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II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 92/46/EEC

of 16 June 1992

laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products

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 raw milk, heat-treated drinking milk, milk for the manufacture of milk-based products and milk-based products are included in the list of products in Annex II to the Treaty; whereas the production of and trade in such milk and products constitute an important source of income for the agricultural population;

Whereas, in order to ensure the rational development of this sector health rules governing the production and placing on the market of milk and milk-based products should be laid down at Community level;

Whereas this principle has already been followed in Council Directive 85/397/EEC of 5 August 1985 on health and animal health problems affecting intra-Community trade in heat-treated milk (4);

Whereas the introduction of such rules will help to ensure a high level of protection of public health;

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

Whereas it seems necessary to exclude from the scope of this Directive certain products sold directly by the producer to the consumer;

Whereas, in order to create the conditions for the internal market, the principles and the rules on checks contained in Directive 89/662/EEC (5) should be extended to all production of milk-based products;

Whereas products placed on the Community market which come from third countries must afford the same degree of protection as regards human health; whereas guarantees equivalent to those offered by products of Community origin should therefore be required in respect of such products and they should be subject to the principles and rules on checks contained in Directive 90/675/EEC (6);

Whereas the hygiene rules must apply to the production, wrapping, storage and transport of the products covered by this Directive;

(1) OJ No C 84, 2. 4. 1990, pp. 112 and 130. OJ No C 306, 26. 11. 1991, p. 7. OJ No C 308, 28. 11. 1991, p. 14.
(2) OJ No C 183, 15. 7. 1991, pp. 60 and 61.
(3) OJ No C 332, 31. 12. 1990, pp. 91 and 102.
(4) OJ No L 226, 24. 8. 1985, p. 13. Last amended by Commission Decision 89/165/EEC (OJ No L 61, 4. 3. 1989, p. 57).
(5) 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 (OJ No L 395, 30. 12. 1989, p. 13). Last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).
(6) 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 (OJ No L 373, 31. 12. 1990, p. 1). Amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

Whereas in order to ensure uniformity of checks at origin, it is necessary to provide for a procedure for the approval of establishments meeting the health conditions laid down in this Directive, to determine the requirements regarding conditions of hygienic production to be complied with by such establishments and to define the criteria to be met by the products covered by this Directive;

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 milk-based products is the best way of satisfying the competent authority of the place of destination that a consignment complies with the provisions of this Directive;

Whereas prime responsibility for compliance with the requirements of this Directive should lie with producers and the competent authority should be obliged to monitor application of this principle of own-checks;

Whereas, to ensure uniform application of this Directive, a Community inspection procedure should be established;

Whereas, in order to allow the time necessary to set up a Community inspection system to ensure that third countries comply with the guarantees provided for in this Directive, national rules on checks should be maintained for a transitional period as regards third countries;

Whereas the extension to all production of milk-based products of the hygiene rules laid down in Directive 85/397/EEC, adapted as necessary in the light of experience, make that Directive redundant;

Whereas the existing situation regarding health conditions for stock farms and production and processing structures differs from one Member State to another;

Whereas provision should therefore be made for gradual compliance with the standards laid down in this Directive and whereas a distinction should thus be maintained for the time being between trade and the national market;

Whereas certain milk-based products may be manufactured from raw milk; whereas, given the nature of these products, it may be necessary to draw up specific conditions applicable thereto and a list of such products as might be marketed;

Whereas account should be taken of certain special cheesemaking techniques;

Whereas 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 to the ultimate consumer [1] and Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs [2] are applicable;

Whereas Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin [3], and in particular Annexes I and III thereto, is applicable as regards the maximum residue levels for pharmacologically active substances in milk;

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

Whereas the adoption of specific rules for the products covered by this Directive is without prejudice to the adoption of rules on food hygiene and safety in general, on which the Commission has submitted a proposal for a framework Directive;

Whereas the deadline for transposition into national law, set at 1 January 1992 in Article 32, should not effect the abolition of veterinary checks at frontiers on 1 January 1993,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER ONE

General Rules

Article 1

1. This Directive lays down health rules for the production and placing on the market of raw milk, heat-treated drinking milk, milk for the manufacture of milk-based products and milk-based products intended for human consumption.

2. This Directive shall not affect national rules applicable to the direct sale to the consumer by a producer of raw milk obtained from a herd officially free of tuberculosis and officially free or free of brucellosis, or of milk-based products made on his holding with such raw milk, provided that the hygiene conditions of the holding comply with the minimum health rules laid down by the competent authority.

(1) OJ No L 33, 8. 9. 1979, p. 1. Last amended by Commission Directive 91/72/EEC (OJ No L 42, 16. 2. 1991, p. 27).
(2) OJ No L 186, 30. 6. 1989, p. 21. Amended by Directive 91/238/EEC (OJ No L 107, 27. 4. 1991, p. 50).
(3) OJ No L 224, 18. 8. 1990, p. 1. Last amended by Commission Regulation (EEC) No 675/92 (OJ No L 73, 19. 3. 1992, p. 8).

3. This Directive shall apply, as regards the health rules, without prejudice to:

— Council Regulation (EEC) No 804/68 of 28 June 1968 on the common organization of the market in milk and milk products (1),

— Council Directive 76/118/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to certain partly or wholly dehydrated preserved milk for human consumption (2),

— Council Directive 83/417/EEC of 25 July 1983 on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption (3),

— Council Regulation (EEC) No 1898/87 of 2 July 1987 on the protection of designations used in marketing of milk and milk products (4).

Article 2

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

1. 'raw milk': milk produced by secretion of the mammary glands of one or more cows, ewes, goats or buffaloes, which has not been heated beyond 40 °C or undergone any treatment that has an equivalent effect;

2. 'milk for the manufacture of milk-based products': either raw milk for processing or liquid or frozen milk obtained from raw milk, whether or not it has undergone an authorized physical treatment, such as heat treatment or thermization, or is modified in its composition, provided that these modifications are restricted to the addition and/or removal of natural milk constituents;

3. 'heat-treated drinking milk': either drinking milk intended for sale to the final consumer and to institutions, obtained by heat treatment and presented in the forms defined in Annex C, Chapter I.A. 4 (a), (b), (c) and (d) or milk treated by pasteurization for sale in bulk at the request of the individual consumer;

4. 'milk-based products': milk products, namely products exclusively derived from milk, it being accepted that substances necessary for their manufacture may be added, provided that these substances are not used to replace in part or in whole any milk constituent, and composite milk products, namely products of which no part replaces or is intended to replace any milk constituent and of which milk or a milk product is an essential part either in terms of quantity or for characterization of the product;

5. 'heat treatment': any treatment involving heating that causes, immediately after it has been applied, a negative reaction to the phosphatase test;

6. 'thermization': the heating of raw milk for at least 15 seconds at a temperature between 57 °C and 68 °C such that after treatment the milk shows a positive reaction to the phosphatase test;

7. 'production holding': an establishment at which one or more milk-producing cows, ewes, goats or buffaloes are kept;

8. 'collection centre': an establishment where raw milk may be collected and possibly cooled and filtered;

9. 'standardization centre': an establishment, which is not attached to a collection centre or a treatment or processing establishment, in which raw milk may be skimmed or the natural constituents modified;

10. 'treatment establishment': an establishment where milk is heat treated;

11. 'processing establishment': an establishment or production holding where milk and/or milk-based products are treated, processed and wrapped;

12. 'competent authority': the central authority of a Member State responsible for carrying out health or public health checks or any authority to which it has delegated that responsibility;

13. 'wrapping': the protection of the products referred to in Article 1 (1) by the use of an initial wrapping or initial container in direct contact with the products concerned as well as the initial wrapper or initial container itself;

14. 'packaging': the placing of one or more wrapped or unwrapped products as referred to in Article 1 (1) in a container, as well as the container itself;

15. 'hermetically sealed container': container which, when sealed, is intended to protect the contents against the entry of micro-organisms during and after heat treatment and which is impervious;

16. 'placing on the market': the stocking or display with a view to sale, offering for sale, sale, delivery or any other manner of disposal in the Community with the exception of retail sale, which must be subject to the checks laid down by national rules for retail business;

(1) OJ No L 148, 28. 6. 1968, p. 13. Last amended by Regulation (EEC) No 1630/91 (OJ No L 150, 15. 6. 1991, p. 19).
(2) OJ No L 24, 30. 1. 1976, p. 49. Last amended by Directive 83/635/EEC (OJ No L 357, 21. 12. 1983, p. 37).
(3) OJ No L 237, 26. 8. 1983, p. 25. Amended by the 1985 Act of Accession.
(4) OJ No L 182, 3. 7. 1987, p. 36. Amended by Regulation (EEC) No 222/88 (OJ No L 28, 1. 2. 1988, p. 1).

17. 'trade': trade between Member States in goods within the meaning of Article 9 (2) of the Treaty.

In addition, the definitions in the provisions listed below shall apply as necessary:

— Article 2 of Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (1),

— Article 2 of Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (2),

— Article 3 of Regulation (EEC) No 1411/71 of 29 June 1971 laying down additional rules on the common organization of the market in milk and milk products falling within Common Customs Tariff heading 04-01 (3), and

— Article 2 of Regulation (EEC) No 1898/87.

CHAPTER II

Rules governing Community production

Article 3

1. Member States shall ensure that raw milk is not used for the manufacture of milk-based products or heat-treated drinking milk unless it meets the following requirements:

(a) it comes from animals and holdings which are checked at regular intervals by the competent authorities, pursuant to Article 13 (1);

(b) it is checked in accordance with Article 10 (2) and Articles 14 and 15 and meets the standards laid down in Annex A, Chapter IV;

(c) it meets the conditions laid down in Annex A, Chapter I;

(d) it comes from holdings which meet the conditions laid down in Annex A, Chapter II;

(e) it meets the hygiene requirements defined in Annex A, Chapter III.

2. Member States shall ensure that milk from healthy animals belonging to herds that do not meet the requirements of Annex A, Chapter I (1) (a) (i) and (b) (i) can be used only for the manufacture of heat-treated milk or for the manufacture of milk-based products after heat treatment under the supervision of the competent authority.

In the case of goat's milk and sheep's milk intended for trade, this heat treatment must take place on the spot.

Article 4

Member States shall ensure that the placing on the market of raw milk for human consumption in that state is authorized only if such milk meets the following requirements:

1. it complies with the provisions of Article 3, Annex A, Chapter IV.A.3 and Annex C, Chapter II.B.1;

2. where it is not sold to the consumer within two hours after the end of milking, it is cooled in accordance with Annex A, Chapter III;

3. it satisfies the requirements of Annex C, Chapter IV;

4. it satisfies any additional requirements which may be set in accordance with the procedure laid down in Article 31. In the meantime national provisions concerning such requirements shall continue to apply subject to the general provisions of the Treaty.

Article 5

Member States shall ensure that heat-treated drinking milk is not placed on the market unless it meets the following conditions:

1. it must have been obtained from raw milk, purified or filtered by the equipment provided for in Annex B, Chapter V (e), which must:

   (i) comply with Article 3;

   (ii) in the case of cow's milk, comply with the provisions of Article 3 (1) (b) and Article 6 (3) of Regulation (EEC) No 1411/71;

   (iii) if appropriate, have passed through a milk-collection centre fulfilling the conditions laid down in Annex B, Chapters I, II, III and VI or have been transferred from one tank to another in good hygiene and distribution conditions;

   (iv) if appropriate, have passed through a milk-standardization centre fulfilling the conditions laid down in Annex B, Chapters I, II, IV and VI.

   If appropriate, milk intended for the production of sterilized milk and UHT milk may have undergone an initial heat treatment in an establishment fulfilling the conditions laid down in point 2. The Hellenic Republic shall be authorized to submit pasteurized milk from another Member State to a second pasteurization before placing it on the market;

(1) OJ No L 121, 29. 7. 1964, p. 1977/64. Last amended by Directive 91/499/EEC (OJ No L 268, 24. 9. 1991, p. 107).
(2) OJ No L 46, 19. 2. 1991, p. 19.
(3) OJ No L 148, 3. 7. 1971, p. 4. Last amended by Regulation (EEC) No 222/88 (OJ No L 28, 1. 2. 1988, p. 1).

2. it must come from a treatment establishment which meets the conditions laid down in Annex B, Chapters I, II, V and VI and has been checked in accordance with Article 10 (2) and Article 14;

3. it must have been treated in accordance with Annex C, Chapter I.A;

4. it must meet the standards laid down in Annex C, Chapter II.B;

5. it must be labelled in accordance with Annex C, Chapter IV, and be wrapped in accordance with Annex C, Chapter III, at a treatment establishment where the milk has been subjected to final treatment;

6. it must have been stored in accordance with Annex C, Chapter V;

7. it must be transported under satisfactory conditions of hygiene in accordance with Annex C, Chapter V;

8. it must be accompanied during transport by an accompanying commercial document which must:

   — in addition to the particulars provided for in Annex C, Chapter IV, bear some indication by which the nature of the heat treatment and the competent authority responsible for supervising the establishment of origin can be identified, if this is not clear from the approval number,

   — be kept by the consignee for at least one year so that it can be produced at the request of the competent authority,

   — until 31 December 1997, in the case of heat-treated milk intended for Greece after transit through the territory of a third country, be approved by the competent authority of the border inspection post at which the transit formalities are carried out to certify that the heat-treated milk concerned meets the requirements of this Directive.

   However, an accompanying document shall not be required in the case of milk transported by the producer for direct delivery to the final consumer;

9. in the case of cow's milk, it must have a freezing point not higher than -0,520 °C and a weight of not less than 1 028 grammes per litre, as determined in whole milk at 20 °C, or the equivalent as determined in totally fat-free milk at 20 °C, and contain a minimum of 28 grammes of protein per litre, obtained by multiplying the percentage total nitrogen content of the milk by 6,38, and a fat-free dry matter content of not less than 8,50 %.

   No later than 1 January 1994, these requirements will, upon a request from a Member State supported by scientific and statistical studies, be re-examined with a view to their amendment, in accordance with the procedure laid down in Article 31 of this Directive, in the light of seasonal considerations, on the understanding that the relationship between the above parameters must be maintained.

Article 6

Member States shall ensure that milk-based products are manufactured only from:

1. either raw milk that complies with the requirements set out in Article 3 and the standards and specifications laid down in Annex C, Chapter I, and if appropriate has passed through a milk-collection or a milk-standardization centre fulfilling the conditions laid down in Annex B, Chapters I, II, III, IV and VI;

2. or milk intended for the manufacture of milk-based products obtained from raw milk which meets the requirements of paragraph 1 and

   (a) comes from a treatment establishment which meets the requirements of Annex B, Chapters I, II, V and VI;

   (b) has been stored and transported in accordance with the requirements of Annex C, Chapter V.

Article 7

A. Milk-based products must:

   1. have been obtained from milk that meets the requirements of Article 6 or from milk-based products that satisfy the requirements of the present Article;

   2. be prepared in a processing establishment that meets the standards and specifications of Annex B, Chapters I, II, V and VI and has been checked in accordance with Article 10 (2) and Article 14;

   3. meet the standards laid down in Annex C, Chapter II;

   4. be wrapped and packaged in accordance with Annex C, Chapter III, and, if they are in liquid form and intended for sale to the final consumer, with point 3 of that Chapter;

   5. be labelled in accordance with Annex C, Chapter IV;

   6. be stored and transported in accordance with Annex C, Chapter V;

   7. be checked in accordance with Article 14 and with Annex C, Chapter VI;

   8. where appropriate, contain only substances, other than milk, that are fit for human consumption;

   9. have undergone heat treatment during the manufacturing process or be made from products that have undergone heat treatment or involve hygiene specifications that are sufficient to meet the guaranteed hygiene criteria for all finished products.

In addition, milk-based products must meet the requirement in Article 5 (8) regarding the accompanying commercial document.

B. Pending possible Community rules on ionization, milk and milk-based products intended for trade must not have been subjected to ionizing radiation.

Article 8

1. For the manufacture of cheese with a period of ageing or ripening of at least 60 days Member States may grant individual or general derogations as follows:

(a) as regards the characteristics of raw milk, from the requirements of Annex A, Chapter IV;

(b) provided that the finished product has the characteristics provided for in Annex C, Chapter II.A, from Article 7 A., points 2 and 4;

(c) from Annex C, Chapter IV.B.2.

General and particular requirements applicable to the manufacture of individual products and standards specific to this type of product shall be adopted, as necessary in accordancy with the procedure laid down in Article 31.

2. In accordance with the procedure laid down in Article 31, Member States may, in so far as certain requirements of this Directive are likely to affect the manufacture of milk-based products with traditional characteristics, be authorized to grant individual or general derogations from Article 7 A.(1) to (4), provided that the milk used in the manufacture of such products meets the requirements of Annex A, Chapter I.

Not later than three months before the date specified in Article 32 Member States shall inform the Commission of the list of products in respect of which they are requesting application of the first subparagraph and of the nature of the derogations requested.

When the decision provided for in the first subparagraph is taken, the general and particular conditions applicable to the manufacture of each specific product shall, if necessary, be determined.

3. A list of products 'made with raw milk' may be drawn up in accordance with the procedure laid down in Article 31.

Article 9

Member States shall ensure that, subject to the provisions of Council Directive 92/47/EEC of 16 June 1992 on the conditions for granting temporary and limited derogations from specific community health rules on the production and marketing of raw milk and milk-based products [1]:

— treatment or processing establishments receiving raw milk which does not meet the standards laid down in Annex A, Chapter IV, cannot be approved in accordance with Articles 10 or 11 and that products from such establishments do not bear the health mark provided for in Annex C, Chapter IV, A.3, and cannot be the subject of trade,

— products which do not meet the standards laid down in Annex C, Chapters I and II, or standards to be fixed pursuant to Article 8 cannot be the subject of trade or be imported from third countries.

Article 10

1. Each Member State shall draw up a list of processing establishments and treatment establishments approved by it — other than those referred to in Article 11 — and a list of approved collection centres and standardization centres. Each such establishment or centre shall have an approval number.

The competent authority shall not approve the establishments or centres in question unless it is satisfied that they comply with the requirements of this Directive.

Where the competent authority finds an obvious failure to comply with the hygiene rules laid down by this Directive or obstacles to an adequate inspection it shall be empowered:

(i) to act in respect of the use of equipment or premises and to take any requisite measures which may go as far as limiting or temporarily suspending production;

(ii) if the measures provided for in (i) or the measures provided for in the last indent of the second subparagraph of Article 14 (1) have proved insufficient, to temporarily suspend approval, if appropriate, for the type of production in question.

If the operator or manager of the establishment or the centre does not make good the shortcoming noted within the period fixed by the competent authority, the latter shall withdraw approval.

The competent authority shall in particular be obliged to comply with the conclusions of any check carried out in accordance with Article 14.

The other Member States and the Commission shall be informed of the suspension or withdrawal of approval.

2. Inspection and supervision of establishments or centres shall be carried out by the competent authority in accordance with Annex C, Chapter VI.

[1] See page 33 of this Official Journal.

The establishment or centre shall remain under the permanent supervision of the competent authority on the understanding that the need for permanent or periodic presence of the competent authority in a given establishment or centre will depend on the size of the establishment or centre, the type of product manufactured, risk assessment and the guarantees offered in accordance with the fifth and sixth indents of the second subparagraph of Article 14 (1).

The competent authority must at all times have free access to all parts of establishments or centres in order to ensure that this Directive is being complied with and, where there is doubt as to the origin of milk or milk-based products, to accounting documents which enable the holding or establishment of origin of the raw material to be traced.

The competent authority must regularly analyse the results of the checks provided for in Article 14 (1). It may, on the basis of these analyses, conduct further examinations at all stages of production or on the products.

The nature of the checks, their frequency and the methods of sampling and of carrying out microbiological examinations shall be established in accordance with the procedure laid down in Article 31.

The results of the analyses shall be written up in a report, the conclusions or recommendations of which shall be notified to the operator or manager of the establishment or centre, who shall rectify the shortcomings noted with a view to improving hygiene.

3. In the event of repeated shortcomings, checks shall be increased and, where appropriate, labels or seals bearing the health mark shall be removed.

4. The detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 31.

Article 11

1. Member States may, when granting approval, grant derogations from the provisions of Article 7 A.(2), Article 14 (2) and Annex B, Chapters I and V, to establishments manufacturing milk-based products whose production is limited.

Member States shall communicate to the Commission not later than three months before the date specified in Article 32 the criteria which they have adopted to assess whether an establishment or a category of establishments may benefit from derogations as referred to in the first subparagraph.

If, after examination of the criteria adopted or following the checks carried out in accordance with Article 17, the Commission considers that these criteria might jeopardize the uniform application of this Directive, such criteria may be amended or supplemented in accordance with the procedure laid down in Article 31. The conditions under which the competent authority of the Member State shall reclassify the establishments in question shall be laid down by the same procedure.

2. On the basis of the information collected by the Commission in accordance with the second subparagraph of paragraph 1, uniform criteria for the application of this Article shall be established before 1 January 1997 in accordance with the procedure laid down in Article 31.

Article 12

Establishments in operation must apply to the competent authority not later than three months before the date specified in Article 32 for classification on the basis of Article 10 or on the basis of Article 11.

Until such time as a decision has been taken by the competent authority of the Member State, or until 31 December 1997 at the latest, all products coming from an establishment which has not been classified must not bear the health mark provided for in Annex C, Chapter IV, A.3 and must be marketed at national level.

Article 13

1. Member States shall ensure that:

— animals on production holdings undergo regular veterinary inspections to ensure that the requirements of Annex A, Chapter I, are being complied with.

  These inspections may take place on the occasion of veterinary checks carried out pursuant to other Community provisions.

  If there are grounds for suspecting that the animal health requirements laid down in Annex A are not being complied with, the competent authority shall check the general state of health of the dairy animals and, should it prove necessary, shall have an additional examination of those animals carried out,

— production holdings shall undergo regular checks to ensure that hygiene requirements are being complied with.

If the inspection or inspections referred to in the first subparagraph show that hygiene is inadequate, the competent authority shall take appropriate steps.

2. Member States shall submit to the Commission the measures which they intend to take for the purposes of the checks provided for in the second indent of the first subparagraph of paragraph 1. The frequency of these checks must take account of the assessment of risk on the production holding concerned.

These measures may be amended or supplemented in accordance with the procedure laid down in Article 31 in order to ensure uniform implementation of this Directive.

3. The general hygiene conditions to be complied with by production holdings, in particular the conditions for the upkeep of premises and those relating to milking, shall be adopted in accordance with the procedure laid down in Article 31.

