to the requirements of Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat ⁽²⁾, as last amended by Directive 89/662/EEC.

Article 6

1. Farmed game meat obtained from cloven-hoofed wild land mammals shall fulfil the relevant conditions referred to in Article 3 and Article 5 (b) to (k) of Directive 64/433/EEC, provided that the original herd undergoes regular veterinary inspection and is not under any restrictions following the survey performed according to Article 11 or as a result of veterinary inspection. The detailed rules for this inspection shall be laid down in accordance with the procedure set out in Article 20.

The animals in question shall be treated at different times from bovine animals, swine, sheep and goats.

The health certificate which must accompany such meat shall correspond to the model in Annex IV to this Directive.

Meat from farmed wild pigs or other species sensitive to *Trichina* infestation shall be subjected to examination by digestion in accordance with Council Directive 77/96/EEC of 21 December 1976 on examination for *Trichinae* (*trichinella spiralis*) upon importation from third countries of fresh meat derived from domestic swine ⁽³⁾ as last amended by Directive 89/321/EEC ⁽⁴⁾.

2. Notwithstanding paragraph 1, the official service may authorize the slaughter of farmed game in the place of origin, where it cannot be transported, in order to avoid any risk for the handler or to protect the welfare of the animals. This authorization may be granted provided that:

- the herd undergoes regular veterinary inspection and is not under any restrictions following the survey performed according to Article 12 or as a result of veterinary inspection,
- a request is submitted by the owner of the animals,
- the official service is informed in advance of the date of slaughtering of the animals,
- the holding has a centre for mustering wild animals where an ante-mortem inspection of the group for slaughter can be carried out,

⁽¹⁾ See page 35 of this Official Journal.

⁽²⁾ OJ No L 302, 31. 12. 1972, p. 24.

⁽³⁾ OJ No L 26, 31. 1. 1977, p. 67.

⁽⁴⁾ OJ No L 133, 17. 5. 1989, p. 33.

- the holding has premises suitable for the slaughter, sticking and bleeding of the animals,
- slaughter by means of sticking and bleeding is preceded by stunning, which must be carried out in the conditions laid down in Directive 74/577/EEC⁽¹⁾; the veterinary service may authorize shooting only in special cases,
- the slaughtered and bled animals are hung as quickly as possible after slaughter and are transported under satisfactory hygiene conditions to a slaughterhouse approved in accordance with Directive 66/433/EEC. Where game slaughtered at the place of rearing cannot be brought within the hour to a slaughterhouse approved in accordance with Article 8 of Directive 64/433/EEC, it must be transported in a container or means of transport in which the ambient temperature is maintained at between 0 °C and 4 °C. Evisceration must be carried out no later than three hours after stunning,
- during transportation to the slaughterhouse the slaughtered animals are accompanied by a certificate issued by the veterinary service attesting to the favourable outcome of the ante-mortem inspection, the correct conduct of bleeding and the time of slaughter; this certificate must correspond to the model in Annex III.

3. Pending the adoption of health rules applicable to meat reserved for the domestic market, the slaughtering of farmed big game and the cutting and storage of the meat referred to in paragraph 1 may, by way of derogation from paragraph 1, be performed in establishments approved by the national authorities for the domestic market, provided that such meat does not enter intra-Community trade.

Article 7

1. Countries of destination may, with due regard for the general provisions of the Treaty, grant one or more countries of consignment general authorizations or authorizations restricted to specific cases, whereby the fresh meat referred to in Article 5 (b) and (i) to (k) of Directive 64/433/EEC may be admitted to their territory.

Such fresh meat may be sent solely in accordance with Article 3 (1) and (3) of Directive 64/433/EEC.

2. If a country of destination grants a general authorization in accordance with paragraph 1, it shall immediately inform the other Member States and the Commission thereof.

3. The countries of consignment shall make all necessary arrangements to ensure that health certificates, a specimen of which is provided in Annex IV, mention that one of the options provided for in paragraph 1 has been taken up.

⁽¹⁾ OJ No L 316, 26. 11. 1974, p. 10.

Article 8

Meat of farmed game birds shall fulfil the conditions referred to in Article 3 of Directive 71/118/EEC.

Meat of farmed game birds intended for intra-Community trade shall be accompanied by the health certificate provided for in Article 8 of Directive 71/118/EEC, which shall correspond to the model in Annex IV to this Directive.

However, notwithstanding Chapter V (23) of Annex I to Directive 71/118/EEC, where, in the case of quail and pigeon, the evisceration technique used does not permit complete health inspection of the viscera of each bird, that inspection may be carried out on a sample of at least 5% of each batch of 500 birds, and in corresponding proportion beyond 500 birds, provided that the batches are homogeneous in terms of their nature, weight and origin.

Where the results are not clearly satisfactory, the opinion expressed on the basis of such sample inspection of the viscera as to whether the slaughtered birds are fit for consumption shall apply to the entire batch.

Article 9

Notwithstanding Article 8, first subparagraph, in the case of meat from farmed game birds obtained and put on the market in their territory, Member States may, with due regard for the general provisions of the Treaty, grant those slaughterhouses or cutting premises situated in their territory which were engaged in that activity prior to the date of notification of this Directive and which expressly so request, a derogation from the slaughter and evisceration provisions laid down in Chapter V of Annex I to Directive 71/118/EEC in the case of the production of partially eviscerated or non-eviscerated farmed game birds.

The use of the health mark provided for in Chapter X of Annex I to Directive 71/118/EEC shall be prohibited in the event that this derogation is exercised.

Article 10

Article 8 shall not apply to meat of farmed game birds which, in isolated cases, is supplied by the producer thereof direct to the final consumer for his own consumption otherwise than by itinerant sale, sale by mail order or sale on a market.

Under the procedure laid down in Article 20, the Commission may adopt the detailed rules for applying this Article and in particular, at the request of Member State, fix the maximum limits of quantities which may be supplied pursuant to the first paragraph.

CHAPTER IV

Common provisions

Article 11

1. Member States shall ensure that a survey of the health of rabbit and farmed game is performed on holdings on their territories at regular intervals.

2. To this end a central service or body shall be entrusted with the task of collecting and using the results of the health inspections carried out in accordance with this Directive, where diseases transmissible to humans or animals or the presence of residues in excess of permitted levels are diagnosed.

3. Where a disease or condition referred to in paragraph 2 is diagnosed, the survey results relating to the specific case shall be communicated as soon as possible to the official service responsible for supervision of the stock from which the animals originate.

4. Depending on the epizootic situation, the official service shall carry out specific tests on farmed game in order to detect the presence of the diseases referred to in Annex I to Directive 82/894/EEC.

The presence of these diseases shall be communicated to the Commission and to the other Member States in accordance with the said Directive.

Article 12

1. Member States shall supplement their plans for measures on residues referred to in Article 4 of Council Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues ⁽¹⁾ in order to subject rabbits and farmed game to the inspections provided for in that Directive and also to monitor wild game for contaminants present in the environment.

2. Taking into account the results of the monitoring referred to Article 11 (4), Member States shall impose limitations on the use of game meat from holdings or territories implicated by the monitoring.

3. The Commission shall adopt the detailed rules for application of this Article in accordance with the procedure laid down in Article 20.

Article 13

Rabbit meat or meat of farmed game birds shall not be used for human consumption if:

⁽¹⁾ OJ No L 275, 26. 9. 1986, p. 36.

- (a) found to have one of the faults listed in point 9 (a) of Annex I;
- (b) originating from animals to which substances likely to make the meat dangerous or harmful to human health have been administered and on which a decision has been taken, in accordance with the procedure provided for in Article 20, following the opinion of the Scientific Veterinary Committee. Pending that decision, national rules on authorized substances shall remain in force in accordance with the general provisions of the Treaty;
- (c) without prejudice to possible Community regulations applicable in the field of ionization, treated with ionizing or ultraviolet radiation or treated with tenderizers or other substances which could affect the organoleptic properties of the meat or colorants other than those used for health marking.

Article 14

1. Each Member State shall draw up a list of the establishments approved by it, each establishment having a veterinary approval number. Member States may approve for slaughtering and cutting of rabbit and farmed game establishments approved according to Directive 71/118/EEC or Directive 64/433/EEC, provided that those establishments are equipped for the processing of rabbit meat and/or farmed game meat and that those operations are performed in such a way as to comply with hygiene rules. Member States shall send this list to the other Member States and to the Commission.

2. No Member State shall approve an establishment unless compliance with this Directive is assured. Member States shall withdraw approval if the conditions for granting it cease to be fulfilled.

3. If a check has been made in accordance with Article 16, the Member State concerned shall take account of the conclusions resulting therefrom. The other Member States and the Commission shall be informed of the withdrawal of approval.

4. Inspection and supervision of approved establishments shall be carried out under the responsibility of the official veterinarian who, without prejudice to the tasks devolved to assistants under Directive 71/118/EEC, may be assisted in purely material tasks by staff specially trained for the purpose. The official veterinarian must at all times have free access to all parts of establishments in order to ensure that this Directive is being complied with.

The detailed rules governing this assistance shall be determined in accordance with the procedure laid down in Article 20.

Article 15

Veterinary experts from the Commission may, insofar as it is necessary to ensure uniform application of this Directive,

make on-the-spot checks in co-operation with the competent authorities of the Member States; they may verify whether approved establishments are actually complying with this Directive. The Commission shall inform the Member States of the results of the checks.

A Member State in whose territory a check is being carried out shall give all the necessary assistance to the experts carrying out their duties.

The general provisions for implementing this Article shall be determined in accordance with the procedure laid down in Article 20.

Article 16

1. The rules laid down in Council Directive 89/662/EEC concerning veterinary checks to be carried out in intra-Community trade with a view to the completion of the internal market shall apply in particular to the organization of, and the action to be taken following the checks carried out by the country of destination and to the safeguard measures to be applied in relation to health problems affecting the production and distribution of rabbit and game meat in the territory of the Community.

2. Directive 89/662/EEC shall be amended as follows:

(a) in Annex A, the following should be added in fine:

— Council Directive 91/495/EEC of 27 November 1990 on public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat. (OJ No L 268, 24. 9. 1991, p. 41) (Excluding rabbit meat and farmed game meat imported from third countries);

(b) in Annex B, the indent 'rabbit and game meat' shall be replaced by 'wild game meat'.

Article 17

Pending the implementation of Community provisions concerning imports of rabbit and game meat from third countries, Member States shall apply to such imports provisions which are at least equivalent to those of this Directive.

However, pending the implementation of these provisions, Member States shall ensure that imports from third countries remain subject to the rules laid down in the third subparagraph of Article 6 (1) (b) of Directive 89/662/EEC and also that:

(i) fresh rabbit meat and fresh farmed game meat may not, under any circumstances, bear the public health marking referred to in Chapter X of Annex I to Directive 71/118/EEC and, if cut and boned, must be treated in accordance with Article 3 (1) (B) of that Directive;

(ii) meat from species susceptible to trichinosis shall be subjected to examination by digestion in accordance with Directive 77/96/EEC.

CHAPTER V

Final provisions

Article 18

This Directive shall not affect Community rules adopted in order to protect wildlife.

Article 19

The Annexes to this Directive shall be amended by the Council acting by a qualified majority on a proposal from the Commission in order in particular to bring it into line with technological progress.

Article 20

1. Where the procedure laid down in this Article is to be used, matters shall without delay be referred by the Chairman, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter called 'the Committee') set up by Decision 68/361/EEC⁽¹⁾.

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

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

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

The Council shall act by a qualified majority.

If, upon expiry of a period of three months from the date of referral to the Council, the Council has not acted, the

⁽¹⁾ OJ No L 255, 18. 10. 1968, p. 23.

Commission shall adopt the proposed measures and implement them immediately, save where the Council has decided against the said measures by a simple majority.

Article 21

Pending implementation of Community health and veterinary inspection rules on the production and marketing of meat of wild game to be adopted not later than 31 March 1991, wild game meat fit for consumption shall be subject to the rules of Article 3 (3), the second indent of the second subparagraph of Article 4 (1) and to Article 5 (2) of Directive 89/662/EEC.

Article 22

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 January 1993. They shall forthwith inform the Commission thereof.

2. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 23

This Directive is addressed to the Member States.

Done at Brussels, 27 November 1990.

For the Council
The President
V. SACCOMANDI

ANNEX I

CHAPTER I

Ante-mortem health inspection of rabbits

1. Animals must undergo ante-mortem inspection before they are slaughtered. As a general rule, such ante-mortem inspection must be carried out at the holding before loading.
 - (a) If the ante-mortem inspection has been carried out at the holding of origin, ante-mortem inspection at the slaughterhouse may be restricted to detecting injuries received in transport if the rabbits have been inspected at the holding of origin within the previous 24 hours and found to be healthy. In addition, the identity of the rabbits must be proved on arrival at the slaughterhouse.

If the ante-mortem inspection at the holding of origin and at the slaughterhouse is not carried out by the same official veterinarian, a health certificate stating the particulars required under Annex III must accompany the animals.
 - (b) If the ante-mortem inspection is not carried out at the holding of origin, rabbits for slaughter must undergo ante-mortem inspection within 24 hours of arrival at the slaughterhouse. The inspection must be repeated immediately before slaughter if more than 24 hours have elapsed since ante-mortem inspection.

The operator of the slaughterhouse or his agent must facilitate operations for performing ante-mortem health inspections and in particular any handling which is considered necessary.

Each animal or batch of animals sent for slaughter must be identified in order to allow the competent authority to determine its origin.
2. The ante-mortem inspection must be carried out by the official veterinarian in accordance with professional rules under suitable lighting.
3. The inspection must determine:
 - (a) whether the animals are suffering from a disease which can be transmitted to humans or animals, whether they show symptoms or whether their general condition is such as to indicate that the disease may occur;
 - (b) whether they show symptoms of a disease or of a disorder affecting their general condition which may make the meat unfit for human consumption.
4. Animals may not be slaughtered for human consumption where it is established that they suffer from the conditions referred to at point 3.
5. The animals referred to at point 4 must be killed separately or after slaughter of all other rabbits and their meat hygienically disposed of.

CHAPTER II

Post-mortem health inspection of rabbits

6. Slaughtered rabbits must be inspected immediately after slaughter.
7. The post-mortem inspection must be carried out under suitable lighting.
8. The post-mortem health inspection must include:
 - (a) visual inspection of the slaughtered animal;
 - (b) palpation and, where necessary, incision of the lungs, liver, spleen, kidneys and parts of the carcass which have undergone any change;
 - (c) investigations of anomalies of consistency, colour, smell and, where appropriate, taste;
 - (d) where necessary, laboratory tests.

9. (a) Rabbits shall be declared totally unfit for human consumption where the post-mortem inspection reveals the following:
- diseases transmissible to man or animals;
 - malignant or multiple tumours; multiple abscesses;
 - extensive parasitic infestation in the subcutaneous or muscle tissues;
 - presence of residues of forbidden substances or residues in excess of permitted Community levels, including substances with a pharmacological effect;
 - poisoning;
 - extensive injuries or extensive blood or serum imbibition;
 - anomalies as regards colour, smell or taste;
 - anomalies as regards consistency, particularly oedema or severe emaciation.
- (b) Parts of slaughtered animals which show localized lesions or contaminations not affecting the health of the rest of the meat shall be declared unfit for human consumption.
- (c) The results of the ante-mortem and post-mortem health inspections shall be recorded by the official veterinarian and, if the presence of the diseases referred to in point 3 or the presence of residues are found, these shall be communicated to the authorities of the official service responsible for supervision of the stock from which the animals originated, as well as to the person responsible for the stock in question.

CHAPTER III

Public health marking

10. The public health marking must be made under the responsibility of the official veterinarian, who shall keep and maintain for that purpose:
- (a) instruments for making the public health marking on meat, to be handed over to the assistant staff only at the actual time of marking and for the length of time necessary for this purpose;
 - (b) labels and wrappers where these already bear one of the marks or of the seals referred to in point 11. These labels, wrappers and seals shall be handed over in the required number to the assistant staff at the time when they must be used.
- 11.1. The public health marking shall consist of the following:
- (a) — on the upper part, the initial letter or letters in capitals of the name of the country of dispatch:
B, D, DK, EL, ESP, F, IRL, I, L, NL, P, UK,
— in the centre, the veterinary approval number of the slaughterhouse or, where appropriate, the cutting premises,
— on the lower part, one of the following sets of initials:
CEE, EEG, EWG, EØF, EEC or EOK,
the letters and figures must be 0,2 cm high or
 - (b) an oval containing the information listed in (a); the letters must be 0,8 cm high and the figures 1,1 cm high.
2. The material used for marking must meet all hygiene requirements and the information referred to in point 1 shall appear on it in perfectly legible form.
3. (a) The public health marking referred to in point 1 (a) must be made:
- on unwrapped carcasses by means of a seal containing the information listed in point 1 (a),
 - on or visibly beneath wrappers or other packaging of packed carcasses,
 - on or visibly beneath wrappers or other packaging of parts of carcasses or offal packed in small quantities;
- (b) The public health marking referred to in point 1 (b) must be made on large packaging.

4. Where a public health marking appears on the wrapper or packaging in accordance with point 3:
 - it must be applied in such a way that it is destroyed when the wrapper or packaging is opened, or
 - the wrapper or packaging must be sealed in such a way that it cannot be re-used after opening.

CHAPTER IV

Storage

12. After post-mortem inspection, rabbit meat must be chilled or frozen and kept at a temperature which must not at any time exceed $-4\text{ }^{\circ}\text{C}$ if chilled or $-12\text{ }^{\circ}\text{C}$ if frozen.

CHAPTER V

Transport

13. The rabbit meat must be dispatched in such a way that during transport it is protected from anything liable to contaminate it or to affect it unfavourably, having regard to the duration and conditions of transport and to the means of transport employed. In particular, vehicles used for this transport must be equipped in such a way as to ensure that the temperatures laid down at point 12 are not exceeded.
-

ANNEX II

MODEL

PUBLIC HEALTH CERTIFICATE

for fresh rabbit meat ⁽¹⁾ intended for consignment to a Member State of the EECExporting country: No ⁽²⁾:

Ministry:

Competent service:

Ref. ⁽²⁾:

I. Identification of meat

Meat of:
(animal species)

Nature of cuts:

Nature of packaging:

Number of packages:

Net weight:

II. Origin of meat

Address(es) and veterinary approval number(s) of the slaughterhouse(s) ⁽⁴⁾:Address(es) and veterinary approval number(s) of the approved cutting premises ⁽⁴⁾:

III. Destination of meat

The meat will be sent

from
(place of loading)to
(country and place of destination)by the following means of transport ⁽³⁾:

Name and address of consignor:

Name and address of consignee:

⁽¹⁾ Fresh rabbit meat which has not been treated to ensure its preservation; however, rabbit meat which has been chilled or frozen shall be considered to be fresh.⁽²⁾ Optional.⁽³⁾ For railway wagons and lorries the registration number, for aircraft the flight number and for ships the name should be given.⁽⁴⁾ Delete as appropriate.

IV. Public health attestation

I, the undersigned, official veterinarian, certify that:

(a) — the rabbit meat described (*),

— the packaging of the meat described above (*)

bears a mark proving that:

— the meat comes from animals slaughtered in approved slaughterhouses (*),

— the meat was cut in approved cutting premises (*);

(b) this meat has been passed as fit for human consumption following a veterinary inspection carried out in accordance with Council Directive 90/495/EEC of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat;

(c) the transport vehicles or containers and the loading conditions of this consignment meet the hygiene requirements laid down in that Directive.

Done at on

.....
(signature of official veterinarian)

(*) Delete as appropriate.

ANNEX III

MODEL

HEALTH CERTIFICATE

for farmed rabbits or game ⁽¹⁾ transported from the farm to the slaughterhouse

Competent service: No ⁽²⁾:

I. Identification of animals

Animal species:

Number of animals:

Identification marking:

II. Origin of animals

Address of holding of origin:

.....

III. Destination of animals

The animals will be sent to the following slaughterhouse:

.....

by the following means of transport:

IV. Attestation

I, the undersigned, official veterinarian, hereby certify that the animals described above underwent an ante-mortem inspection at the above holding at on and were found to be healthy.

Done at on

.....
(signature of official veterinarian)

⁽¹⁾ Under the conditions provided for in Article 6 (3) of Directive 90/495/EEC.
⁽²⁾ Optional.