Article 14

1. Member States shall ensure that the operator or manager of the treatment and/or processing establishment takes all necessary measures to ensure that, at all stages of production, the relevant specifications of this Directive are complied with.

To that end, the operator or manager of the establishment must constantly carry out his own checks based on the following principles:

— identification of critical points in the establishment on the basis of the processes used,

— monitoring and checking of such critical points by appropriate methods,

— taking samples for analysis in a laboratory recognized 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 or registered record of the information required in accordance with the preceding indents with a view to submitting it to the competent authority. The results of the different checks and tests shall in particular be kept for a period of at least two years, save in the case of milk-based products which cannot be stored at ambient temperature, for which this period shall be reduced to two months after the use-by or minimum durability date,

— when the laboratory examination or any other information at their disposal reveals that there is a serious health risk, inform the competent authority thereof,

— in the event of an immediate human health risk, withdraw from the market the quantity of products obtained in technologically similar conditions and likely to present the same risk. This withdrawn quantity must stay under the supervision and control of the competent authority until it is destroyed, used for purposes other than human consumption or, after authorization by the competent authority, reprocessed in an appropriate manner to ensure its safety.

In addition, the operator or manager of the establishment must guarantee the correct administration of the health marking.

The requirements of the second subparagraph, first and second indents, and of the third subparagraph must have been communicated to the competent authority, which must regularly monitor compliance therewith.

2. The operator or manager of the establishment must apply or organize a staff training programme enabling workers to comply with conditions of hygienic production adapted to the production structure, unless such staff already have adequate qualifications attested by diplomas. The competent authority responsible for the establishment must be involved in the planning and implementation of the programme or, in the case of a programme already in existence on the date of notification of this Directive, in the monitoring of the programme.

3. Where there are reasonable grounds for suspecting that the requirements of this Directive are not being complied with, the competent authority shall carry out the necessary checks and, if that suspicion is confirmed, take appropriate measures, up to and including the suspension of approval.

4. The detailed rules for the application of this Article shall, if necessary, be determined in accordance with the procedure laid down in Article 31.

Article 15

1. By 30 June 1993 at the latest Member States shall submit to the Commission, in accordance with the principles and rules of Council Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues [1], the national measures to be implemented to extend to raw milk, heat-treated milk and milk-based products examination for:

— residues in group III (antibiotics, sulphonamides and similar anti-microbial substances) in Annex I, A. to that Directive,

— residues in group II (other residues) in Annex I, B. to that Directive.

2. Member States shall ensure that in the context of the checks provided for in Article 14 tests are carried out to detect any residues of substances having a pharmacological or hormonal action, and of antibiotics, pesticides, detergents and other substances which are harmful or which might alter the organoleptic characteristics of milk or milk-based products or make their consumption dangerous or harmful to human health, insofar as those residues exceed the permitted tolerance limits.

If the milk or milk-based products examined show traces of residues which exceed the permitted tolerances, they must be excluded from human consumption.

[1] OJ No L 275, 26. 9. 1986, p. 36. Amended by Decision 89/187/EEC (OJ No L 66, 10. 3. 1989, p. 37).

Examinations for residues must be carried out in accordance with proven methods which are scientifically recognized, and in particular those laid down at Community or international level.

3. The competent authority shall make spot checks on compliance with the requirements of pharagraph 2.

4. The following shall be established in accordance with the procedure laid down in Article 31:

— the detailed rules for and the frequency of the checks provided for in paragraph 3,

— the tolerances and reference methods provided for in paragraph 2.

In accordance with the same procedure, a decision may be taken to extend the examinations to substances other than those referred to in paragraph 1.

5. Until the entry into force of the implementing measures for this Article, national rules shall remain applicable, subject to the general provisions of the Treaty.

Article 16

1. Milk tanks, premises, installations and working equipment may be used for other foodstuffs provided that all appropriate measures are taken to prevent contamination or deterioration of drinking milk or milk-based products.

2. Tanks used for milk must bear a clear indication that they may be used only for the transport of foodstuffs.

3. Where establishments produce foodstuffs containing milk or milk-based products together with other ingredients which have not undergone heat treatment or another treatment having an equivalent effect, such milk, milk-based products and ingredients must be stored separately to prevent cross-contamination, and treated or processed in premises suitable for the purpose.

4. The detailed rules for the application of this Article, and in particular the conditions relating to washing, cleaning and disinfecting before reuse, and the conditions of transport, shall be adopted in accordance with the procedure laid down in Article 31.

Article 17

Experts from the Commission may, in so far as is necessary for the uniform application of this Directive and in cooperation with the competent authorities, make on-site checks. In particular, they may verify by checking a representative percentage of establishments whether the competent authorities are ensuring that approved establishments are 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 detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 31.

Article 18

Member States shall ensure that the manufacture of products covered by this Directive in which some milk constituents are replaced by products other than milk-based products is subject to the hygiene rules laid down in this Directive.

Article 19

1. The provisions of Directive 89/662/EEC shall apply, in particular with respect to the organization of and the action to be taken on the checks carried out by the Member State of destination and the safeguard measures to be taken.

2. Without prejudice to the specific provisions of this Directive, the competent authority shall, where it is suspected that this Directive is not being complied with or there is doubt as to whether the products referred to in Article 1 are fit for consumption, carry out any checks it deems appropriate.

3. Member States shall take the appropriate administrative or penal measures to penalize any infringement of this Directive, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state of the products referred to in Article 1, that the marks on the products concerned do not comply with the rules, that the products have not undergone the checks provided for in this Directive or that they were not used for the purpose originally intended.

Article 20

1. In accordance with the procedure laid down in Article 31, the following may be established:

— the requirements applicable to any product with authorization to be placed on the market in a Member State but whose composition or presentation might give rise to differing interpretation in different Member States,

— the methods for checking that the hermetically sealed containers are impervious,

— the reference methods and, where necessary, the criteria governing routine methods of analysis and testing to be

used to monitor compliance with the requirements of this Directive, and the methods of sampling,

— limits and methods to enable a distinction to be made between different types of heat-treated milk as defined in Annex C, Chapter I,

— the methods of analysis for the standards referred to in Annex A, Chapter IV, and in Annex C, Chapter I and II.

Pending the decisions referred to in the first subparagraph, any internationally accepted analysis and test methods shall be recognized as reference methods.

2. By way of derogation from Articles 3 and 6, it may be decided, in accordance with the procedure laid down in Article 31, that some provisions of this Directive shall not apply to milk-based products containing other foodstuffs, where percentage of milk or milk-based product is not essential within the meaning of Article 2 (4).

The derogations referred to in the first subparagraph may not relate to:

(a) the animal health requirements laid down in Annex A, Chapter I and the conditions for approval of establishments laid down in Annex B, Chapter I;

(b) the marking requirements laid down in Annex C, Chapter IV;

(c) the inspection requirements laid down in Annex C, Chapter VI.

In granting derogations both the nature and the composition of the product shall be taken into account.

3. Notwithstanding paragraph 2, Member States shall ensure that all milk-based products placed on the market are wholesome products prepared from milk or from milk-based products meeting the requirements of this Directive.

Article 21

The Council, acting by a qualified majority on a proposal from the Commission, shall amend the Annexes as necessary, in particular to adapt them to take account of scientific and technological progress.

CHAPTER III

Imports from third countries

Article 22

The conditions applicable to imports from third countries of raw milk, heat-treated milk and milk-based products covered by this Directive must be at least equivalent to those laid down in Chapter II for Community production.

Article 23

1. For the purposes of uniform application of Article 22, the provisions of the following paragraphs shall apply.

2. In order to be imported into the Community, milk or milk-based products must:

(a) come from a third country on the list to be drawn up in accordance with paragraph 3 (a);

(b) be accompanied by a health certificate corresponding to a specimen to be drawn up in accordance with the procedure laid down in Article 31, signed by the competent authority of the exporting country and certifying that the milk or milk-based products meet the requirements of Chapter II or any additional conditions or offer the equivalent guarantees referred to in paragraph 3 and come from establishments offering the guarantees provided for in Annex B.

3. The following shall be established in accordance with the procedure laid down in Article 31:

(a) a provisional list of third countries or parts of third countries able to provide Member States and the Commission with guarantees equivalent to those provided for in Chapter II and a list of the establishments for which they are able to give these guarantees.

This provisional list shall be compiled from the lists of establishments approved and inspected by the competent authorities, once the Commission has checked that these establishments comply with the principles and general rules laid down in this Directive;

(b) updates of that list in the light of the checks provided for in paragraph 4;

(c) the specific requirements and equivalent guarantees established for third countries, which may not be more favourable than those provided for in Chapter II;

(d) the types of heat treatment to be prescribed for certain third countries presenting an animal health risk.

4. Experts from the Commission and the Member States shall carry out on-the-spot inspections to verify whether the guarantees given by the third country regarding the conditions of production and placing on the market can be considered equivalent to those applied in the Community.

The experts from the Member States responsible for 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 of and procedure for these inspections, including those to be carried out in the event of a decision in accordance with paragraph 6, shall be determined in accordance with the procedure laid down in Article 31.

5. Pending the organization of the inspections referred to in paragraph 4, national rules applicable to inspection in third countries shall continue to apply, subject to notification, through the Standing Veterinary Committee, of any failure to comply with hygiene rules found during these inspections.

6. The Council, acting by a qualified majority on a proposal from the Commission, may replace individual recognition of treatment or processing establishments by recognition, on a reciprocal basis, of establishments in a third country which are subject to effective, regular inspection by the competent authority such that the said authority is able to guarantee compliance with the requirements of paragraph 2(b).

Article 24

The principles and general rules 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.

Article 25

1. Member States shall ensure that the products covered by this Directive are imported into the Community only if:

— they are accompanied by a certificate to be issued by the competent authority of the third country at the time of loading.

The specimen certificate shall be drawn up in accordance with the procedure laid down in Article 31,

— they have satisfied the checks required by Directive 90/675/EEC and 91/496/EEC [1].

2. Pending the establishment of detailed rules for the application of this Article, the national rules applicable to imports from third countries for which such requirements have not been adopted at Community level shall continue to apply, provided they are not more favourable than those laid down in Chapter II.

Article 26

The lists provided for in Article 23 may include only third countries or parts of third countries:

(a) from which imports are not prohibited as a result of the existence of diseases as referred to in Annex A or of any other disease exotic to the Community or pursuant to Articles 6, 7 and 14 of Directive 72/462/EEC [2];

(b) which, in view of their legislation and the organization of their competent authority and of their inspection services, the powers of such services and the supervision to which they are subject, have been recognized, in accordance with Article 3 (2) of Directive 72/462/EEC, as capable of guaranteeing the implementation of their legislation in force;

(c) the veterinary services of which are able to guarantee that health requirements at least equivalent to those laid down in Chapter II are being complied with.

CHAPTER IV

Final provisions

Article 27

1. Each Member State shall designate one or more national reference laboratories for the analysis and testing of milk and milk-based products, and shall forward a list thereof to the Commission.

These laboratories shall be responsible for:

— coordinating the activities of the laboratories whose task it is to conduct analyses to check the chemical or bacteriological standards and to conduct the tests provided for in this Directive,

— assisting the competent authority in organizing the system of checking milk and milk-based products,

— periodically organizing comparative tests,

— disseminating the information supplied by the Community reference laboratory referred to in Article 28 to the competent authorities and the laboratories carrying out analyses and tests on milk and milk-based products.

[1] Council Directive 91/496/EEC 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 (OJ No L 268, 24. 9. 1991, p. 56).

[2] Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries (OJ No L 302, 31. 12. 1972, p. 28). Last amended by Directive 91/497/EEC (OJ No L 268, 24. 9. 1991, p. 69).

2. The Commission shall publish the list of national reference laboratories and updates thereof in the *Official Journal of the European Communities.*

Article 28

The Community reference laboratory for the analysis and testing of milk and milk products is indicated in Annex D, Chapter I.

The duties and tasks of that laboratory are set out in Chapter II of that Annex and include the coordination of the activities of the national reference laboratories referred to in Article 27.

Article 28 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field (1) shall apply.

Article 29

1. Directive 85/397/EEC is hereby repealed with effect from 1 January 1994.

2. Council Directive 89/384/EEC of 20 June 1989 establishing the detailed procedures for carrying out checks to ensure that the freezing point of untreated milk laid down in Annex A of Directive 85/397/EEC (2) is complied with, Commission Directive 89/362/EEC of 26 May 1989 on general conditions of hygiene in milk production holdings (3) and Commission Decision 91/180/EEC of 14 February 1991 laying down certain methods of analysis and testing of raw milk and heat-treated milk (4) shall continue to apply for the purposes of the present Directive.

In accordance with the procedure laid down in Article 31, these acts may be amended to adapt the scope thereof to the content of the present Directive or to adapt them subsequently to advances in science and technology.

Article 30

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

1. the following indent shall be added to Annex A:

'— Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products (OJ No L 268, 14. 9. 1992, p. 1).';

2. the following indent shall be deleted from Annex A:

'— Council Directive 85/397/EEC of 5 August 1985 on health and animal health problems affecting intra-Community trade in heat-treated milk (OJ No L 226, 24. 8. 1985, p. 13), as last amended by Regulation (EEC) No 3768/85 of 20 December 1985 (OJ No L 362, 31. 12. 1985, p. 8).';

3. the following indent shall be deleted from Annex B:

'— raw milk and milk-based products.'.

Article 31

1. Where the procedure laid down in this Article is to be followed, matters shall without delay be referred to the Standing Veterinary Committee set up by Decision 68/361/EEC (5), hereinafter referred to as 'the Committee', by its Chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representatives of the Commission, after consulting the Management Committee for Milk and Milk Products established by Regulation (EEC) No 804/68 where matters of chemistry or technology are involved, shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on such measures 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. Within the Committee the votes of the representatives of the Member States shall be weighted in the manner set out in Article 148 (2) of the Treaty. The Chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged and implement them immediately if they are in accordance with the opinion of the Committee.

(b) Where 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, within three months of the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, except where the Council has rejected those measures by a simple majority.

Article 32

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

(1) OJ No L 224, 18. 8. 1990, p. 19. Last amended by Decision 91/133/EEC (OJ No L 66, 13. 3. 1991, p. 18).
(2) OJ No L 181, 28. 6. 1989, p. 50.
(3) OJ No L 156, 8. 6. 1989, p. 30.
(4) OJ No L 93, 13. 4. 1991, p. 1.
(5) OJ No L 225, 18. 10. 1968, p. 23.

comply with this Directive before 1 January 1994. 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.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field governed by this Directive.

3. The setting of the deadline for transposition into national law at 1 January 1994 shall be without prejudice to the abolition of veterinary checks at frontiers provided for in Directive 89/662/EEC.

Article 33

This Directive is addressed to the Member States.

Done at Luxembourg, 16 June 1992.

For the Council

The President

Arlindo MARQUES CUNHA

ANNEX A

REQUIREMENTS RELATING TO THE ACCEPTANCE OF RAW MILK AT TREATMENT AND/OR PROCESSING ESTABLISHMENTS

CHAPTER I

Animal health requirements for raw milk

1. Raw milk must originate as follows:

   (a) from cows or buffaloes:

      (i) belonging to a herd which, pursuant to paragraph 1 of Annex A to Directive 64/432/EEC, is;

         — officially tuberculosis-free,

         — brucellosis-free or officially brucellosis-free;

      (ii) which do not show any symptoms of infectious diseases communicable to human beings through milk;

      (iii) incapable of giving the milk abnormal organoleptic characteristics;

      (iv) whose general state of health is not impaired by any visible disorder and which are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognizable inflammation of the udder;

      (v) which do not show any udder wound likely to affect the milk;

      (vi) which, in the case of cows, yield at least two litres of milk per day;

      (vii) which have not been treated with substances dangerous or likely to be dangerous to human health that are transmissible to milk, unless the milk has complied with an official waiting period laid down in Community provisions or, if absent, in national provisions;

   (b) from sheep and goats:

      (i) belonging to a sheep and goat holding officially free or free of brucellosis *(Brucella melitensis)* within the meaning of Article 2 (4) and (5) of Directive 91/68/EEC;

      (ii) which satisfy the requirements laid down in (a), with the exception of those in points (i) and (vi).

2. When different animal species are kept together on the holding, each species must satisfy the health conditions which would be required if it were alone.

3. If goats are kept together with cows they must undergo a tuberculosis check in accordance with arrangements to be determined in accordance with the procedure laid down in Article 31 of this Directive.

4. Raw milk must be excluded from treatment, processing, sale and consumption if it:

   (a) is obtained from animals to which substances within the meaning of Directives 81/602/EEC (1) and 88/146/EEC (2) have been administered illegally;

   (b) contains residues of substances within the meaning of Article 15 of this Directive which exceed the permitted level.

(1) Council Directive 81/602/EEC of 31 July 1981 concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action (OJ No L 222, 7. 8. 1981, p. 32). Last amended by Directive 85/358/EEC (OJ No L 191, 23. 7. 1985, p. 46).

(2) Council Directive 88/146/EEC of 7 March 1988 prohibiting the use in livestock farming of certain substances having a hormonal action (OJ No L 70, 16. 3. 1988, p. 16).

CHAPTER II

Hygiene of the holding

1. The raw milk must come from holdings which are registered and checked in accordance with Article 13 (1). Where buffaloes, sheep and goats are not kept in the open, the premises used must be designed, constructed, maintained and managed in such a way as to ensure:

   (a) good conditions of housing, hygiene, cleanliness and health of the animals; and

   (b) satisfactory hygiene conditions for milking, handling, cooling and storing milk.

2. Premises where milking is performed or milk is stored, handled or cooled must be so sited and constructed as to avoid all risk of contamination of the milk. They must be easy to clean and disinfect and have at least:

   (a) walls and flooring which are easy to clean in those areas liable to soiling or infection;

   (b) flooring laid in such a way as to facilitate the draining of liquids and satisfactory means of disposing of waste;

   (c) adequate ventilation and lighting;

   (d) an appropriate and sufficient supply of potable water, complying with the parameters laid down in Annexes D and E to Directive 80/778/EEC [1], for use in milking and in cleaning the equipment and instruments referred to in Chapter III B of this Annex;

   (e) adequate separation from all sources of contamination such as lavatories and dung heaps;

   (f) fittings and equipment which are easy to wash, clean and disinfect.

   In addition, premises for the storage of milk must have suitable milk refrigeration equipment, must be protected against vermin and must have adequate separation from any premises where animals are housed.

3. If a movable milking bail is used, the requirements in point 2 (d) and (f) must be satisfied and in addition the bail must:

   (a) be sited on fresh ground which is free from any accumulation of excreta or other waste matter;

   (b) provide protection for the milk during the whole period in which it is in use;

   (c) be so constructed and finished as to permit the interior surfaces to be kept clean.

4. Where milk-producing animals are kept untethered in the open, the holding must also have a milking parlour or milking area adequately separated from the housing area.

5. The isolation of animals which are infected, or suspected of being infected, with any of the diseases referred to in Chapter I.1 or the separation of the animals referred to in Chapter I.3 from the rest of the herd must be possible and effective.

6. Animals of all species must be kept away from premises and sites where milk is stored, handled or cooled.

CHAPTER III

Hygiene in milking, the collection of raw milk and its transport from the production holding to the collection or standardization centre or to the treatment establishment or processing establishment — Hygiene of staff

A. *Hygiene in milking*

1. Milking must be carried out hygienically and under the conditions established by Directive 89/362/EEC.

[1] Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption (OJ No L 229, 30. 8. 1980, p. 11). Last amended by Directive 90/656/EEC (OJ No L 353, 17. 12. 1990, p. 59).

2. Immediately after milking, the milk must be placed in a clean place which is so equipped as to avoid adverse effects on the milk.

   If the milk is not collected within two hours of milking, it must be cooled to a temperature of 8 °C or lower in the case of daily collection or 6 °C or lower if collection is not daily. While the milk is being transported to the treatment and/or processing establishment its temperature must not exceed 10 °C.

B. *Hygiene of premises, equipment and tools*

1. Equipment and instruments or their surfaces which are intended to come into contact with milk (utensils, containers, tanks, etc., intended for milking, collection or transport) must be made of smooth material which is easy to clean and disinfect, resists corrosion and does not transfer substances to the milk in such quantities as to endanger human health, impair the composition of the milk or adversely affect its organoleptic characteristics.

2. After use, the utensils used for milking, the mechanical milking equipment and the containers which come into contact with the milk must be cleaned and disinfected. After each journey, or after each series of journeys where there is only a very short space of time between unloading and the following loading, but in any event at least once a day, containers and tanks used for transporting raw milk to the milk collection or standardization centre or to the milk treatment or processing establishment must be cleaned and disinfected before reuse.

C. *Staff hygiene*

1. Absolute cleanliness shall be required of staff. Specifically:

   (a) persons performing milking and handling raw milk must wear suitable clean milking clothes;

   (b) milkers must wash their hands immediately before the milking commences and keep them clean as far as practicable throughout the milking.

   For this purpose, near the place of milking, suitable facilities are required to enable persons performing milking or handling raw milk to wash their hands and arms.

2. The employer shall take all the requisite measures to prevent persons liable to contaminate raw milk from handling it, until there is evidence that such persons can do so without risk of contamination.

   Any person performing milking or handling raw milk shall be required to show that there is no medical 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 laid down in Article 31 of this Directive.

D. *Production hygiene*

1. A monitoring system shall be established under the supervision of the competent authority to prevent water being added to raw milk. This system shall in particular include regular checks on the freezing point of milk from each production facility, in accordance with the following procedure:

   (a) the raw milk of each holding must be checked regularly by random sampling. Where the milk of a single holding is delivered directly to a treatment or processing establishment, these samples are to be taken either when the milk is collected from the holding, provided that precautions are taken to prevent any fraud during transport, or before unloading at the treatment or processing establishment when the milk is delivered there directly by the farmer.

   If the results of a check lead the competent authority to suspect that water is being added, it shall take an authentic sample on the holding. An authentic sample is a sample representing the milk of one completely supervised morning or evening milking beginning not less than eleven hours or more than thirteen hours after the previous milking.

   Where milk is delivered from several holdings, samples may only be taken when the raw milk enters the treatment or processing establishment or collection or standardization centre, provided that spot checks are, however, carried out on the holdings.

If the results of a check lead to suspicion that water has been added, samples shall be taken at all holdings which took part in the collection of the raw milk at issue.

If necessary, the competent authority shall take authentic samples within the meaning of the second subparagraph above;

(b) if the results of the check show that water has not been added, the raw milk may be used for producing raw drinking milk, heat-treated milk or milk for the manufacture of milk-based products for human consumption.

2. The treatment and/or processing establishment shall inform the competent authority when the maximum standards fixed for the plate count and somatic cell count have been reached. The competent authority shall take the appropriate measures.

3. If, within three months of notification of the results of the checks referred to in point 1 (a) and of the investigation provided for in Chapter IV.D, and after the standards of Chapter IV have been exceeded, milk from the holding in question does not meet those standards, that holding shall no longer be authorized to supply raw milk until such milk again meets the said standards.

Milk must not be used for human consumption if it contains antibiotic residues in a quantity which, in respect of any one of the substances referred to in Annexes I and III to Regulation (EEC) No 2377/90 (1), exceeds the levels authorized therein; the combined total of residues of antibiotic substances may not exceed a value to be fixed in accordance with the procedure laid down in Article 31 of this Directive.

CHAPTER IV

Standards to be met for collection of raw milk from the production holding or for acceptance at treatment or processing establishments

A. *Raw cow's milk*

Without prejudice to the limits laid down in Annexes I and III to Regulation (EEC) No 2377/90:

1. Raw cow's milk intended for the production of heat-treated drinking milk, fermented milk, junket, jellied or flavoured milk and cream must meet the following standards:

Plate count 30 °C (per ml)	⩽ 100 000 (a)
Somatic cell count (per ml)	⩽ 400 000 (b)

(a) Geometric average over a period of two months, with at least two samples a month.
(b) Geometric average over a period of three months, with at least one sample a month, or, where production levels vary considerably according to season, method of calculating results to be adjusted in accordance with the procedure laid down in Article 31 of this Directive.

2. Raw cow's milk for the manufacture of milk-based products other than those referred to in point 1 must meet the following standards:

	from 1. 1. 1994	from 1. 1. 1998
Plate count 30 °C (per ml)	⩽ 400 000 (a)	⩽ 100 000 (a)
Somatic cell count (per ml)	⩽ 500 000 (b)	⩽ 400 000 (b)

(a) Geometric average over a period of two months, with at least two samples a month.
(b) Geometric average over a period of three months, with at least one sample a month, or, where production levels vary considerably according to season, method of calculating results to be adjusted in accordance with the procedure laid down in Article 31 of this Directive.

(1) Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ No L 224, 18. 8. 1990, p. 1). Last amended by Commission Regulation (EEC) No 675/92 (OJ No L 73, 19. 3. 1992, p. 8).

3. Raw cow's milk intended for direct human consumption and raw cow's milk for the manufacture of products 'made with raw milk' whose manufacturing process does not involve any heat treatment must:

   (a) meet the standards of point 1;

   (b) in addition meet the following standard (1):

   Staphylococcus aureus (per ml):

   n = 5

   m = 500

   M = 2 000

   c = 2.

B. *Raw buffalo milk*

Without prejudice to compliance with the limits laid down in Annexes I and III to Regulation (EEC) No 2377/90:

1. Raw bufallo milk for the manufacture of milk-based products must meet the following standards:

	from 1. 1. 1994
Plate count 30 °C (per ml)	⩽ 1 000 000 (a)
Somatic cell count (per ml)	⩽ 500 000 (b)

(a) Geometric average over a period of two months, with at least two samples a month.
(b) Geometric average over a period of three months, with at least one sample a month.

The standards for plate count at 30 °C and somatic cell count to apply as from 1 January 1998 will be set in accordance with Article 21 of this Directive.

2. Raw bufallo milk intended for the manufacture of products 'made with raw milk' whose manufacturing process does not involve any heat treatment must meet the following requirements:

plate count 30 °C (per ml): ⩽ 500 000

somatic cell count (per ml): ⩽ 400 000

staphylococcus aureus: as for cow's milk.

C. *Raw goat's milk and sheep's milk:*

Without prejudice to compliance with the limits laid down in Annexes I and III to Regulation (EEC) No 2377/90:

1. Raw goat's milk or sheep's milk intended for the production of heat-treated drinking milk or for the manufacture of heat-treated milk-based products must meet the following standards:

	from 1. 1. 1994
Plate count 30 °C (per ml)	⩽ 1 000 000 (a)

(a) Geometric average over a period of two months, with at least two samples a month.

The standards relating to the plate count and somatic cell count applicable as from 1 January 1998 will be determined in accordance with Article 21 of this Directive.

(1) Where
n = number of sample units comprising the sample;
m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all sample units does not exceed 'm';
M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more sample units is 'M', or more;
c = number of sample units where the bacteria count may be between 'm' and 'M', the sample being considered acceptable if the bacteria count of the other sample units is 'm' or less.

2. Raw goat's or sheep's milk intended for the manufacture of products 'made with raw milk' whose manufacturing process does not involve any heat treatment must meet the following standards:

Plate count 30 °C (per ml)	⩽ 500 000 (a)
Staphylococcus aureus (per ml)	as for raw cow's milk

(a) Geometric average over a period of two months, with at least two samples a month.

D. When the maximum standards laid down in A, B and C are exceeded and when subsequent investigation indicates a potential danger to health, the competent authority shall take appropriate measures.

E. Compliance with the standards of A, B and C must be checked by random sampling, either on collection at the production holding or on acceptance of the raw milk at the treatment or processing establishment.

ANNEX B

CHAPTER I

General conditions for approval of treatment establishments and processing establishments

Treatment establishments and processing establishments shall have at least:

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 raw materials and products covered by this Directive.

   Production of heat-treated milk or manufacture of milk-based products which might pose a risk of contamination to other products covered by this Directive must be carried out in a clearly separated working area;

2. in areas where the raw materials are handled, prepared and processed and the products referred to in this Directive manufactured:

   (a) solid, waterproof flooring which is easy to clean and disinfect and laid in such a way as to facilitate the drainage of water and provided with equipment to remove water;

   (b) walls which have smooth surfaces and are easy to clean, durable and impermeable, covered with a light-coloured coating;

   (c) in premises where exposed, non-packaged raw materials or products are handled, prepared or processed, ceilings or roof linings which are easy to clean;

   (d) doors in non-corrodible 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 with hot and cold running water, or water pre-mixed to a suitable temperature, for cleaning and disinfecting hands. In work rooms and lavatories taps must not be hand-operable. These facilities must be provided with cleaning and disinfecting products and hygienic means of drying hands;

   (h) facilities for cleaning tools, equipment and installations;

3. in rooms where the raw materials and the products covered by this Directive are stored, the same conditions as those at 2, except in:

   — chilling and refrigeration rooms, where a floor which is easy to clean and disinfect and laid in such a way as to facilitate the draining of water is sufficient,

   — freezing and deep-freezing rooms, where waterproof and rotproof flooring which is easy to clean is sufficient.

   In such cases, a sufficiently powerful refrigeration plant to keep the raw materials and products at the temperatures prescribed in this Directive must be available.

   The use of wooden walls in the rooms referred to in the second indent of the first subparagraph does not constitute grounds for withdrawing approval provided they were built before 1 January 1993.

   The capacity of the storerooms must be adequate to store the raw materials used and the products covered by this Directive;

4. facilities for hygienic handling and protection of raw materials and non-packaged or wrapped finished products during loading and unloading;

5. appropriate arrangements for protection against pests;

6. instruments and working equipment intended to come into direct contact with raw materials and products made of corrosion-resistant material and easy to clean and disinfect;

7. special watertight, non-corrodible containers in which to put raw materials or products not intended for human consumption. Where such raw materials or products are removed through conduits, these must be so constructed and installed as to avoid any risk of contamination of the other raw materials or products;

8. appropriate facilities for the cleaning and disinfecting of equipment and utensils;

9. a waste water disposal system which meets hygiene requirements;

10. a supply of potable water only, within the meaning of Directive 80/778/EEC. However, the supply of non-potable water is authorized in exceptional cases for steam production, fire-fighting and refrigeration equipment, provided that the pipes installed for this purpose preclude the use of this water for other purposes and present no direct or indirect risk of contamination of the product. Non-potable water pipes must be clearly distinguished from those used for potable water;

11. an appropriate number of changing rooms with smooth, waterproof, washable walls and floors, wash basins and flush lavatories. The latter must not open directly on to the work rooms. Wash basins must be equipped for hand-washing and have hygienic means of drying hands; wash-basin taps must not be hand-operable;

12. if the volume of products treated requires regular or permanent presence, an adequately equipped lockable room for the exclusive use of the competent authority;

13. a room or a secure place for the storage of detergents, disinfectants and similar substances;

14. a room or cupboard for storing cleaning and maintenance material;

15. adequate facilities for cleaning and disinfecting tanks used for transporting milk and liquid or powdered milk-based products. However, such facilities are not compulsory if there is a requirement for the means of transport to be cleaned and disinfected in installations officially approved by the competent authority.

CHAPTER II

General conditions of hygiene in treatment establishments and processing establishments

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

1. Equipment and instruments used for working on raw materials and products, floors, ceilings or roof linings, walls and partitions, must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for raw materials or products.

2. No animals may enter rooms in which milk and milk-based products are manufactured and stored. 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 rooms 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 products for which approval has been granted. However, following authorization by the competent authority, they may be used at the same time or other times for work on other foodstuffs fit for human consumption.

4. Potable water, within the meaning of Directive 80/778/EEC, must be used for all purposes. However, by way of exception, non-potable water may be used for the cooling of equipment, steam production and fire-fighting, 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 raw materials and products covered by this Directive.

5. 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, raw materials and products covered by this Directive.

   Their containers must be clearly identifiable and must bear labels with instructions for their use.

   Their use must be followed by thorough rinsing of such instruments and working equipment with potable water.

B. *General conditions of hygiene applicable to staff*

1. Absolute cleanliness is required of staff. This applies particularly to persons handling exposed, non-packaged raw materials and products covered by this Directive. Specifically:

   (a) staff must wear suitable clean working clothes and clean headgear which completely encloses the hair;

   (b) staff assigned to the handling and preparation of raw materials and products covered by this Directive must be required to wash their hands at least each time work is resumed and/or where contamination has occurred; wounds to the skin must be covered by a waterproof dressing;

   (c) smoking, spitting, eating and drinking in rooms where raw materials and products covered by this Directive are worked on or stored shall be prohibited.

2. The employer shall take all the requisite measures to prevent persons liable to contaminate the products covered by this Directive from handling them, until there is evidence that such persons can do so without risk of contamination.

   When recruited, any person working on and handling the products covered by this Directive shall be required to prove, by a medical certificate, that there is no medical 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 laid down in Article 31 of this Directive.

CHAPTER III

Special requirements for registration of collection centres

In addition to the general requirements laid down in Chapter I, collection centres must have at least:

(a) cooling equipment or appropriate means for cooling milk and, if milk is stored at the collection centre, a cold-storage installation;

(b) if milk is purified at the collection centre, centrifuges or any other apparatus suitable for the physical purification of milk.

CHAPTER IV

Special requirements for registration of standardization centres

In addition to the general requirements laid down in Chapter I, standardization centres must have at least:

(a) containers for the cold storage of raw milk, standardization equipment and containers for the storage of standardized milk;

(b) centrifuges or any other apparatus suitable for the physical purification of milk.

CHAPTER V

Special requirements for the approval of treatment establishments and processing establishments

In addition to the general requirements laid down in Chapter I, treatment establishments and processing establishments must have at least:

(a) equipment for the mechanical filling and proper automatic sealing of containers which are to be used for packaging heat-treated drinking milk, after filling, excluding churns and tanks, insofar as such operations are carried out there;

(b) equipment for the cooling and cold storage of heat-treated milk, liquid milk-based products and, in the cases provided for in Annex A, Chapters III and IV, raw milk, in so far as such operations are carried out there. Cold stores must be equipped with correctly calibrated temperature-measuring apparatus;

(c) — in the case of wrapping in disposable containers, an area for the storage of such containers and for storage of the raw materials intended for their manufacture,

— in the case of wrapping in re-usable containers, a special area for their storage and equipment designed to clean and disinfect them mechanically;

(d) containers for storing raw milk, standardization equipment and containers for storing standardized milk;

(e) if appropriate, centrifuges or any other suitable means for physically purifying milk;

(f) heat-treatment equipment approved or authorized by the competent authority, fitted with:

— an automatic temperature control,

— a recording thermometer,

— an automatic safety device preventing insufficient heating,

— an adequate safety system preventing the mixture of pasteurized or sterilized milk with incompletely heated milk, and

— an automatic recording device for the safety system referred to in the preceding indent;

(g) equipment for the cooling, wrapping and storage of frozen milk-based products in so far as such operations are carried out there;

(h) equipment for drying and wrapping powdered milk-based products insofar as such operations are carried out there.

CHAPTER VI

Hygiene requirements relating to the premises equipment and staff of treatment establishments and processing establishments

In addition to the general requirements laid down in Chapter II, establishments must comply with the following conditions:

1. Cross-contamination between operations by equipment, ventilation or staff must be avoided. If appropriate, and in the light of the risk analysis referred to in Article 14 of this Directive, rooms intended for production processes shall be divided into wet and dry areas, each having its own operating conditions.

2. As soon as possible after each journey, or after each series of journeys where there is only a very short space of time between unloading and the following loading, but in any event at least once each working day, containers and tanks used for transporting raw milk to the milk collection or standardization centre or to the milk treatment or processing establishment must be cleaned and disinfected before reuse.

3. Equipment, containers and installations which come into contact with milk or milk-based products or other perishable raw materials during production must be cleaned and disinfected at the end of each work phase and at least once each working day.

4. The treatment premises must in principle be cleaned at least once each working day.

5. For the cleaning of other equipment, containers and installations which come into contact with microbiologically stable milk-based products and with rooms in which such substances are placed, the operator or manager of the establishment shall draw up a cleaning programme based on the risk analysis referred to in Article 14 of this Directive. This programme must meet the requirement referred to in point 1 of this Chapter and must also ensure that there is no health risk to products covered by this Directive as a result of inadequate cleaning methods.

ANNEX C

CHAPTER I

Requirements for the manufacture of heat-treated milk and milk-based products

A. *Requirements for the production of heat-treated drinking milk*

1. Heat-treated drinking milk must be obtained from raw milk which complies with the standards laid down in Annex A, Chapter IV.

2. Upon acceptance at a treatment establishment milk must, unless treated within four hours of acceptance, be cooled to a temperature not exceeding + 6 °C and maintained at that temperature until heat-treated.

   If raw milk is not treated within 36 hours of acceptance, a further test must be carried out on that milk before it is heat-treated. If it is found by means of a direct or indirect method that the plate count of that milk at 30 °C exceeds 300 000 per ml the milk in question must not be used for the production of heat-treated drinking milk.

3. The manufacture of heat-treated drinking milk shall include all necessary measures, in particular random sampling checks, relating to:

   (a) the plate count, to ensure that:

   — raw milk, if it is not treated within 36 hours of acceptance, does not exceed immediately before heat treatment a plate count at 30 °C of 300 000 per ml,

   — milk which has been subjected to a previous pasteurzation has, immediately before the second heat treatment, a plate count at 30 °C not exceeding 100 000 per ml;

   (b) the presence of extraneous water in the milk

   Heat-treated drinking milk shall be subjected to regular checks for the presence of extraneous water, in particular by verification of the freezing point. For this purpose a control system shall be established under the supervision of the competent authority. When extraneous water is detected the competent authority shall take appropriate measures.

   In establishing a control system the competent authority shall take account of;

   — the results of the checks on raw milk referred to in Annex A, Chapter III D.1, and in particular their variation and average,

   — the effect of storage and processing of milk under Good Manufacturing Practices (GMP) on the freezing point.

   Member States shall communicate to the Commission all details of the control system which they apply and its justification before 1 June 1994.

   Heat-treated drinking milk may be subjected to any test which gives an indication of the microbiological condition of the milk before heat treatment. The rules for the application of such tests and the criteria to be met in this regard shall be established in accordance with the procedure laid down in Article 31 of this Directive.

4. (a) *Pasteurized milk* must:

   (i) have been obtained by means of a treatment involving a high temperature for a short time (at least 71,7 °C for 15 seconds or any equivalent combination) or a pasteurization process using different time and temperature combinations to obtain an equivalent effect;

   (ii) show a negative reaction to the phosphatase test and a positive reaction to the peroxidase test. However, the production of pasteurized milk which shows a negative reaction to the perioxidase test is authorized, provided that the milk is labelled as 'high-temperature pasteurized';

   (iii) immediately after pasteurization, have been cooled to a temperature not exceeding 6 °C as soon as possible.

   (b) *UHT milk* must:

   — have been obtained by applying to the raw milk a continuous flow of heat entailing the application of a high temperature for a short time (not less than + 135 °C for not less than a second) — the aim being to destroy all residual spoilage micro-organisms and their spores — using aseptic opaque containers, or containers made opaque by the packaging, but so that the chemical, physical and organoleptic changes are minimal,

   — be of preservability such that no deterioration can be observed by means of random sampling checks after it has spent 15 days in a closed container at a temperature of + 30 °C; where necessary, provision can also be made for a period of seven days in a closed container at a temperature of + 55 °C.

Where the 'ultra high temperature' milk treatment process is employed by direct contact of milk and steam, the steam must be obtained from potable water and must not leave deposits of foreign matter in the milk or affect it adversely. Moreover, the use of this process must not cause any change in the water content of the treated milk.

(c) *Sterilized milk* must:

— have been heated and sterilized in hermetically sealed wrappings or containers, the seal of which must remain intact,

— in the event of random sampling, be of preservability such that no deterioration can be observed after it has spent 15 days in a closed container at a temperature of + 30 °C; where necessary, provision can also be made for a period of seven days in a closed container at a temperature of + 55 °C.

(d) Pasteurized milk which has been subjected to high-temperature pasteurization, UHT milk and sterilized milk may be produced from raw milk which has undergone thermization or an initial heat treatment in another establishment. In this case the time-temperature set must be lower than or equivalent to pasteurization and the milk must show a positive reaction to the peroxidase test before the second treatment. Recourse to this practice must be brought to the attention of the competent authority. Mention of the first treatment must be made on the document provided for in Article 5 (8) of this Directive.

(e) Heating processes, the temperatures and duration of heating in respect of pasteurized, UHT and sterilized milk, the types of heating equipment, the flow-diversion valve and the types of temperature controlling and recording devices shall be approved or authorized by the competent authority of the Member States in accordance with Community or international standards.

(f) The data produced by recording thermometers must be dated and kept for two years so that they can be shown upon request to the officials appointed by the competent authority to inspect the establishment, save in the case of microbiologically perishable products, for which this period may be reduced to two months after the use-by or minimum durability date.

5. *Heat-treated drinking milk* must:

(a) meet the microbiological standards laid down in Chapter II;

(b) not contain pharmacologically active substances in quantities higher than the limits laid down in Annexes I and III to Regulation (EEC) No 2377/90; the combined total of residues of all antibiotic residues may not exceed a value to be fixed in accordance with the procedure laid down in Regulation (EEC) No 2377/90.

B. *Requirements for milk for the manufacture of milk-based products*

1. The operator or manager of the processing establishment must take all necessary steps to ensure that the raw milk is treated, or in the case of products 'made with raw milk' used, within 36 hours of acceptance, if the milk is kept at a temperature not exceeding 6 °C, or within 48 hours of acceptance if the milk is kept at a temperature of 4 °C or lower.

2. Heat-treated milk intended for the manufacture of milk-based products must be obtained from raw milk which complies with the standards laid down in Annex A, Chapter IV.

3. Heat-treated milk must meet the following requirements:

(a) *thermized milk* must:

(i) have been obtained from raw milk which, if it is not treated within 36 hours of acceptance by the establishment, has a plate count at 30 °C prior to thermization which does not exceed 300 000 per ml;

(ii) have been obtained by treatment as defined in Article 2 (6) of this Directive;

(iii) if it is used for the production of pasteurized, UHT or sterilized milk, meet the following standards before treatment: plate count at 30 °C equal to or less than 100 000 per ml;

(b) *pasteurized milk* must

(i) have been obtained by means of a treatment involving a high temperature for a short time (at least 71,7 °C for 15 seconds or any equivalent combination) or a pasteurization process using different time and temperature combinations to obtain an equivalent effect;

(ii) show a negative reaction to the phosphatase test and a positive reaction to the peroxidase test. However, the production of pasteurized milk which shows a negative reaction to the peroxidase test is authorized, provided that the milk is labelled as 'high-temperature pasteurized';

(c) UHT milk must have been obtained by applying to the raw milk a continuous flow of heat entailing the application of a high temperature for a short time (not less than + 135 °C for not less than a second) — the aim being to destroy all residual spoilage micro-organisms and their spores — so that the chemical, physical and organoleptic changes are minimal.

CHAPTER II

Microbiological criteria for milk-based products and drinking milk

A. *Microbiological criteria for certain milk-based products on removal from the processing establishment*

1. Compulsory criteria: Pathogenic micro-organisms

Type of micro-organism	Product	Standard (ml, g) (a)
— *Listeria monocytogenes*	— Cheese, other than hard cheese	Absent in 25 g (c) n = 5, c = 0
	— Other products	Absent in 1 g
— *Salmonella* spp.	— All except milk powder	Absent in 25 g (c) n = 5, c = 0
	— Milk powder	Absent in 25 g (c) n = 10, c = 0

In addition, pathogenic micro-organisms and their toxins must not be present in quantities such as to affect the health of consumers.

(a) Where:
n = number of sample units comprising the sample;
m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all sample units does not exceed 'm';
M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more sample units is 'M' or more;
c = number of sample units where the bacteria count may be between 'm' and 'M' the sample being considered acceptable if the bacteria count of the other sample units is 'm' or less.
(b) Testing not compulsory for sterilized milk and milk-based products where the heat treatment was applied after wrapping or packaging.
(c) The 25 g sample to consist of 5 specimens of 5 g taken from different parts of the same product.

If these standards are exceeded, the foodstuffs must be excluded from human consumption and withdrawn from the market in accordance with the fifth and sixth indents of Article 14 (1) of this Directive.

Sampling programmes will be drawn up in the light of the nature of the products and the risk analysis.