ANNEX IV

MODEL

HEALTH CERTIFICATE

for fresh farmed game meat ⁽¹⁾ intended for consignment to a Member State of the EEC

Exporting country: No ⁽²⁾:

Ministry:

Competent service:

Ref. ⁽²⁾:

I. Identification of meat

Meat of:
(animals species)

Nature of cuts:

Nature of packaging:

Number of packages:

Net weight:

II. Origin of meat

Address(es) and veterinary approval number(s) of the slaughterhouse(s) ⁽⁴⁾:

Address(es) and veterinary approval number(s) of the approved cutting premises ⁽⁴⁾:

III. Destination of meat

The meat will be sent

from
(place of loading)

to
(country and place of destination)

by the following means of transport ⁽³⁾:

Name and address of consignor:

Name and address of consignee:

⁽¹⁾ Fresh meat of farmed game birds and of farmed wild mammals which has not been treated to ensure its preservation; however, meat which has been chilled or frozen shall be considered to be fresh.
⁽²⁾ Optional.
⁽³⁾ For railway wagons and lorries the registration number, for aircraft the flight number and for ships the name should be given.
⁽⁴⁾ Delete as appropriate.

IV. Health attestation

I, the undersigned, official veterinarian, certify that:

- (a) — the meat of the species described above (*),
— the packaging of the meat described above (*),
bears a mark proving that:
 - the meat comes from animals slaughtered in approved slaughterhouses (*),
 - the meat was cut in approved cutting premises (*);
- (b) this meat has been passed as fit for human consumption following a veterinary inspection carried out in accordance with:
 - the Council Directive 77/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat (*),
 - Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat (*);
- (c) the transport vehicles or containers and the loading conditions of this consignment meet the hygiene requirements laid down in that Directive.

Done at, on

.....
(Signature of official veterinarian)

(*) Delete as appropriate.

COUNCIL DIRECTIVE

of 15 July 1991

laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC

(91/496/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Whereas live animals are included in the list in Annex II to the Treaty;

Whereas laying down principles at Community level on the organization of veterinary checks on animals coming from third countries helps to safeguard supplies and ensure market stability while also harmonizing the measures necessary to ensure the protection of animal health;

Whereas Article 23 of Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market ⁽³⁾ provides, in particular, that the Council must lay down the rules and general principles applicable to checks on imports from third countries of animals covered by the said Directive;

Whereas each consignment of animals from third countries must be subjected to documentary and identity checks upon entry into the territory of the Community;

Whereas principles valid throughout the Community should be fixed concerning the organization and follow-up of physical checks to be carried out by the competent veterinary authorities;

Whereas provision must be made for safeguard arrangements; whereas, in this context, the Commission must be able to act, particularly by visiting the places concerned and adopting measures appropriate to the circumstances;

⁽¹⁾ OJ No C 89, 6. 4. 1991, p. 5.

⁽²⁾ OJ No C 183, 15. 7. 1991.

⁽³⁾ OJ No L 224, 18. 8. 1990, p. 29. Directive amended by Directive 91/174/EEC (OJ No L 85, 5. 4. 1991, p. 37).

Whereas, if the checking system is to function smoothly there must be an approval procedure and border inspection posts must be inspected and there should be exchanges of officials empowered to carry out checks on live animals coming from third countries;

Whereas the laying down of common principles at Community level is all the more necessary given that, with the completion of the internal market in prospect, internal border controls are to be abolished;

Whereas Directives 89/662/EEC ⁽⁴⁾, 90/425/EEC, and 90/675/EEC should be amended in order to adapt them to this Directive;

Whereas the provision of certain transitional measures of limited duration appears to be necessary in order to facilitate the transition to the new checking arrangements instituted by this Directive;

Whereas the task of adopting measures for the application of this Directive should be entrusted to the Commission,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Veterinary checks in respect of animals from third countries entering the Community shall be carried out by the Member States in accordance with this Directive.

2. This Directive shall not apply to veterinary checks on family pets accompanying travellers for non-commercial purposes, other than *equidae*.

Article 2

1. For the purposes of this Directive, the definitions contained in Article 2 of Directive 90/425/EEC shall apply as necessary.

2. In addition:

(a) 'documentary check' shall mean verification of the veterinary certificates or documents accompanying an animal;

⁽⁴⁾ OJ No L 395, 30. 12. 1989, p. 13.

- (b) 'identity check' shall mean verification, by visual inspection only, for consistency between the documents or certificates and the animals and for the presence and conformity of the marks which must appear on the animals;
- (c) 'physical check' shall mean a check of the animal itself, possibly including sampling and laboratory testing and, where appropriate, additional checks during quarantine;
- (d) 'importer' shall mean any natural or legal person who presents animals for importation into the Community;
- (e) 'consignment' shall mean a quantity of animals of the same species, covered by the same veterinary certificate or document, conveyed by the same means of transport and coming from the same third country or same part of such country;
- (f) 'border inspection post' shall mean any inspection post located in the immediate vicinity of the external border of one of the territories referred to in Annex I to Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries ⁽¹⁾ and designated and approved in accordance with Article 6.
- (ii) that the veterinary checks have been paid for, and that, where relevant, a deposit covering any cost provided for in the second and third indents of Article 10 (1), Article 10 (6) and Article 12 (2) has been lodged;
- (d) the customs authority does not authorize release for free circulation in the territories referred to in Annex I to Directive 90/675/EEC unless, without prejudice to the specific provisions to be adopted in accordance with the procedure laid down in Article 23, proof has been supplied that the requirements in (c) have been fulfilled.

2. Detailed rules for implementing this Article shall be adopted, as the need arises, in accordance with the procedure laid down in Article 23.

Article 4

1. Member States shall ensure that, irrespective of the customs destination of the animals, each consignment of animals from a third country is subjected by the veterinary authority to a documentary check and identity check at one of the border inspection posts situated in one of the territories referred to in Annex I to Directive 90/675/EEC and approved for that purpose, in order to verify:

- their origin,
- their subsequent destination, particularly in the case of transit or in the case of animals, trade in which has not been harmonized at Community level or which are subject to specific requirements recognized by a Community decision in respect of the Member State of destination,
- that the particulars which appear on the certificates or documents afford the guarantees required by Community rules or, in the case of animals, trade in which has not been harmonized at Community level, the guarantees required under the national rules applicable in the various cases covered by this Directive.

2. Without prejudice to the exemptions pursuant to Article 8, the official veterinarian must carry out a physical check on animals presented at the border inspection post. That check must include, in particular:

- (a) a clinical examination of the animals in order to ensure that they conform to the information provided in the accompanying certificate or document and that they are clinically healthy.

In accordance with the procedure laid down in Article 23, derogation may be made, subject to certain conditions and in accordance with rules to be established under the same procedure, from the principle of individual clinical examination in respect of certain categories and species of animals;

- (b) any laboratory tests which it is thought necessary should be carried out or which are provided for by Community rules;
- (c) possible official samples to be examined for residues and analysed as soon as possible;

CHAPTER I

Organization and follow-up of checks

Article 3

1. Member States shall ensure that:

- (a) importers are obliged to give one working day's notice to the veterinary staff of the border inspection post where the animals are to be presented specifying the number, nature and estimated time of arrival of the animals;
- (b) the animals are conveyed directly, under official supervision, to the border inspection post referred to in Article 6 or, where applicable, to a quarantine centre as provided for in the second indent of the first subparagraph of Article 10 (1);
- (c) the animals may not leave such post or centre unless, without prejudice to the special provisions to be adopted in accordance with the procedure provided for in Article 23, proof has been supplied:
- (i) in the form of the certificate provided for in the second indent of Article 7 (1) or in Article 8, that the veterinary checks have been carried out on the animals in question in accordance with Article 4 (1) and (2) (a), (b) and (d) and Articles 8 and 9 to the satisfaction of the competent authority;

⁽¹⁾ OJ No L 373, 31. 12. 1990, p. 1.

- (d) verification of compliance with the minimum requirements laid down by Council Directive 77/489/EEC of 18 July 1977 on the protection of animals during international transport ⁽¹⁾.

For the purposes of a subsequent check on transport and, where appropriate, on compliance with the additional requirements of the holding of destination, the official veterinarian shall communicate the necessary information to the competent authorities of the Member State of destination by means of the information exchange system provided for in Article 20 of Directive 90/425/EEC.

The official veterinarian may be assisted in certain of these tasks by qualified staff with special training, working under his direction.

3. However, by way of derogation from paragraphs 1 and 2, for animals entering a port or an airport in the territory defined in Annex I to Directive 90/675/EEC, the identity check and the physical check may be carried out at such port or airport of destination, provided that such port or airport has a border inspection post as referred to in Article 6, and that the animals continue their journey, as the case may be, by sea or by air in the same vessel or in the same aircraft. In such cases, the competent authority which carried out the documentary check shall, either directly or through the local veterinary authority, inform the official veterinarian of the inspection post of the Member State of destination by means of the information exchange system referred to in Article 20 of Directive 90/425/EEC that the animals have passed through.

4. All expenditure incurred by the application of this Article shall be chargeable to the consignor, the consignee or their agent, without reimbursement by the Member State.

5. The detailed rules for applying this Article, including those relating to the training and qualification of assistants, shall be adopted, as the need arises, in accordance with the procedure laid down in Article 23.

Article 5

Entry into one of the territories defined in Annex I to Directive 90/675/EEC shall be prohibited where the checks show that:

- (a) animals of species in respect of which import rules have been harmonized at Community level come, without prejudice to the special conditions provided for in Article 19 of Directive 90/426/EEC ⁽²⁾ as concerns the movement and import of *equidae* coming from third countries, from a territory or part of a territory of a third country not included in the lists drawn up in accordance with Community rules for the species concerned or from which imports are prohibited pursuant to a Community decision;

⁽¹⁾ OJ No L 200, 8. 8. 1977, p. 10.

⁽²⁾ OJ No L 224, 18. 8. 1990, p. 42.

- (b) animals other than those referred to in (a) do not comply with the requirements provided for in the national rules corresponding to the various cases covered by this Directive;
- (c) animals are suffering from or are suspected to be suffering from or infected by a contagious disease or a disease presenting a risk for public health or animal health, or any other reason provided for in Community rules;
- (d) the exporting third country has not complied with the requirements provided for in Community rules;
- (e) animals are not in a fit state to continue their journey;
- (f) the veterinary certificate or document accompanying animals does not meet the conditions set pursuant to Community rules or, where rules have not been harmonized, the requirements provided for in the national rules corresponding to the various cases covered by this Directive.

The detailed rules for applying this Article shall be adopted in accordance with the procedure laid down in Article 23.

Article 6

1. Border inspection posts must satisfy the requirements of this Article.

2. Border inspection posts must be:

- (a) located at the point of entry into one of the territories referred to in Annex I to Directive 90/675/EEC;

However, where necessitated by geographical constraints (such as unloading wharf, railway station, passes) and provided that in such a case the inspection post is located far from holdings or places where animals likely to be infected by contagious diseases are kept, siting of an inspection post at a certain distance from the point of entry may be tolerated;

- (b) located in a customs area enabling other administrative formalities to be carried out, including customs formalities relating to importation;
- (c) designated and approved in accordance with paragraph 3;
- (d) placed under the authority of an official veterinarian, who shall be effectively responsible for the checks. The official veterinarian may be assisted by specially trained auxiliary staff working under his direction.

3. Before 1 January 1992, and once border posts have been shortlisted by national authorities, acting in conjunction with the Commission departments which will verify their compliance with the minimum requirements set out in Annex A, Member States shall submit to the Commission the list of border inspection posts responsible for carrying out veterinary checks on animals, and shall provide the following information:

- (a) nature of the border inspection post:
- port,
 - airport,
 - road checkpoint,
 - rail checkpoint;
- (b) nature of the animals which could be checked at the border inspection post in question given the equipment and veterinary staff available, indicating any animals that cannot be checked at those border inspection posts and for registered equidae the operating hours of a specially approved border inspection post;
- (c) staff assigned to veterinary checks:
- number of official veterinarians with at least one official veterinarian on duty at all times that the border inspection post is open,
 - number of specially qualified auxiliary staff or assistants;
- (d) description of the equipment and premises available for carrying out:
- the documentary check,
 - the physical check,
 - sampling,
 - the general tests laid down in Article 4 (2) (b),
 - the specific tests ordered by the official veterinarian;
- (e) capacity of the premises available to house animals where necessary pending the test results;
- (f) nature of the equipment allowing a rapid exchange of information, particularly with other border inspection posts;
- (g) volume of trade (types and quantities of animals passing through this border inspection post).

4. Acting in conjunction with the competent national authorities, the Commission shall inspect the border inspection posts designated in accordance with paragraph 3 in order to satisfy itself that there is uniform application of the rules on veterinary checks and that the various border inspection posts in fact possess the necessary infrastructures and meet the minimum requirements laid down in Annex A.

Before 1 January 1992, the Commission shall submit to the Standing Veterinary Committee a report on the outcome of the inspection referred to in the first subparagraph, together with proposals taking into account the conclusions of the report, with a view to establishing a Community list of border inspection posts. That list shall be approved and subsequently updated in accordance with the procedure laid down in Article 22.

The abovementioned report shall cover any problems that would be encountered by certain Member States if the shortlisting referred to in the first subparagraph of paragraph 3 were to result in a large number of border inspection posts being excluded at 1 July 1992.

To take account of any such problem, some of the border inspection posts may be kept in operation and granted a maximum of three years to comply with the requirements of this Directive as regards equipment and structures.

The Commission shall publish the list of approved border inspection posts, and any subsequent updates, in the *Official Journal of the European Communities*.

5. As the need arises, the Commission shall adopt any detailed rules required for implementing this Article in accordance with the procedure laid down in Article 23.

Article 7

1. Where animals of species for which import rules have been harmonized at Community level are not to be placed on the market in the territory of the Member State which carried out the checks referred to in Article 4, the official veterinarian of the border inspection post shall, without prejudice to the specific requirements applicable to *equidae* registered and accompanied by the identification document provided for by Directive 90/427/EEC ⁽¹⁾:

- provide the person concerned with a copy or, if the consignment of animals is split, several individually authenticated copies of the original certificates relating to the animals; the period of validity of such copies shall be no more than 10 days,
- issue a certificate which matches the model to be drawn up by the Commission in accordance with the procedure laid down in Article 23 attesting that the checks referred to in Articles 4 (1) and (2) (a), (b) and (d) have been carried out to the satisfaction of the official veterinarian, and specifying the nature of the samples that have been taken and the results of any laboratory tests, or when those results are expected,
- keep the original certificate or certificates accompanying the animals.

2. Detailed rules for the application of paragraph 1 shall be adopted in accordance with the procedure laid down in Article 23.

3. Once animals have passed through border inspection posts trade in the animals referred to in paragraph 1 and allowed into the territories referred to in Annex I to Directive 90/675/EEC shall be conducted in accordance with the rules for veterinary checks laid down in Directive 90/425/EEC.

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 55.

In particular, the information from the competent authority of the place of destination given by means of the information exchange system provided for in Article 20 of Directive 90/425/EEC, must specify whether:

- animals are intended for a Member State or an area having specific requirements,
- samples have been taken but the results are not known when the means of transport leaves the border inspection post.

Article 8

A. Member States shall ensure that:

1. veterinary checks on imports of animals of species not covered by Annex A to Directive 90/425/EEC are carried out in accordance with the following provisions:

- (a) where animals are presented directly at one of the border posts of the Member State which intends to import them, they shall undergo at that post all the checks provided for in Article 4;
- (b) where animals are presented at a border inspection post situated in another Member State, with the latter's prior agreement:
 - (i) either all the checks referred to in Article 4 shall be carried out at that post on behalf of the Member State of destination in order, in particular, to ensure that the latter's animal health requirements have been complied with;
 - (ii) or, in the event of agreement between the competent central authorities of the two Member States and, where appropriate, those of the Member State or Member States of transit, only the checks provided for in Article 4 (1) shall be carried out at that post, in which case the checks provided for in Article 4 (2) shall be carried out in the Member State of destination.

In the latter case, however, animals may leave the border inspection post where the documentary check and identity check have been carried out only in sealed vehicles and only after the official veterinarian:

- has indicated on the copy, or, where the consignment is split, on the copies, of the original certificates that the animals have passed through and that the check has been carried out,
- has informed, by means of the information exchange system provided for in Article 20 of Directive 90/425/EEC, the veterinary authority of the place of destination or, where appropriate, of the Member State or Member States of transit, that the animals have passed through,

- notwithstanding Article 3 (1) (c), has given a discharge to the competent customs authority of the border inspection post in respect of the animals presented.

In the case of animals intended for slaughter, Member States may have recourse only to the solution set out in (i).

Member States shall inform the Commission and the representatives of the other Member States meeting in the Standing Veterinary Committee, of cases of recourse to the solution set out in (ii);

2. pending adoption of the specific decisions provided for under Community rules, animals the trade in which has been harmonized at Community level but which come from a third country for which uniform animal health conditions have not yet been established shall be imported subject to the following conditions:

- they must have remained in the third country of dispatch at least during the periods provided for in Article 10 (1) of Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine, ovine and caprine animals and swine, fresh meat or meat products from third countries ⁽¹⁾,
- they must undergo the checks provided for in Article 4,
- they may not leave the border inspection post or the quarantine centre unless such checks show that the animal or consignment of animals:
 - (i) either, without prejudice to specific requirements applicable to the third countries concerned in respect of diseases foreign to the Community, complies with the animal health requirements applicable in trade in the species concerned as laid down in the Directives referred to in Annex A to Directive 90/425/EEC or with the animal health requirements laid down in Directive 72/462/EEC;
 - (ii) or, in respect of one or more specific diseases, fulfils the conditions of equivalence recognized, in accordance with the procedure laid down in Article 23, on the basis of reciprocity, between the requirements of the third country and those of the Community;
- if they are intended for a Member State benefiting from the additional guarantees provided for in Article 3 (1) (e) (iii) and (iv) of

⁽¹⁾ OJ No L 302, 31. 12. 1972, p. 28. Directive last amended by Directive 91/266/EEC (OJ No L 134, 29. 5. 1991, p. 45).

Directive 90/425/EEC, they must satisfy the relevant requirements laid down in respect of intra-Community trade.

- after they have passed through the border inspection post, they must, in the case of animals for slaughter, be conveyed to the slaughterhouse of destination, or, in the case of animals for breeding and production or aquaculture animals, be conveyed to the holding of destination;
- 3. if the checks provided for in points 1 and 2 show that the animal or the consignment of animals does not comply with the requirements laid down therein, the animal or consignment may not leave the border inspection post or quarantine centre and Article 12 shall be applicable;
- 4. where the animals referred to in point 1 are not intended to be placed on the market in the territory of the Member State which has carried out the veterinary checks, the provisions of Article 7, and in particular those relating to the issue of the certificate, shall apply;
- 5. at the place of destination, animals for breeding and production shall remain under the official supervision of the competent veterinary authorities. After an observation period to be determined in accordance with the procedure laid down in Article 23, the animals may enter intra-Community trade under the conditions laid down in Directive 90/425/EEC.

Animals for slaughter shall be subject, in the slaughterhouse of destination, to the Community rules relating to the slaughter of the species concerned.

- B. Detailed rules for the application of this Article shall be adopted, as the need arises, in accordance with the procedure laid down in Article 23.

Article 9

1. Member States shall authorize the transit of animals from one third country to another third country provided that:
 - (a) such transit has been previously authorized by the official veterinarian of the border inspection post of the Member State in the territory of which the animals must be presented in order to undergo there the checks provided for in Article 4 and, where appropriate, by the competent central authority of the Member State or Member States of transit;
 - (b) the party concerned supplies proof that the first third country to which the animals are being sent, after transit through one of the territories referred to in Annex I to Directive 90/675/EEC, undertakes under no circumstances to reject or to send back the animals, the

importation or transit of which it has authorized and undertakes to comply, in the territories referred to in Annex I to Directive 90/675/EEC, with Community rules on protection during transport;

- (c) the check referred to in Article 4 shows to the satisfaction of the veterinarian, if applicable after the animals have passed through a quarantine centre, that the animals fulfil the requirements of this Directive or, in the case of animals referred to in Annex A to Directive 90/425/EEC, afford health guarantees recognized in accordance with the procedure laid down in Article 23 as being at least equivalent to those requirements;
- (d) the competent authority of the border inspection post notifies the fact that the animals have passed through to the competent authorities of the Member State or Member States of transit and of the border post of exit, by means of the information exchange system referred to in the second subparagraph of Article 12 (4);
- (e) in the case of passage through one of the territories referred to in Annex I to Directive 90/675/EEC, such transit is carried out under the Community transit procedure (external transit) or under any other customs transit procedure provided for in Community rules; the only handling authorized during transit shall be that carried out at the point of entry into or exit from one of the territories referred to in Annex I and operations to ensure the animals' welfare.

2. All expenditure incurred pursuant to this Article shall be chargeable to the consignor, the consignee or their representative without compensation by the Member State.

Article 10

1. In cases where Community rules or the national rules of the place of destination, in areas which have not been harmonized and in compliance with the general rules of the Treaty, provide for live animals to be placed in quarantine or isolation, such quarantine or isolation may take place:

- for disease other than foot-and-mouth disease, rabies and Newcastle disease, at a quarantine centre situated in the third country of origin, provided that it has been approved by the procedure laid down in Article 22 and is regularly inspected by the Commission's veterinary experts,
- at a quarantine centre situated within Community territory which meets the requirements laid down in Annex B,
- on the holding of destination.

Special safeguards to be complied with during transport between the quarantine centre farms of origin and of destination and border inspection posts and in the quarantine centres referred to in the first indent of the preceding subparagraph may be laid down in accordance with the procedure provided for in Article 23.

2. If the official veterinarian responsible for the border inspection post orders placing in quarantine, that quarantine must take place, depending on the hazard diagnosed by the official veterinarian:

- either at the border inspection post itself or in its immediate vicinity,
- or on the holding of destination,
- or at a quarantine centre situated in the vicinity of the holding of destination.

3. The general conditions to be fulfilled for the quarantine centres referred to in the first and second indents of paragraph 1 are laid down in Annex B.

The special approval conditions applicable to the different animal species shall be adopted in accordance with the procedure laid down in Article 23.

4. The procedure laid down in Article 22 must be followed for the approval and subsequent updating of the list of quarantine centres referred to in the first and second indents of paragraph 1 and the first indent of paragraph 2. Quarantine centres shall be subject to the inspection provided for in Article 19.

The Commission shall publish the list of quarantine centres and any subsequent updates in the *Official Journal of the European Communities*.

5. The second subparagraph of paragraph 1 and paragraphs 3 and 4 shall not apply to quarantine centres which are solely for the animals referred to in Article 8 (A) (1).

6. All expenditure incurred pursuant to this Article shall be chargeable to the consignor, the consignee or their representative without compensation by the Member State.

7. Before 1 January 1996, the Commission shall submit to the Council a report, possibly accompanied by proposals, on the need for Community quarantine centres and financial assistance from the Community for their operation.

Article 11

1. Without prejudice to the remaining provisions of this Chapter, the official veterinarian or the competent authority shall, where it is suspected that veterinary legislation has not been complied with or there is doubt as to the identity of an animal, carry out any veterinary checks he or it deems appropriate.

2. Member States shall take the appropriate administrative or penal measures to penalize any infringement of veterinary legislation by natural or legal persons where it is found that Community rules have been infringed, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state of the animals, that identification marks do not comply with

those rules or that the animals were not presented for inspection at a border post or that the animals have not been sent to the destination originally intended.

Article 12

1. Where the checks referred to in this Directive show that an animal does not satisfy the requirements laid down in Community rules or, on matters not yet harmonized, in national rules, or where such checks reveal an irregularity, the competent authority, after consultation with the importer or his representative, shall decide either:

- (a) to shelter, feed and water and, if necessary, treat the animals; or
- (b) as the case may be, to place them in quarantine or to isolate the consignment;
- (c) to re-dispatch, within a time limit to be set by the competent national authority, the consignment of animals outside the territories referred to in Annex I to Directive 90/675/EEC where animal health or animal welfare requirements so allow.

In this case, the official veterinarian of the border inspection post must:

- inform the other border inspection posts, in accordance with paragraph 4, that the consignment has been rejected, indicating the infringements observed,
- under arrangements to be defined in accordance with the procedure laid down in Article 23, cancel the veterinary certificate or document accompanying the rejected consignment,
- at intervals to be determined, inform the Commission, via the competent central authority, as to the nature and frequency of the infringements observed.

If re-dispatch is impossible, in particular for reasons of the welfare of the animals, the official veterinarian:

- may, after agreement by the competent authority and after ante-mortem inspection, authorize slaughter of the animals for human consumption under the condition laid down by Community rules,
- must, otherwise, order slaughter of the animals for purposes other than human consumption or order deduction of the carcasses, specifying the conditions regarding control of the use of the products obtained.

The competent central authority shall inform the Commission of cases where recourse is had to these derogations in accordance with paragraph 4.

The Commission shall keep the Standing Veterinary Committee regularly informed of such cases.

2. The importer or his representative shall be liable for the costs incurred in the measures provided for in paragraph 1, the process of destroying the consignment or using the meat for other purposes.

The yield of the sale of the products referred to in the third subparagraph of paragraph 1 (c) must revert to the owner of the animals or his representative, after deduction of the above costs.

3. Detailed rules for the application of this Article shall be adopted, as the need arises, in accordance with the procedure laid down in Article 23.

4. The competent authorities of the Member States, the border inspection posts and the Commission will be informed in the context of the programme for developing the computerization of procedures for veterinary checks.

To that end, the Commission, acting in accordance with the procedure provided for in Article 23, will introduce a computerized data-processing system linking the border inspection services and the competent veterinary authorities at the Commission, and including all data on imports of animals from third countries (Shift project), which will be linked to the system for exchanges of information between veterinary authorities provided for in Article 20 of Directive 90/425/EEC.

5. The competent authorities shall, where appropriate, communicate any information at their disposal in accordance with Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters ⁽¹⁾.

Article 13

In accordance with the procedure laid down in Article 23, the Commission shall, on the basis of the plans referred to in the second subparagraph, adopt the rules applicable to imports of animals for slaughter intended for local consumption and of breeding or production animals in certain parts of the territories referred to in Annex I to Directive 90/675/EEC to take account of the natural constraints specific to these territories, including their remoteness from the mainland part of Community territory.

To that end, by 31 December 1991 at the latest, Member States shall submit a plan to the Commission setting out the procedures for carrying out checks on imports, into the regions referred to in the first subparagraph, of animals from third countries. These plans must specify the checks carried out to prevent animals introduced into the territories

concerned or products obtained from those animals being dispatched under any circumstances to other parts of Community territory.

Article 14

For the purposes of carrying out the checks referred to in Article 7 (3) of this Directive, the identification and registration provided for in Article 3 (1) (c) of Directive 90/425/EEC must, except in the case of animals for slaughter and registered equidae, be carried out at the place of destination of the animals, where appropriate after the observation period provided for in Article 8A (5) of this Directive.

The procedures for identifying or marking animals for slaughter shall be determined according to the procedure provided for in Article 23.

Article 15

1. Member States shall collect a health fee when the animals referred to in this Directive are imported to cover the costs occasioned by health inspections and checks, as provided for in Articles 4, 5, and 8.

2. The Council, acting by a qualified majority on a proposal from the Commission shall, before 1 July 1992, take a decision on the level or levels of the fees referred to in paragraph 1 and on the detailed rules and principles for the implementation of this Directive, and on possible exceptions.

Article 16

Under the procedure provided for in Article 23 and on a reciprocal basis, less frequent identity checks and/or physical checks may, without prejudice to controls to see that the welfare requirements during transport are being complied with, be applied under certain conditions, and in particular in the light of the results of checks carried out prior to the adoption of this Directive.

The Commission shall take into account the following criteria for granting derogations of this nature:

- (a) the guarantees offered by the third country in question with respect to compliance with Community requirements, particularly those of Directives 72/462/EEC and 90/426/EEC;
- (b) the health situation of animals in the third country concerned;
- (c) information on the health situation in the third country;
- (d) nature of the measures to monitor and to combat disease applied by the third country;
- (e) structures and powers of the veterinary service;
- (f) rules on the authorization of certain substances and compliance with the requirements set out in Article 7 of

⁽¹⁾ OJ No L 351, 2. 12. 1989, p. 34.

Council Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues ⁽¹⁾;

- (g) outcome of the Community inspection visits;
- (h) outcome of the import controls carried out.

Article 17

Rights of appeal existing under the laws in force in the Member States against decisions by the competent authorities shall not be affected by this Directive.

Decisions taken by the competent authority of the Member State of destination and the reasons for such decision shall be notified to the importer concerned by such decisions or his representative.

If the importer concerned or his representative so requests, the said decisions and reasons shall be forwarded to him in writing with details of the rights of appeal which are available to him under the law in force in the Member State in which the frontier inspection post is situated, and of the procedure and time limits applicable.

CHAPTER II

Safeguard provisions

Article 18

1. If a disease referred to in Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community ⁽²⁾, a zoonosis or other disease or phenomenon liable to present a serious threat to animal or human health occurs or spreads in the territory of a third country, or if any other serious animal health reason so warrants, in particular in the light of the findings of its veterinary experts, the Commission may, acting on its own initiative or at the request of a Member State, adopt one of the following measures without delay and depending on the gravity of the situation:

- suspend imports coming from all or part of the third country concerned, and where appropriate from the third country of transit,
- set special conditions in respect of animals coming from all or part of the third country concerned.

2. If one of the checks provided for in this Directive indicates that a consignment of animals is likely to

⁽¹⁾ OJ No L 275, 26. 9. 1986, p. 36.

⁽²⁾ OJ No L 378, 31. 12. 1982, p. 58. Directive as last amended by Decision 90/134/EEC (OJ No L 76, 22. 3. 1990, p. 23).

constitute a danger for animal or human health, the competent veterinary authority shall immediately take the following measures:

- it shall seize and destroy the consignment,
- it shall immediately inform the other border inspection posts and the Commission of the findings and of the origin of the animals, in accordance with Article 12 (4).

3. In the case provided for in paragraph 1, the Commission may take interim protective measures in respect of animals covered by Article 9.

4. Representatives of the Commission may make an immediate visit to the third country concerned.

5. In the case where a Member State informs the Commission officially of the need to take safeguard measures and the Commission has not invoked paragraphs 1 and 3 or made a referral to the Standing Veterinary Committee in accordance with paragraph 6, that Member State may take interim protective measures in respect of the animals in question.

Where a Member State takes interim protective measures in respect of a third country under the terms of this paragraph, it shall inform the other Member States and the Commission in accordance with Article 12 (5).

6. Within 10 working days, the Standing Veterinary Committee shall have the matter referred to it, pursuant to the terms of Article 22, with a view to the extension, amendment or repeal of the measures provided for in paragraphs 1, 3 and 5.

7. Decisions to extend, amend or repeal measures decided on pursuant to paragraphs 1, 2, 3 and 6 shall be taken in accordance with the procedure laid down in Article 22.

8. Detailed rules for the application of this Chapter shall be adopted, where the need arises, in accordance with the procedure laid down in Article 23.

CHAPTER III

Inspection

Article 19

1. Veterinary experts from the Commission may, in conjunction with the competent national authorities and to the extent necessary for uniform application of the requirements of this Directive, verify that the border inspection posts approved in accordance with Article 6 and the quarantine centres approved in accordance with Article 10 satisfy the criteria listed respectively in Annexes A and B.

2. Veterinary experts from the Commission may, in conjunction with the competent authorities, make on-the-spot checks.
3. A Member State in whose territory an inspection is made shall provide the veterinary experts from the Commission with any assistance they may require in the performance of their tasks.
4. The Commission shall inform the Member States of the outcome of the checks.
5. Where the Commission deems that the outcome of checks so justifies, it shall review the situation within the Standing Veterinary Committee. It may adopt the necessary decisions in accordance with the procedure laid down in Article 22.
6. The Commission shall monitor developments; in the light of such developments and in accordance with the procedure laid down in Article 22, it may amend or repeal the decisions referred to in paragraph 5.
7. Detailed rules for the application of this Article shall be adopted, where the need arises, in accordance with the procedure laid down in Article 23.

Article 20

Where, on the basis of the checks carried out at the point where the animals are marketed, a competent authority of a Member State considers that this Directive is not being complied with at a border inspection post of another Member State, it shall contact the competent national authority of that Member State without delay.

The latter shall take all the necessary measures and inform the competent authority of the first Member State of the nature of the checks made, the decision taken and the reasons for such decisions.

If the competent authority of the first Member State believes the measures are insufficient it shall examine, with the competent authority of the Member State in question, the ways and means in which the situation could be remedied, where necessary by visiting the Member State in question.

Where the checks referred to in the first subparagraph show repeated non-compliance with this Directive, the competent authority of the Member State of destination shall inform the Commission and the competent authorities of the other Member States.

The Commission must, at the request of the competent authority of the Member State of destination or on its own initiative, send an inspection team to the Member State in question in conjunction with the competent national authorities. Depending on the type of infringement observed, that team may remain in the Member State in question until the decisions referred to in the final subparagraph have been taken.

Pending the Commission's findings, the Member State in question must, at the request of the Member State of destination, step up checks at the border inspection post or quarantine centre concerned.

The Member State of destination may, for its part, intensify checks on animals coming from these sources.

At the request of one of the two Member States concerned, and in accordance with the procedure laid down in Article 22, the Commission must, where the irregularities are confirmed by the inspection referred to in the fifth subparagraph, take the appropriate measures. These measures must be confirmed or reviewed as soon as possible in accordance with the same procedure.

Article 21

1. Each Member State shall draw up a programme for the exchange of staff designated to carry out the veterinary checks on animals coming from third countries.
2. The Commission and the Member States shall coordinate the programmes referred to in paragraph 1 within the Standing Veterinary Committee.
3. Member States shall take all the measures necessary to allow implementation of the programmes resulting from the coordination referred to in paragraph 2.
4. Each year, in the Standing Veterinary Committee, the implementation of programmes shall be reviewed on the basis of reports drawn up by the Member States.
5. Member States shall take into account the experience gained, in order to improve and develop the exchange programmes.
6. A financial contribution from the Community may be granted in order to promote the efficient development of exchange programmes. Detailed rules for such contribution and the estimated amount to be charged to the general budget of the European Communities are laid down in Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽¹⁾.
7. Detailed rules for the application of paragraphs 1, 4 and 5 shall be adopted, where the need arises, in accordance with the procedure laid down in Article 23.

CHAPTER IV

General provisions

Article 22

Where reference is made to the procedure provided for in this Article, action shall be taken in accordance with Article 17 of Directive 89/662/EEC.

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 19. Decision amended by Decision 91/133/EEC (OJ No L 66, 13. 3. 1991, p. 18).

Article 23

Where reference is made to the procedure provided for in this Article, action shall be taken in accordance with Article 18 of Directive 89/662/EEC.

Article 24

The Annexes to this Directive shall, where the need arises, be amended in accordance with the procedure laid down in Article 23.

Article 25

This Directive shall be without prejudice to obligations arising from customs rules.

Article 26

1. Articles 12 and 28 of Directive 72/462/EEC shall be deleted.

Pending the decisions provided for in Articles 5 and 6 of this Directive, the acts adopted pursuant to Article 12 of Directive 72/462/EEC shall continue to apply.

2. Articles 20 and 21 of Directive 90/426/EEC and Articles 27 and 29 (2) of Directive 90/539/EEC shall be deleted.

Article 27

1. Directive 89/662/EEC is hereby amended as follows:

(a) in article 19 (2) '31 December 1992' shall be replaced by '31 December 1996';

(b) Article 22 shall be replaced by the following:

'Article 22

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive on 1 July 1992.'

2. Directive 90/425/EEC shall be amended as follows:

(a) Article 7 shall be replaced by the following:

'Article 7

1. Member States shall ensure that, during checks carried out at the places where animals and products referred to in Annex I from a third country may be brought into the territories defined in Annex I to Directive 90/675/EEC, such as ports, airports and border inspection posts with third countries, the following measures are taken:

(a) certificates or documents accompanying the animals and products are checked;

(b) Community animals and products shall be subject to the control rules laid down in Article 5;

(c) products from third countries shall be subject to the rules laid down in Directive 90/675/EEC;

(d) animals from third countries shall be subject to the rules laid down in Directive 91/496/EEC.

2. However, as from 1 January 1993 and by way of derogation from paragraph 1, all animals or products transported by means of transport providing a regular and direct link between two geographical points of the Community shall be subject to the rules for control provided for in Article 5.'

(b) Article 23 shall be replaced by the following:

'Article 23

The Council shall, on the basis of a Commission report, accompanied by possible proposals on which the Council will decide by a qualified majority, re-examine:

— the provisions of Article 10 and of Article 5 (2) (a) before 1 January 1993,

— other provisions before 1 January 1996.'

(c) In Article 26:

in the first subparagraph, point (ii) shall be replaced by:

'(ii) the other provisions of this Directive on 1 July 1992.';

the second subparagraph shall be deleted.

3. Directive 90/675/CEE is hereby amended as follows:

(a) in Article 19, paragraph 6 shall be replaced by the following:

'6. Within 10 working days, the Standing Veterinary Committee shall have the matter referred to it, pursuant to the terms of Article 23, with a view to the extension, amendment or repeal of the measures provided for in paragraphs 1, 3 and 5. The procedure provided for in Article 23 may also be used to adopt the necessary decisions, including those relating to intra-Community movement of products and to transit.

(b) In Article 32, 'by 31 December 1991' shall be replaced by 'on 1 July 1992'.

Article 28

Acting in accordance with the procedure laid down in Article 23, the Commission may adopt for three years the transitional measures necessary to facilitate the transition to the new checking arrangements provided for in this Directive.

Article 29

Member States may make use of the Community financial assistance provided for in Article 38 of Directive 90/424/EEC for the implementation of this Directive, in particular for setting up networks for exchanges of information between veterinary services and border posts.

Article 30

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with:

- (a) the provisions of Article 6 (3) and Articles 13, 18 and 21 on 1 December 1991;
- (b) the other provisions of this Directive on 1 July 1992.

They shall forthwith inform the Commission thereof.

When these measures are adopted by the Member States, they shall contain a reference to this Directive or shall be

accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2. Detailed rules for applying this Directive, and in particular those concerning Article 8 (3), shall be adopted and the system referred to in the second subparagraph of Article 12 (4) brought into force on 1 July 1992.

If the date referred to in the preceding subparagraph cannot be met, the transitional measures provided for in Article 28 shall be taken on that date.

Article 31

This Directive is addressed to the Member States.

Done at Brussels, 15 July 1991.

For the Council
The President
P. BUKMAN

ANNEX A

General conditions for the approval of border inspection posts

In order to obtain Community approval, border inspection posts must have:

- 1) a dedicated access lane for the transport of live animals so that the animals are spared unnecessary waiting;
- 2) facilities (which must be easy to clean and disinfect) for loading and unloading the different means of transport, inspection, feeding, watering and treatment of the animals, with adequate space, lighting and ventilation for the number of animals to be inspected;
- 3) sufficient numbers, in relation to the numbers of animals dealt with by the border inspection post, of veterinary and auxiliary staff specially trained to carry out checks on the accompanying documents and the clinical checks referred to in Articles 4, 5, 8 and 9 of this Directive;
- 4) sufficiently large premises at the disposal of the staff responsible for carrying out veterinary checks, including changing rooms, showers and toilets;
- 5) appropriate premises and facilities for taking and processing the samples for the routine checks laid down in Community rules;
- 6) the services of a specialized laboratory able to carry out special tests on the samples taken at the post;
- 7) the services of an undertaking in the immediate vicinity which has the facilities and equipment to house, feed, water, treat and, if necessary, slaughter the animals;
- 8) where such posts serve as stopping or transfer points for animals during transport, suitable facilities for the animals to be unloaded, watered, fed, housed properly where necessary and given the requisite treatment or if necessary to be slaughtered on the spot in a way which spares them unnecessary suffering;
- 9) appropriate equipment permitting the rapid exchange of information with other border inspection posts and the competent veterinary authorities referred to in Article 20 of Directive 90/425/EEC;
- 10) equipment and facilities for cleaning and disinfecting.

ANNEX B

General conditions for the approval of quarantine centres

1. The requirements of Annex A, points 2, 4, 5, 7, 9 and 10 shall apply.
2. In addition, quarantine centres must:
 - be placed under the permanent control and under the responsibility of the official veterinarian,
 - be located at a distance from holdings or other places where animals are kept which are likely to be infected by contagious diseases,
 - have an efficient control system so as to ensure adequate surveillance of the animals.