2. Analytical criteria: organisms indicating poor hygiene

Type of micro-organism	Product	Standard (ml, g)
— *Staphylococcus aureus*	Cheese made from raw milk and from thermized milk	m = 1 000 M = 10 000 n = 5 c = 2
	Soft cheese (made from heat-treated milk)	m = 100 M = 1 000 n = 5 c = 2
	Fresh cheese Powdered milk Frozen milk-based products (including ice-cream)	m = 10 M = 100 n = 5 c = 2

Type of micro-organism	Product	Standard (ml, g)
Escherichia coli	Cheese made from raw milk and from thermized	m = 10 000 M = 100 000 n = 5 c = 2
	Soft cheese (made from heat-treated milk)	m = 100 M = 1 000 n = 5 c = 2

In all cases where these standards are exceeded there must be a review of the implementation of the methods for monitoring and checking critical points applied in the processing establishment pursuant to Article 14 of this Directive. The competent authority shall be informed of the corrective procedures included in the production monitoring system to prevent any repetition of the occurrence.

In addition, whenever the standard M is exceeded in the case of cheese made from raw milk and from thermized milk or soft cheese testing must be carried out for the possible presence of toxins in such products by means of a method to be determined in accordance with the procedure laid down in Article 31 of this Directive.

If strains of enterotoxinogenic *Staphylococcus aureus* or strains of *Escherichia coli* that are presumed to be pathogenic are identified, all the batches involved shall be withdrawn from the market. In this case the competent authority shall be informed of the findings, pursuant to the fifth indent of Article 14 (1) of this Directive, and of the action taken to withdraw the suspect batches and the corrective procedures introduced into the production monitoring system.

3. Indicator organisms: guidelines

Type of micro-organism	Product	Standard (ml, g)
— Coliformes 30 °C	Liquid milk-based products	m = 0 M = 5 n = 5 c = 2
	Butter made from pasteurized milk or cream	m = 0 M = 10 n = 5 c = 2
	Soft cheese (made from heat-treated milk)	m = 10 000 M = 100 000 n = 5 c = 2
	Powdered milk-based products	m = 0 M = 10 n = 5 c = 2
	Frozen milk-based products (including ice-cream)	m = 10 M = 100 n = 5 c = 2
— Plate count	Liquid heat-treated unfermented milk-based products (a)	m = 50 000 M = 100 000 n = 5 c = 2
	Frozen milk-based products (including ice-cream) (b)	m = 100 000 M = 500 000 n = 5 c = 2

(a) After incubation at 6 °C for five days (plate count at 21 °C).
(b) Plate count at 30 °C.

These guidelines should help producers in ensuring proper operation of their establishments and in implementing the system and the procedure for carrying out their own checks on their production.

4. In addition, heat-treated milk-based products must meet the following standards after incubation for 15 days at 30 °C:

   (a) plate count at 30 °C (per 0,1 ml): $\leqslant$ 10,

   (b) organoleptic test: normal.

B. *Microbiological criteria for drinking milk*

1. Raw cow's milk for drinking in that state must meet the following standards after wrapping:

   Plate count at 30 °C (per ml): $\leqslant$ 50 000 (a)

   — *Staphylococcus aureus* (per ml)

   m = 100, M = 500, n = 5, c = 2

   — Salmonella: absent in 25 g

   n = 5, c = 0

   In addition, pathogenic micro-organisms and their toxins must not be present in quantities such as to affect the health of consumers.

2. In the random sampling checks carried out in the treatment establishment pasteurized milk must meet the following microbiological standards (1):

Pathogenic micro-organisms:	absent in 25 g n = 5, c = 0, m = 0, M = 0
Coliforms (per ml):	n = 5, c = 1, m = 0, M = 5
After incubation at 6 °C for five days Plate count at 21 °C (per ml):	n = 5, c = 1, m = 5×10^4, M = 5×10^5.

3. In the random sampling checks carried out in the treatment establishment, sterilized milk and UHT milk must meet the following standards after incubation at 30 °C for 15 days:

— plate count (30 °C):	$\leqslant$ 10 (per 0,1 ml)
— organoleptic check:	normal
— pharmacologically active substances:	not exceeding the limits set in Annexes I and III to Regulation (EEC) No 2377/90.

   The combined total of residues of all substances may not exceed a value to be fixed in accordance with the procedure laid down in Regulation (EEC) No 2377/90.

4. When the maximum standards and compulsory criteria are exceeded and when subsequent investigation indicates a potential danger to health, the competent authority shall take appropriate measures.

C. Where necessary, detailed rules may be established in accordance with the procedure laid down in Article 31 of this Directive for the application of this Chapter and in particular:

   — criteria other than those set out in paragraphs A and B in respect of drinking milk and milk-based products,

   — microbiological criteria applicable, under conditions managed and controlled by the operator or manager of the establishment, to the use-by date.

(a) Geometric average over a period of two months, with at least two samples a month.

(1) Where:

n = number of sample units comprising the sample;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all sample units does not exceed 'm';

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more sample units is 'M' or more;

c = number of sample units where the bacterial count may be between 'm' and 'M', the sample still being considered acceptable if the bacterial count of the other sample units is bacteria 'm' or less.

CHAPTER III

Wrapping and packaging

1. Wrapping and packaging must take place under satisfactory hygiene conditions in rooms provided for that purpose.

2. Without prejudice to Directive 89/109/EEC [1], wrapping and packaging must comply with all the rules of hygiene, and be strong enough to protect effectively the products covered by this Directive.

3. Bottling, filling of containers with heat-treated milk and liquid milk-based products and sealing of containers and of packaging must be carried out automatically.

4. Wrapping or packaging may not be reused for the products covered by this Directive, with the exception of certain types of containers which may be reused after thorough cleaning and disinfecting.

   Sealing must be carried out in the treatment establishment in which the heat treatment has been carried out immediately after filling, by means of sealing devices which ensure that the milk is protected from any adverse effects of external origin on its characteristics. The sealing system must be so designed that once the container has been opened, the evidence that it has been opened remains clear and easy to check.

5. The operator or manager of the establishment must ensure for control purposes that in addition to the information required by Chapter IV the following information is visibly and legibly displayed on the packaging of the heat treated milk and milk-based products:

   — the nature of the heat treatment which the raw milk has undergone,

   — an information whereby the date of heat treatment may be established and, in the case of pasteurized milk, the temperature at which the product must be stored.

6. Product manufacture and packaging operations may take place in the same room, notwithstanding point 1, if the packaging is as described in 2 and subject to the following conditions:

   (a) the room must be sufficiently large and so equipped that the hygiene of the oprations is assured;

   (b) the wrapping and packaging must have been brought to the treatment or processing establishment in a protective cover in which they were placed immediately after manufacture and which protects them from any damage during transport to the establishment and must have been stored there under hygiene conditions in a room intended for that purpose;

   (c) the rooms for storing the packaging material must be free from dust and vermin and separated from rooms containing substances which might contaminate the products. Packaging must not be placed directly on the floor;

   (d) packaging must be assembled under hygienic conditions before being brought into the room. A derogation from this requirement may be granted in the case of the automatic assembly of packaging, provided there is no risk of contamination of the products;

   (e) packaging must be brought into the room under hygienic conditions and used without delay. It may not be handled by staff handling unwrapped products;

   (f) immediately after packaging, the products must be placed in the storage rooms provided for the purpose.

CHAPTER IV

Conditions governing health marking and labelling

A. *Conditions governing health marking*

1. The products covered by this Directive must carry a health mark. Marking must be carried out during or immediately after manufacture in the establishment, in an easily visible place. The mark shall be legible,

[1] Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (OJ No L 40, 11. 2. 1989, p. 38).

indelible and its characters easily distinguishable. The health mark may be applied to the product or to the wrapping, if the product is individually wrapped, or to a label affixed to this wrapping. However, where a product is individually wrapped and packaged, it will suffice for the health mark to be applied to the packaging.

2. Where products marked in accordance with point 1 are subsequently placed in a packaging, the health mark must also be applied to the packaging.

3. (a) The health mark must give the following particulars within an oval surround:

(i) either:

— above: the initial letter or letters of the consigning country in capitals, i.e. for the Community, the letters, B — DK — D — EL — E — F — IRL — I — L — NL — P — UK, followed by the approval number of the establishment,

— below: one of the following sets of initials: CEE — EØF — EWG — EOK — EEC — EEG;

(ii) or:

— above, the name of the consigning country in capitals,

— in the centre, the approval number of the establishment,

— below, one of the following sets of initials: CEE — EØF — EWG — EOK — EEC — EEG;

(b) the health mark may be applied to the product, wrapping or packaging by an ink stamp or by branding, or it may be printed on or applied to a label. In the case of products in hermetically-sealed containers, the mark must be indelibly applied either to the lid or to the container;

(c) the health mark may also consist of an irremovable plate of resistant material complying with all the hygiene requirements and bearing the information specified in (a).

B. *Conditions governing labelling*

Without prejudice to the provisions of Directive 79/112/EEC, the labelling must clearly show for inspection purposes:

1. the words 'raw milk' for raw milk intended for direct human consumption;

2. the words 'made with raw milk' for milk-based products manufactured from raw milk whose manufacturing process does not include any heat treatment, including thermization;

3. for other milk-based products the nature of any heat treatment applied at the end of the manufacturing process;

4. for milk-based products in which growth of micro-organisms can occur, the use-by or minimum durability date.

CHAPTER V

Storage and transport requirements

1. Products covered by this Directive which cannot be stored at ambient temperature must be stored at the temperatures established by the manufacturer to ensure their durability. In particular, the maximum temperature at which pasteurized milk may be kept until it leaves the establishment and during transport must be 6 °C. When stored under cooled conditions the storage temperatures must be registered and the cooling rate must be such that the product reaches the required temperature as quickly as possible.

2. Tanks, churns and other containers which are used for the transport of pasteurized milk must comply with all the rules of hygiene and in particular the following:

— their inside surfaces and any other part which may come into contact with the milk must be made of smooth material which is easy to wash, clean and disinfect, resists corrosion and does not transfer substances to the milk in such quantities as to endanger human health, impair the composition of the milk or adversely affect its organoleptic characteristics,

— they must be designed so that the milk can drain away completely; if they are fitted with taps, these must be easy to remove, dismantle, wash, clean and disinfect,

— they must be washed, cleaned and disinfected immediately after each use and as necessary before further use; cleaning and disinfection must be carried out in accordance with Annex B, Chapter VI, 2 and 3,

— they must be hermetically sealed before and during transport by means of a watertight sealing device.

3. Vehicles and containers used for transporting pasteurized milk must be designed and equipped in such a way that the required temperatures can be maintained throughout the period of transport.

4. Vehicles used for transporting heat-treated drinking milk and milk in small containers or in churns must be in good condition. They may not be used to transport any other product or object likely to cause the milk to deteriorate. Their internal surfaces must be smooth and easy to wash, clean and disinfect. The interiors of vehicles intended for transporting milk must comply with all the rules of hygiene. Vehicles intended for the transport of heat-treated milk in small containers or churns must be so designed as to give the containers or churns adequate protection against all contamination and atmospheric influences and may not be used to transport animals.

5. To that end, the competent authority must regularly check that the means of transport and loading conditions meet the hygiene requirements of this Chapter.

6. The products covered by this Directive must be dispatched in such a way that they are protected from anything liable to contaminate them or to cause them to deteriorate, having regard to the duration and conditions of transport and the means of transport employed.

7. During transport, the temperature of pasteurized milk transported in tanks or packed in small containers and in churns must not exceed 6 °C. However, the competent authorities may grant a derogation from this requirement for doorstep deliveries.

8. In accordance with the procedure laid down in Article 31 of this Directive, the Commission may establish additional conditions for the storage and transport of specific milk-based products.

CHAPTER VI

Health checks and supervision of production

1. Establishments shall be subject to supervision by the competent authority, which must ensure that the requirements of this Directive are met and in particular:

   (a) check:

      (i) the cleanliness of the premises and equipment and staff hygiene;

      (ii) the efficacy of the checks carried out by the establishment, in accordance with Article 14 of this Directive, notably by examining the results and taking samples;

      (iii) the microbiological and hygienic condition of the milk-based products;

      (iv) the efficacy of the treatment of the milk-based products and heat-treated drinking milk;

      (v) the hermetically sealed containers by means of random sampling;

      (vi) the appropriate health marking of the milk-based products;

      (vii) storage and transport conditions;

   (b) take any samples required for laboratory tests;

   (c) make any other checks it considers necessary to ensure compliance with this Directive.

2. The competent authority must have free access at all time to the cold stores and all working premises to check that these provisions are being strictly complied with.

ANNEX D

CHAPTER I

Community reference laboratory

Laboratoire central d'hygiène alimentaire
43 rue de Dantzig
75015 PARIS

CHAPTER II

Duties and tasks of the Community reference laboratory

1. The Community reference laboratory for the analysis and testing of milk and milk products shall be responsible for:

   — providing national reference laboratories with details of analytical methods and comparative testing,

   — coordinating the application, by national reference laboratories, of the methods referred to in the first indent, in particular by organizing comparative testing,

   — coordinating research into new analytical methods and informing national reference laboratories of advances in this field,

   — conducting initial and further training courses for the benefit of staff from national reference laboratories,

   — providing scientific and technical assistance to the Commission, including the Community Bureau of References, especially in cases where the results of analyses are contested between Member States.

2. The Community reference laboratory shall ensure that the following operating conditions are maintained.

   It must:

   — have suitably qualified staff with adequate training in the techniques applied to the analysis and testing of milk and milk products,

   — possess the equipment and substances needed to carry out the tasks provided for in paragraph 1,

   — have an appropriate administrative infrastructure,

   — ensure that its staff respect the confidential nature of certain subjects, results or communications,

   — have sufficient knowledge of international standards and practices,

   — have available, if appropriate, an updated list of reference substances held by the Community Bureau of References and an updated list of the manufacturers and suppliers of such substances.

COUNCIL DIRECTIVE 92/47/EEC

of 16 June 1992

on the conditions for granting temporary and limited derogations from specific Community health rules on the production and placing on the market of milk and milk-based products

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 milk and milk products are included on the list of products in Annex II to the Treaty; whereas production of and trade in such milk and products constitute an important source of income for the farming population;

Whereas, in order to ensure the rational development of this sector, to increase its productivity and progressively to establish the conditions for an internal market, health rules applying to production and placing on the market have been laid down at Community level by Directive 92/46/EEC (4)

Whereas it is possible that, because of particular circumstances, some establishments will be unable, by the date of application of the said Directive, 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 temporary and limited derogations to be granted for establishments in operation before 1 January 1993;

Whereas the granting of derogations from specific Community health rules to certain establishments must be without prejudice to the requirement that all operations connected with production and placing on the market conform to the hygiene rules laid down by the aforesaid Directive;

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, p. 60.
(3) OJ No C 332, 31. 12. 1990, p. 62.
(4) See page 1 of this Official Journal.

HAS ADOPTED THIS DIRECTIVE

Article 1

Member States shall ensure that from 1 January 1998:

— all establishments fulfil the requirements of Directive 92/46/EEC,

— drinking milk and milk-based products from such establishments bear the health mark specified in Annex C, Chapter IV.A.3 of Directive 92/46/EEC.

Article 2

1. Member States may, until 31 December 1997, 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 92/46/EEC for their approval, to derogate from some of the requirements laid down in Chapters I and V of Annex B to that Directive if drinking milk and milk-based products from such establishments do not bear the health mark specified in Annex C, Chapter IV.A.3 of the said Directive and are not intended for trade.

2. Derogations as referred to in paragraph 1 may be granted only to establishments which have, before 1 April 1993, submitted an application for a 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 establishment to comply with the requirements referred to in paragraph 1.

Where financial assistance is requested from the Community, only applications complying with the requirements of Directive 92/46/EEC can be accepted.

Member States shall submit to the Commission before 1 July 1993 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 the products manufactured, the checks to be made on products from the establishment in question and the staff responsible for carrying out those checks.

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 cease to be authorized to place drinking milk or milk-based products on the market until they have been judged to comply with the conditions of approval referred to in paragraph 1. This measure may apply to only part of the establishment and the products concerned.

On receipt of the list submitted by a Member State in accordance with the fourth subparagraph, the Commission shall have two months within which to examine that list and to submit it, if necessary after amendment, to the Standing Veterinary Committee, which shall decide in accordance with the procedure laid down in Article 4.

3. The list of establishments which have been granted derogations shall be published by the Commission.

Article 3

1. Member States may, until 31 December 1997, authorize establishments which are unable to obtain supplies of milk which meets the conditions laid down in Annex A, Chapter IV, of Directive 92/46/EEC to place drinking milk or milk-based products on the national market if such milk or milk-based products do not bear the health mark provided for in Annex C, Chapter IV.A.3 of that Directive and are not intended for trade.

2. Establishments approved in accordance with Article 10 or Article 11 of Directive 92/46/EEC may receive the authorization provided for in paragraph 1 for part of their production under the following conditions:

— the operator or manager of the establishment must take all necessary measures, under the supervision of the competent authority, to ensure that raw milk or milk-based products which do not meet the requirements of Annex A, Chapter IV, of Directive 92/46/EEC are treated or processed in a clearly separated place or at a completely different time from milk and products which do meet these requirements and are intended for trade,

— the operator or manager of the establishment must show to the satisfaction of the competent authority that the measures taken to keep a constant check on the use of the health mark ensure that it cannot be mistakenly applied to the products referred to in paragraph 1, and must keep at the disposal of the competent authority a record of raw materials and finished products which will allow the two separate circuits to be verified.

Article 4

Where reference is made to the procedure provided for in this Article, the rules applicable shall be those set out in Article 31 of Directive 92/46/EEC.

Article 5

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 2 (2) before 1 January 1993 and with the other provisions of this Directive before 1 January 1994. 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.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 6

This Directive is addressed to the Member States.

Done at Luxembourg, 16 June 1992.

For the Council

The President

Arlindo MARQUES CUNHA

COUNCIL DIRECTIVE 92/45/EEC

of 16 June 1992

on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game 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 (1),

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

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

Whereas game meat is included in the list of products in Annex II to the Treaty; whereas the placing on the market of wild game meat constitutes an additional 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 wild 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 such meat, with a view to the completion of the internal market;

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

Whereas it is necessary to lay down the hygiene conditions in which wild game meat must be obtained, processed and inspected, in order to prevent food-borne infections or food poisoning;

Whereas it is necessary to stipulate the hygiene rules to be complied with by wild game processing houses for the purposes of approval for 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 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 (4);

Whereas wild game and wild-game meat imported from third countries should be subject to the minimum requirements laid down by this Directive for trade between Member States, and compliance therewith should be monitored in accordance with the principles and rules set out in Directive 90/675/EEC (5);

Whereas it is appropriate to permit derogations for small quantities of wild game meat;

Whereas it is appropriate to grant temporary derogations to allow wild game processing houses to comply with the new requirements;

Whereas the Commission should be charged with adopting measures to implement this Directive; whereas, to that end, a procedure should be set up establishing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas the deadline for transposition into national law, set at 1 January 1994 in Article 23, should not affect the abolition of veterinary checks at frontiers on 1 January 1993,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

1. This Directive lays down public health and animal health rules applicable to the killing of wild game and to the preparation and placing on the market of wild game meat.

(1) OJ No C 327, 30. 12. 1989, p. 40, and OJ No C 311, 12. 12. 1990, p. 5.
(2) OJ No C 260, 15. 10. 1990, p. 154.
(3) OJ No C 124, 21. 5. 1990, p. 7.
(4) OJ No L 395, 30. 12. 1989, p. 13. Last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).
(5) 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 (OJ No L 373, 31. 12. 1990, p. 1). Amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

2. This Directive shall not apply to:

(a) small numbers of wild game, unskinned or unplucked, and, in the case of small wild game, ineviscerated, supplied directly by the hunter to the consumer or to the retailer;

(b) small quantities of wild-game meat supplied directly to the final consumer;

(c) the cutting and storage of wild-game meat in retail shops or in premises adjacent to sales points, where the cutting and storage are performed solely for the purpose of supplying the consumer directly on the spot.

The above operations shall continue to be subject to the public health checks provided for in national rules governing retailing.

3. The provisions of this Directive concerning trade or imports from third countries shall not apply to trophies or to killed wild game carried by travellers in their private vehicle provided that only a small quantity of small wild game or a single large wild game animal is involved and the circumstances indicate that there is no question of the meat of such game being intended for trade or commercial use, and provided that the game in question does not come from a country or a part of a country trade from which is prohibited pursuant to Article 11 (2) and 3 or Article 18.

Article 2

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

(a) 'wild game': wild land mammals which are hunted (including wild mammals living within an enclosed area under conditions of freedom similar to those enjoyed by wild game) and wild birds which are not covered by Article 2 of Council Directive 91/495/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 [1];

(b) 'large wild game': wild ungulates;

(c) 'small wild game': wild mammals of the Leporidae family and wild game birds intended for human consumption;

(d) 'wild-game meat': all parts of wild game which are fit for human consumption;

(e) 'wild game processing house': an establishment approved in accordance with Article 7 in which wild game is processed and wild game meat is obtained and inspected in accordance with the hygiene rules laid down in this Directive;

(f) 'collection centre': any place where killed wild game is kept in accordance with the hygiene rules in Annex I, Chapter IV (2) prior to being transported to a processing house;

(g) 'placing on the market': holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market of wild game meat for human consumption in the Community, excluding supplies pursuant to Article 1 (2);

(h) 'trade': trade between Member States within the meaning of Article 9 (2) of the Treaty.

2. For the purposes of this Directive the definitions in Article 2 of Directive 89/662/EEC and 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 [2], and the definition of fresh meat in Article 2 (b) of Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat [3], shall apply as necessary.

CHAPTER II

Provisions applicable to Community production and trade

Article 3

1. Member States shall ensure that wild game meat:

(a) comes from wild game which:

— has been killed in a hunting area by means authorized under national legislation governing hunting,

— does not come from a region subject to restrictions pursuant to Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat [4], 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 [5] and Council Directive 91/495/EEC or from a hunting area subject to restrictions pursuant to Articles 10 and 11 of this Directive,

— immediately after killing has been prepared in accordance with Annex I, Chapter III, and transported within a maximum of 12 hours to a processing house as referred to in (b) or to a

[1] OJ No L 268, 24. 9. 1991, p. 41.

[2] OJ No L 224, 18. 8. 1990, p. 29. Last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

[3] OJ No L 121, 29. 7. 1964, p. 2012/64. Last amended by Directive 91/497/EEC (OJ No L 268, 24. 9. 1991, p. 69).

[4] OJ No L 302, 31. 12. 1972, p. 24. Last amended by Directive 91/266/EEC (OJ No L 134, 29. 5. 1991, p. 45).