COUNCIL DIRECTIVE

of 29 July 1991

amending and consolidating Directive 64/433/EEC on health problems affecting intra-Community trade in fresh meat to extend it to the production and marketing of fresh meat

(91/497/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposals from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas meat from bovine animals, swine, sheep and goats and domestic solipeds is included in the list of products in Annex II to the Treaty; whereas production of and trade in fresh meat constitutes an important source of income for part of the farming population;

Whereas in order to ensure the rational development of this sector and to increase productivity, public health rules governing production and placing on the market must be laid down at Community level;

Whereas the Community has to adopt measures for the gradual establishment of the internal market over a period expiring on 31 December 1992;

Whereas Directive 64/433/EEC ⁽⁴⁾ laid down the health requirements to be complied with in intra-Community trade in meat from bovine animals, swine, sheep and goats and domestic solipeds;

Whereas Directive 89/662/EEC ⁽⁵⁾ laid down rules on the checks to be applied with a view to the completion of the internal market, and in particular abolished veterinary checks at frontiers between Member States;

Whereas to take account of the abolition of the said checks and of the introduction of more stringent guarantees at origin when it is no longer possible to distinguish between products for the domestic market and products to be marketed in another Member State, the requirements of Directive 64/433/EEC should be adapted and extended to all meat production;

Whereas to that end it is necessary to harmonize the conditions under which certain meat is declared unfit for human consumption;

Whereas Directive 64/433/EEC has been substantially amended on a number of occasions; whereas for the sake of clarity that Directive should be consolidated;

Whereas it is necessary to adapt the references in Council Directive 72/462/EEC of 12 December 1972, on health and veterinary inspection problems upon importation of bovine animals and swine and ovine and caprine animals and fresh meat or meat products from third countries ⁽⁶⁾, in the light of that consolidation,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 64/433/EEC is hereby replaced by the text annexed to this Directive.

Article 2

Directive 72/462/EEC is hereby amended as follows:

- 1) in the third indent of Article 1 (1), the text in brackets shall be replaced by the following:

'(including the species *Bubalus bubalis* and *Bison bison*)';

- 2) In Article 4 (c):

(a) in the second subparagraph

— '13' shall be replaced by '14',

⁽¹⁾ OJ No C 84, 2. 4. 1990, p. 8, and proposal forwarded on 10 November 1983 (not published in the Official Journal).

⁽²⁾ OJ No C 183, 15. 7. 1991.

⁽³⁾ OJ No C 332, 31. 12. 1990, p. 53.

⁽⁴⁾ OJ No 121, 29. 7. 1964, p. 2012/64. Directive last amended by Directive 89/662/EEC (OJ No L 395, 30. 12. 1989, p. 13).

⁽⁵⁾ OJ No L 395, 30. 12. 1989, p. 13. Directive amended by Directive 90/675/EEC (OJ No L 373, 31. 12. 1990, p. 1).

⁽⁶⁾ OJ No L 302, 31. 12. 1972, p. 28. Directive as last amended by Directive 91/69/EEC (OJ No L 46, 19. 2. 1991, p. 37).

- '24' shall be deleted,
 - '41 (C)' shall be replaced by '42 (A) (2)';
- (b) the following subparagraph shall be added:
- 'In accordance with the same procedure, specific guarantees may be required concerning the quality of the potable water used by establishments and the medical supervision of staff working on and handling fresh meat.'

3) In Article 17:

(a) paragraph 2:

- in (b) 'Chapter V' shall be replaced by 'Chapter VI',
- in (c) 'Chapter VI' shall be replaced by 'Chapter VII',
- in (d) 'Chapter VII' shall be replaced by 'Chapter VIII',
- in (e) 'Chapter X' shall be replaced by 'Chapter XI' and 'Chapter XIII' shall be replaced by 'Chapter XIV',
- in (g) 'Chapter XIV' shall be replaced by 'Chapter XV'.

(b) paragraph 3:

- 'Chapter XIII' shall be replaced by 'Chapter XIV';

4) In Article 18:

(a) paragraph 1 (b):

- (i) 'Chapter VIII' shall be replaced by 'Chapter IX';

(ii) 'Chapter IX' shall be replaced by 'Chapter X';

(iii) 'Chapter XI' shall be replaced by 'Chapter XII';

(b) paragraph 3:

- 'paragraph 45 (d) of Chapter VIII' shall be replaced by 'paragraph 46 of Chapter IX';

5) in Article 20 (d) 'paragraph 57 of Chapter X' shall be replaced by 'paragraph 58 of Chapter XI'.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 January 1993. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 July 1991.

For the Council

The President

H. VAN DEN BROEK

ANNEX

COUNCIL DIRECTIVE 64/433/EEC

of 26 June 1964

on health conditions for the production and marketing of fresh meat

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

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

Whereas Council Regulation (EEC) No 805/68 of 27 June 1968 on the common organization of the market in beef and veal ⁽¹⁾, Council Regulation (EEC) No 2759/75 of 29 October 1975 on the common organization of the market in pigmeat ⁽²⁾ and Council Regulation (EEC) No 3013/89 of 25 September 1989 on the common organization of the market in sheepmeat and goatmeat ⁽³⁾, laid the basis for the free movement of beef and veal, pigmeat, sheepmeat and goatmeat;

Whereas, so long as intra-Community trade is hindered by differences between the health requirements of Member States concerning meat, the implementation of the abovementioned regulations will not have the desired effect;

Whereas, to eliminate such differences, the health provisions of the Member States must be approximated in line with the above regulations;

Whereas the object of this approximation must be in particular to standardize health requirements for meat in slaughterhouses and cutting rooms and during storage and transportation; whereas a system of approval should be introduced for slaughterhouses and cutting plants which meet the health requirements laid down by this Directive, together with a Community inspection procedure to ensure

that the conditions for such approval are observed; whereas provision should also be made for approval of cold stores;

Whereas low-capacity establishments should be approved by means of simplified structure and infrastructure criteria, while complying with the rules of hygiene laid down in this Directive;

Whereas health marking of meat and authorization of the transport document by the official veterinarian of the establishment of origin is the best way of satisfying the competent authorities of the place of destination that a consignment of meat complies with the provisions of this Directive; whereas the health certificate should be maintained for the purposes of verifying the destination of certain meat;

Whereas the rules, principles and safeguard measures established by Council Directive 90/675/CEE of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries ⁽⁴⁾ should apply here;

Whereas in the context of trade between the Member States, the rules laid down in Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view of the completion of the internal market ⁽⁵⁾ should also be applied;

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive lays down health rules for the production and placing on the market of fresh meat intended for human consumption from domestic animals of the following species: bovine animals (including the species *Bubalus bubalis* and *Bison bison*), swine, sheep and goats, and domestic solipeds.

⁽⁴⁾ OJ No L 373, 31. 12. 1990, p. 1.

⁽⁵⁾ OJ No L 395, 30. 12. 1989, p. 13. Directive amended by Directive 90/675/EEC (OJ No L 373, 31. 12. 1990, p. 1).

⁽¹⁾ OJ No L 148, 28. 6. 1968, p. 24. Regulation last amended by Regulation (EEC) No 3577/90 (OJ No L 353, 17. 12. 1990, p. 23).

⁽²⁾ OJ No L 282, 1. 11. 1975, p. 1. Regulation last amended by Regulation (EEC) No 1249/89 (OJ No L 129, 11. 5. 1989, p. 12).

⁽³⁾ OJ No L 289, 7. 10. 1989, p. 1. Regulation amended by Regulation (EEC) No 3577/90 (OJ No L 353, 17. 12. 1990, p. 23).

2. This Directive shall not apply to the cutting and storage of fresh meat performed in retail shops or in premises adjacent to sale points, where the cutting and storage are performed solely for the purpose of supplying the consumer directly on the spot.

3. This Directive shall apply without prejudice to specific Community rules on minced meat.

4. This Directive shall not affect any restrictions imposed, in compliance with the general provisions of the Treaty, on the retail sale of meat from solipeds.

Article 2

For the purposes of this Directive:

- (a) 'meat' means all parts of domestic bovine animals (including the species *Bubalus bubalis* and *Bison bison*), swine, sheep, goats and solipeds which are suitable for human consumption;
- (b) 'fresh meat' means meat, including meat vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any treatment other than cold treatment to ensure preservation;
- (c) 'mechanically recovered meat' means meat obtained by mechanical means from flesh-bearing bones apart from the bones of the head, the extremities of the limbs below the carpal and tarsal joints and, in the case of swine, the coccygeal vertebrae, and intended for establishments approved in accordance with Article 6 of Directive 77/99/EEC⁽¹⁾;
- (d) 'carcase' means the whole body of a slaughtered animal after bleeding, evisceration and removal of the limbs at the carpus and tarsus, removal of the head, tail and the udder, and in addition, in the case of bovine animals, sheep, goats and solipeds, after flaying. However, in the case of pigs, removal of the limbs at the carpus and tarsus and removal of the head may be waived where the meat is intended for treatment in accordance with Directive 77/99/EEC;
- (e) 'offal' means fresh meat other than that of the carcase as defined in (d), even if it remains naturally connected to the carcase;
- (f) 'viscera' means offal from the thoracic, abdominal and pelvic cavities, including the trachea and oesophagus;
- (g) 'official veterinarian' means the veterinarian designated by the competent central authority of the Member State;
- (h) 'exporting country' means the Member State from which fresh meat is sent;

- (i) 'country of destination' means the Member State to which fresh meat is sent from another Member State;
- (j) 'means of transport' means the freight-carrying parts of motor vehicles, rail vehicles and aircraft and the holds of ships or containers for transport by land, sea or air;
- (k) 'establishment' means an approved slaughterhouse, an approved cutting plant, an approved cold store or a unit grouping together several such establishments;
- (l) 'wrapping' means the protection of fresh meat by the use of an initial wrapping or initial container in direct contact with the fresh meat concerned and the initial wrapper or initial container itself;
- (m) 'packaging' means the placing of wrapped fresh meat in a second container and the latter container itself;
- (n) 'special emergency slaughtering' means: any slaughtering ordered by a veterinary surgeon following an accident or serious physiological and functional problems. Special emergency slaughtering may take place outside the slaughterhouse where the veterinary surgeon considers that transport of the animal would be impossible or would subject the animal to unnecessary suffering.

Article 3

1. Each Member State shall ensure that:
 - A. carcases, half carcases or half carcases cut into no more than three wholesale cuts, and quarters:
 - (a) have been obtained in a slaughterhouse meeting the conditions laid down in Chapters I and II of Annex I and approved and supervised in accordance with Article 10, or in a slaughterhouse specifically approved in accordance with Article 4;
 - (b) come from a slaughter animal inspected ante mortem by an official veterinarian in accordance with Chapter VI of Annex I and passed fit, as a result of such inspection, for slaughter for the purposes of this Directive;
 - (c) have been treated under satisfactory hygiene conditions in accordance with Chapters V and VII of Annex I;
 - (d) have been inspected post mortem by an official veterinarian in accordance with Chapter VIII of Annex I and do not show any change except for traumatic lesions which occurred shortly before slaughter or localized malformations or changes, provided that it is established, if necessary by appropriate laboratory tests, that these lesions,

⁽¹⁾ OJ No L 26, 31. 1. 1977, p. 85. Directive last amended by Directive 89/662/EEC (OJ No L 395, 30. 12. 1989, p. 13).

malformations or changes do not render the carcass and offal unfit for human consumption or dangerous to human health;

(e) bear a health mark in accordance with Chapter XI of Annex I;

(f) are accompanied during transportation by:

(i) until 30 June 1993, the health certificate issued by the official veterinarian at the time of loading, which must correspond in form and content to the model in Annex V and be drawn up in the official language or languages of the country of destination at least. It must consist of a single sheet of paper;

(ii) from 1 July 1993, an accompanying commercial document authorized by the official veterinarian. This document must:

- in addition to the particulars provided for in point 50 of Chapter X of Annex I, including in the case of frozen meat the month and year of freezing in clear, bear a code number by which the official veterinarian can be identified,
- be kept by the consignee for at least one year so that it can be produced at the request of the competent authority;

(iii) a health certificate in accordance with Chapter XI of Annex I, in the case of meat from a slaughterhouse situated in a restricted region or area or meat to be sent to another Member State, after transit through a third country in a sealed lorry.

Detailed rules for applying (ii), and in particular those concerning the allocation of code numbers and the compilation of one or more lists identifying the official veterinarians, shall be adopted in accordance with the procedure laid down in Article 16;

(g) are stored in accordance with Chapter XIV of Annex I after post-mortem inspection under satisfactory hygiene conditions in establishments approved in accordance with Article 10 and supervised in accordance with Chapter X of Annex I;

(h) are transported under satisfactory hygiene conditions in accordance with Chapter XV of Annex I;

B. cuts or pieces smaller than those referred to in section A, or boned meat:

(a) are boned or cut in a cutting plant meeting the conditions laid down in Chapters I and III of Annex I and approved and supervised in accordance with Article 10;

(b) are boned or cut and obtained in accordance with Chapter IX of Annex I and come from:

— fresh meat which complies with the requirements set out in section A, except those referred to in subparagraph (h), and which is transported in accordance with Chapter XV of Annex I, or

— fresh meat imported from third countries in accordance with Directive 90/675/EEC;

(c) have been stored under conditions which comply with Chapter XIV of Annex I in establishments approved in accordance with Article 10 and supervised in accordance with Chapter X of Annex I;

(d) have been checked by an official veterinarian in accordance with Chapter X of Annex I;

(e) meet the wrapping and packaging requirements laid down in Chapter XII of Annex I;

(f) meet the requirements of section A (c), (e), (f) and (h);

C. offal comes from an approved slaughterhouse or an approved cutting plant. Entire offal must comply with the requirements of sections A and B. Sliced offal must comply with the requirements of section B.

Offal may not be sliced except for livers of animals of the bovine species where such livers are sliced in an approved cutting plant. The extension of this derogation to livers of animals of other species may be decided by the Council acting by a qualified majority on a proposal from the Commission;

D. fresh meat which has been stored in accordance with this Directive in a cold store approved by a Member State and which has not thereafter undergone any handling, except in connection with storage:

(a) meets the requirements of section A (c), (e), (g) and (h) and section B and C or is fresh meat imported from third countries in accordance with the requirements of Directive 90/675/EEC;

(b) is accompanied during transportation to the place of destination by the accompanying commercial document or the certificate referred to in paragraph (A) (f).

Where meat is to be accompanied by a certificate, the latter shall be completed by the official veterinarian on the basis of the health certificates attached to the consignment of fresh meat when they were put into storage and shall, in the case of importation, state the origin of the fresh meat;

E. fresh meat produced in accordance with this Directive which has been stored in a cold store of a third country

approved in accordance with Council Directive 72/462/EEC ⁽¹⁾ under customs control and which has not thereafter undergone any handling, except in connection with storage:

- (a) meets the requirements of section A, B and C;
- (b) meets the specific guarantees concerning checking and certification of compliance with storage and transport requirements;
- (c) is accompanied by a certificate which corresponds to a model to be drawn up under the procedure laid down in Article 16.

The specific guarantees concerning checking, certification of compliance with storage and transport requirements and the issuing of the certificate shall be adopted in accordance with the procedure laid down in Article 16.

2. However, without prejudice to Community animal health requirements, paragraph 1 shall not apply to:

- (a) fresh meat intended for uses other than human consumption;
- (b) fresh meat intended for exhibition, special studies or analysis, provided that official control makes it possible to ensure that the meat is not used for human consumption and that, when the exhibition is over or when the special studies or the analysis have been carried out, the meat, with the exception of that used for the purposes of analysis, is destroyed;
- (c) fresh meat intended exclusively as supplies for international organizations.

Article 4

A. Member States shall ensure that from 1 January 1993 slaughterhouses in operation as at 31 December 1991 and handling not more than 12 livestock units ⁽²⁾ per week with a maximum of 600 livestock units per year are subject to the following requirements if they do not satisfy the requirements of Annex I:

- 1. They must be the subject of special veterinary registration and be given a specific approval number linked to the local supervisory unit.

In order to be approved by the competent national authorities:

- (a) the establishment must fulfil the conditions for approval laid down in Annex II;

⁽¹⁾ OJ No L 302, 31. 12. 1972, p. 28. Directive last amended by Directive 91/69/EEC (OJ No L 46, 19. 2. 1991, p. 37).

⁽²⁾ Bovines and solipeds: 1,0 livestock unit,
Pigs: 0,33 livestock units,
Sheep: 0,15 livestock units.

- (b) the operator of the slaughterhouse, the owner or his agent must keep a register of
 - animals entering the establishment and slaughter products leaving it,
 - the checks carried out,
 - the results of those checks.

This information shall be communicated to the competent authority at its request;

- (c) the slaughterhouse must notify the veterinary service of the time of slaughter and the number and the origin of the animals to allow it to carry out the ante mortem inspection in accordance with Chapter VI of Annex I, either on the farm or immediately prior to slaughter;
- (d) the official veterinarian or an auxiliary must be present at the time of slaughter to ensure compliance with the hygiene rules laid down in Chapters V, VII and VIII of Annex I.

Where the official veterinarian cannot be present at the time of slaughter, the meat may not leave the establishment until the official veterinarian has carried out the post mortem inspection, which must take place on the day of slaughter;

- (e) the competent authority must monitor the chain of distribution of meat coming from the establishment and the appropriate marking of products declared unfit for consumption as well as their subsequent destination and use.

Member States shall draw up a list of establishments benefiting from such derogations and shall forward it, and any subsequent amendments thereto, to the Commission;

- (f) the competent authority must ensure that fresh meat from the establishments referred to in (e) is marked with stamps approved for the purpose in accordance with the procedure laid down in Article 16, showing the administrative district of the health unit under which the establishment comes.

- 2. Derogations may also be granted by the competent authority in accordance with Annex II in the case of cutting plants which are not situated in an approved establishment and which produce not more than three tonnes per week.

The provisions of Chapters VII and IX and point 48 of Chapter X of Annex I shall not apply to storage and cutting operations in the establishments referred to in the first subparagraph.

- 3. Meat that has been judged to comply with the hygiene and health inspection requirements laid down by this Directive must be marked with a stamp

showing the administrative district of the health unit responsible for the establishment of origin. The model of this stamp shall be determined in accordance with the procedure laid down in Article 16.

4. Meat from the establishments referred to in this Article must:

- (i) be kept for direct sale on the local market, fresh or processed, to retailers or to the consumer without pre-packaging or pre-wrapping;
- (ii) be transported from the establishment to the consignee under hygienic conditions of transport.

B. If necessary, new establishments may, by way of derogation from the structure and infrastructure requirements of Annex I to this Directive, be approved in accordance with the procedure laid down in Article 16, provided that the requirements of section A are met.

C. The Commission's veterinary experts may, in conjunction with the competent national authorities and insofar as necessary for the uniform application of this Article, carry out on-site checks on a representative number of establishments benefitting from the conditions laid down in this Article.

D. Detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 16.

E. The Council shall, before 1 January 1998, review the provisions of this Article on the basis of a report from the Commission.

Article 5

1. Member States shall ensure that the official veterinarian declares unfit for human consumption:

(a) meat for animals:

- (i) in which, without prejudice to the diseases specified in Annex C to Directive 90/425/EEC ⁽¹⁾, one of the following diseases has been diagnosed:

- generalized actinobacillosis or actinomycosis,
- blackleg,
- generalized tuberculosis,
- generalized lymphadenitis,
- glanders,
- rabies,
- tetanus,

— acute salmonellosis,

— acute brucellosis,

— swine erysipelas,

— botulism,

— septicæmia, pyæmia, toxæmia or viraemia;

- (ii) showing acute lesions of broncho-pneumonia, pleurisy, peritonitis, metritis, mastitis, arthritis, pericarditis, enteritis or meningo-encephalomyelitis confirmed by a detailed inspection, possibly supplemented by a bacteriological examination and a search for residues of substances with a pharmacological effect.

However, where the results of these special examinations are favourable, the carcasses shall be declared fit for human consumption after the parts unfit for consumption have been removed;

- (iii) affected by the following parasitic diseases: generalized sarcocystosis, generalized cysticercosis, trichinosis;

(iv) dead, stillborn or unborn;

(v) slaughtered too young, and the meat of which is oedematous;

(vi) showing signs of emaciation or advanced anaemia;

(vii) showing multiple tumours, abscesses or serious injuries in different areas of the carcass or in different viscera;

(b) meat from animals:

- (i) which have produced a positive or inconclusive reaction to tuberculin and in which an examination carried out in accordance with point 41 (G) of Chapter VIII of Annex I has revealed only localized tuberculous lesions in a number of organs or a number of areas of the carcass.

However, where a tuberculous lesion has been found in the lymph nodes of the same organ or part of the carcass only the affected organ or part of the carcass and the associated lymph nodes shall be declared unfit for human consumption;

- (ii) which have reacted positively or inconclusively to brucellosis confirmed by lesions indicating acute infection.

Even if no such lesion has been found the udder, genital tract and blood must nevertheless be declared unfit for human consumption;

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 29. Directive last amended by Directive 91/174/EEC (OJ No L 85, 5. 4. 1991, p. 37).

- (c) — the parts of carcasses showing signs of major serious or haemorrhagic infiltrations, localized abscesses or localized contamination,
- offal and viscera with pathological lesions of infectious, parasitic or traumatic origin;
- (d) meat which:
- is feverish,
- shows serious anomalies as regards colour, smell, consistency or taste;
- (e) where the official veterinarian is satisfied that a carcass or offal is affected with caseous lymphadenitis or any other suppurative condition and that the said condition is not generalized or associated with emaciation:
- (i) any organ and its associated lymph node, if the aforesaid condition exists on the surface or in the substance of that organ or lymph node;
- (ii) in any case to which (i) does not apply, the lesion and such of the surrounding parts as he may think appropriate having regard to the age and degree of activity of the lesion, on the understanding that an old firmly encapsulated lesion may be regarded as inactive;
- (f) meat resulting from trimming of the sticking point;
- (g) where the official veterinarian is satisfied that the whole or any part of a carcass or any offal is affected by any disease or condition other than those referred to in the preceding points, the whole carcass and the offal or such lesser part thereof as he may think appropriate;
- (h) carcasses the offal from which has not undergone post mortem inspection;
- (i) the blood of an animal the meat of which has been declared unfit for human consumption in accordance with the preceding points and blood contaminated by stomach contents or any other substance;
- (j) meat from animals to which have been administered:
- (i) substances prohibited under Directives 81/602/EEC ⁽¹⁾ and 88/146/EEC ⁽²⁾;
- (ii) products likely to render meat dangerous or harmful to human health and on which a decision will have to be taken in accordance with the procedure laid down in Article 16 after obtaining the opinion of the Scientific Veterinary Committee.
- (iii) tenderizers;
- (k) meat containing residues of substances authorized in accordance with the exceptions provided for in Article 4 of Directive 81/602/EEC and Articles 2 and 7 of Directive 88/146/EEC, residues of medicinal products, antibiotics, pesticides or of other substances which are harmful or likely to make the consumption of fresh meat dangerous or harmful to human health, if such residues exceed the permitted level laid down by Community rules;
- (l) meat contaminated or tainted to an extent to be decided on by the procedure laid down in Article 16 after obtaining the opinion of the Scientific Veterinary Committee;
- (m) the liver and kidneys of animals more than two years old from regions in which plans implemented in accordance with Article 4 of Directive 86/469/EEC ⁽³⁾ have revealed the generalized presence of heavy metals in the environment;
- (n) meat which, without prejudice to possible Community regulations applicable in the field of ionization, has been treated with ionizing or ultraviolet radiation;
- (o) meat which gives off a pronounced sexual odour.
2. Additions or amendments to paragraph 1 may be adopted, in particular for tuberculosis, brucellosis and salmonella, in accordance with the procedure laid down in Article 16 and after obtaining the opinion of the Scientific Veterinary Committee.

Article 6

1. Member States shall ensure that:

- (a) without prejudice to the cases provided for in Article 5 (1) (a) (iii) and Article 5 (2), fresh pigmeat or horsemeat referred to in Article 3, if not tested for trichinosis in accordance with Annex I to Directive 77/96/EEC ⁽⁴⁾, undergoes cold treatment in accordance with Annex IV to that Directive;

⁽¹⁾ OJ No L 222, 7. 8. 1981, p. 32. Directive last amended by

Directive 85/358/EEC (OJ No L 191, 23. 7. 1985, p. 46).

⁽²⁾ OJ No L 70, 16. 3. 1988, p. 16.

⁽³⁾ OJ No L 275, 26. 9. 1986, p. 36.

⁽⁴⁾ OJ No L 26, 31. 1. 1977, p. 67. Directive last amended by Commission Directive 89/321/EEC (OJ No L 133, 17. 5. 1989, p. 33).

- (b) meat from:
- i) male pigs used for breeding;
 - (ii) cryptorchid and hermaphrodite pigs;
 - (iii) without prejudice to the cases provided for in Article 5 (1) (o) uncastrated male pigs with a carcase weight in excess of 80 kilograms, except where the establishment is able to guarantee by means of a method recognized by the procedure laid down in Article 16, or in the absence of such a method by a method recognized by the competent authority concerned, that carcases giving off a pronounced boar taint may be detected,
- bears the special mark provided for by Decision 84/371/EEC ⁽¹⁾ and undergoes one of the treatments provided for in Directive 77/99/EEC;
- (c) mechanically recovered meat undergoes heat treatment in accordance with Directive 77/99/EEC;
- (d) after removal of parts unfit for consumption, fresh meat and offal from animals with non-generalized infestation by *Cysticercus bovis* or *Cysticercus cellulosae* undergo cold treatment using a method recognized in accordance with the procedure laid down in Article 16;
- (e) animals having undergone special emergency slaughtering may only be authorized for human consumption on the local market and only if the following conditions have been fulfilled:
- the holding of origin is not subject to health policy restrictions,
 - prior to slaughtering the animal has been subjected to an ante-mortem inspection by a veterinarian in accordance with Article 3 (1) (A) (b),
 - the animal has been slaughtered after stunning, bled and possibly eviscerated on the spot; the veterinarian may waive stunning and authorize shooting in special cases,
 - the slaughtered and bled animal is transported as quickly as possible after slaughter under satisfactory hygiene conditions to a slaughterhouse approved in accordance with this Directive. Where the slaughtered animal cannot be brought within the hour to such a slaughterhouse, it must be transported in a container or means of transport in which the ambient temperature is maintained at between 0° and 4°C. Evisceration, unless it has been effected at the time of slaughtering, must be carried out within a maximum of three hours after slaughtering; if evisceration is carried out on the spot, the viscera must be sent with the carcase to the slaughterhouse,
- during transportation to the slaughterhouse the slaughtered animal is accompanied by a certificate issued by the veterinary surgeon who has ordered slaughtering attesting to the favourable outcome of the ante-mortem inspection, the correct conduct of bleeding, the time of slaughter and the nature of any treatment administered to the animal and, if appropriate, the result of the inspection of the viscera; this certificate must correspond to a model to be drawn up in accordance with the procedure laid down in Article 16,
 - the carcase of the slaughtered animal is, until such time as the post mortem inspection carried out in accordance with Article 3 (1) (A) (d) supplemented where applicable by a bacteriological examination has identified it as wholly or partly fit for human consumption, so handled that it does not come into contact with carcases of meat and offal intended for human consumption;
- (f) meat from an area subject to animal health restrictions is subject to specific rules to be determined on a case-by-case basis in accordance with the procedure laid down in Article 16;
- (g) the treatment provided for in the preceding points is carried out in the establishment of origin or in any other establishment designated by the official veterinarian;
- (h) meat must be marked with the stamp provided for in Article 4 (A) (3).
2. The Council, acting by a qualified majority on a proposal from the Commission shall determine, before 1 July 1992, the parts of Community territory in which derogations from the requirement in 1 (a) may be permitted provided that:
- the absence of trichinosis is proved by epidemiological studies,
 - live animals and slaughtered animals are subjected to an effective method of detection and control.

Article 7

1. Member States shall ensure that:
- (a) meat declared unfit for human consumption can be clearly distinguished from meat declared fit for human consumption;
 - (b) meat declared unfit for human consumption is treated in accordance with Directive 90/667/EEC ⁽²⁾.
2. Detailed rules for implementing this Article shall if necessary be determined in accordance with the procedure laid down in Article 16.

⁽¹⁾ OJ No L 196, 26. 7. 1984, p. 46.

⁽²⁾ OJ No L 363, 27. 12. 1990, p. 51.

Article 8

1. Without prejudice to Directive 86/469/EEC, animals or their meat must undergo an examination for residues where the official veterinarian suspects their presence on the basis of the findings of the health inspection.

This examination shall check for residues both of substances having pharmacological action and of the conversion products thereof, and for other substances transmitted to meat which are likely to be harmful to human health.

If the meat examined shows traces of residues in quantities which exceed the permitted tolerances, it must be declared unfit for human consumption.

These examinations for residues must be carried out in accordance with proven methods which are scientifically recognized, in particular those laid down in Community rules or other international standards.

It must be possible to evaluate the results of the examination for residues using reference methods established in accordance with the procedure laid down in Article 16.

In accordance with the procedure laid down in Article 16, at least one reference laboratory shall be designated in each Member State to carry out the examination for residues.

2. Acting on a proposal from the Commission, the Council shall determine the tolerances for substances transmitted to meat which are likely to be harmful to human health, other than those established in Council Directive 86/363/EEC⁽¹⁾ and Council Regulation (EEC) No 2377/90⁽²⁾.

Article 9

Member States shall ensure:

- (i) the permanent presence of at least one official veterinarian in a slaughterhouse approved in accordance with Article 10 throughout the ante-mortem and post-mortem inspections;
- (ii) the presence at least once a day of an official veterinarian in a cutting plant approved in accordance with Article 10 when work is undertaken on meat, to check the conditions of hygiene of the plant and the record of fresh meat entering and leaving the plant;
- (iii) the regular presence of an official veterinarian in a cold store.

The official veterinarian may be assisted by auxiliaries placed under his authority and responsibility in carrying out the following operations:

- (a) ante-mortem inspection, the auxiliary's role being to make an initial check on the animals and to help with purely practical tasks;
- (b) post-mortem inspection, provided that the official veterinarian is actually able to supervise the work of the auxiliaries on the spot;
- (c) the health control of cut and stored meat;
- (d) the inspection and supervision of approved establishments in accordance with Article 10.

The maximum number of auxiliaries that may assist the official veterinarian in his task shall be fixed by the Council, acting on a proposal from the Commission, before 1 January 1992. The number must be small enough to enable the official veterinarian to exercise effective supervision of the post-mortem inspection.

Only persons who satisfy the requirements of Annex III may be appointed as auxiliaries following a test organized by the competent central authority of the Member State or by the authority appointed by that central authority.

In order to provide the assistance referred to above, the auxiliaries shall form part of an inspection team under the control and responsibility of the official veterinarian. They must be independent of the establishment. The competent authority of the Member State concerned shall determine the composition of the inspection team for each establishment in such a way that the official veterinarian is able to supervise the above operations.

Detailed rules governing the assistance referred to in this Article shall, insofar as necessary, be determined in accordance with the procedure laid down in Article 16.

Article 10

1. Each Member State shall draw up a list of approved establishments, other than those referred to in Article 4, each establishment having a veterinary approval number. The Member States shall send this list to the other Member States and to the Commission.

Cutting plants referred to in the second indent of the second paragraph of point 19 of Annex I must also be subject to approval in accordance with Directive 71/118/EEC⁽³⁾. Reference will be made to such special approval in the list of cutting plants published by the Commission.

A Member State shall not approve an establishment unless it is satisfied that it complies with this Directive.

⁽¹⁾ OJ No L 221, 7. 8. 1986, p. 43.

⁽²⁾ OJ No L 224, 18. 8. 1990, p. 1.

⁽³⁾ OJ No L 55, 8. 3. 1971, p. 23. Directive last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48).

Where hygiene is found to be inadequate and where the measures provided for in point 41 (F) of Chapter VIII of Annex I have proved insufficient to remedy the situation, the competent national authority shall temporarily suspend approval.

If the operator of the establishment, the owner or his agent does not make good the shortcomings noted within the period fixed by the competent national authority the latter shall withdraw approval.

The Member State in question shall take account here of the conclusions of any check carried out in accordance with Article 12. The other Member States and the Commission shall be informed of the suspension or withdrawal of approval.

2. The operator of the establishment, the owner or his agent must, in accordance with the second subparagraph of paragraph 4, conduct regular checks on the general hygiene of conditions of production in his establishment, *inter alia*, by means of microbiological controls.

Checks must cover utensils, fittings and machinery at all stages of production and, if necessary, products.

The operator of the establishment, the owner or his agent must be in a position, upon request from the official service, to inform the official veterinarian or the Commission's veterinary experts of the nature, frequency and results of the checks conducted to this end, together with the name of the investigating laboratory if need be.

The nature of the checks, their frequency, as well as the sampling methods and the methods for bacteriological examination shall be established in accordance with the procedure laid down in Article 16.

3. The operator of the establishment, the owner or his agent must establish a staff training programme enabling workers to comply with conditions of hygienic production adapted to the production structure.

The official veterinarian responsible for the establishment must be involved in the planning and implementation of that programme.

4. Inspection and supervision of establishments shall be carried out under the responsibility of the official veterinarian who, in accordance with Article 9, may be assisted in purely material tasks by auxiliaries. The official veterinarian must at all times have free access to all parts of establishments in order to ensure that this Directive is being complied with and, where there is doubt as to the origin of meat or slaughtered animals, to accounting documents which enable him to trace the holding of origin of a slaughtered animal.

The official veterinarian must regularly analyse the results of the checks provided for in 2. He may, on the basis of this analysis, conduct further microbiological examinations at all stages of production or on the products.

The result of these analyses shall be written up in a report, the conclusions and recommendations of which shall be notified to the operator of the establishment, the owner or his agent, who shall rectify the shortcomings noted with a view to improving hygiene.

Article 11

Member States shall entrust to a central service or body the tasks of collecting and making use of the results of the ante-mortem and post-mortem inspections carried out by the official veterinarian as regards the diagnosis of diseases transmissible to man.

Where such a disease is diagnosed, the results of the specific case shall be communicated as soon as possible to the competent veterinary authorities responsible for supervision of the herd from which the animals originated.

Member States shall submit to the Commission information on certain diseases and particularly cases where diseases transmissible to man have been diagnosed.

The Commission, acting in accordance with the procedure laid down in Article 16, shall adopt detailed rules for implementing this Article, and in particular:

- the regularity with which information must be submitted to the Commission,
- the type of information,
- the diseases to which the collection of information is to apply,
- procedures for collecting and using information.

Article 12

1. Veterinary experts from the Commission may, in so far as is necessary to ensure uniform application of this Directive and in cooperation with the competent national authorities, make on-site checks; they may in particular verify whether approved establishments are in fact complying with this Directive. The Commission shall inform the Member States of the results of the checks carried out.

A Member State in whose territory a check is being carried out shall give all the necessary assistance to the experts in carrying out their duties.

The general provisions for implementing this Article shall be adopted in accordance with the procedure laid down in Article 16.

After obtaining the opinion of the Member States in the Standing Veterinary Committee, the Commission shall draw up a recommendation concerning the rules to be followed in carrying out the checks provided for in this paragraph.

2. Before 1 January 1995 the Council shall review this Article on the basis of a report from the Commission, which may be accompanied by proposals.

Article 13

1. In accordance with the procedure laid down in Article 16, Member States may be authorized to apply the provisions of Article 4 to slaughterhouses handling a maximum of 20 livestock units per week and 1 000 livestock units per year:

- (a) if they are situated in regions suffering from special geographical constraints or affected by supply difficulties;
- (b) if, as at 1 July 1991, they are carrying out a restructuring programme in the context of a national plan in existence on that date.

In accordance with the same procedure, and by way of derogation from the conversion rates for the limits fixed in terms of livestock units in the first paragraph of Article 4 (A), the authorization provided for in the first subparagraph of this paragraph may be extended to establishments handling a maximum of 60 pigs per week, where the following requirements are met:

- (a) the owner of the establishment has received specific training, recognized by the competent authority, in production hygiene;
- (b) the animals to be slaughtered are the property of the owner of the establishment, or have been purchased by him to meet the requirements referred to in (d);
- (c) the meat is produced in premises which meet the requirements of Annex II and are situated in the establishment;
- (d) the meat produced is used solely to supply the establishment or sold directly to the consumer on the spot.

When decisions granting derogations are adopted, specific requirements, in particular a definition of the local market, may be provided for.

Establishments benefiting from such derogations shall be subject to Community inspection for approved establishments.

2. In accordance with the procedure laid down in Article 16:

- derogations from the second, third and fourth indents of point 14 (c) of Chapter II, from point 42 (A) (2) of Chapter VIII and point 46 (d) of Chapter IX of Annex I

may be granted, on request, to any Member State providing similar guarantees. These derogations shall fix health conditions which are at least equivalent to those of Annex I,

- additional requirements adapted to the specific situation of the Member States concerned with respect to certain diseases likely to endanger human health may be decided on,
- special conditions for the approval of establishments situated in wholesale markets may be decided on.

Article 14

1. Without prejudice to the specific provisions of this Directive, the official veterinarian or the competent authority shall, where it is suspected that veterinary legislation has not been complied with, or there is doubt as to whether meat is fit for consumption, carry out any veterinary checks he or it deems appropriate.

2. Member States shall take the appropriate administrative or penal measures to penalize any infringement of Community veterinary legislation, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state of the meat, that identification marks do not comply with the rules, that the meat was not presented for inspection or that the meat was not used for the purpose originally intended.

Article 15

The Annexes to the Directive shall be amended by the Council acting by a qualified majority on a proposal from the Commission, in particular to adapt them to advances in technology.

Article 16

1. Where the procedure laid down in this Article is to be followed, matters shall without delay be referred to the Standing Veterinary Committee by its chairman, either on his own initiative or at the request of the representative of a Member State.

2. The Commission representative shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on such measures within a time limit which the chairman shall lay down according to the urgency of the matter. Opinions shall be delivered by a majority of 54 votes, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. The Commission shall adopt the measures and implement them immediately where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee or if no

opinion is delivered, the Commission shall without delay propose to the Council the measure to be adopted. The Council shall adopt the measures by a qualified majority.

If, within three months from the date on which a proposal was submitted to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately, save where the Council has decided against these measures by a simple majority.

Article 17

Before 1 July 1994 the Commission shall submit to the Council a report, possibly accompanied by proposals on which the Council will take a decision by the voting procedure laid down in Article 43 of the Treaty, on methods

of inspection which ensure a level of animal health equivalent to that guaranteed by the methods of ante-mortem and post-mortem inspection described in Chapters VI and VIII of Annex I.

Article 18

The rules laid down in Directive 89/662/EEC shall apply in particular to checks at origin, to the organization of and follow-up to the checks to be carried out by the Member State of destination, and to the protective measures to be implemented.

Article 19

This Directive is addressed to the Member States.

ANNEX I

CHAPTER I

GENERAL CONDITIONS FOR THE APPROVAL OF ESTABLISHMENTS

Establishments must have at least:

1. In rooms where fresh meat is produced, worked on or stored and in areas and corridors through which fresh meat is transported:
 - (a) waterproof flooring which is easy to clean and disinfect, rotproof and laid in such a way as to facilitate the draining of water: the water must be channelled towards drains fitted with gratings and traps to prevent odours. However:
 - in the case of rooms referred to in point 14 (d) and (f) of Chapter II, point 15 (a) of Chapter III and point 16 (a) of Chapter IV, channeling of water towards drains fitted with gratings and traps is not required and, in the case of premises referred to in point 16 (a), a device with which water may easily be removed is sufficient,
 - in the case of rooms referred to in point 17 (a) of Chapter IV and in areas and corridors through which fresh meat is transported, waterproof and rotproof flooring is sufficient;
 - (b) smooth, durable, impermeable walls, with a light-coloured, washable coating up to a height of at least two metres, and of at least three metres in slaughter-rooms; in chilling or refrigeration rooms and in stores the walls must be coated at least to storage height. Wall to floor junctions must be rounded or similarly finished except in the rooms referred to in point 17 (a) of Chapter IV.