[5] OJ No L 268, 24. 9. 1991, p. 35.

collection centre where it must be chilled to the temperatures specified in Annex I, Chapter III, and from which it must be taken to a processing house as referred to in (b) within 12 hours or, in the case of remote regions where climatological conditions so permit, within a period to be fixed by the competent authority to enable the official veterinarian of the said processing house to carry out the post mortem inspection provided for in Annex I, Chapter V, under satisfactory conditions;

(b) is obtained:

(i) either in a wild game processing house fulfilling the general conditions of Annex I, Chapters I and II, and approved for the purposes of the present Chapter in accordance with Article 7;

(ii) in the case of large wild game, in an establishment approved in accordance with Article 10 of Directive 64/433/EEC, or, in the case of small wild game, in accordance with Article 5 of Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat [1] provided that:

— such game is skinned in rooms separate from those reserved for meat covered by those Directives, or at different times,

— such establishments are given special approval for the purposes of this Directive,

— measures are taken to allow clear identification of meat obtained pursuant to the present Directive and meat obtained pursuant to Directives 64/433/EEC and 71/118/EEC;

(c) comes from killed animals which have undergone visual inspection by the official veterinarian:

— to detect any anomalies. The official veterinarian may base his diagnosis on any information supplied by the hunter, where appropriate on the basis of a certificate laid down by the authority responsible for hunting rules, on the behaviour of the animal before killing,

— to check that death is not due to causes other than hunting;

(d) comes from wild game which:

— has been handled under satisfactory hygiene conditions, in accordance with Annex I, Chapters III and IV,

— has undergone, in accordance with Annex I, Chapter V, post-mortem inspection by an official veterinarian or, by auxiliaries holding the professional qualifications to be specified in accordance with the procedure laid down in Article 22, acting under the supervision of the official veterinarian,

— has not shown any change except for traumatic lesions which occurred during killing or localized malformations or changes, provided that it is established, if necessary by appropriate laboratory tests, that these do not render the meat unfit for human consumption or dangerous to human health,

— on which, in the case of small wild game which has not immediately after killing been eviscerated in accordance with Annex I, Chapter V (1), an official veterinary health inspection has been carried out on a representative sample of animals from the same source.

If the official veterinarian finds a disease communicable to man or defects as referred to in Annex I, Chapter V (4), he must carry out more checks on the entire batch. In the light of the results of these further checks, he must either exclude the entire batch from human consumption or inspect each carcase individually.

2. The official veterinarian must ensure that wild game meat is excluded from human consumption:

(i) if it is found to contain defects as referred to in Annex I, Chapter V (3) (e), or if it has been seized in accordance with paragraph 4 of that Chapter;

(ii) if the checks provided for in the third indent of paragraph 1 (d) of this Article have revealed the presence of a disease communicable to man;

(iii) if it comes from animals which have ingested substances which are likely to make the meat dangerous or harmful to human health and on which a decision has been taken, by the procedure laid down in Article 22, after the opinion of the Scientific Veterinary Committee has been obtained. Pending the implementation of such a decision, national rules on these substances shall remain in force, subject to the general provisions of the Treaty;

(iv) if, without prejudice to any Community legislation applicable to ionization, it has been treated with ionizing or ultra-violet radiation or by means of substances likely to affect its organoleptic properties or using colourings other than those used for health marking.

3. Meat of wild boar or of other species susceptible to trichinosis must undergo analysis by the digestion method in accordance with Council Directive 77/96/EEC of 21 December 1976 on the examination for trichinae *(trichinella spiralis)* upon importation from third countries of fresh meat derived from domestic swine [2] or a trichinoscopic examination with microscopic observation of several samples from each animal taken from the jaw and diaphragmatic muscles, from the muscles of the lower front

[1] OJ No L 55, 8. 3. 1971, p. 23. Last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48).

[2] OJ No L 26, 31. 1. 1977, p. 67. Last amended by Directive 89/321/EEC (OJ No L 133, 17. 5. 1989, p. 33).

leg, from the intercostal muscles and the tongue muscles at least.

Before 1 January 1994, the Council, acting by a qualified majority on a proposal from the Commission and after obtaining the opinion of the Scientific Veterinary Committee, shall lay down the methods for the analysis by digestion which are suitable for detecting trichinosis in wild boar or other species of wild game susceptible to trichinosis; the same procedure shall apply with regard to the trichinoscopic or microscopic examination for the detection of trichinosis.

4. Wild game meat declared fit for human consumption must:

(i) bear a health mark in accordance with Annex I, Chapter VIII.

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 22, in order to take into account notably the different forms of commercial presentation, providing they conform to the hygiene rules laid down in this Directive.

Commission Directive 80/879/EEC of 3 September 1980 on health marking of large packagings of fresh poultrymeat [1] shall apply to meat of small wild game;

(ii) after post-mortem inspection, be stored in accordance with Annex I, Chapter X, under satisfactory hygiene conditions in wild game processing houses approved in accordance with Article 7 of this Directive, or in establishments approved in accordance with Article 10 of Directive 64/433/EEC or Article 5 of Directive 71/118/EEC, or in cold stores approved and inspected in accordance with Article 10 of Directive 64/433/EEC;

(iii) be accompanied during transportation by:

— an accompanying commercial document as authorized by the official veterinarian. This document must:

— in addition to the particulars provided for in Annex I, Chapter VII (2), 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.

Detailed rules for applying this point, 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 22,

— a public animal health certificate corresponding to the specimen in Annex II, in the case of meat from a wild game processing house 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;

(iv) be transported under satisfactory hygiene conditions in accordance with Annex I, Chapter XI;

(v) in the case of parts of carcases or boned meat of small wild game birds, also be obtained in conditions similar to those provided for in Article 3 B. of Directive 71/118/EEC, in establishments specially approved for this purpose in accordance with Article 7 of the present Directive;

(vi) without prejudice to 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 to the ultimate consumer [2], be labelled with an indication of the animal species.

Article 4

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 Council Directive 90/667/EEC of 27 November 1990 laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedstuffs of animal or fish origin and amending Directive 90/425/EEC [3].

2. Meat from an area subject to animal health restrictions shall be subject to specific rules to be determined on a case-by-case basis in accordance with the procedure laid down in Article 22.

3. Detailed rules for implementing this Article shall if necessary be determined in accordance with the procedure laid down in Article 22.

Article 5

Member States shall ensure that only the following are the subject of trade:

1. skinned and eviscerated wild game meeting the requirements of Articles 3 and 4, or fresh wild game meat;

2. unskinned or unplucked and uneviscerated small game, not frozen or deep-frozen which is controlled in accordance with the third indent of Article 3 (1) (b) (ii), provided it is handled and stored separately from fresh meat covered by Directive 64/433/EEC, poultry meat and skinned or plucked game meat;

[1] OJ No L 251, 24. 9. 1980, p. 10.

[2] OJ No L 33, 8. 2. 1979, p. 1. Last amended by Directive 91/72/EEC (OJ No L 42, 16. 2. 1991, p. 27).

[3] OJ No L 363, 27. 12. 1990, p. 51.

3. unskinned large game which:

(a) meets the requirements of Article 3 (1) (a) first and second indents, Article 3 (1) (c), and Article 3 (1) (d) first indent;

(b) the viscera of which have undergone post-mortem inspection in a wild game processing house;

(c) is accompanied by a health certificate corresponding to a specimen to be drawn up in accordance with the procedure laid down in Article 22, signed by the official veterinarian to certify that the result of the post mortem inspection provided for in (b) was satisfactory and that the meat has been declared fit for human consumption;

(d) has been cooled to a temperature of between -1 °C and:

(i) +7 °C and kept at that temperature during transportation to a processing house within a maximum period of seven days from the post mortem inspection referred to in (b), or

(ii) +1 °C and kept at that temperature during transportation to a processing house within a maximum period of 15 days from the post-mortem inspection referred to in (b).

Meat from such unskinned wild game cannot bear the health mark provided for in Article 3 (4) (i) unless, after skinning in the processing house of destination, it has undergone post mortem inspection in accordance with Annex I, Chapter V, and has been declared fit for human consumption by the official veterinarian.

Article 6

Member States shall ensure that:

— wild game processing houses which do not meet the standards laid down in Annex I, Chapter I, and which are not covered by the derogations provided for in Article 8 cannot be approved in accordance with Article 7 and that products from such establishments do not bear the health mark provided for in Annex I, Chapter VII and cannot be the subject of trade,

— wild game which does not meet the requirements of Article 3 cannot be the subject of trade or be imported from third countries,

— offal of wild game declared fit for human consumption cannot be the subject of trade unless it has undergone appropriate treatment in accordance with Council Directive 77/99/EEC on health problems affecting intra-Community trade in meat products [1].

[1] OJ No L 26, 31. 1. 1977, p. 85 and for the consolidated enacting terms, OJ No L 57, 2. 3. 1992, p. 4. Last amended and updated by Directive 92/5/EEC (OJ No L 57, 2. 3. 1992, p. 1).

Article 7

1. Each Member State shall draw up a list of approved wild game processing houses, each having a veterinary approval number. Member State may approve, for the processing of wild game, establishments approved in accordance with Directive 64/433/EEC and 71/118/EEC, provided that such establishments are equipped to process wild game meat and that they work in conditions ensuring compliance with the hygiene rules. Member States shall send this list to the other Member States and to the Commission.

A Member State shall not approve a wild game processing house unless it is satisfied that it complies with this Directive.

Where hygiene is found to be inadequate and where the measures provided for in Annex I, Chapter V (5), second subparagraph have proved insufficient to remedy the situation, the competent authority shall temporarily suspend approval.

If the operator or manager of the wild game processing house does not make good the shortcomings noted within the period fixed by the competent authority, the latter shall withdraw approval.

The Member State in question shall take account 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 or manager of the wild game processing house must, in accordance with 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 or manager of the wild game processing house must 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 22.

3. The operator or manager of the wild game processing house 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 wild game processing house must be involved in the planning and implementation of that programme.

4. Inspection and supervision of wild game processing houses shall be carried out under the responsibility of the official veterinarian, who may be assisted by auxiliaries in accordance with Article 9 of Directive 64/433/EEC. The official veterinarian must at all times have free access to all parts of processing houses in order to ensure that this Directive is being complied with and, where there is doubt as to the origin of meat or killed wild game, to relevant documents which enable him to trace the hunting area of origin.

The official veterinarian must regularly analyse the results of the checks provided for in paragraph 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 or manager of the establishment, who shall rectify the shortcomings noted with a view to improving hygiene.

Article 8

1. Member States may, until 31 December 1996, authorize wild game processing houses which, on the date on which this Directive is notified, have not been judged to comply with the conditions for approval, to derogate from some of the requirements laid down in Annex I provided that meat from such establishments bears the national mark.

2. Derogations as referred to in paragraph 1 may be granted only to processing houses which have, before 1 April 1993, submitted an application for a derogation to the competent authority.

This application must be accompanied by a work plan and programme indicating the period within which it would be possible for the processing house to comply with the requirements referred to in paragraph 1.

3. Member States shall communicate to the Commission before 1 October 1992 the criteria which they have adopted to determine whether an establishment or category of establishments is covered by the provisions of this Article.

Article 9

Member States shall entrust to a central service or body the tasks of collecting and making use of the results of the post-mortem inspection carried out by the official veterinarian as regards the diagnosis of diseases communicable to man.

Whereas 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 hunting area where the wild game in question originated.

Member States shall submit to the Commission information on certain diseases and particularly cases where diseases communicable to man have been diagnosed.

The Commission acting in accordance with the procedure laid down in Article 22, shall adopt detailed rules for implementing this Article, and in particular:

— the frequency with which information must be submitted to the Commission,

— the type of information,

— the disease to which the collection of information is to apply,

— procedures for collecting and using information.

Article 10

1. Member States shall ensure that a survey of the health of wild game is performed in hunting areas 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 communicable to man or to animals or the presence of residues in excess of permitted levels are diagnosed.

3. Where a disease or condition as referred to in paragraph 2 is diagnosed, the survey results relating to the specific case shall be communicated as soon as possible to the competent authority responsible for supervision of the hunting area.

4. Depending on the epizootic situation, the competent authority shall carry out specific tests on wild game in order to detect the presence of the diseases referred to in Annex I to Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community [1].

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

Article 11

1. Member States shall supplement their plans for measures to detect residues referred to in Article 4 of Council Directive 86/469/EEC of 16 September 1986 concerning

[1] OJ No L 378, 31. 12. 1982, p. 58. Last amended by Decision 90/134/EEC (OJ No L 76, 22. 3. 1990, p. 23).

the examination of animals and fresh meat for the presence of residues (1) in order, where necessary, to subject wild game meat to the inspections provided for in that Directive in order to make spot checks on the presence of contaminants in the environment.

2. Taking into account the results of the monitoring referred to in paragraph 1 and in Article 10 (4), Member States shall ensure that wild game and wild game meat from hunting areas implicated by the monitoring is excluded from trade.

3. The Commission shall adopt detailed rules for implementing this Article in accordance with the procedure laid down in Article 22.

Article 12

Veterinary experts from the Commission may, in so far as is necessary for the uniform application of this Directive and in cooperation with the competent national authorities, make on-site checks. In particular, they may verify by checking a representative percentage of wild game processing houses whether the competent authorities are ensuring that approved processing houses are 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.

Detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 22.

Article 13

1. With 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 wild game meat is fit for consumption, carry out any veterinary checks he or it deems appropriate.

2. Member States shall take administrative and/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 wild game meat, that identification marks do not comply with the rules, that the wild game meat was not presented for inspection or that such meat was not used for the purpose originally intended.

Article 14

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 wild game meat in the territory of the Community.

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

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

'— Council Directive 92/45/EEC of 16 June 1992 on public health and animal health problems relating to the killing of wild game and the placing on the market of wild game meat (OJ No L 268, 14. 9. 1992, p. 35).';

(b) in Annex B, the indent '— wild game meat' shall be deleted.

3. In Article 2 (d) of Directive 77/99/EEC, the following indent shall be added:

'— Article 2 (1) (d) of Council Directive 92/45/EEC (*) and meeting the requirements of Articles 3 and 5,

(*) OJ No L 268, 14. 9. 1992, p. 35.'

CHAPTER III

Provisions applicable to imports into the Community

Article 15

The conditions applicable to the placing on the market of wild game meat imported from third countries shall be at least equivalent to those laid down for the production and placing on the market of wild game meat obtained in accordance with Chapter II, excluding those in Articles 6 and 8.

Article 16

1. For the purpose of uniform application of Article 15, the provisions of the following paragraphs shall apply.

2. In order to be imported into the Community, wild game or wild game meat must:

(a) come from third countries or parts of third countries from which imports are not prohibited on animal health grounds;

(b) come from a third country on the list to be drawn up in accordance with paragraph 3 (a);

(c) be accompanied by a health certificate corresponding to a specimen to be drawn up in accordance with the

(1) OJ No L 275, 26. 9. 1986, p. 36. Amended by Decision 89/187/EEC (OJ No L 66, 10. 3. 1989, p. 37).

procedure laid down in Article 22, signed by the competent authority and certifying that the products meet the requirements of Chapter II or any additional conditions or offer the equivalent guarantees referred to in paragraph 3 (c) and come from establishments offering the guarantees provided for in Annex I.

3. The following shall be established in accordance with the procedure laid down in Article 22:

(a) a provisional list of third countries or parts of third countries able to provide Member States and the Commission with the conditions and guarantees referred to in paragraph 2 (c) and a list of establishments for which they are able to give these guarantees.

This provisional list shall be compiled from the lists of establishments approved and inspected by the competent authorities of the Member States, once the Commission has checked that they abide by the principles and general rules laid down in this Directive;

(b) updates of that list in the light of the checks provided for in paragraph 4;

(c) the specific conditions and the equivalent guarantees relating to the requirements of this Directive, other than those enabling meat to be excluded from human comsumption in accordance with Article 3 (2) (d) and those of Article 5 and those laid down in Annex I, Chapters IV and V, and, as regards the trichinoscopic examination by the digestion method, in accordance with Directive 77/96/EEC, on the understanding that such conditions and guarantees may not be less stringent than those laid down in Chapter II, excluding those in Articles 6 and 8.

4. Experts from the Commission and the Member States shall carry out on-the-spot inspections to verify whether:

(a) the guarantees given by the third country regarding the conditions of production and placing on the market can be considered equivalent to those applied in the Community;

(b) the conditions of Article 18 are fulfilled.

The experts from the Member States responsible for 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 of and procedure for these inspections shall be determined in accordance with the procedure laid down in Article 22.

5. Pending the organization of the inspections referred to in paragraph 4, national rules applicable to inspection in third countries shall continue to apply, subject to notification, through the Standing Veterinary Committee, of any failure to comply with hygiene rules found during these inspections.

Article 17

1. Member States shall ensure that wild game or wild game meat covered by this Directive is imported into the Community only if it:

— is accompanied by the certificate provided for in Article 16 (1) (c), covering public and animal health requirements issued by the competent authority at the time of loading,

— has satisfied the checks required by Directive 90/675/EEC.

2. Pending the establishment of detailed rules for implementing this Article:

— the national rules applicable to imports from third countries for which such requirements have not been adopted at Community level shall continue to apply, provided they are not more favourable than those laid down in Chapter II,

— imports must take place under the conditions laid down in Article 11 of Directive 90/675/EEC,

— trade in wild game or wild game meat imported in accordance with this paragraph must be subject to the prior agreement of the country of destination.

Article 18

The lists provided for in Article 16 (2) may include only third countries or parts of third countries:

(a) from which imports are not prohibited as a result of the existence of one of the diseases referred to in Annex A to the OIE list, or of any other disease exotic to the Community, or pursuant to Articles 6, 7 and 14 of Directive 72/462/EEC [1], or Articles 9 to 12 of Directive 91/494/EEC;

(b) which, in view of their legislation and the organization of their veterinary services and of their inspection services, the powers of such services and the supervision to which they are subject, have been recognized, in accordance with Article 3 (2) of Directive 72/462/EEC or Article 9 (2) of Directive 91/494/EEC, as capable of guaranteeing the implementation of their legislation in force; or

[1] Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries (OJ No L 302, 31. 12. 1972, p. 28). Last amended by Directive 91/497/EEC (OJ No L 268, 24. 9. 1991, p. 69).

(c) the veterinary services of which are able to guarantee that health requirements at least equivalent to those laid down in Chapter II are being complied with.

Article 19

1. The principles and rules 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.

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 that Directive shall continue to apply, without prejudice to compliance with the principles and rules referred to in the first subparagraph of this Article.

CHAPTER IV

Final provisions

Article 20

This Directive shall not affect Community rules adopted for the conservation of wildlife.

Article 21

The Annexes 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 22

1. Where the procedure laid down in this Article is to be followed, matters shall without delay be referred to the Standing Veterinary Committee (hereinafter called 'the Committee') set up by Decision 68/361/EEC [1] by its Chairman, 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 and implement them immediately 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, within three months from the date of referral to the Council, the Council has not acted, the Commission shall adopt the proposed measures save where the Council has rejected the said measures by a simple majority.

Article 23

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1994. 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.

2. Member States shall communicate to the Commission the test of the main provisions of national law which they adopt in the field governed by this Directive.

3. The setting of the deadline for transposition into national law at 1 January 1994 shall be without prejudice to the abolition of veterinary checks at frontiers provided for in Directive 89/662/EEC.

Article 24

This Directive is addressed to the Member States.

Done at Luxemburg, 16 June 1992.

For the Council

The President

Arlindo MARQUES CUNHA

[1] OJ No L 255, 18. 10. 1968, p. 23.

ANNEX I

CHAPTER I

General conditions for the approval of processing houses

Processing houses must have at least:

1. the following rooms:

   — a sufficiently large refrigerated room for reception of wild game,

   — a room for inspection and, if necessary, evisceration, skinning and plucking,

   — a sufficiently large room for cutting and other preparation, in so far as this is done by the establishment; this room must have an adequate chilling facility as well as a temperature-measuring instrument,

   — a room for packaging and dispatching, where these operations are carried out in the processing house and where the conditions laid down in Chapter VIII, point 5 of this Directive are met; if these conditions are not met there must be a separate room for dispatching,

   — sufficiently large chilling or refrigeration rooms for storing wild game meat;

2. in rooms where meat is produced, worked on or stored and in areas and corridors through which 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 chilling or refrigeration rooms a device with which water may easily be removed is sufficient,

   — in the case of stores and in areas and corridors through which meat is transported, waterproof and rotproof floorig is sufficient;

   (b) smooth, durable, impermeable walls, with a light-coloured, washable coating up to a height of at least two metres; 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 stores.

   However, the use of wooden walls in stores in wild game processing houses in operation on the date of notification of this Directive does not constitute grounds for withholding approval;

   (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;

3. (a) as near as possible to the work stations, a suffcicient 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;

4. appropriate arrangements for protection against pests such as insects and rodents;

5. (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 joins, must be maintained smooth. Use of wood is forbidden except in rooms where the only meat stored is hygienically packaged 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 workingday. Where such meat is removed through conduits, these must be so constructed and installed as to avoid any risk of contamination of the meat;

(e) facilities for the hygienic storage of materials for wrapping and packaging where such activities are carried out in the establishment;

6. 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;

7. an adequate pressurized supply of potable water complying with the parameters laid down in Annexes D and E to Directive 80/778/EEC. 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 meat. Non-potable water pipes must be clearly distinguished from those used for potable water;

8. an adequate supply of hot potable water within the meaning of Directive 80/778/EEC [1];

9. liquid and solid disposal systems which meet hygiene requirements;

10. an adequately equipped lockable room for the exclusive use of the veterinary service; or, in the case of stores, suitable facilities;

11. facilities enabling the veterinary inspections provided for in this Directive to be carried out efficiently at any time;

12. 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 storing hygienically packaged 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 basin taps must not be hand or arm-operable. There must be a sufficient number of such wash basins near the lavatories;

13. a place and adequate facilities for cleaning and disinfecting means of transport except in the case of cold stores receiving and dispatching hygienically packaged meat only. However, these places and facilities are not compulsory if provisions exist requiring that means of transport be cleaned and disinfected at officially authorized facilities;

14. a room or a secure place for the storage of detergents, disinfectants and similar substances.

(1) Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption (OJ No L 353, 17. 12. 1990, p. 59).

CHAPTER II

Hygiene of the staff, premises and equipment in the establishments

1. Absolute cleanliness shall be required of staff, premises and equipment. Specifically:

   (a) staff handling meat or working in rooms and areas in which meat is handled, packaged or transported must in particular wear clean and easily cleanable headgear and footwear, light-coloured working clothes and, where necessary, neck shields or other protective clothing. Staff engaged in 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 infected game or infected meat must immediately afterwards carefully wash their hands and arms with hot water and then disinfect them. Smoking is forbidden in work rooms, storerooms, load-in, reception, marshalling and load-out areas, and in other areas and corridors through which wild game meat is transported;

   (b) no animal may enter the establishments. 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 reused when they have been soiled.