However, the use of wooden walls in the rooms referred to in point 17 of Chapter IV does not constitute grounds for withdrawing approval provided they were built before January 1983;
 - (c) doors in hard-wearing, non-corrodible material and, if of wood, with a smooth and impermeable covering on all surfaces;
 - (d) insulation materials which are rotproof and odourless;
 - (e) adequate ventilation and good extraction of steam;
 - (f) adequate natural or artificial lighting which does not distort colours;
 - (g) a clean and easily cleaned ceiling; failing that, a roof covering with an interior surface which fulfils these conditions;
2.
 - (a) as near as possible to the work stations, a sufficient number of facilities for cleaning and disinfecting hands and for cleaning tools with hot water. Taps must not be hand-operable. For washing hands, these facilities must have hot and cold running water or water premixed to a suitable temperature, cleaning and disinfecting products and hygienic means of drying hands;
 - (b) facilities for disinfecting tools, with hot water supplied at not less than 82°C;
3. appropriate arrangements for protection against pests such as insects and rodents;
4.
 - (a) instruments and working equipment such as cutting tables, tables with detachable cutting surfaces, containers, conveyor belts and saws, made of corrosion-resistant material not liable to taint meat and easy to clean and disinfect. Surfaces coming into, or capable of coming into, contact with meat, including welds and joints, must be maintained smooth. The use of hygienically packaged fresh meat;
 - (b) corrosion-resistant fittings and equipment meeting hygiene requirements for:
 - meat handling,
 - storing meat containers, in such a way that neither the meat nor the containers come into direct contact with the floor or walls;
 - (c) facilities, including suitably laid out and equipped reception and marshalling areas, for the hygienic handling and protection of meat during loading and unloading;

- (d) special watertight non-corrodible containers, with lids and fasteners to prevent unauthorized persons from removing things from them, for keeping meat not intended for human consumption, or a lockable room for such meat if the quantities are large enough to necessitate this or if the meat is not removed or destroyed at the end of each working day; where such meat is removed through conduits, these must be so constructed and installed as to avoid any risk of contamination of the fresh meat;
 - (e) facilities for the hygienic storage of materials for wrapping and packaging where such activities are carried out in the establishment;
5. refrigeration equipment to keep the internal temperature of the meat at the levels required by this Directive. This equipment must include a system for draining off water of condensation without any possibility of contamination of the meat;
 6. a pressurized supply of potable water within the meaning of Directive 80/778/EEC ⁽¹⁾ only. However, a non-potable water supply is authorized in exceptional cases for steam production, fire fighting and the cooling of refrigeration equipment, provided that the pipes installed for this purpose preclude the use of this water for other purposes and present no risk of contamination of fresh meat. Non-potable water pipes must be clearly distinguished from those used for potable water;
 7. an adequate supply of hot potable water within the meaning of Directive 80/778/EEC;
 8. liquid and solid disposal systems which meet hygiene requirements;
 9. an adequately equipped lockable room for the exclusive use of the veterinary service; or, in the case of stores referred to in point 17 of Chapter IV, suitable facilities;
 10. facilities enabling the veterinary inspections provided for in this Directive to be carried out efficiently at any time;
 11. an adequate number of changing rooms with smooth, waterproof, washable walls and floors, wash basins, showers and flush lavatories so equipped as to protect the clean parts of the building from contamination.

Lavatories must not open directly onto the work rooms. Showers are unnecessary in cold stores receiving and shipping hygienically wrapped fresh meat only. Wash basins must have hot and cold running water or water premixed to a suitable temperature, materials for cleaning and disinfecting the hands and hygienic means of drying hands. Wash basins taps must not be hand-operable or arm-operable. There must be a sufficient number of such wash basins near the lavatories;

12. a place and adequate facilities for cleaning and disinfecting means of transport for meat except in the case of cold stores receiving and shipping hygienically packed fresh meat only. A separate such place and adequate facilities for means of transport for livestock must be provided in the case of slaughterhouses. However, these places and facilities are not compulsory if provisions exist requiring that means of transport be cleaned and disinfected at officially authorized facilities;
13. a room or a secure place for the storage of detergents, disinfectants and similar substances.

CHAPTER II

SPECIAL CONDITIONS FOR THE APPROVAL OF SLAUGHTERHOUSES

14. In addition to the general requirements slaughterhouses must have at least:
 - (a) adequate lairage or, climate permitting, waiting pens for the animals; walls and floors must be durable, impermeable and easy to clean and disinfect; these facilities must be equipped for watering the animals, and for feeding them if necessary, and if appropriate a drainage system;

⁽¹⁾ OJ No L 229, 30. 8. 1980, p. 11. Directive last amended by Directive 81/858/EEC (OJ No L 319, 7. 11. 1981, p. 19).

- (b) slaughter premises large enough for work to be carried out satisfactorily. In slaughter premises where both pigs and other animal species are slaughtered, a special place must be provided for slaughtering pigs; however, such a special place is not essential if the slaughter of pigs and that of other animals take place at different times; but in such cases scalding, depilation, scraping and singeing must be carried out in special places which are clearly separated from the slaughter line either by an open space of at least five metres or by a partition at least three metres high;
- (c) separate rooms sufficiently large and exclusively reserved for:
- emptying and cleaning stomachs and intestines.
- Separate rooms will not, however, be necessary if these operations involving stomachs are carried out by means of closed-circuit mechanical equipment having an appropriate system of ventilation and satisfying the following requirements:
- (i) the equipment must be installed and arranged in such a manner that operations for separating intestines from the stomach and for the emptying and cleaning of stomachs are carried out hygienically. It must be located in a special place which is clearly separated from any exposed fresh meat by a partition stretching from the floor to a height of at least three metres and surrounding the area where these operations are carried out;
 - (ii) the design and operation of the machine must effectively prevent any contamination of the fresh meat;
 - (iii) an air extractor must be installed and must function in such a fashion as to eliminate odours and any risk of aerosol contamination;
 - (iv) the machine must be equipped with a device permitting closed-circuit evacuation of the residual water and the content of stomachs to the drainage system;
 - (v) the circuit followed by stomachs to and from the machine must be both clearly separated and at a distance from the circuit followed by other fresh meat. Immediately after they have been emptied and cleaned, the stomachs must be removed in a hygienic manner;
 - (vi) stomachs must not be handled by staff who handle other fresh meat. Staff handling stomachs must not have access to other fresh meat;
- dressing guts and tripe if this is carried out in the slaughterhouse. However, those operations may be performed in the same room referred to in the first indent provided that cross-contamination is avoided;
 - preparing and cleaning offal other than that referred to in the preceding indents, including a separate place for storing heads at a sufficient distance from other offal, if these operations are carried out in the slaughterhouse and do not take place on the slaughterline;
 - the storage of hides, horns, hooves and pigs' bristles, in the event of these not being removed directly from a slaughterhouse on the day of slaughter, in closed, leak-proof containers pending their removal;
- (d) a separate place for packaging offal if this is done in the slaughterhouse;
- (e) lockable premises or, climate permitting, suitably sited pens with separate drainage for sick or suspect animals; lockable premises reserved for the slaughter of such animals, the storage of detained meat and the storage of meat declared unfit for human consumption. Premises reserved for the slaughter of these animals are not essential in an establishment not authorized by the competent authority for slaughter of these animals or where such slaughter is performed at the end of normal slaughtering, provided that steps are taken to prevent contamination of meat declared fit for human consumption. In this case the premises must be specially cleaned and disinfected under official supervision before being used again for slaughtering of animals which are neither sick nor suspect;
- (f) sufficiently large chilling or refrigerating rooms equipped with corrosion-resistant fittings designed to prevent fresh meat coming into contact with the floor or the walls when it is being moved or held;
- (g) means of controlling access to and exit from the slaughterhouse;
- (h) a clear separation between the soiled and clean working areas of the building so as to protect the clean areas from contamination;

- (i) equipment such that, after stunning, dressing can be carried out as far as possible on the suspended animal; under no circumstances may the suspended animal come into contact with the floor during dressing;
- (j) an overhead system of rails for the further handling of meat;
- (k) if dung is stored in the slaughterhouse precincts, a special section for such dung;
- (l) a room suitable equipped for carrying out an examination for trichinella where such test is carried out in the establishment.

CHAPTER III

SPECIAL CONDITIONS FOR THE APPROVAL OF CUTTING PLANTS

15. In addition to the general requirements, cutting plants must have at least:
- (a) chilling or refrigerating rooms large enough for meat preservation, and, where packaged meat is stored in the establishment, a separate such room for packaged meat. Unpackaged meat may not be stored in such chilling or refrigerating rooms unless it is first cleaned and disinfected;
 - (b) a room for cutting and boning and wrapping equipped with a recording thermometer or recording telethermometer;
 - (c) a room for packaging, where such operations are carried out in the cutting plant, unless the conditions provided for in point 63 of Chapter XII are fulfilled;
 - (d) a room for the storage of packaging and wrapping materials, where such operations are carried out in the cutting plant.

CHAPTER IV

SPECIAL CONDITIONS FOR THE APPROVAL OF COLD STORES

16. In addition to the general requirements, stores in which fresh meat is stored in accordance with the first paragraph in point 66 of Chapter XIV must have at least:
- (a) sufficiently large chilling and refrigeration rooms, which are easy to clean and in which fresh meat can be stored at the temperatures provided for under the first paragraph of point 66;
 - (b) a recording thermometer or recording telethermometer in or for each storage area.
17. In addition to the general requirements, stores in which fresh meat is stored in accordance with the fourth paragraph of point 66 of Chapter XIV must have at least:
- (a) sufficiently large chilling and refrigeration rooms, which are easy to clean and in which fresh meat can be stored at the temperature provided for in the fourth paragraph of point 66;
 - (b) a recording thermometer or recording telethermometer in or for each storage area.

CHAPTER V

HYGIENE OF THE STAFF, PREMISES AND EQUIPMENT IN THE ESTABLISHMENTS

18. Absolute cleanliness shall be required of staff, premises and equipment:
- (a) staff handling exposed or wrapped fresh meat or working in rooms and areas in which such meat is handled, packaged or transported must in particular wear clean and easily cleanable headgear, footwear and light-coloured working clothes and, where necessary, clean neck shields or other protective clothing. Staff engaged in slaughtering animals or working on or handling meat must wear clean working clothes at the commencement of each working day and must renew such clothing during the day as necessary and

must wash and disinfect their hands several times during the working day and each time work is resumed. Persons who have been in contact with sick animals or infected meat must immediately afterwards carefully wash their hands and arms with hot water and then disinfect them. Smoking is forbidden in workrooms, storerooms, load-in, reception, marshalling and load-out areas, and in other areas and corridors through which fresh meat is transported;

- (b) no animal may enter the establishment except, in the case of slaughterhouses, animals for slaughter and with reference to the precincts of these slaughterhouses, animals necessary for their operation. Rodents, insects and other vermin must be systematically destroyed;
 - (c) equipment and instruments used for working on meat shall be kept clean and in a good state of repair. They shall be carefully cleaned and disinfected several times during the working day, at the end of the day's work and before being re-used when they have been soiled.
19. Premises, instruments and working equipment must not be used for purposes other than work on fresh meat or farmed game meat authorized in accordance with Directive 91/495/EEC ⁽¹⁾.

This restriction shall not apply to:

- transport equipment used on the premises referred to in point 17 (a), where the meat is packaged,
- the cutting of poultrymeat or wild game meat or rabbit meat or the producing of meat preparations, provided that such operations are carried out at a different time to the cutting of fresh meat or farmed game meat referred to in the first paragraph and the cutting room is completely cleaned and disinfected before being made use of again for the cutting of fresh meat or farmed game meat.

Meat-cutting instruments must be solely for cutting meat.

20. Meat and meat containers shall not come into direct contact with the ground.
21. Potable water must be used for all purposes; however, non-potable water may be used in exceptional cases for steam production provided that the pipes installed for this purpose preclude the use of this water for other purposes and present no danger of contamination of fresh meat. In addition, non-potable water may be used in exceptional cases for cooling refrigeration equipment. Non-potable water pipes must be clearly distinguished from pipes used for potable water.
22. The spreading of sawdust or any other similar substance on the floor of the workrooms and fresh meat storage rooms is prohibited.
23. Detergents, disinfectants and similar substances must be used in such a way that instruments, working equipment and fresh meat are not adversely affected. Their use must be followed by thorough rinsing of such instruments and working equipment with potable water.
24. Persons likely to contaminate meat are prohibited from working on it and handling it.

When recruited, any person working on and handling fresh meat shall be required to prove, by a medical certificate, that there is no impediment to such employment. The medical supervision of such a person shall be governed by the national legislation in force in the Member State concerned.

CHAPTER VI

ANTE-MORTEM HEALTH INSPECTION

25. Animal must undergo ante-mortem inspection on the day of their arrival at the slaughterhouse or before the beginning of daily slaughtering. The inspection must be repeated immediately before slaughter if the animal has been in the lairage overnight.

The operator of the slaughterhouse, the owner or his agent must facilitate operations for performing ante-mortem health inspections and in particular any handling which is considered necessary.

Each animal to be slaughtered shall bear an identifying mark enabling the competent authority to determine its origin.

⁽¹⁾ See page 41 of this Official Journal.

26. (a) The official veterinarian must make the ante-mortem inspection in accordance with professional rules and under suitable lighting.
- (b) The official veterinarian must, in respect of animals delivered to slaughterhouse, check an compliance with Community rules on animal welfare.
27. The inspection must determine:
- (a) whether the animals are suffering from a disease which is communicable to man and to animals or whether they show symptoms or are in a general condition such as to indicate that such a disease may occur;
- (b) whether they show symptoms of disease or of a disorder of their general conditions which is likely to make their meat unfit for human consumption; attention must also be paid to any signs that the animals have had substances with pharmacological effects administered to them or have consumed any other substances which may make their meat harmful to human health;
- (c) whether they are tired, agitated or injured.
28. (a) Tired or agitated animals must be rested for at least 24 hours unless the official veterinarian decides otherwise.
- (b) Animals in which one of the diseases referred to in point 27 (a) and (b) has been diagnosed must not be slaughtered for human consumption.
- (c) Slaughter of animals suspected of suffering from one of the diseases referred to in point 27 (a) and (b) must be deferred. These animals must undergo detailed examination in order to make a diagnosis.

Where the post-mortem inspection is necessary in order to make a diagnosis, the official veterinarian shall request that the animals in question are slaughtered separately or at the end of normal slaughtering.

Those animals shall undergo detailed post-mortem inspection supplemented, if the veterinarian considers it necessary for confirmation, by an appropriate bacteriological examination and a search for residues of substances with a pharmacological effect which may be presumed to have been administered to treat the pathological state observed.

CHAPTER VII

SLAUGHTER, CUTTING AND MEAT-HANDLING HYGIENE

29. Slaughter animals brought into slaughter premises must be slaughtered immediately and bleeding, flaying or removing the bristles, dressing and evisceration must be carried out in a way which avoids any contamination of the meat.
30. Bleeding must be complete; blood intended for human consumption must be collected in absolutely clean containers. It must not be stirred by hand, only with instruments which meet hygiene requirements.
31. Immediate and complete flaying is compulsory, except for pigs, without prejudice to the derogation provided for in the second sentence of point 41 (D) (a) of Chapter VIII. When not flayed, pigs must have their bristles removed immediately. Debristling agents may be used for this operation, provided that the pigs are thoroughly rinsed afterwards with potable water.

However, skinning of heads of calves and ovines is not necessary provided that those heads are handled in such a way as to avoid any contamination of fresh meat.

32. Evisceration must be carried out immediately and completed not later than 45 minutes after stunning or, in the case of ritual slaughter, half an hour after bleeding. The lungs, heart, liver, kidney, spleen and mediastinum may either be detached or left attached to the carcass by their natural connections.

If detached, they must be numbered or identified in some way to enable them to be recognized as belonging to a given carcass: this also applies to the head, tongue, digestive tract and any other part of the animal required for inspection or possibly required for the execution of checks laid down in Directive 86/469/EEC. The abovementioned parts must remain near the carcass until the inspection is complete. However, provided it shows no pathological symptom or lesion, the penis may be discarded immediately. For all species the kidneys must be removed from their fatty covering: in the case of bovine animals, swine and solipeds the peri-renal capsule must also be removed.

33. Implements must not be left in the meat; cleansing of meat by wiping with a cloth or other materials, and inflation, are prohibited. However, inflation of an organ may be authorized for ritual purposes, but in that event the inflated organ must be excluded from human consumption.
34. Carcasses of solipeds, pigs over four week old and bovine animals over six month old must be submitted for inspection split lengthwise into half carcasses down the spinal column. If the inspection so necessitates, the official veterinarian may require any head or any carcase to be split lengthwise.

However, to take account of technological requirements or local habits of consumption the competent authority may authorize the submission for inspection of pig heads not split in half.
35. Until the inspection has been completed, it must not be possible for carcasses and offal not inspected to come into contact with carcasses and offal already inspected, and the removal, cutting or further treatment of the carcase shall be forbidden.
36. It must not be possible for meat detained or declared unfit for human consumption, stomachs, intestines and inedible by-products to come into contact with meat declared fit for human consumption, and the former must be placed as soon as possible in special rooms or containers located and laid out in such a way as to avoid any contamination of other fresh meat.
37. If the blood or the offal of several animals is collected in the same container before the completion of the post-mortem inspection, the entire contents must be declared unfit for human consumption if the carcase of one of the animals concerned has been declared unfit for human consumption.
38. The handling, trimming, further treatment and transport of meat, including offal, must be performed meeting all hygiene requirements. Where such meat is packaged, point 14 (d) of Chapter II and the conditions of Chapter XI must be complied with. Packaged meat must be stored in a separate room from exposed fresh meat.

CHAPTER VIII

POST-MORTEM HEALTH INSPECTION

39. All parts of the animal including the blood must be inspected immediately after slaughter to determine whether the meat is fit for human consumption.
40. The post-mortem inspection must include:
 - (a) visual inspection of the slaughtered animal and the organs belonging to it;
 - (b) palpation of the organs referred to in point 41 and, if the official veterinarian deems it to be necessary, of the uterus;
 - (c) incision of certain organs and lymph nodes and, depending on the conclusions reached by the official veterinarian, the uterus. If visual inspection or palpation of certain organs indicates that the animal has lesions which can contaminate the carcasses, equipment, staff or work premises, these organs must not be incised in the slaughter-room or any other part of the establishment where fresh meat might be contaminated;
 - (d) investigation of anomalies in consistency, colour, smell and, where appropriate, taste;
 - (e) where necessary, laboratory tests in particular for the substances referred to in Article 5 (1) (j) and (k).
41. The official veterinarian must be proceed in particular in the following way:
 - A. Bovine animals over six weeks old
 - (a) visual inspection of the head and the throat. The submaxillary, retro-pharyngeal and parotid lymph nodes (*Lnn. retropharyngiales, mandibulares and parotidei*) must be incised and examined. The external masseters, in which two incisions must be made parallel to the mandible, and the internal masseters (internal pterygoid muscles), which must be incised along one plane, must be examined;

The tongue, having been freed to permit a detailed visual inspection of the mouth and the fauces, must be visually inspected and palpated. The tonsils must be removed;

- (b) inspection of the trachea; visual examination and palpation of the lungs and the oesophagus; the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*) must be incised and examined. The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;
- (c) visual inspection of the pericardium and the heart, the latter being incised lengthwise so as to open the ventricles and to cut through the interventricular septum;
- (d) visual inspection of the diaphragm;
- (e) visual inspection and palpation of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); incision of the gastric surface of the liver and at the base of the caudate lobe to examine the bile ducts; inspection and palpation of the pancreatic lymph nodes;
- (f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*), palpation of the gastric and mesenteric lymph nodes, and, if necessary, incision of those lymph nodes;
- (g) visual inspection and, if necessary, palpation of the spleen;
- (h) visual inspection of the kidney and incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (i) visual inspection of the pleura and the peritoneum;
- (j) visual inspection of the genital organs;
- (k) visual inspection and, if necessary, palpation and incision of the udder and its lymph nodes (*Lnn. supramammarii*). In cows, each half of the udder must be opened by a long, deep incision as far as the lactiferous sinuses (*sinus lactiferes*) and the lymph nodes of the udder must be incised, except when the udder is excluded from human consumption.

B. Bovine animals under six weeks old

- (a) visual inspection of the head and the throat. The retropharyngeal lymph nodes (*Lnn. retropharyngiales*) must be incised and examined. The mouth and the fauces must be inspected and the tongue must be palpated. The tonsils must be removed;
- (b) visual inspection of the lungs, the trachea and the oesophagus; palpation of the lungs; the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*) must be incised and examined.

The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in the posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;
- (c) visual inspection of the pericardium and the heart, the latter being incised lengthwise so as to open the ventricles and to cut through the interventricular septum;
- (d) visual inspection of the diaphragm;
- (e) visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); palpation and, if necessary, incision of the liver and its lymph nodes;
- (f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*), palpation of the gastric and mesenteric lymph nodes, and, if necessary, incision of those lymph nodes;
- (g) visual inspection and, if necessary, palpation of the spleen;
- (h) visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (i) visual inspection of the pleura and the peritoneum;
- (j) visual inspection and palpation of the umbilical region and the joints; in the event of doubt, the umbilical region must be incised and the joints opened. The synovial fluid must be examined;

C. Swine

- (a) visual inspection of the head and the throat; the submaxillary (*Lnn. mandibulares*) lymph nodes must be examined and incised. The mouth, the fauces, and the tongue must be visually inspected. The tonsils must be removed;
- (b) visual inspections of the lungs, trachea and oesophagus; palpation of the lungs and of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption;
- (c) visual inspection of the pericardium and the heart, the latter being incised lengthwise so as to open the ventricles and to cut through the interventricular septum;
- (d) visual inspection of the diaphragm;
- (e) visual inspection and palpation of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); palpation of the liver and its lymph nodes;
- (f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*), palpation of the gastric and mesenteric lymph nodes, and, if necessary, incision of those lymph nodes;
- (g) visual inspection and, if necessary, palpation of the spleen;
- (h) visual inspection of the kidneys and incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (i) visual inspection of the pleura and the peritoneum;
- (j) visual inspection of the genital organs;
- (k) visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*), incision of the supramammary lymph nodes in sows;
- (l) visual inspections and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened.

D. Sheep and goats

- (a) visual inspection of the head after flaying and, in the event of doubt, examination of the throat, the mouth, the tongue and the retro-pharyngeal and parotid lymph nodes. Without prejudice to animal health conditions, these examinations are not necessary if the competent authority is able to guarantee that the head, including the tongue and the brains, is excluded from human consumption;
- (b) visual inspection of the lungs, the trachea and the oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*); in the event of doubt, these organs and lymph nodes must be incised and examined;
- (c) visual inspection of the pericardium and the heart; in the event of doubt the heart must be incised and examined;
- (d) visual inspection of the diaphragm;
- (e) visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;
- (f) visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);
- (g) visual inspection and, if necessary, palpation of the spleen;
- (h) visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (i) visual inspection of the pleura and the peritoneum;
- (j) visual inspection of the genital organs;
- (k) visual inspection of the udder and its lymph nodes;
- (l) visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened.

E. Domestic solipeds

- (a) visual inspection of the head, and after freeing the tongue, the throat; the submaxillary retro-pharyngeal and parotid lymph nodes (*Lnn. retropharyngiales, mandibulares* and *parotidei*) must be palpated and, if necessary, incised. The tongue, having been freed to permit a detailed inspection of the mouth and the fauces, must be visually examined and palpated. The tonsils must be removed;
 - (b) visual inspection of the lungs, the trachea and the oesophagus; palpation of the lungs; the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*) must be palpated and, if necessary, incised. The trachea and the main branches of the bronchi must be opened lengthwise and the lungs incised in their posterior third, perpendicular to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption;
 - (c) visual inspection of the pericardium and the heart, the latter being incised lengthwise so as to open the ventricles and to cut through the interventricular septum;
 - (d) visual inspection of the diaphragm;
 - (e) visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); palpation of the liver and its lymph nodes; if necessary, incision of the liver and the hepatic and pancreatic lymph nodes;
 - (f) visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); incision, if necessary, of the gastric and mesenteric lymph nodes.
 - (g) visual inspection and, if necessary, palpation of the spleen;
 - (h) visual inspection of the kidneys, palpation of the kidneys and incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
 - (i) visual inspection of the pleura and the peritoneum;
 - (j) visual inspection of the genital organs of stallions and mares;
 - (k) visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*) and, if necessary, incision of the supramammary lymph nodes;
 - (l) visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened;
 - (m) all grey or white horses must be inspected for melanosis and melanomata as regards the muscles and lymph nodes (*Lnn. lymphonodi subrhomboides*) of the shoulders beneath the scapular cartilage by loosening the attachment of one shoulder. The kidneys must be exposed and examined by incision through the entire kidney.
- F. In the event of doubt, the official veterinarian may perform the further cuts and inspections of the relevant parts of the animals necessary in order to reach a final decision.

Where the official veterinarian finds that the hygiene rules laid down in this Chapter are clearly being breached or that adequate health inspection is being hampered, he shall be empowered to take action with regard to the use of equipment or premises and to take any measure required, up to and including a reduction in the rate of production or interruption of the production process.

- G. Where incision of the above lymph nodes is obligatory, they must be systematically subjected to multiple incisions and a visual inspection.

42. A. In addition, the official veterinarian must systematically carry out:

- 1) an investigation for cystercosis in swine: this investigation must include examination of the directly visible muscular surfaces, in particular the thigh muscles, the pillars of the diaphragm, the intercostal muscles, the heart, the tongue and the larynx and, if necessary, the abdominal wall and the psoas muscles freed from fatty tissue;
- 2) an investigation for glanders in solipeds by means of careful examination of mucous membranes from the trachea, larynx, nasal cavities, sinuses and their ramifications, after splitting the head in the median plane and excision of the nasal septum.
- 3) Fresh meat from swine and horses which contains skeletal muscles (striated muscles) must undergo an investigation for trichinosis.

This investigation must be carried out in accordance with proven methods which are scientifically recognized, in particular methods which are defined in Community directives or in other international standards.

The results must be assessed using a reference method fixed in accordance with the procedure laid down in Article 16 of this Directive and after the Scientific Veterinary Committee has delivered its opinion; the reliability of the method must be at least as great as that of the trichinoscopy provided for in point 1 of Annex I to Directive 77/96/EEC.

The Commission shall publish the reference method in the *Official Journal of the European Communities*.

- B. The results of the ante-mortem and post-mortem health inspections shall be recorded by the official veterinarian and, where diseases transmissible to man as referred to in Article 6 are diagnosed, communicated to the competent veterinary authorities responsible for supervision of the herd from which the animals originated, as well as to the person responsible for the herd in question.

CHAPTER IX

REQUIREMENTS FOR MEAT INTENDED FOR CUTTING

43. Cutting pieces smaller than those referred to in Article 3 (1) (A), de-boning or the slicing of offal of animals of the bovine species is authorized in approved cutting plants only.
44. The operator of the plant, the owner or his agent must facilitate operations for supervising the plant, in particular any handling which is considered necessary, and must place the necessary facilities at the disposal of the supervisory service. In particular, he must be able on request to inform the official veterinarian responsible for supervision of the source of the meat brought into his cutting plant.
45. Without prejudice to the second paragraph of point 19 of Chapter V, meat which does not fulfil the requirements of Article 3 (1) (B) (b) of this Directive may not be placed in approved cutting plants unless placed in special storage areas; it must be cut up in other places or at other times than meat which does fulfil those requirements. The official veterinarian must at all times have access to all storage rooms and work rooms in order to satisfy himself that the preceding provisions are rigorously observed.
46. (a) Fresh meat must be brought into the rooms provided for in point 15 (b) of Chapter III progressively as needed. As soon as it is cut, and where appropriate packaged, the meat must be transferred to the relevant chilling or refrigerating room referred to above in point 15 (a) of Chapter III.
- (b) Meat entering a cutting premises must be checked and, if necessary, trimmed. The work station for this task must be equipped with suitable facilities and adequate lighting.
- (c) During cutting, boning, wrapping and packaging the internal temperature of the meat must be kept at a constant + 7°C or less. During cutting, the temperature of the cutting room must not exceed + 12°C. During slicing, wrapping and packaging, the internal temperature of livers must be kept at a constant + 3°C or less.

During cutting, boning, slicing, dicing, wrapping and packaging the temperature of livers, kidneys and head meat must be kept at a constant + 3°C or less.

- (d) By way of derogation from paragraphs (a) and (c), meat may be cut while warm. In that event, the meat must be transferred directly from the slaughter premises to the cutting room. In addition, the slaughter premises and the cutting room must be located in the same group of buildings and sufficiently near to each other for the meat to be transferred in a single operation, and cutting must be carried out immediately after transfer. As soon as it is cut, and where appropriate packaged, it must be transferred to an appropriate chilling room.
- (e) Cutting must be carried out in such a way as to avoid any soiling of the meat. Splinters of bone and clots of blood must be removed. Meat obtained from cutting and not intended for human consumption must be collected in the facilities, containers or rooms referred to in point 4 (d) as it is cut.

CHAPTER X

HEALTH CONTROL OF CUT MEAT AND STORED MEAT

47. Approved cutting plants and approved cold stores must be supervised by an official veterinarian.
48. Supervision by the official veterinarian must include the following tasks:
- supervision of the entry and exit of fresh meat,
 - health inspection of fresh meat held in the establishment referred to in point 47,
 - health inspection of fresh meat prior to cutting and when it leaves the establishments referred to in point 47,
 - supervision of the cleanliness of the premises, facilities and instruments provided for in Chapter V, and of staff hygiene, including their clothing,
 - any other supervision which the official veterinarian considers necessary for ensuring compliance with this Directive.

CHAPTER XI

HEALTH MARKING

49. Health marking must be carried out under the responsibility of the official veterinarian. For this purpose, he shall keep and maintain under his responsibility:
- (a) the instruments intended for meat health marking which he may hand over to auxiliaries only at the time of marking and for the length of time required for this purpose;
 - (b) the labels and wrapping material when marked as provided for in this chapter. The labels and wrapping material shall be given to the auxiliaries at the time when they are to be used and in the required number.
50. The health mark must be:
- (a) either an oval mark at least 6,5 cm wide by 4,5 cm high bearing the following information in perfectly legible characters:
 - on the upper part, the initials of the consigning country in capitals (i.e. one of the following):
B — DK — D — EL — E — F — IRL — I — L — NL — P — UK,
followed by the veterinary approval number of the establishment,
 - on the lower part, one of the following sets of initials: CEE, EØF, EWG, EOK, EEC, or EEG;
 - (b) or an oval mark at least 6,5 cm wide by 4,5 cm high, bearing the following information in perfectly legible characters:
 - on the upper part, the name of the consigning country in capitals,
 - in the centre, the veterinary approval number of the establishment,
 - on the lower part, one of the following sets of initials: CEE, EØF, EWG, EOK, EEC or EEG.

The letters must be at least 0,8 cm high and the figures at least 1 cm high.

The health mark may, in addition, include an indication of the official veterinarian who carried out the health inspection of the meat.
51. Carcasses must be stamped in ink or hot-branded in accordance with point 50:
- those weighing more than 65 kilograms must be marked on each half-carcass, in the following places at least: external surface of the thighs, loins, back, breast and shoulder,
 - other carcasses must be marked in at least four places, on the shoulder and on the external surface of the thighs.

52. The livers of bovine animals, swine and solipeds must be hot-branded in accordance with point 50.
- All other offal must be stamped in ink or hot-branded in accordance with point 50, unless wrapped or packaged and marked in accordance with points 55 and 56.
53. Cuts obtained in cutting plants from officially marked carcasses must be stamped in ink or hot-branded in accordance with point 50, unless they are wrapped or packaged, and ribs must be marked in a way making it possible to identify the slaughterhouse of origin.
54. Packaging must always be marked in accordance with point 55.
55. Packaged cut meat and packaged offal referred to in point 52 second paragraph, and point 53, including sliced livers of animals of the bovine species, must bear a health mark in accordance with point 50. The mark must include the veterinary approval number of the cutting plant instead of that of the slaughterhouse. The mark must be applied to a label fixed to the packaging, or printed on the packaging, in such a way that it is destroyed when the packaging is opened; the label must also show a serial number. However, when cut meat or offal is wrapped in accordance with point 62 of Chapter XII, the label referred to above may be affixed to the wrapping. In the case of offal packaged in a slaughterhouse, the number included in the mark must be the veterinary approval number of the slaughterhouse concerned.
56. In addition to the requirements of point 55, where fresh meat is wrapped in commercial portions intended for direct sale to the consumer a reproduction of the health mark provided for under point 50 (a) must also be printed on the wrapping or on a label affixed to the wrapping. The mark must include the veterinary approval number of the cutting plant. The dimension requirements of point 50 need not apply to the mark required under this point. However, in the case of offal wrapped in a slaughterhouse, the number included in the mark must be the veterinary approval number of the slaughterhouse concerned.
57. Meat from solipeds and its packaging must bear a special mark, to be determined in accordance with the procedure laid down in Article 16 of this Directive.
58. The colours to be used for the stamp must be authorized in accordance with the Council Directive on the approximation of the rules of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption ⁽¹⁾.

CHAPTER XII

WRAPPING AND PACKAGING OF FRESH MEAT

59. (a) Packaging (for example packing cases, paperboard boxes) must fulfil all rules of hygiene, and in particular:
- must not alter the organoleptic characteristics of the meat,
 - must not be capable of transmitting to the meat substances harmful to human health,
 - must be strong enough to ensure effective protection of the meat during transportation and handling.
- (b) Packaging must not be re-used for meat unless it is made of corrosion-resistant materials which are easy to clean and has been previously cleaned and disinfected.
60. Where fresh cut meat or offal is wrapped, this operation must be carried out immediately after cutting and in accordance with hygiene requirements.

With the exception of cuts of solid outer pig fat and belly, cut meat and offal must in all cases be provided with a protective wrapping unless it is suspended throughout its transport.

Such wrapping must be transparent and colourless and must also fulfil the conditions of the first and second indents of point 59 (a); it may not be used again for wrapping meat.

Sliced livers of animals of the bovine species must be individually wrapped. A package may contain only a complete sliced organ presented in its original form.

⁽¹⁾ OJ No L 115, 11. 11. 1962, p. 2645/62. Directive as last amended by Directive 85/7/EEC (OJ No L 2, 3. 1. 1985, p. 22).

61. Wrapped meat must be packaged.
62. However, when wrapping fulfils all the protective conditions of packaging it need not be transparent and colourless and placing in a second container is not necessary provided that the other conditions of point 59 are fulfilled.
63. Cutting, boning, wrapping and packaging operations may take place in the same room subject to the following conditions:
 - (a) the room must be sufficiently large and so arranged that the hygiene of the operations is assured;
 - (b) the packaging and wrapping must be enclosed in a sealed protective cover immediately after manufacture; this cover must be protected from damage during transport to the establishment and stored under hygienic conditions in a separate room in the establishment;
 - (c) the rooms for storing packaging material must be dust and vermin-free and have no air connection with rooms containing substances which might contaminate fresh meat. Packaging must not be stored on the floor;
 - (d) packaging must be assembled under hygienic conditions before being brought into the room;
 - (e) packaging must be hygienically brought into the room and used without delay. It must not be handled by staff handling fresh meat;
 - (f) immediately after packaging the meat must be placed in the storage room provided.
64. The packaging referred to in this chapter may contain only cut meat from the same animal species.

CHAPTER XIII

HEALTH CERTIFICATE

65. The original copy of the health certificate which must accompany meat during transportation to the place of destination must be issued by an official veterinarian at the time of loading.

The certificate must correspond in form and content to the model in Annex IV and be drawn up in the official language or languages of the place of destination at least. It must consist of a single sheet of paper.

CHAPTER XIV

STORAGE

66. Fresh meat must be chilled immediately after the post-mortem inspection and kept at a constant internal temperature of not more than + 7°C for carcasses and cuts and + 3°C for offal.

Derogations from this equipment may, for technical reasons relating to maturation of the meat, be granted by the competent authority on a case-by-case basis for the transportation of meat to cutting plants or butcher shops in the immediate vicinity of the slaughterhouse, provided that such transportation takes not more than one hour.

Fresh meat for freezing must come directly from an approved slaughterhouse or an approved cutting plant.

Freezing of fresh meat may be performed only in rooms of the same establishment where the meat has been obtained or cut or in an approved cold store, by means of appropriate equipment.

When intended for freezing, cuts referred to in Article 3 (1) (A) of this Directive, the cuts referred to in point 53 of Chapter XI of this Annex and offal must be frozen without delay unless maturation is required for health reasons. In the latter case they must be frozen immediately after maturation.

Carcases, half carcasses, half carcasses cut into no more than three wholesale cuts, and quarters intended for freezing must be frozen without undue delay after a period of stabilization.

Cut meat intended for freezing must be frozen without undue delay after cutting.

Frozen meat must reach an internal temperature of -12°C or lower and may not be stored at higher temperatures thereafter.

Fresh meat which has undergone a freezing process must bear an indication of the month and year in which it was frozen.

67. No other product which may affect the hygiene of the meat or contaminate it may be stored in the rooms referred to in points 16 and 17 of Chapter IV unless the meat is packaged and stored separately.
68. The storage temperature of the storage rooms referred to in points 16 and 17 of Chapter IV must be recorded.

CHAPTER XV

TRANSPORT

69. Fresh meat must be transported in means of transport provided with a hermetic closing system or, in the case of fresh meat imported in accordance with Directive 90/675/EEC or fresh meat transiting through the territory of a third country in sealed means of transport, designed and equipped in such a way that the temperatures specified in Chapter XIV are maintained throughout transportation.

By way of derogation from the first paragraph, carcasses, half carcasses, half carcasses cut into no more than three wholesale cuts, and quarters may be transported at temperatures higher than those laid down in Chapter XIV under conditions to be set after consultation of the Scientific Committee in accordance with the procedure laid down in Article 16 of this Directive.

70. Means of transport intended for transporting such meat must meet the following requirements:
 - (a) their inside surfaces or any other part which may come into contact with the meat must be of corrosion-resistant material which cannot affect the organoleptic characteristics of the meat or render the meat harmful to human health; these surfaces must be smooth and easy to clean and disinfect;
 - (b) they must be provided with efficient devices for protecting the meat against insects and dust and be watertight;
 - (c) for transporting carcasses, half carcasses, half carcasses cut into no more than three wholesale cuts, quarters and unpackaged cut meat, they must be equipped with corrosion-resistant fittings for suspending the meat fixed at a height such that the meat cannot touch the floor. This provision shall not apply to frozen meat in hygienic packaging. In the case of transport by air, however, fittings for suspending the meat are not required provided that suitable corrosion-resistant facilities are provided for hygienically loading, holding and unloading the meat.
71. Means of transport intended for transporting meat may in no case be used for transporting live animals or any products likely to affect or contaminate meat.
72. No other product likely to affect the hygiene of the meat or to contaminate it may be transported at the same time as the meat in the same means of transport unless appropriate precautions are taken. Packaged meat must be transported in separate means of transport from unpackaged meat unless, within the same means of transport, an adequate physical separation is provided so as to protect unpackaged meat from packaged meat. In addition, stomachs may not be transported therein unless scalded or cleaned, nor heads and feet unless they are skinned or scalded and depilated.

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73. Fresh meat may not be transported in a vehicle or container which is not clean and has not been disinfected.
74. Carcases, half carcases and quarters, half carcases cut into no more than three wholesale cuts, excluding frozen meat packaged in accordance with hygiene requirements, must be suspended throughout transport except in the case of air transport in accordance with point 70 (c).
- Other cuts and offal must be suspended or placed on supports if not packaged or contained in corrosion-resistant containers. Such supports, packaging or containers must meet hygiene requirements and, in particular as regards packaging, the provisions of this Directive. The viscera must always be transported in strong waterproof and greaseproof packaging which may only be re-used after cleaning and disinfection.
75. The official veterinarian must ensure before dispatch that transport vehicles and loading conditions meet the hygiene requirements of this Chapter.
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ANNEX II

CHAPTER I

GENERAL CONDITIONS FOR APPROVAL OF LOW-CAPACITY ESTABLISHMENTS

Low-capacity establishments must have at least:

1. in rooms where fresh meat is produced and worked on:
 - (a) waterproof flooring which is easy to clean and disinfect, rotproof and laid in such a way as to facilitate the draining of water; the water must be channelled towards drains fitted with gratings and traps to prevent odours;
 - (b) smooth, durable, impermeable walls, with a light-coloured, washable coating up to a height of at least two metres, and of at least three metres in slaughter rooms.