2. Premises, instruments and working equipment must not be used for purposes other than work on fresh meat, poultry meat or game meat. The cutting of wild game animals and wild game birds must be carried out at a different time and the cutting room must be completely cleaned and disinfected before being made use of again for the cutting of meat of another category.

   Meat-cutting instruments must be used solely for cutting meat.

3. Implements must not be left in the meat; cleansing of meat by wiping with a cloth or other materials, and inflation, are prohibited.

4. Meat and meat containers must not come into direct contact with the ground.

5. 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 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.

6. The spreading of sawdust or any other similar substance on the floor of the workrooms and meat storage rooms is prohibited.

7. Detergents, disinfectants and similar substances must be used in such a way that instruments, working equipment and meat are not affected. Such instruments and working equipment must be rinsed thoroughly with potable water after use.

8. Persons likely to contaminate meat are prohibited from working on it and handling it.

   When recruited, any person working on and handling meat shall be required to prove, by a medical certificate, that there is no medical 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 III

Hygiene in respect of the preparation of wild game and the cutting and handling of wild game meat

1. Wild game must undergo the following operations immediately after killing:

   — large wild game must be drawn and eviscerated,

— the thoracic viscera, even if detached from the carcase, and the liver and the spleen, must accompany the game and be identified in such a way that the official veterinarian can carry out the post-mortem inspection of the vicera in conjunction with the rest of the carcase; the other abdominal viscera must be removed and inspected on the spot. The head may be removed as a trophy,

— small wild game may, without prejudice to the case provided for in the third indent of Article 3 (1) (a) of this Directive, be totally or partially eviscerated on the spot or in a processing house where the game is transported to the said house at an ambient temperature not exceeding 4 °C within 12 hours of being killed.

2. Wild game must be chilled immediately after the operations provided for in paragraph 1 so that the internal temperature is + 7 °C or lower in the case of large game or + 4 °C or lower in the case of small game. If the external temperature is not sufficiently low, killed game must be moved as soon as possible, and in any event not more than 12 hours after being killed, to a wild game processing house or to a collection centre on the understanding that:

— large wild game must be transported under satisfactory hygiene conditions, in particular avoiding heaping and stacking, to a wild game processing house as soon as possible after the operations provided for in paragraph 1,

— during transportation to the processing house, wild game whose viscera have already undergone veterinary inspection must be accompanied by a certificate issued by the veterinarian attesting to the favourable outcome of the inspection and stating the estimated time of killing.

3. Evisceration must be carried out without undue delay upon arrival at the wild game processing house, except in the case provided for in Article 3 (1) (d), if it has not been carried out on the spot. The lungs, heart, liver, kidney, spleen and mediastinum may either be detached or left attached to the carcase by their natural connections.

4. Until the inspection has been completed, it must not be possible for carcases and offal not inspected to come into contact with carcases and offal already inspected, and the removal, cutting or further treatment of the carcase shall be forbidden.

5. 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 meat.

6. The dressing, handling, further treatment and transport of meat, including offal, must be performed in compliance with all hygiene requirements. Where such meat is packaged, the conditions of Chapter VIII must be complied with. Packaged meat must be stored in a separate room from exposed meat.

7. The competent authorities shall lay down specific rules applicable to inspection of trophies to be kept by the hunter.

CHAPTER IV

Requirements for wild game meat intended for cutting

1. Cutting pieces smaller than carcases, or half-carcases in the case of large wild game, and boning are authorized only in processing houses approved in accordance with Article 7 of this Directive or in accordance with Directives 64/433/EEC and 71/118/EEC and equipped with skinning and cutting rooms.

2. The operator or manager of the establishment 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 meat brought into his establishment or the origin of killed wild game.

3. (a) Wild game meat must be brought into the work rooms as and when it is needed. As soon as it is cut, and where appropriate packaged, the meat must be transferred to an appropriate chilling or refrigeration room.

(b) Wild game meat entering a cutting room must be checked and, if necessary, trimmed. The work station for these operations must be equipped with suitable facilities and adequate lighting.

(c) During cutting, boning, wrapping and packaging the internal temperature of the wild game meat must be kept at a constant + 7 °C or lower in the case of large wild game or + 4 °C or lower in the case of small wild game. During cutting, the temperature of the cutting room must not exceed + 12 °C.

(d) Cutting must be carried out in such a way as to avoid any soiling of the wild game 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 provided for in Chapter I, point 5 (d) as it is cut.

CHAPTER V

Post-mortem health inspection

1. All parts of wild game must be inspected, within 18 hours of admission to the processing house, to determine whether the wild game meat is fit for human consumption; in particular, the body cavity must be opened to permit visual inspection.

2. If the official veterinarian so requires, the spinal column and the head must be split lengthwise.

3. In his post-mortem inspection, the official veterinarian must carry out:

   (a) a visual inspection of the wild game and the organs belonging to it.

   If the results of the visual inspection do not enable an assessment to be made, a more extensive inspection must be carried out in a laboratory. These more extensive inspections may be restricted to a number of samples sufficient to assess all the game killed during a hunt;

   (b) investigation of anomalies of consistency, colour or odour;

   (c) palpation of organs, if he considers it necessary;

   (d) an analysis of residues by sampling, particularly where there are serious grounds for believing it to be justified.

   Where a more extensive inspection is carried out on the basis of such serious grounds, the veterinarian must wait until that inspection has been concluded before going on to assess all the game killed during a specific hunt, or parts of it which may be supposed, owing to the circumstances, to present the same anomalies;

   (e) detection of characteristics indicating that the meat presents a health risk. This applies particularly in the following cases:

      (i) abnormal behaviour or disturbance of the general condition of the live animal reported by the hunter;

      (ii) presence of tumours or abcesses where they are numerous or affect different internal organs or muscles;

      (iii) arthritis, orchitis, changes in the liver or the spleen, inflammation of the intestines or the umbilical region;

      (iv) presence of foreign bodies in the body cavities, especially in the stomach and intestines or in the urine, where the pleura or the peritoneum are discoloured;

      (v) formation of a significant amount of gas in the gastro-intestinal tract with discolouring of the internal organs;

      (vi) considerable anomalies in the colour, consistency or odour of muscle tissues or organs;

      (vii) open fractures in so far as they are not directly linked to the hunt;

      (viii) emaciation and/or general or localized oedema;

      (ix) signs that organs have recently adhered to the pleura and the peritoneum;

      (x) other obvious extensive changes, such as discolouring and putrefaction.

4. The official veterinarian must order the confiscation of any wild game meat:

   — presenting lesions, apart from recent lesions stemming from the killing, and localized malformations or anomalies, in so far as these lesions, malformations or anomalies render the wild game meat unfit for human consumption or dangerous to human health,

   — from animals which have not been killed in accordance with national rules on hunting,

   — in respect of which the findings listed in paragraph 3 (e) were made during post mortem inspection,

   — from small wild game which has been seized in accordance with the fourth indent of Article 3 (1) (d),

   — which has been found to be infested with trichinae.

5. 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 an interruption of the production process.

6. The results of the post-mortem health inspections shall be recorded by the official veterinarian and, where diseases communicable to man as referred to in the third indent of Article 3 (1) (d) or Article 9 are diagnosed, communicated to the competent veterinary authorities responsible for supervision of the hunting area from which the wild game originated, as well as to the person responsible for the said area.

CHAPTER VI

Health control of cut wild game meat and stored wild game meat

Superverision by the official veterinarian must include the following tasks:

— supervision of the entry and exit of meat,

— health inspection of meat held in processing houses,

— health inspection of meat prior to cutting and when it leaves the processing houses referred to in the second indent,

— supervision of the cleanliness of the premises, facilities and instruments provided for in Chapter I, and of staff hygiene, including their clothing,

— any other supervision which the official veterinarian considers necessary for ensuring compliance with this Directive.

CHAPTER VII

Health marking

1. Health marking must be carried out under the responsibility of the official veterinarian, who shall keep for that purpose:

   (a) instruments for meat health marking, to be handed over to the assistant staff only at the actual time of marking and for the lenght 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 paragraph 2. These labels, wrappers and seals shall be handed over in the required number by the official veterinarian to the assistant staff at the time when they are to be used.

2. (a) The health mark must be:

   (i) a pentagonal mark bearing, in perfectly legible characters, the following information:

   — on the upper part the full name or the initial letter or letters of the country of dispatch in capitals: for the Community, the following letters: B/D/DK/EL/ESP/F/IRL/I/L/NL/P/UK,

   — in the centre, the veterinary approval number of the wild game processing house or, where appropriate, the cutting premises,

   — on the lower part, one of the following sets of initials: CEE, EØF, EWG, EOK, EEC, EEG, or initials identifying the third country of origin.

   The height of the letters and the figures must comply with the requirements of Annex I, Chapter XI, of Directive 64/433/EEC in the case of large wild game, and of Annex I, Chapter III, of Directive 91/495/EEC in the case of small wild game;

   (ii) a pentagonal stamp sufficiently large to contain the information listed in point (a);

   (b) The material used for marking must meet all hygiene requirements and the information referred to in point (a) must appear on it in perfectly legible form.

   (c) (i) The health marking referred to in point (a) must be applied:

   — to exposed carcases by means of a seal containing the information listed in point (a),

— on or visibly beneath wrappers or other packaging of packed carcases,

— on or visibly beneath wrappers or other packaging of parts of carcases or offal wrapped in small quantities.

(ii) The health marking referred to in point (a) (ii) must be applied to large packaging.

CHAPTER VIII

Wrapping and packaging of wild game meat

1. (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 reused for wild game meat unless it is made of corrosion-resistant materials which are easy to clean and has been previously cleaned and disinfected.

2. Where cut wild game meat is wrapped, this operation must be carried out immediately after cutting and in accordance with hygiene requirements.

Such wrapping must be transparent and colourless and must also fulfil the conditions of the first and second indents of paragraph 1 (a); it may not be used again for wrapping wild game meat.

3. Wrapped wild game meat must be packaged.

4. 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 paragraph 1 are fulfilled.

5. 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 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 meat;

(f) immediately after packaging the meat must be placed in the storage room provided.

6. The packaging referred to in this chapter may contain only cut wild game meat from the same animal species.

CHAPTER IX

Health certificate

The original copy of the health certificate which must accompany wild game 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 specimen in Annex II 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 X

Storage

After post mortem inspection, wild game meat must be chilled or frozen and kept at a temperature which must not at any time exceed 4 °C in the case of small wild game and 7 °C in the case of large wild game if chilled or – 12 °C if frozen.

CHAPTER XI

Transport

1. Wild game meat must be dispatched in such a way that during transport it is protected from anything liable to contaminate it or to impair it, 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 in Chapter X are not exceeded.

2. Wild game meat may not be transported in a vehicle or container which is not clean and has not been disinfected.

3. Carcases, or half carcases, excluding frozen meat packaged in accordance with hygiene requirements, must be suspended throughout transport except in the case of air transport.

   Other cuts 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. They may only be reused after cleaning and disinfection.

4. The official veterinarian must ensure before dispatch that transport vehicles and loading conditions meet the hygiene requirements of this Chapter.

ANNEX II

SPECIMEN

PUBLIC/ANIMAL HEALTH CERTIFICATE

for wild game meat (1) intended for consignment to a Member State after transit through a third country

Exporting country: ..... No (2): .....

Ministry: .....

Competent service: .....

Reference (2): .....

I. **Identification of meat**

Wild game 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 establishments: .....

.....

.....

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

.....

.....

III. **Destination of wild game 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) Wild game meat which has not been treated, other than by chilling or freezing to ensure its preservation.
(2) Optional.
(3) Indicate the number or registration number (railway wagons and lorries), the flight number (aircraft) or the name (ship).
(4) Delete as appropriate.

IV. **Health attestation**

I, the undersigned, official veterinarian, CERTIFY that:

a) the wild game meat of the species described above was obtained in a processing house situated in a region or area subject to animal health restrictions and has been passed as fit for human consumption following a veterinary inspection carried out in accordance with Directive 92/45/EEC (1).

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

c) the wild game or wild game meat (2) is intended for consignment to a Member State after transit through a third country.

Done at ....., on .....

.....

(Signature of official veterinarian)

(1) Including the trichinoscopic examination provided for in Article 3 (3).
(2) Delete whichever B not applicable.

COUNCIL DIRECTIVE 92/65/EEC

of 13 July 1992

laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/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 live animals and products of animal origin are included in the list of products in Annex II to the Treaty; whereas the placing on the market of such animals and products constitutes a source of income for part of the farming population;

Whereas in order to ensure the rational development in this sector and increase productivity, animal health rules for the animals and products should be laid down at Community level;

Whereas the Community must adopt the measures intended to establish the internal market progressively over a period expiring on 31 December 1992;

Whereas in view of the abovementioned objectives the Council has laid down animals health rules applicable to cattle, swine, sheep and goats, equidae, poultry and hatching eggs, fish and fish products, bivalve molluscs, semen of bulls and boars, ovine embryos, fresh meat, poultrymeat, meat products, game meat and rabbit meat;

Whereas animal health rules should be adopted for the placing on the market of animals and products of animal origin which are not yet covered by the abovementioned rules;

Whereas provision should be made for applying this Directive without prejudice to Council Regulation (EEC) No 3626/82 of 3 December 1982 on the implementation in the Community of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (4);

Whereas, as regards certain technical aspects, reference must be made to Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (5) and Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease (6);

Whereas, in respect of the organization of checks and the follow-up thereto, as well as the safeguard measures to be implemented, reference must be made to the general rules laid down in 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 (7);

Whereas, save where otherwise provided, trade in animals and products of animal origin must be liberalized, without prejudice to recourse to possible safeguard measures;

Whereas, given the significant risk of the spread of diseases to which animals are exposed, for certain animals and products of animal origin particular requirements should be specified to be imposed when they are placed on the market for the purposes of trade, particularly when intended for regions with a high health status;

Whereas the specific situation pertaining in the United Kingdom of Great Britain and Northern Ireland and in Ireland given the insular position of those countries, and the fact that they have been free of rabies for a considerable period of time, warrants particular provisions to ensure that the placing on the market in the United Kingdom and Ireland of dogs and cats which do not originate in those countries

(1) OJ No C 327, 30. 12. 1989, p. 57 and OJ No C 84, 2. 4. 1990, p. 102.
(2) OJ No C 38, 19. 2. 1990, p. 134 and OJ No C 149, 18. 6. 1990, p. 263.
(3) OJ No C 62, 12. 3. 1990, p. 47 and OJ No C 182, 23. 7. 1990, p. 25.
(4) OJ No L 384, 31. 12. 1982, p. 1. Last amended by Regulation (EEC) No 197/90 (OJ No L 29, 31. 1. 1990, p. 1).
(5) OJ No 121, 29. 7. 1964, p. 1977/64. Last amended by Directive 91/499/EEC (OJ No L 268, 24. 9. 1991, p. 107).
(6) OJ No L 315, 26. 11. 1985, p. 11. Amended by Directive 90/423/EEC (OJ No L 224, 18. 8. 1990, p. 13.).
(7) OJ No L 224, 18. 8. 1990, p. 29. Last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

does not involve a risk of introducing rabies into those States, without however affecting the abolition of veterinary checks at the frontiers between Member States;

Whereas a health certificate is the most appropriate means of guaranteeing and monitoring compliance with these requirements;

Whereas, to maintain the health situation in the Community, when the animals and products of animal origin referred to in this Directive are placed on the market, they should be made subject to the minimum requirements laid down for trade and compliance therewith monitored in accordance with the principles and rules laid down in 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);

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

Whereas the deadline for transposition into national law, set at 1 January 1994 in Article 29, should not affect the abolition of veterinary checks at frontiers on 1 January 1993,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

This Directive lays down the animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC.

This Directive shall apply without prejudice to the provisions adopted pursuant to Regulation (EEC) No 3626/82.

This Directive shall not affect the national rules applicable to pet animals, although their retention may not jeopardize the abolition of veterinary checks at the frontiers between Member States.

(1) OJ No L 373, 31. 12. 1990, p. 1. Amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

Article 2

1. For the purposes of this Directive:

(a) 'trade' means trade as defined by Article 2 (3) of Directive 90/425/EEC;

(b) 'animals' means specimens of animal species other than those referred to in Directives 64/432/EEC, 90/426/EEC (2), 90/539/EEC (3), 91/67/EEC (4), 91/68/EEC (5), 91/492/EEC (6) and 91/493/EEC (7);

(c) 'approved body, institute or centre' means any permanent, geographically limited establishment, approved in accordance with Article 13, where one or more species of animal are habitually kept or bred, whether or not for commercial ends, and exclusively for one or more of the following purposes:

— display of the animals and education of the public

— conservation of the species;

— basic or applied scientific research or breeding of animals for the purposes of such research;

(d) 'notifiable diseases' means the diseases listed in Annex A.

2. In addition, the definitions, other than those of approved centres and bodies, contained in Article 2 of Directives 64/432/EEC, 91/67/EEC and 90/539/EEC shall apply *mutatis mutandis*.

(2) Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of equidae (OJ No L 224, 18. 8. 1990, p. 42). Amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

(3) Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs (OJ No L 303, 31. 10. 1990, p. 6). Last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991), p. 56).

(4) Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (OJ No L 46, 19. 2. 1991, p. 1).

(5) Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ No L 46, 19. 2. 1991, p. 1).

(6) 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 moluscs (OJ No L 268, 24. 9. 1991, p. 1).

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

CHAPTER II

Provisions applicable to trade

Article 3

The Member States shall ensure that the trade referred to in Article 1, first paragraph, is not prohibited or restricted for animal health reasons other than those arising from the application of this Directive or from Community legislation, and in particular any safeguard measures taken.

Article 4

Member States shall take the necessary measures to ensure that, for the purposes of applying Article 4 (1) (a) of Directive 90/425/EEC, the animals referred to in Articles 5 to 10 of this Directive may without prejudice to Article 13 and to the particular provisions to be adopted in implementation of Article 24, be the subject of trade only if they satisfy the conditions laid down in Articles 5 to 10 and come from the holdings or businesses referred to in Article 12 (1) and (3) of this Directive which are registered by the competent authority and which undertake to:

— have the animals held examined regularly in accordance with Article 3 (3) of Directive 90/425/EEC,

— notify the competent authority, aside from the outbreak of notifiable diseases, of the outbreak of the diseases referred to in Annex B for which the Member State concerned has drawn up a control or monitoring programme,

— comply with the specific national measures to control a disease which is of particular importance to a given Member State and is covered by a programme drawn up in accordance with Article 14 or a decision under Articles 15 (2),

— place on the market for the purposes of trade only animals which show no signs of disease and which come from holdings or areas not subject to any ban on animal health grounds and with respect to animals not accompanied by a health certificate or a commercial document provided for in Articles 5 to 11, only animals accompanied by self-certification by the operator stating that the animals in question do not at the time of dispatch show any obvious signs of disease and that his holding is not subject to any animal-health restrictions,

— comply with the requirements ensuring the welfare of the animals held.

Article 5

1. Member States shall ensure that trade in apes (simiae and prosimiae) is restricted solely to animals consigned from and to a body, institute or centre approved by the competent authorities of the Member States in accordance with Article 13 and that such animals are accompanied by a veterinary certificate corresponding to the specimen in Annex E, the declaration in which must be completed by the official veterinarian of the body, institute or centre of origin to guarantee the animals' health.

2. The competent authority of a Member State may, by way of derogation from paragraph 1, authorize the acquisition by an approved body, institute or centre of apes belonging to an individual.

Article 6

A. Without prejudice to Article 14 and 15, Member States shall ensure that ungulates of species other than those referred to in Directives 64/432/EEC, 90/426/EEC and 91/68/EEC may be the subject of trade only if they meet the following requirements:

1. in general they:

(a) must be identified in accordance with Article 3 (1) (c) of Directive 90/425/EEC;

(b) must not be intended for slaughter under a programme for the eradication of an infectious disease;

(c) must not have been vaccinated against foot-and-mouth disease and must satisfy the relevant requirements of Directive 85/511/EEC and Article 4a of Directive 64/432/EEC;

(d) must come from a holding referred to in Article 3 (2) (b) and (c) of Directive 64/432/EEC which is not the subject of animal health measures, particularly those taken under Directives 85/511/EEC, 80/217/EEC [1] and 91/68/EEC and have been kept therein permanently since birth or for the last thirty days before dispatch;

(e) if imported:

— must come from a third country included in a column entitled 'other ungulates' to be inserted in the list drawn up in accordance with Article 3 of Directive 72/462/EEC [2],

[1] Council Directive 80/217/EEC of 22 January 1980 introducing Community measures for the control of classical swine fever (OJ No L 47, 21. 2. 1980, p. 11). Last amended by Directive 87/486/EEC (OJ No L 280, 3. 10. 1987, p. 21).

[2] Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries (OJ No L 302, 31. 12. 1972, p. 28). Last amended by Directive 91/497/EEC (OJ No L 268, 24. 9. 1991, p. 69).

— must meet specific animal health conditions, to be laid down under the procedure provided for in Article 26, which are at least equivalent to the requirements of this Article;

(f) must be accompanied by a certificate corresponding to the specimen given in Annex E bearing the following declaration:

'Declaration

I, the undersigned (official veterinarian) certify that the ruminant/suida (a) other than that covered by Directive 64/432/EEC:

(a) belongs to the ..... species;

(b) at the time of examination, does not show any clinical sign of any disease to which it is susceptible;

(c) comes from an officially tuberculosis-free/officially brucellosis-free or brucellosis-free herd/a holding not subject to swine-fever restrictions (a) or from a holding where it was subjected with negative results to the tests laid down in Article 6 (2) (a) (ii) of Directive 92/65/EEC.

(a) Delete as appropriate';

2. in the case of ruminants:

(a) they must come from an officially tuberculosis-free and officially brucellosis-free herd in accordance with Directive 64/432/EEC or Directive 91/68/EEC and satisfy, as regards animal health rules, the relevant requirements laid down for the bovine species in Article 3 (2) (c), (d), (f), (g) and (h) of Directive 64/432/EEC or Article 3 of Directive 91/68/EEC;

(b) where they do not come from a herd meeting the conditions laid down in (a), they must come from a holding in which no case of brucellosis or tubercolosis has been recorded in the 42 days preceding loading of the animals and in which the ruminants have, in the 30 days prior to their dispatch, undergone with negative results:

— a tuberculosis reaction test, and

— a test designed to show the absence of antibodies to brucellosis.

The requirements as regards these tests and the definition of the tuberculosis and brucellosis status of these holdings shall be established in accordance with the procedure laid down in Article 26 of this Directive.

Pending the decisions provided for in the preceding subparagraph, national rules shall continue to apply, particularly as regards tuberculosis;

3. in the case of suidae:

(a) they must not have come from an area which is the subject of prohibition measures associated with the presence of African swine fever in accordance with Article 9a of Directive 64/432/EEC;

(b) they must come from a holding which is not subject.to any of the restrictions laid down in Directive 80/217/EEC as a result of classical swine fever;

(c) they must come from a brucellosis-free holding in accordance with Directive 64/432/EEC and satisfy the relevant animal health requirements laid down for swine in Directive 64/432/EEC;

(d) where they do not come from a herd meeting the conditions set out in (c), they must, in the 30 days prior to their dispatch, have undergone with negative results a test designed to show the absence of antibodies to brucellosis.

B. Directive 64/432/EEC is amended as follows:

1. in Article 2 (b) and (c), for 'bovine animal(s)' read 'animal(s) of the bovine species (including *Bubalus bubalus*)';

2. the following Article is inserted:

'Article 10a

Under the procedure laid down in Article 12, the health certificates, a specimen of which is reproduced in Annex F, may be amended or supplemented, in particular in order to take account of the requirements of Article 6 of Directive 92/65/EEC.'

Article 7

A. Member States shall ensure that birds other than those referred to in Directive 90/539/EEC may be the subject of trade only if they meet the following requirements:

1. in general they must:

(a) come from a holding in which avian influenza has not been diagnosed in the 30 days preceeding the dispatch;

(b) come from a holding or an area not subject to restrictions under measures to be applied to combat Newcastle disease.

Pending the implementation of the Community measures referred to in Article 19 of Directive 90/539/EEC, national requirements for combating Newcastle disease shall continue to apply, in compliance with the general provisions of the Treaty;

(c) have, in accordance with the third indent of Article 10 (1) of Directive 91/496/EEC, been quarantined, if they have been imported from a third country, in the holding to which they were taken after they entered the territory of the Community;

2. in addition, psittacidae must:

(a) not come from a holding nor have been in contact with animals from a holding on which psittacosis *(Chlamydia psittaci)* has been diagnosed.

The period of prohibition since the last recorded case and the period of treatment under veterinary supervision recognized under the procedure provided for in Article 26 must be at least two months;

(b) be identified in accordance with Article 3 (1) (c) of Directive 90/425/EEC.

The methods for identifying psittacidae, and in particular sick psittacidae, shall be established under the procedure provided for in Article 26;

(c) be accompanied by a commercial document signed by the official veterinarian or by the veterinarian responsible for the holding or business of origin and empowered for this purpose by the competent authority.

B. In the second subparagraph of Article 2 (2) of Council Directive 91/495/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 [1], the words 'and ratites *(Ratitae)*' shall be inserted in the third line after the words 'Directive 90/539/EEC'.

In point 1 of Article 2 (2) of Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from, third countries of poultry and hatching eggs [2], the words 'and ratites *(Ratitae)*' shall be inserted after the words 'and partridges.'

[1] OJ No L 268, 24. 9. 1991, p. 41.
[2] OJ No L 303, 31. 10. 1990, p. 6.

Article 8

Member States shall ensure that bees *(Apis melifera)* may be the subject of trade only if they meet the following requirements:

(a) come from an area which is not the subject of a prohibition order associated with an occurrence of American foulbrood.

The period of prohibition must continue for at least 30 days following the last recorded case and the date on which all hives within a radius of three kilometres have been checked by the competent authority and all infected hives burned or treated and inspected to the satisfaction of the said competent authority.

In accordance with the procedure laid down in Article 26, and after consulting the Scientific Veterinary Committee, the requirements applied to bees *(Apis melifera)* or equivalent requirements may be applied to bumble bees;

(b) are accompanied by a health certificate corresponding to the specimen in Annex E the declaration in which is completed by the competent authority to certify that the requirements laid down in (a) are met.

Article 9

1. Member States shall ensure that lagomorphs may be the subject of trade only if they meet the following requirements:

(a) they must not come from or have been in contact with animals from a holding on which rabies is present or is suspected of having been present within the last month;

(b) they must come from a holding in which no animal shows clinical signs of myxomatosis.

2. Member States which require a health certificate for movements of lagomorphs in their territory may require animals being sent to them to be accompanied by a health certificate corresponding to the specimen in Annex E, supplemented by the following declaration:

'I, the undersigned, . . ., certify that the above consignment satisfies the requirements of Article 9 of Directive 92/65/EEC and that the animals showed no clinical sign of disease on examination.'

This certificate must be issued by the official veterinarian or by the veterinarian responsible for the holding of origin and empowered for this purpose by the competent authority and for industrial breeding, by the official veterinarian. Member States wishing to use this option shall inform the Commission which must ensure that the requirement laid down in the first paragraph has been satisfied.

3. Ireland and the United Kingdom may require the submission of a health certificate guaranteeing that the requirement laid down in paragraph 1 (a) has been satisfied.

Article 10

1. Member States shall ensure that there is a prohibition on trade in ferrets, mink and foxes which come from or have been in contact with animals from a holding on which rabies is present or is suspected of having been present within the previous six months, inasmuch as no systematic vaccination programme is applied.

2. To be the subject of trade, with the exception of trade between the Member States referred to in paragraph 3, dogs and cats must satisfy the following requirements:

(a) animals more than three months old must:

— show no sign of disease, and particularly of contagious diseases of the species, on the day they are dispatched from the holding,

— be tattooed or have a micro-chip identification system implanted in accordance with detailed rules to be laid down under the procedure provided for in Article 26,

— have after the age of three months, been vaccinated against rabies with an annual booster injection or, at intervals authorized by the Member States of dispatch for that vaccine, by injection of an inactivated vaccine of at least one international antigenic unit (WHO standard) measured in accordance with the activity test by the method described by the European Pharmacopoeia and recognized under the procedure laid down in Article 26.

The vaccination must be certified by an official veterinarian or by the veterinarian responsible for the holding of origin and empowered for this purpose by the competent authority. The vaccination certificate must bear the name of the vaccine and its batch number (self-adhesive label if possible):

— dogs must have been vaccinated against canine distemper,

— be accompanied by an individual passport allowing the animal to be clearly identified and showing the dates of vaccination and/or a certificate corresponding to the specimen shown in Annex E supplemented by the following declaration completed by an official veterinarian or by the veterinarian responsible for the holding of origin and empowered for this purpose by the competent authority:

'I, the undersigned ..... certify that the cats/dogs covered by this certificate satisfy the requirements of Article 10 (2) (a) and (b) and (3) (b) of Directive 92/65/EEC (a) and come from a holding in which no case of rabies has been recorded in the last six months.

(a) Delete as applicable';

(b) animals less than three months old must:

— satisfy the requirements of the first and fifth indents of (a),

— not come from a holding which is the subject of restrictions on the movement of animals on animal health grounds,

— have been born on the holding of origin and have been maintained in captivity since birth.

3. As from 1 July 1994, by way of derogation from paragraph 2, the placing on the market in the United Kingdom and Ireland of cats and dogs not originating in those countries shall be subject to the following conditions:

(a) in general, cats and dogs must

(i) come from a registered holding, registration of which must be suspended by the competent authority where the conditions provided for in Article 4 are no longer met;

(ii) on the day they are dipatched from the holding in question, show no sign of contagious disease;

(iii) have been provided with a system of identification in accordance with detailed rules to be established under the procedure laid down in Article 26;

(iv) have been born on the holding and have been maintained in captivity there since birth with no contact with wild animals susceptible to rabies;

(v) in the case of dogs, have been vaccinated against canine distemper;

(vi) be transported in a means of transport recognized for these purposes by the competent authority of the Member States of dispatch;

(vii) be accompanied by an individual vaccination record allowing the animal and its origin to be clearly identified and showing the dates of vaccination, and by a certificate corresponding to a specimen to be drawn up under the procedure laid down in Article 26 and completed by an official veterinarian or by the veterinarian responsible for the holding of origin and empowered for this purpose by the competent authority;

(b) in addition, they must:

(i) either have been vaccinated against rabies after the age of three months and at least six months before dispatch by injection of an inactivated vaccine of at

least 1 international antigenic unit (WHO standard) measured in accordance with the activity test by the method described by the European pharmacopoeia and recognized under the procedure laid down in Article 26, with annual booster injection, or at intervals authorized by the Member State of dispatch for that vaccine.

The vaccination must be certified by an official veterinarian or by the veterinarian responsible for the holding of origin and empowered for this purpose by the competent authority. The vaccination certificate must bear the name of the vaccine and its batch number (self-adhesive label if possible).

Moreover, have undergone, following a vaccination, a serological test showing a protective antibody titre of at least 0,5 international units, which serological test should be carried out in accordance with WHO specifications. If the test is carried out after the first vaccination it must be carried out between the first and third month after the vaccination.

(ii) or, where the conditions provided for in (i) are not met, be sent under supervision to a quarantine station approved by the Member State of destination to undergo a six-month period of quarantine.

Until 1 July 1994, national regulations applicable with respect to rabies shall remain in force, although such retention may not affect the abolition of veterinary checks at the frontiers between Member States.

4. Ireland and the United Kingdom may without prejudice to paragraphs 2 and 3, retain their national regulations on quarantine for all carnivores, primates, bats and other animals susceptible to rabies covered by this Directive which cannot be shown to have been born on the holding of origin and kept in captivity since birth, although the retention of those regulations may not jeopardize the abolition of veterinary checks at the frontiers between Member States.

5. Decision 90/638/EEC is amended as follows:

1. the following indent is added to Article 1:

'— for programmes to control rabies: the criteria set out in Annex III.';

2. the following Annex is added:

'ANNEX III

Criteria for programmes to control rabies

Programmes to control rabies shall contain at least:

(a) the criteria referred to in points 1 to 7 of Annex 1;

(b) detailed information regarding the region or regions in which the oral immunization of foxes is to take place and its natural limits. This region or these regions must cover at least 6 000 km² or the total national area of a Member State and may include adjacent areas of a third country;

(c) detailed information regarding the vaccines to be used, the distribution system, the density and frequency of bait-laying;

(d) where appropriate, all details and the cost and purpose of schemes to conserve or preserve flora and fauna undertaken by voluntary organizations on the territory covered by these projects.'

6. The Council, acting by a qualified majority on a proposal from the Commission, shall designate a specific institute to establish the criteria necessary for the standardization of the serological tests and shall decide on its responsibilities.

7. Member States shall ensure that the costs of applying the serological test are borne by the importers.

8. This Article, and in particular the application of the serological test provided for in paragraph 3 (b), will be reviewed before 1 January 1997 in the light of developments in the rabies situation in the Member States.

Article 11

1. The Member States shall ensure that, without prejudice to the decisions to be taken in implementation of Articles 21 and 23, only semen, ova and embryos meeting the conditions laid down in paragraphs 2, 3 and 4 are the subject of trade.

2. Semen of the ovine, caprine and equine species must, without prejudice to any criteria to be complied with for the entry of equids in stud books for certain specific breeds:

— have been collected and processed with a view to artificial insemination in a centre approved from the health point of view in accordance with Annex D (I), or, in the case of ovine and caprine animals by way of derogation from the above, in a holding satisfying the requirements of Directive 91/68/EEC,

— have been collected from animals meeting the conditions laid down in Annex D (II) (admission and routine checks on animals),

— have been collected, processed and preserved in accordance with Annex D (III),

— have been accompanied during transport to another Member State by a health certificate corresponding to a specimen to be determined under the procedure provided for in Article 26.

3. Ova and embryos of the ovine/caprine and equine species and of swine must:

— have been removed by a collection team approved by the competent authority of the Member State and processed in an appropriate laboratory from donor females meeting the conditions laid down in Annex D (IV),

— have been treated and stored in accordance with Annex D (III),

— be accompanied during transport to another Member State by a health certificate corresponding to a specimen to be defined under the procedure laid down in Article 26.

Semen used for the insemination of donor females must comply with the provisions of paragraph 2 in the case of sheep, goats and equids and with the provisions of Directive 90/429/EEC for swine. Any additional guarantees may be determined under the procedure laid down in Article 26.

4. Before 31 December 1997 the Commission shall submit a report together with any appropriate proposals on the implementation of this Article in the light in particular of scientific and technological developments.

Article 12

1. The rules on checks established by Directive 90/425/EEC shall apply, in particular as regards the organization of and follow-up to the checks to be carried out, to the animals, semen, ova and embryos covered by this Directive which are accompanied by a health certificate. Other animals must come form holdings subject to the principles of that Directive as regards checks on origin and destination.

2. Article 10 of Directive 90/425/EEC shall apply to animals, semen, ova and embryos covered by this Directive.

3. For the purpose of trade, Article 12 of Directive 90/425/EEC shall extend to dealers who keep, on a permanent or occasional basis, animals referred to in Articles 7, 9 and 10.

4. The communication of the place of destination as provided for in Article 4 (2) of Directive 90/425/EEC shall, in respect of animals, semen, ova or embryos accompanied by a health certificate in accordance with this Directive, take place using the Animo system.

5. Without prejudice to the specific provisions of this Directive, the competent authority shall, where it is suspected that this Directive has not been complied with or there is doubt as to the health of the animals or the quality of the semen, ova and embryos referred to in Article 1, carry out any checks it deems appropriate.

6. Member States shall take the appropriate administrative or penal measures to penalize any infringement of this Directive, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state of the animals referred to in Article 1, that the identification of the animals or the marking of the semen, ova and embryos in question does not comply with this Directive or that the animals or products in question have not undergone the checks provided for in this Directive.

Article 13

1. Trade in animals of species susceptible to the diseases listed in Annex A or to the diseases listed in Annex B, where the Member State of destination applies the guarantee provided for in Articles 14 and 15, and trade in semen, ova or embryos of such animals consigned to and from bodies, institutes or centres approved in accordance with Annex C shall be subject to production of a transport document corresponding to the specimen in Annex E. This document, which must be completed by the veterinarian responsible for the body, institute or centre of origin, must specify that the animals, semen, ova or embryos come from a body, institute or centre approved in accordance with Annex C and must accompany them during transport.

2. (a) To be approved, bodies, institutes or centres shall, as regards notifiable diseases, submit to the competent authority of the Member State all relevant supporting documents relating to the requirements contained in Annex C.

(b) After receiving the file relating to the request for approval or for renewal of approval, the competent authority shall examine it in the light of the information it contains and, where appropriate, of the results of the tests conducted on the spot.

(c) The competent authority shall withdraw approval in accordance with point 3 of Annex C.

(d) Each Member State shall send the Commission a list of approved bodies, institutes and centres, together with any changes to the list. The Commission shall forward this information to the other Member States.

Article 14

1. Where a Member State draws up or has drawn up, either directly or through the breeders, a voluntary or compulsory control or monitoring programme for one of the

diseases referred to in Annex B, it may present the programme to the Commission outlining in particular:

— the distribution of the disease in its territory,

— whether the disease is notifiable,

— reasons for undertaking the programme, taking account of its cost-effectiveness and the significance of the disease,

— the geographical area in which the programme is to be implemented,

— the status categories to be applied to establishments, the requirements for each species when being introduced into a holding and the test procedures to be used,

— the programme monitoring procedures, including the extent of the breeders' involvement in implementing the control or monitoring programme,

— the action to be taken if, for any reason, a holding loses its status,

— the measures to be taken if the results of the tests carried out under the programme are positive,

— the non-discriminatory nature of trade in the territory of the Member State concerned with respect to intra-Community trade.

2. The Commission shall examine the programmes presented by the Member States. Programmes may be approved under the procedure provided for in Article 26 in compliance with the criteria laid down in paragraph 1. Under the same procedure, the additional guarantees, general or limited, which may be required in trade, shall be defined at the same time or at the latest three months after presentation of the programmes. Such guarantees must not exceed those which the Member State implements nationally.

3. Programmes submitted by Member States may be amended or supplemented under the procedure laid down in Article 26. Under the same procedure, amendments may be made to the guarantees referred to in paragraph 2.

Article 15

1. Where a Member State considers that its territory or part of its territory is free from one of the diseases listed in Annex B to which the animals covered by this Directive are susceptible, it shall present to the Commission appropriate supporting documentation, setting out in particular:

— the nature of the disease and the history of its occurrence in its territory,

— the results of surveillance testing based on serological, microbiological, pathological or epidemiological investigation,

— the period during which this disease was notifiable to the competent authorities,

— the period over which the surveillance was carried out,

— where applicable, the period during which vaccination against the disease has been prohibited and the geographical area concerned by the prohibition,

— the arrangements for verifying the absence of the disease.

2. The Commission shall examine the documentation provided for in paragraph 1 and submit to the Standing Veterinary Committee a decision approving or rejecting the plan submitted by the Member State. If the plan is accepted, the additional guarantees, general or specific, which may be required in trade shall be defined under the procedure laid down in Article 26. They must not exceed those which the Member State implements nationally.

Pending a decision, the Member State concerned may maintain in its trade dealings the relevant requirements needed in order to maintain its status.

3. The Member State concerned shall notify the Commission of any change in the particulars specified in paragraph 1. The guarantees defined as laid down in paragraph 2 may, in the light of such notification, be amended or withdrawn under the procedure laid down in Article 26.

CHAPTER III

Provisions applicable to imports into the Community

Article 16

The conditions applicable to imports of animals, semen, ova and embryos covered by this Directive must be at least equivalent to those laid down in Chapter II.

Article 17

1. For the purposes of uniform application of Article 16, the provisions of the following paragraphs shall apply.

2. Only animals, semen, ova and embryos referred to in Article 1 which satisfy the following requirements may be imported into the Community:

(a) they must come from a third country on a list to be drawn up in accordance with paragraph 3 (a);

(b) they must be accompanied by a health certificate corresponding to a specimen to be drawn up under the procedure laid down in Article 26, signed by the competent authority of the exporting country and certifying that the animals, semen, ova and embryos

meet the additional conditions or offer the equivalent guarantees referred to in paragraph 4 and come from approved centres, bodies, institutes or collection centres offering such guarantees.

3. The following shall be established under the procedure laid down in Article 26:

(a) without prejudice to the list provided for in Article 6 (A) (1) (e), a provisional list of third countries or parts of third countries able to provide Member States and the Commission, before the date laid down in Article 29, with guarantees equivalent to those provided for in Chapter II and a list of the collection centres for which they are able to give these guarantees.

This provisional list shall be compiled from the lists of establishments approved and inspected by the competent authorities once the Commission has checked that these establishments comply with the principles and general rules laid down in this Directive

(b) updates of that list in the light of the checks provided for in paragraph 4;

(c) the specific animal health requirements — in particular for the protection of the Community from certain exotic diseases — or guarantees equivalent to those provided for in this Directive.

The specific requirements and equivalent guarantees established for third countries may not be more favourable than those provided for in Chapter II.

4. The list provided for in paragraph 3 may include only third countrys or parts of third countries:

(a) from which imports are not prohibited:

— as a result of the existence of one of the diseases referred to in Annex A or of any other disease exotic to the Community,

— pursuant to Articles 6, 7 and 14 of Directive 72/462/EEC and Article 17 of Directive 91/495/EEC and of Directive 71/118/EEC [1] or, in the case of the other animals covered by this Directive, under a decision taken in accordance with the procedure laid down in Article 26 account being taken of their state of health;

(b) which, in view of their legislation and the organization of their veterinary services and inspection services, the powers of such services and the supervision to which they are subject, have been recognized, in accordance with Article 3 (2) of Directive 72/462/EEC, as capable of guaranteeing the implementation of their legislation in force;

(c) the veterinary services of which are able to guarantee that health requirements at least equivalent to those laid down in Chapter II are being complied with.

5. Experts from the Commission and the Member States shall carry out on-the-spot inspections to verify whether the guarantees given by the third country regarding the conditions of production and placing on the market can be considered equivalent to those applied in the Community.

The experts from the Member States responsible for 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.

6. Pending the organization of the inspections referred to in paragraph 5, national rules applicable to inspection in third countries shall continue to apply, subject to notification, through the Standing Veterinary Committee, of any failure to comply with the guarantees offered in accordance with paragraph 3, found during these inspections.

Article 18

1. Member States shall ensure that the animals, semen, ova and embryos covered by this Directive are imported into the Community only if they:

— are accompanied by a certificate to be drawn up by the official veterinarian.

The specimen certificate shall, depending on the species, be drawn up under the procedure laid down in Article 26,

— have satisfied the checks required by Directives 90/675/EEC and 91/496/EEC [2],

— have undergone, prior to shipment to Community territory, a check by an official veterinarian to ensure that the transport conditions specified in Directive 91/628/EEC [3] have been complied with, in particular as regards watering and feeding,

— have, in the case of the animals referred to in Articles 5 to 10, been quarantined before being placed on the market, in accordance with detailed rules to be established under the procedure laid down in Article 26.

[1] Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat (OJ No L 55, 8. 3. 1971, p. 23). Last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48).

[2] Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directive 89/662/EEC, 90/425/EEC and 90/675/EEC (OJ No L 268, 24. 9. 1991, p. 56).

[3] Council Directive 91/628/EEC of 19 November 1991 on the protection of animals during transport and amending Directives 90/425/EEC and 91/496/EEC (OJ No L 340, 11. 12. 1991, p. 17).

2. Pending the establishment of specific rules for this Article, the national rules applicable to imports from third countries for which such requirements have not been adopted at Community level shall continue to apply, provided they are not more favourable than those laid down in Chapter II.

Article 19

The following shall be decided under the procedure laid down in Article 26:

(a) specific animal health requirements, for imports into the Community, and the nature and content of accompanying documents for animals intended for zoos, circuses, amusement parks or experimental laboratories, according to the species;

(b) additional guarantees to those provided for in respect of the various animal species covered by this Directive, to protect the Community species concerned.

Article 20

The principles and rules 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.

Pending implementation of the decisions provided for in Article 8 (3) and Article 30 of Directive 91/496/EEC, the relevant national rules for applying Article 8 (1) and (2) of the said Directive shall continue to apply, without prejudice to compliance with the principles and rules referred to in paragraph 1 of this Article.

CHAPTER IV

Common final provisions

Article 21

Any specimens of certificates applicable to trade and the animal health conditions to be met in order for it to be possible to trade in animals, semen, ova and embryos other than those covered by Article 5 to 11 shall, where the need arise, be determined under the procedure laid down in Article 26.