However, the use of wooden walls in the rooms referred to in point 16 of Chapter III of Annex I does not constitute grounds for withdrawing approval provided they were built before 1 July 1991;
 - (c) doors in easily cleanable, rotproof and odourless material.

Where meat is stored in the establishment concerned, that establishment must have storage premises which satisfy the aforementioned requirements;
 - (d) insulation materials which are rotproof and odourless;
 - (e) adequate ventilation and if necessary good extraction of steam;
 - (f) adequate natural or artificial lighting which does not distort colours;
2.
 - (a) as near as possible to the work stations, a sufficient number of facilities for cleaning and disinfecting hands and for cleaning tools with hot water. For washing hands, these facilities must have hot and cold running water or water premixed to a suitable temperature, cleaning and disinfecting products and hygienic means of drying hands;
 - (b) facilities on the spot or in an adjacent room for disinfecting tools, with hot water supplied at not less than 82°C;
3. appropriate arrangements for protection against pests such as insects and rodents;
4.
 - (a) instruments and working equipment such as cutting tables, tables with detachable cutting surfaces, containers, conveyor belts and saws, made of corrosion-resistant material, not liable to taint meat and easy to clean and disinfect. The use of wood is forbidden;
 - (b) corrosion-resistant fittings and equipment meeting hygiene requirements for:
 - meat handling,
 - storing meat containers, in such a way that neither the meat nor the containers come into direct contact with the floor or walls;
 - (c) special watertight non-corrodible containers, with lids and fasteners to prevent unauthorized persons from removing things from them, for keeping meat not intended for human consumption; such meat must be removed or destroyed at the end of each working day;
5. refrigeration equipment to keep the internal temperature of the meat at the levels required by this Directive. This equipment must include a drainage system linked to the waste-water pipes which presents no risk of contamination of the meat;
6. a pressurized supply of potable water within the meaning of Directive 80/778/EEC only. However, a non-potable water supply is authorized in exceptional cases for steam production, fire fighting and the cooling of refrigeration equipment, provided that the pipes installed for this purpose preclude the use of this water for other purposes and present no risk of contamination of fresh meat. Non-potable water pipes must be clearly distinguished from those used for potable water;
7. an adequate supply of hot potable water within the meaning of Directive 80/778/EEC;

8. a system for the hygienic disposal of waste water;
9. at least one wash basin and flush lavatories. The latter must not open directly onto the work rooms. The wash basin must have hot and cold running water or water premixed to a suitable temperature, hygienic materials for cleaning and disinfecting the hands and hygienic means of drying hands. The wash basin must be near the lavatories.

CHAPTER II

SPECIAL CONDITIONS FOR THE APPROVAL OF LOW-CAPACITY SLAUGHTERHOUSES

10. In addition to the general requirements, low-capacity slaughterhouses must have at least:
 - (a) sufficiently large lairage for animals passing the night within the slaughterhouse precincts;
 - (b) a slaughter room and, in view of the operations carried out during slaughter, rooms in keeping with such activities large enough for work to be carried out satisfactorily from the viewpoint of hygiene;
 - (c) a clearly separated place within the slaughter room, intended for stunning and bleeding;
 - (d) in the slaughter room, walls washable up to a height of at least three metres or up to the ceiling. During slaughter, steam must be adequately extracted;
 - (e) equipment such that, after stunning, dressing can be carried out as far as possible on the suspended animal; under no circumstances may the suspended animal come into contact with the floor during dressing;
 - (f) a refrigerating room of sufficient capacity in relation to the size and type of animals slaughtered, with in any case a separate lockable section of a minimum size reserved for observing the carcasses undergoing analysis.

Derogations from this requirement may be granted by the competent authority on a case-by-case basis where meat is removed immediately from such slaughterhouses for delivery to cutting plants or butcher shops in the immediate vicinity of the slaughterhouse, provided that transportation takes not more than one hour.
11. In the slaughter room, it shall be forbidden to empty or clean stomachs and intestines or to store hide, horns, hooves and pigs' bristles.
12. If dung cannot be evacuated from the slaughterhouse precincts every day, it must be stored in a clearly separated place.
13. Animals brought into the slaughter rooms must be immediately stunned and slaughtered.
14. Sick or suspect animals must not be slaughtered in the establishment concerned except where a derogation is granted by the competent authority.

Where a derogation is granted, slaughter must be performed under the supervision of the competent authority and steps taken to prevent contamination; the premises must be specially cleaned and disinfected under official supervision before being used again.

ANNEX III

PROFESSIONAL QUALIFICATIONS OF AUXILIARIES

1. Only candidates who prove that they have followed a theoretical course, including laboratory demonstrations, authorized by the competent authorities of the Member States on the subjects referred to in point 3 (a) of this Annex for at least 400 hours and have had practical training under the supervision of an official veterinarian for a period of at least 200 hours shall be eligible for the test referred to in the fourth paragraph of Article 9 of this Directive. The practical training shall take place in slaughterhouses, cutting plants, cold stores and inspection posts for fresh meat.
2. However, auxiliaries fulfilling the requirements of Annex II to Directive 71/118/EEC may follow a training course in which the theoretical part is reduced to 200 hours.
3. The test referred to in the fourth paragraph of Article 9 of this Directive shall consist of a theoretical part and a practical part and shall cover the following subjects:
 - (a) theoretical part:
 - basic knowledge of anatomy and physiology of slaughtered animals,
 - basic knowledge of pathology of slaughtered animals,
 - basic knowledge of pathological anatomy of slaughtered animals,
 - basic knowledge of hygiene and in particular industrial hygiene, slaughter, cutting and storage hygiene and hygiene of work,
 - knowledge of methods and procedure for the slaughter, inspection, preparation, wrapping, packaging and transport of fresh meat,
 - knowledge of the laws, regulations and administrative provisions relating to the carrying out of their work,
 - sampling procedures;
 - (b) practical part:
 - inspection and assessment of slaughtered animals,
 - determination of animal species through examination of typical parts of the animal,
 - determination of a number of parts of slaughtered animals in which changes have occurred, and comments thereon,
 - post-mortem inspection in a slaughterhouse,
 - hygiene control,
 - sampling.

ANNEX IV

SPECIMEN

HEALTH CERTIFICATE

for fresh meat ⁽¹⁾ referred to in Article 3 (A) (1) (f) (iii) of Directive 64/433/EEC

No ⁽²⁾:

Place of loading:

Ministry:

Department:

Reference ⁽²⁾:

I. Identification of meat

Meat of:
(animal species)

Nature of cuts:

Nature of packaging:

Number of cuts or packages:

Month(s) and years(s) when frozen:

Net weight:

II. Origin of meat

Address(es) and veterinary approval number(s) of the approved slaughterhouse(s):

Address(es) and veterinary approval number(s) of the approved cutting plant(s):

Address(es) and veterinary approval number(s) of the approved cold store(s):

III. Destination of meat

The meat will be sent from
from
(place of loading)

to
(country and place of destination)

by the following means of transport ⁽³⁾:

Name and address of consignor:

Name and address of consignee:

⁽¹⁾ Fresh meat: in accordance with the Directive referred to in IV of this certificate, this means all parts fit for human consumption from domestic bovine animals, swine, sheep and goats and solipeds which have not undergone any preserving process: however, chilled and frozen meat shall be considered to be fresh meat.

⁽²⁾ Optional.

⁽³⁾ In the case of rail trucks and lorries, state the registration number, in the case of aircraft the flight number, and in the case of boats the name and, where necessary, the number of the container.

IV. Health attestation

I, the undersigned official veterinarian, certify that the meat described above was obtained under the conditions governing production and control laid down in Directive 64/433/EEC:

- in a slaughterhouse situated in a restricted region or area (*),
- and is intended for a Member State after transit through a third country (*).

Done at on

.....
(name and signature of the official veterinarian)

(*) Delete where not applicable.

ANNEX V

SPECIMEN

HEALTH CERTIFICATE

for fresh meat intended for consignment to a Member State ⁽¹⁾

No ⁽²⁾:

Exporting country:

Ministry:

Department:

Ref.:
(optional)

I. Identification of meat

Meat of:
(animal species)

Nature of cuts:

Nature of packaging:

Number of cuts or packages:

Month(s) and years(s) when frozen:

Net weight:

II. Origin of meat

Address(es) and veterinary approval number(s) of the approved slaughterhouse(s):

Address(es) and veterinary approval number(s) of the approved cutting plant(s):

Address(es) and veterinary approval number(s) of the approved cold store(s)

III. Destination of meat

The meat will be sent from
(place of loading)

to
(country and place of destination)

by the following means of transport ⁽³⁾:

Name and address of consignor:

Name and address of consignee:

⁽¹⁾ Fresh meat: in accordance with the Directive referred to in IV of this certificate, this means all parts fit for human consumption from domestic bovine animals, swine, sheep and goats and solipeds which have not undergone any preserving process; however, chilled and frozen meat shall be considered to be fresh meat.

⁽²⁾ Optional.

⁽³⁾ In the case of trail trucks and lorries, state the registration number, in the case of aircraft the flight number, and in the case of boats the name and, where necessary, the number of the container.

IV. Health attestation

I, the undersigned official veterinarian, certify that the meat described above was obtained under the conditions governing production and control laid down in Directive 64/433/EEC on health problems affecting intra-Community trade in fresh meat and that it is, therefore, considered as such to be fit for human consumption.

Done at,

.....
(signature of the official veterinarian)

COUNCIL DIRECTIVE

of 29 July 1991

on the conditions for granting temporary and limited derogations from specific Community health rules on the production and marketing of fresh meat

(91/498/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas fresh meat is included on the list of products in Annex II to the Treaty; whereas their marketing provides a source of income for a large part of the farming population;

Whereas, to ensure rational development of the sector, increase productivity and progressively to establish the conditions for an internal market, health rules applying to production and marketing have been laid down at Community level by Directive 64/433/EEC ⁽⁴⁾ as amended and codified by Directive 91/497/EEC ⁽⁵⁾;

Whereas it is possible that, because of particular circumstances, some establishments will be unable, by 1 January 1993, to comply with all of the specific rules laid down; whereas in order to take account of local situations and to prevent abrupt closures of establishments, arrangements should be made for limited and temporary derogations for establishments in operation before 1 January 1992;

Whereas the granting of derogations from specific Community health rules to certain establishments is without prejudice to the requirement that all production and marketing operations conform to the hygiene rules laid down by Directive 64/433/EEC;

Whereas to forestall any risk of abuse, these derogations must be strictly controlled by the Commission; whereas to this end, there should be a procedure for close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee,

⁽¹⁾ OJ No C 84, 2. 4. 1990, p. 100.

⁽²⁾ OJ No C 183, 15. 7. 1991.

⁽³⁾ OJ No C 332, 31. 12. 1990, p. 62.

⁽⁴⁾ OJ No L 121, 29. 7. 1964, p. 2012/64.

⁽⁵⁾ See page 69 of this Official Journal.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Member States shall ensure that from 1 January 1996:

- all establishments fulfil the requirements of Directive 64/433/EEC,
- meat from such establishments bears the health mark specified in Annex I, Chapter X of Directive 64/433/EEC or, in the case of establishments referred to in Article 4 of the said Directive, bears the health mark specified in paragraph 3 of that Article.

Article 2

1. Member States may, until 31 December 1995, authorize establishments which, on the date on which this Directive is notified, have not been judged to comply with the requirements laid down by Directive 64/433/EEC for their approval, to derogate from some of the requirements laid down in points 1 to 13 of Annex I to Directive 64/433/EEC provided that meat from such establishments bears the national mark.

2. Derogations as referred to in paragraph 1 may be granted only to establishments which have, before 1 April 1992, submitted an application for a derogation to the relevant national authority.

This application must be accompanied by a work plan and programme indicating the period within which it would be possible for the establishment to comply with the requirements referred to in paragraph 1.

Where financial assistance is requested from the Community, only requests in respect of projects complying with the requirements of Directive 64/433/EEC can be accepted.

Member States shall submit to the Commission before 1 July 1992 a list of the establishments for which it is proposed to grant a derogation. This list shall, for each individual establishment, specify the type and duration of the derogations envisaged, the nature of checks made on meat from the establishment in question and the staff responsible for carrying out those checks.

National approval of establishments which have not submitted applications for a derogation by the date referred to in the first subparagraph or whose applications have been

refused by the Member State concerned shall be withdrawn before 1 January 1993.

On receipt of the list referred to in the fourth paragraph submitted by a Member State, the Commission shall have two months within which to examine that list and its submission, if necessary after amendment to the Standing Veterinary Committee which shall decide in accordance with the procedure laid down in Article 6.

3. The list of establishments which have been granted derogations shall be published by the Commission.

Article 3

With effect from 1 July 1992, Article 2 of Council Directive 88/409/EEC of 15 June 1988 laying down the health rules applying to meat intended for the domestic market and the levels of the fees to be charged, pursuant to Directive 85/73/EEC, in respect of the inspection of such meat ⁽¹⁾ shall be replaced by the following:

'Article 2

As from 1 January 1996 Member States shall take the necessary steps to ensure that all fresh meat produced in their territory for marketing there is obtained in an approved establishment in accordance with the provisions of Directive 64/433/EEC.'

Article 4

Until 31 December 1997, the Hellenic Republic shall be authorized to continue, in less-favoured sparsely populated areas to be recognized in accordance with the procedure laid down in Article 6, the slaughtering of sheep and goats which, from 15 February to 15 May, is carried out in premises which do not satisfy the requirements of Annexes I and II to Directive 64/433/EEC and to derogate with respect to the requirement for hot water from the provisions of Annex II, point 2 (a) to that Directive.

The Hellenic Republic shall ensure that meat obtained under this derogation can be placed on the market only in Greece and only after it has undergone a post-mortem inspection by

an official veterinarian and has received the health mark provided for in Article 4A (3) of Directive 64/433/EEC.

The Council shall, on the basis of a report from the Commission, accompanied by possible proposals on which it will decide by a qualified majority, re-examine this Article.

Article 5

The Federal Republic of Germany may, in accordance with the procedure set out in Article 6, obtain a further period for establishments situated in the *Länder* of the former German Democratic Republic within the framework of current restructuring plans.

Article 6

Where reference is made to the procedure provided for in this Article, the rules applicable shall be those set out in Article 16 of Directive 64/433/EEC.

Article 7

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 2(2) on 1 January 1992 and with the other provisions of this Directive on 1 January 1993. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 29 July 1991.

For the Council

The President

H. VAN DEN BROEK

⁽¹⁾ OJ No L 194, 22. 7. 1988, p. 28.

COUNCIL DIRECTIVE
of 26 June 1991
amending Directive 64/432/EEC as regards the diagnosis of bovine brucellosis and enzootic bovine leukosis
(91/499/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAS ADOPTED THIS DIRECTIVE:

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

Article 1

The Annexes to Directive 64/432/EEC are hereby amended in accordance with the Annex to this Directive.

Having regard to the proposal from the Commission,

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1992. They shall forthwith inform the Commission thereof.

Having regard to the opinion of the European Parliament ⁽¹⁾,

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such a reference shall be laid down by the Member States.

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Article 3

This Directive is addressed to the Member States.

Whereas Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine ⁽³⁾, as last amended by Directive 90/422/EEC ⁽⁴⁾, lays down the methods for maintaining the status of officially brucellosis free herds and enzootic bovine leukosis free herds;

Done at Luxembourg, 26 June 1991.

Whereas, due to new scientific knowledge and technical developments in the diagnosis and control of bovine brucellosis and enzootic bovine leukosis, an adjustment of existing Community measures in this field has proved necessary,

For the Council
The President
R. STEICHEN

⁽¹⁾ OJ No C 48, 25. 2. 1991, p. 214.

⁽²⁾ OJ No C 60, 8. 3. 1991, p. 43.

⁽³⁾ OJ No L 121, 29. 7. 1964, p. 1977/64.

⁽⁴⁾ OJ No L 224, 18. 8. 1990, p. 9.

ANNEX

Amendment to the Annexes to Directive 64/432/EEC

1. In Annex A, II.A.1.(c), point (ii) shall be replaced by the following:

- (ii) are checked annually to establish that brucellosis is not present by three ring tests or three milk Elisa carried out at intervals of at least three months or two ring tests or two milk Elisa carried out at an interval of at least three months and one serological test (sero-agglutination test or buffered brucella antigen test or plasma agglutination test or plasma ring test or micro-agglutination test or individual blood Elisa) carried out at not less than six weeks after the second ring test or second milk Elisa. If ring tests or milk Elisa are not carried out, two serological tests (sero-agglutination test or buffered brucella antigen test or plasma agglutination test or plasma ring test or micro-agglutination test or individual blood Elisa) shall be carried out each year at intervals of at least three months and not more than six months.

Where, in a Member State or region thereof in which all bovine herds are subject to official operations to combat brucellosis, not more than 1 % of bovine herds are infected, it shall be sufficient to carry out each year two ring tests or two milk Elisa at an interval of at least three months, or one serological test (sero-agglutination test or buffered brucella antigen test or plasma-agglutination test or plasma-ring test or micro-agglutination tests or individual blood Elisa).

Where ring tests are carried out on bulk tanks, the number of those tests referred to in the preceding subparagraphs shall be doubled and the intervals between the tests shall be halved.

2. The following point shall be added to Annex C:

'H. The Elisa for detecting bovine brucellosis as described under Annex G'.

3. In Annex G, chapter II:

- (a) The following words shall be added to the title:

'and bovine brucellosis';

- (b) Point C shall be replaced by the following:

'C. Enzyme-linked immunosorbent assay (Elisa) for detecting enzootic bovine leukosis and bovine brucellosis.

1. For the Elisa method, the material and reagents to be used are as follows:

- (a) solid phase microplates, cuvettes or any other solid phase;
- (b) the antigen is fixed to the solid phase with or without the aid of polyclonal or monoclonal catching antibodies. If antigen is coated directly to the solid phase, all test samples giving positive reactions have to be retested against control antigen in the case of EBL. The control antigen should be identical to the antigen except for the BLV antigens. If catching antibodies are coated to the solid phase the antibodies must not react to antigens other than BLV antigens;
- (c) the biological fluid to be tested;
- (d) a corresponding positive and negative control;
- (e) conjugate;
- (f) a substrate adapted to the enzyme used;
- (g) a stopping solution, if necessary;
- (h) solutions for the dilution of the test samples for preparations of the reagents and for washing;
- (i) a reading system appropriate to the substrate used.

2. Standardization and sensitivity of test:

- (a) For enzootic bovine leukosis: the sensitivity of the Elisa assay must be of such a level that E4 serum is scored positive when diluted 10 times (serum samples) or 250 times (milk samples) more than the dilution obtained of individual samples when these are included in pools. In assays where samples (serum and milk) are tested individually E4 serum diluted 1 to 10 (in

negative serum) or 1 to 250 (in negative milk) must be scored positive when tested in the same assay dilution as used for the individual test samples. The official institutes indicated in point A.2 will be responsible for checking the quality of the Elisa method, and in particular to determine, for each production batch, the number of samples to be pooled on the basis of the count obtained for the E4 serum.

The E4 serum will be supplied by the National Veterinary Laboratory, Copenhagen.

(b) For brucellosis:

1. bulk milk samples are classified negative if they give a reaction less than 50 % of that given by a 1 in 10 000 dilution of the second international brucellosis standard serum made up in negative milk;
2. individual serum samples are classified negative if they give a reaction less than 10 % of that given by a 1 in 200 dilution of the second international brucellosis standard serum made up in saline solution or in any other recognized dilution, in accordance with the procedure laid down in Article 12 after receiving the opinion of the Scientific Veterinary Committee.

The brucellosis Elisa standards shall be as specified in Annex C, A.1 and A.2 (to be used at the dilutions indicated on the label).

3. Conditions for use of the Elisa test for EBL and bovine brucellosis

The Elisa method may be used on a sample of milk or whey taken from the milk collected from a farm with at least 30 % of dairy cows in milk.

If use is made of one of these abovementioned possibilities, measures must be taken to ensure that the samples taken can be identified with the animals from which the milk or sera examined were taken.

If one of the samples scores positive, the provisions laid down in Annex A, chapter II.A.1.(c) (i) with regard to bovine brucellosis and in chapter I.A.(1) of this Annex with regard to EBL shall apply.