Article 22

The Annexes to this Directive shall, where the need arises, be amended under the procedure laid down in Article 26.

Article 23

Under the procedure laid down in Article 26, special requirements may be laid down, if appropriate, by way of derogation from Article 6 (A) (1) (e) and from Chapter II, for the movement of circus and fairground animals and for trade in animals, semen, ova and embryos intended for zoos.

Article 24

1. The Member States shall be authorized to subject the entry into their territory of the animals (including cage birds), semen, ova and embryos referred to in this Directive which have passed through the territory of a third country to production of a health certificate certifying compliance with the requirements of this Directive.

2. Member States which have recourse to the possibility laid down in paragraph 1 shall inform the Commission and the other Member States within the Standing Veterinary Committee.

Article 25

The following shall be added to Annex A to Directive 90/425/EEC:

'Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (1) to Directive 90/425/EEC (OJ No L 268, 14. 9. 1992, p. 54).'

Article 26

Where reference is made to the procedure provided for in this Article, the Standing Veterinary Committee set up by Decision 68/361/EEC [1] shall act in accordance with the rules laid down in Article 17 of Directive 89/662/EEC.

Article 27

Member States which implement an alternative control system providing guarantees equivalent to those laid down in this Directive as regards movements within their terrritory of the animals, semen, ova and embryos which it covers, may grant one another derogations from Article 6 (A) (1) (f), Article 8 (b) and Article 11 (1) (d) on a reciprocal basis.

Article 28

Under the procedure laid down in Article 26, transitional measures may be adopted for a period of three years to

[1] OJ No L 255, 18. 10. 1968, p. 23.

facilitate the transition to the new arrangements established by this Directive.

Article 29

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1994. 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. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.

3. The setting of the deadline for transposition into national law at 1 January 1994 shall be without prejudice to the abolition of veterinary checks at frontiers provided for in Directive 89/662/EEC and 90/425/EEC.

Article 30

This Directive is addressed to the Member States.

Done at Brussels, 13 July 1992.

For the Council

The President

J. GUMMER

ANNEX A

NOTIFIABLE DISEASES IN THE CONTEXT OF THIS DIRECTIVE (a)

Diseases	Species concerned
Newcastle disease, avian influenza	Birds
Psittacosis	Psittacidae
American foulbrood	Bees
Foot-and-mouth disease	Ruminants
Brucellosis (Brucella ssp.)	
Tuberculosis	
Classical swine fever	Suidae
African swine fever	
Foot-and-mouth disease	
Rabies (b)	All susceptible species

(a) Without prejudice to the notifiable diseases provided for in Annex I to Directive 82/894/EEC.
(b) In accordance with Article 2 of Directive 89/455/EEC.

ANNEX B

LIST OF DISEASES FOR WHICH NATIONAL PROGRAMMES MAY BE RECOGNIZED UNDER THIS DIRECTIVE

Mink	Viral enteritis Aleutian disease
Bees	European foulbrood varroasis and acariasis
Apes and felids	Tuberculosis
Ruminants	Tuberculosis
Lagomorphs	Myxomatosis Viral haemorrhagic disease Tularaemia

ANNEX C

CONDITIONS GOVERNING APPROVAL OF BODIES, INSTITUTES OR CENTRES

1. In order to be granted official approval under Article 13 (2) of this Directive, a body, institute or centre as defined in Article 2 (1) (c) must:

   (a) be clearly demarcated and separated from its surroundings;

   (b) be situated at a reasonable distance from agricultural establishments whose health status might be jeopardized by the presence of the approved body, institute or centre;

   (c) be under the control of a veterinarian (1) who monitors the animals, which it must be possible to catch, confine and cage at any time;

   (d) have adequate quarantine facilities;

   (e) have one or more appropriate premises to practise post-mortem examination;

   (f) be free of the diseases listed in Annex A and, as regards the diseases covered in the country concerned by a programme pursuant to Article 14, the diseases listed in Annex B;

   (g) keep up-to-date records indicating:

   — the number of animals of each species present in the establishment, with information as to their ages,

   — the number of animals arriving in the establishment or leaving it, together with information on their transport and the animals' health,

   — observations made during the quarantine period,

   — the results of regular examinations of excreta,

   — the results of blood tests or any other diagnostic procedures,

   — cases of disease and, where appropriate, the treatment administered,

   — the results of the dissection of any animals that die in the establishment, including still-born animals;

   (h) have facilities for appropriate disposal of the bodies of animals which die of a disease;

   (i) be monitored by an official veterinarian who must carry out at least two health checks per year.

   Health checks must include at least:

   — one inspection of all the animals in the establishment,

   — representative samples taken from all the species susceptible to the diseases referred to in Annexes A and B (2) or detection of these diseases by other methods. These samples must be analysed by an approved laboratory to check whether they contain agents of the diseases for each species in Annex A. Samples may be taken throughout the year.

   The results of the laboratory tests on the samples taken during the health checks must reveal no evidence of the pathogens in question;

   — examination of the records which must be kept.

2. Approval shall be retained where the following requirements are met:

   (a) the animals brought into the establishment must come from another approved centre, institute or body;

   (b) if animals covered by Directive 64/432/EEC are held in an approved centre, institute or body, they may leave the establishment only under official control;

   (c) health checks in the approved centre, institute or body must be carried out twice a year, in accordance with point 1 (h) of this Annex.

   (d) the results of the laboratory tests on the samples must reveal no trace of agents of the diseases referred to in Annexes A and B (2);

(1) Responsible for day-to-day compliance with the animal health requirements of this Directive.
(2) Inasmuch as one of these diseases is notifiable in the Member State concerned.

(e) any suspect deaths or the presence of any other symptom suggesting that animals have contracted one or more of the diseases referred to in Annexes A and B [1] must be notified without delay to the competent authority.

3. Approval may be suspended, restored or withdrawn in the following circumstances:

(a) where notification is given within the meaning of 2 (d) of this Annex, the competent authority shall temporarily suspend approval of the approved centre, body or institute;

(b) a sample taken from a suspect animal is forwarded to the approved laboratory to test for the presence of the pathogens in question. The test results shall immediately be forwarded to the competent authority;

(c) where the official department has been informed of suspicions as to the presence of one of the diseases referred to in Annexes A and B [1], it shall reacts, as regards the laboratory tests, the epizootiological examination, the measures to be taken against the disease and the withdrawal of approval, as if the disease had been notified, in accordance with the Directive governing measures in this field to be taken against the diseases and trade in animals;

(d) where the test results show no signs of the pathogens concerned, the offical department shall reinstate approval;

(e) the body, institute or centre shall again be approved only where, after eradication of the sources of infection, the conditions laid down in point 1 of this Annex, with the exception of point 1 (f), are again fulfilled;

(f) the competent authority shall inform the Commission of the suspension, restoration or withdrawal of approval.

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[1] Inasmuch as one of these diseases is notifiable in the Member State concerned.

ANNEX D

CHAPTER I

I. *Conditions governing the approval of semen collection centres*

Semen collection centres must:

1. be placed under the supervision of a 'centre veterinarian';
2. have different and physically separate premises for:
   - accommodating and isolating animals,
   - collecting semen,
   - cleaning and disinfecting equipment,
   - processing semen,
   - storing semen;
3. be built or kept separate in such a way as to prevent any contact with animals outside the centre;
4. have premises such as described at 2 which are easily cleaned and disinfected,

II. *Conditions for the supervision of semen collection centres*

Semen collection centres must:

1. be monitored to ensure that only animals whose semen is to be collected are kept there. However, other domestic animals may stay in these centres provided they meet the general conditions set out below,
2. be monitored to ensure that a register is kept showing
   - the identity of the animals present in the centre,
   - any movements of animas (entering and leaving),
   - the health checks made,
   - the health history,
   - the destination of the semen,
   - the storage of the semen;
3. be inspected at least twice a year by an official veterinarian to ensure that the approval and supervision conditions are met;
4. employ competent staff who have received adequate training on disinfection and hygiene techniques to allow the spread of disease to be avoided;
5. be monitored to ensure that
   - the collection, processing and storage of semen is carried out only in premises set aside for these purposes,
   - all utensils coming into contact with the semen or the donor animal during collection or processing are properly disinfected or sterilized before each use,
   - any recipient for the storage or transport of semen is disinfected or sterilized before use;
6. be sure to use:
   - products of animal origin used in the processing of the semen (additive or diluent) which present no health risks or which have undergone prior processing to preclude such risks,
   - a cryogenic agent which has not previously been used for other products of animal origin;
7. ensure that each quantity of semen is adequately identified in such a way that the date of collection, the breed and the identity of the donor animal may be established as well as the name of the approved centre which made the collection.

CHAPTER II

Conditions applicable in collection centres

Requirements as regards the admission of donor males

A. STALLIONS

Only stallions which, to the satisfaction of the official veterinarian, meet the following requirements may be used for the collection of semen:

1. they must be in good health at the time of collection

2. they must satisfy the requirements of Directive 90/426/EEC and come from holdings which also satisfy those requirements;

3. during the 60 days before the first collection they must have undergone with negative results the following tests:

   (a) to detect equine infectious anaemia, an agar-gel immunodiffusion test, known as the 'Coggins test':

   (b) to detect viral artheritis, a sero-neutralization test (dilution < $^1/_4$) supplemented, in the event of a positive result, by virological examination of total semen with a negative result;

   (c) to detect contagious equine metritis by isolating the *Taylorella equigenitalis* germ, at least a test of samples taken from the urethra and the pre-ejaculatory fluid.

   The result of these tests must be certified by a laboratory recognized by the competent authority.

   During the period mentioned in the first paragraph of 3 above, and during the collection period, stallions may not be allowed do serve naturally.

B. SHEEP AND GOATS

1. Only sheep and goats from centres or holdings which, to the satisfaction of the official veterinarian, meet the following requirements may be used for the collection of semen:

   (a) they are in good health on the day the semen is collected;

   (b) they meet the requirements laid down in Articles 4, 5 and 6 of Directive 91/68/EEC on intra-Community trade.

   In addition, donor animals must undergo, during the thirty days before the collection, with negative results:

   — a test to detect brucellosis (B. melitensis) in accordance with Annex C to Directive 91/68/EEC,

   — a test for contagious epididymitis (B. ovis) in accordance with Annex D to Directive 91/68/EEC,

   — a test for the Border disease virus;

   (c) they have undergone the relevant tests or checks designed to guarantee compliance with the requirements set out in (a) and (b) above.

2. The tests referred to in 1. must be carried out by a laboratory approved by the Member State.

C. If any of the tests referred to in A or B proves positive, the animal must be isolated and the semen collected from it since the last negative test may not be placed on the market. The same applies to semen collected from the other animals at the holding or collection centre since the date on which the positive test was carried out. Trade may not resume until the health status of the centre has been re-established.

CHAPTER III

Requirements applicable to semen, ova and embryos

Semen, ova and embryos must have been collected, processed, washed and preserved with a biological product free of living micro-organisms in accordance with the following principles:

(a) the washing of ova and embryos must be carried out in accordance with Article 11 (3) of this Directive. Their pellucid zone must remain intact before and after washing. Only ova and embryos from one and the same donor may be washed at any one time. After washing, the pellucid zone of each ovum or embryo must be examined over its entire surface area under a magnification of at least 50 and be certified as being intact and free of any foreign body adhering to it;

(b) the medium and solutions used for the collection, freezing and conservation of ova and embryos must be sterilized in accordance with approved methods as laid down in Article 11 (3) and handled in such a way that they remain sterile. Antibiotics must be added to the collection, washing and conservation mediums in accordance with detailed rules to be determined under the procedure laid down in Article 26;

(c) all materials used for the collection, handling, washing, freezing and conservation of ova or embryos must be sterilized before use;

(d) they must have been subjected, in accordance with Article 11 (2), to additional tests to be established under the procedure provided for in Article 26, in particular of the collection or washing liquids, so as to establish that no pathogens are present;

(e) they must be kept in sterile recipients (ampoules, straws, duly identified by a method to be established under the procedure laid down in Article 26):

— containing only products from one male or female donor,

— sealed at the time of freezing in alcohol or fresh liquid nitrogen, and labelled,

and be placed in sterilized liquid nitrogen containers which present no risk of contamination to the products;

(f) they must be stored in approved conditions for a minimum period of 30 days prior to dispatch;

(g) they must be transported in flasks which have been cleaned, disinfected or sterilized before use.

CHAPTER IV

Donor females

Females may be used for the collection of embryos or ova only if they meet, to the satisfaction of the official veterinarian, the requirements of the relevant Directives on intra-Community trade in live animals for breeding and production for the breed concerned, viz. Directive 64/432/EEC for swine, Directive 90/426/EEC for equids and Directive 91/68/EEC for ovine and caprine animals and come from herds which also meet the said requirements.

ANNEX E

CERTIFICATE

EUROPEAN COMMUNITY

1. Consigner (name and address in full) 3. Consignee (name and address in full)	**HEALTH CERTIFICATE** **No** **ORIGINAL (a)** 2. Member State of origin 4. COMPETENT AUTHORITY
	5. Address — of holding of origin or of officially approved body, institute or centre of origin (b) — of holding or dealer of destination or of officially approved body, institute or centre of destination (b)
6. Place of loading 7. Means of transport	
8. Species	
9. Number of animals/hives/or queens (with attendants) (b)	
10. Batch identification	
11. ATTESTATION (c) Done at ....., on	Signature: Name in block capitals: Title and position:

(a) A separate certificate is to be provided for each consignment and the original must accompany the consignment to the final destination; its period of validity is 10 days.
(b) Delete as appropriate.
(c) Complete in accordance with Articles 5 to 11 of Directive 92/65/EEC in the 24 hours before the animals are loaded.

COUNCIL DIRECTIVE 92/67/EEC

of 14 July 1992

amending Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the internal market

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 the Community is to adopt measures to establish the internal market progressively during the period up to 31 December 1992;

Whereas Directive 89/662/EEC (3) stipulates that the veterinary checks in certain animal products are no longer to be carried out at the Community's internal frontiers;

Whereas, since adoption of Directive 89/662/EEC, the Council has set principles for the organization of veterinary checks on products from third countries brought into the Community; whereas in this connection account must be taken of the provisions of 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 (4) and of Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (5);

Whereas, pursuant to the third subparagraph of Article 14 of Directive 89/662/EEC the Council is to determine the final arrangements applicable to trade in the products listed in Annex B before 31 December 1991;

Whereas, pursuant to the fourth subparagraph of Article 21 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 (6), these must be included in the scope of Directive 89/662/EEC and of the said Directive the animals and products of animal origin not covered by the said Directives.

Whereas, pursuant to Article 21 of Directive 89/662/EEC, the Council is to determine the arrangements applicable on the expiry of the transitional provisions laid down in Article 20; whereas in this connection account must be taken of the progress made in the Community both on setting rules for products from third countries and on harmonization of control measures for foot-and-mouth disease and swine fever, as embodied in Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease, Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine and Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat or meat products from third countries (7), and in Council Directive 91/685/EEC of 11 December 1991 amending Directive 80/217/EEC introducing Community measures for the control of classical swine fewer (8);

Whereas, given the favourable progress of harmonization on veterinary matters, all veterinary checks at internal frontiers on animal products should be discontinued with effect from 1 July 1992,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

1. in Article 6 (2) the date of 1 January 1993 shall be replaced by 1 July 1992;

2. in the first subparagraph of Article 8 (2) the words 'except in case covered by the fourth subparagraph,' shall be added;

(1) OJ No C 164, 1. 7. 1992, p. 28.
(2) Opinion delivered on 1 July 1992 (not yet published in the Official Journal).
(3) OJ No L 395, 30. 12. 1989, p. 13. Last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).
(4) OJ No L 373, 31. 12. 1990, p. 1. Amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).
(5) OJ No L 268, 24. 9. 1991, p. 56. Amended by Directive 89/628/EEC (OJ No L 340, 11. 12. 1991, p. 17).
(6) OJ No L 224, 18. 8. 1990, p. 29. Amended by Directive 91/628/EEC (OJ No L 340, 11. 12. 1991, p. 17).
(7) OJ No L 224, 18. 8. 1990, p. 13.
(8) OJ No L 377, 31. 12. 1991, p. 1.

3. in the fourth subparagraph of Article 8 (2) the words 'and without prejudice to the aforementioned rights of appeal' shall be deleted;

4. in the first subparagraph of Article 14 of the words 'Until 31 December 1992' shall be deleted;

5. in Article 14, the second and third subparagraphs shall be replaced by the following subparagraph:

'Member States shall notify the Commission and the other Member States of the conditions and procedures applicable to trade in the products referred to in the first subparagraph.';

6. Article 16 shall be replaced by the following:

'Article 16

1. Member States shall submit to the Commission, in harmonized form, basic information on veterinary checks carried out under this Directive.

2. The Commission shall examine the information referred to in paragraph 1 within the Standing Veterinary Committee, it may, in accordance with the procedure laid down in Article 18, adopt suitable measures.

3. Detailed rules for the application of this Article, in particular with regard to frequency of communication of information, the form in which it is to be given and its nature, shall be drawn up in accordance with the procedure laid down in Article 18.';

7. Article 19 (1) shall be deleted;

8. Article 20 shall be replaced by the following:

'Article 20

With a view to the progressive implementation of the checking arrangements provided for by this Directive, Member States may, until 31 December 1992, carry out, during transport:

— a documentary check on the products referred to in Annex A and B or on products imported from third countries,

— sample veterinary checks of a non-discriminatory nature on the products referred to in Annex B.';

9. Article 21 shall be deleted;

10. the following subparagraph shall be added to Annex B:

'Other products of animal origin not covered by Annex A to this Directive or by Annex A or Annex B, section B, to Directive 90/425/EEC (*); these products shall be defined in accordance with the procedure provided for in Article 18.

(*) OJ No L 224, 18. 8. 1990, p. 29. Directive last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).'

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1992. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, the provisions shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of domestic law they adopt in the field covered by this Directive.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 14 July 1992.

For The Council

The President

J. GUMMER

COUNCIL DIRECTIVE 92/60/EEC

of 30 June 1992

amending Directive 90/425/EEC 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

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 the Community is to adopt measures designed to establish the internal market progressively over a period expiring on 31 December 1992;

Whereas Directive 90/425/EEC (3) provides that veterinary checks on certain live animals and animal products are no longer to be carried out at the Community's internal borders;

Whereas, since adopting Directive 90/425/EEC, the Council has fixed the principles governing the organization of veterinary checks on live animals and animal products entering the Community from third countries; whereas, in this respect, account should be taken of Council Directive 70/675/EEC of 10 December 1990, laying down the principles govering the organization of veterinary checks on products entering the Community from third countries (4) and Council Directive 91/496/EEC 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 (5);

Whereas the fourth paragraph of Article 21 of Directive 90/452/EEC provides for the inclusion in the scope of the said Directive, and of 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 (6) of live animals and products of animal origin not covered by the said Directives;

Whereas Article 25 of Directive 90/425/EEC stipulates that the arrangements which are to apply when the transitional provisions provided for in Article 24 expire must be determined; whereas, in this regard, account should be taken of the progress made in the Community as regards both the adoption of rules concerning live animals and animal products from third countries and the harmonization of measures to control foot-and-mouth disease and swine fever, specifically Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease, Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine and Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat or meat products from third countries (7) and Council Directive 91/685/EEC of 11 December 1991 amending Directive 80/217/EEC introducing Community measures for the control of classical swine fever (8);

Whereas, particularly in the light of the progress made in harmonizing veterinary rules, provision should be made for the abolition, from 1 July 1992, of veterinary checks carried out at internal borders on all live animals and animal products;

Whereas, however, provision must be made for specific rules concerning the veterinary checks applicable to movements of pets accompanied by and under the responsibility of a natural person, where such movements are not the subject of a commercial transaction,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/425/EEC is herby amended as follows:

1. the following paragraph shall be added to Article 1:

   'This Directive shall not apply to veterinary checks on movements between Member States of pets accompanied by and under the responsibility of a natural person, where such movements are not the subject of a commercial transaction.';

2. in Article 7 (2), '1 January 1993' shall be replaced by '1 July 1992';

(1) OJ No C 122, 14. 5. 1992, p. 18.
(2) OJ No C 176, 13. 7. 1992.
(3) OJ No L 224, 18. 8. 1990, p. 29. Last amended by Directive 91/628/EEC (OJ No L 340, 11. 12. 1991, p. 17).
(4) OJ No L 373, 31. 12. 1990, p. 1.
(5) OJ No L 268, 24. 9. 1991, p. 56.
(6) OJ No L 395, 30. 12. 1989, p. 13.
(7) OJ No L 224, 18. 8. 1990, p. 13.
(8) OJ No L 377, 31. 12. 1991, p. 1.

3. in the first paragraph of Article 21, the words 'until 31 December 1992' shall be deleted;

4. the second paragraph of Article 21 is replaced by the following:

'Member States shall communicate to the Commission and the other Member States the conditions and procedures applicable to trade in the animals and products referred to in the first paragraph.';

5. the last sentence of the fourth paragraph of Article 21 shall be deleted;

6. Article 22 shall be replaced by the following:

'Article 22

1. Member States shall submit to the Commission, using a harmonized model, the relevant information concerning the checks carried out pursuant to this Directive.

2. The Commission shall examine the information referred to in paragraph 1 within the Standing Veterinary Committee. It may adopt appropriate measures in accordance with the procedure laid down in Article 18.

3. Detailed rules for the application of this Article, in particular the frequency of communication of information, the model to be used and the type of information required, shall be laid down in accordance with the procedure laid down in Article 18.';

7. Article 24 shall be replaced by the following:

'Article 24

Until 31 December 1992 in order to permit the gradual implementation of the checking arrangements laid down by this Directive, Member States may operate:

— documentary checks during transport of animals and products covered by Annexes A and B or imported from third countries,

— spot veterinary checks of a non-discriminatory nature during transport of animals and products covered by Annex B;';

8. Article 25 shall be deleted;

9. Part A of Annex B shall be replaced by the following:

'A. Veterinary legislation — Other live animals not covered by Annex A.I.';

10. Part B of Annex B shall be replaced by the following:

'B. Veterinary legislation — Semen, ova and embryos not covered by Annex A.I.'

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with 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. Member States shall communicate to the Commission the texts of the main provisions of domestic law which they adopt in the field governed by this Directive.

Article 3

This Directive is addressed to the Member States.

Done at Luxembourg, 30 June 1992.

For the Council

The President

Arlindo MARQUES CUNHA