►B

COUNCIL DIRECTIVE

of 21 December 1976

►M12 on health problems affecting the production and marketing of meat products and certain other products of animal origin ◄

(77/99/EEC)

(OJ L 26, 31.1.1977, p. 85)

Amended by:

		Official Journal		
		No	page	date
►M1	Council Directive 80/214/EEC of 22 January 1980	L 47	3	21.2.1980
►M2	Council Directive 81/476/EEC of 24 June 1981	L 186	20	8.7.1981
►M3	Council Directive 85/327/EEC of 12 June 1985	L 168	49	28.6.1985
►M4	Council Directive 85/328/EEC of 20 June 1985	L 168	50	28.6.1985
►M5	Council Directive 85/586/EEC of 20 December 1985	L 372	44	31.12.1985
►M6	Council Regulation (EEC) No 3768/85 of 20 December 1985	L 362	8	31.12.1985
►M7	Council Regulation (EEC) No 3805/87 of 15 December 1987	L 357	1	19.12.1987
►M8	Council Directive 88/658/EEC of 14 December 1988	L 382	15	31.12.1988
►M9	Council Directive 89/227/EEC of 21 March 1989	L 93	25	6.4.1989
►M10	Council Directive 89/662/EEC of 11 December 1989	L 395	13	30.12.1989
►M11	Council Directive 92/45/EEC of 16 June 1992	L 268	35	14.9.1992
►M12	Council Directive 92/5/EEC of 10 February 1992	L 57	1	2.3.1992
►M13	Council Directive 92/116/EEC of 17 December 1992	L 62	1	15.3.1993
►M14	Council Directive 92/118/EEC of 17 December 1992	L 62	49	15.3.1993
►M15	Council Directive 95/68/EC of 22 December 1995	L 332	10	30.12.1995
►M16	Council Directive 97/76/EC of 16 December 1997	L 10	25	16.1.1998

Amended by:

►A1	Act of Accession of Greece	L 291	17	19.11.1979
►A2	Act of Accession of Austria, Sweden and Finland	C 241	21	29.8.1994
	(adapted by Council Decision 95/1/EC, Euratom, ECSC)	L 1	1	1.1.1995

Corrected by:

►C1 Corrigendum, OJ L 68, 15.3.1977, p. 35 (77/99/EEC)

►C2 Corrigendum, OJ L 76, 24.3.1977, p. 26 (77/99/EEC)

►C3 Corrigendum, OJ L 44, 20.2.1990, p. 34 (88/658/EEC)

▼B

COUNCIL DIRECTIVE

of 21 December 1976

►M12 on health problems affecting the production and marketing of meat products and certain other products of animal origin ◄

(77/99/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament ([1]),

Whereas, since the establishment of the common organization of the markets, meat products may move freely within the Community; whereas, however, intra-Community trade in these products is curbed by the existence of different health requirements in this sector in the various Member States; whereas, in order to remove such disparities, it is necessary to substitute common provisions for these national requirements;

Whereas, in order to guarantee the quality of the products in question from the health point of view, it is necessary to use, in their manufacture, only that fresh meat obtained in accordance with the Community standards laid down in Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat ([2]), as last amended by Directive 75/379/EEC ([3]), Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat ([4]), as last amended by Directive 75/379/EEC, and also 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 ([5]), as last amended by Directive 75/379/EEC; whereas meat products must be manufactured, stored and trasnported in conditions offering every guarantee as regards health; whereas the need for manufacturing and processing establishments to obtain approval is likely to facilitate supervision of compliance with these conditions; whereas provision should be made for a procedure intended to settle any disputes which may arise between Member States as to the justification of the approval of a manufacturing establishment;

Whereas, moreover, Community control arrangements should be introduced to ensure that the standards laid down in this Directive are applied uniformly in all Member States; whereas provision should be made for the procedure for such controls to be determined according to a Community procedure within the Standing Veterinary Committee set up by the Council Decision of 15 October 1968 ([6]);

Whereas provision should be made for the possibility of derogating from certain provisions of this Directive in respect of certain meat products which contain other foodstuffs and which contain a minimal percentage of meat; whereas these derogations should be made according to a Community procedure within the Standing Veterinary Committee;

Whereas, as regards intra-Community trade, the issue of a health certificate drafted by the competent authority is considered to be the best way of assuring the competent authorities of the country of destination that a consignment of meat products complies with this Directive;

([1]) OJ No C 114, 11. 11. 1971, p. 40.
([2]) OJ No 121, 29. 7. 1964, p. 2012/64.
([3]) OJ No L 172, 3. 7. 1975, p. 17.
([4]) OJ No L 55, 8. 3. 1971, p. 23.
([5]) OJ No L 302, 31. 12. 1972, p. 28.
([6]) OJ No L 255, 18. 10. 1968, p. 23.

▼B

whereas this certificate must accompany the consignment of these products to the place of destination;

Whereas Member States must have the right to prohibit the introduction into their territory of meat products from another Member State which prove unfit for human consumption or do not comply with Community health provisions;

Whereas, in such cases, the consignor should, at his own request or upon request of his representative, be allowed to have the meat products returned to him unless there are health reasons to the contrary;

Whereas, in case of prohibition or restriction, the reasons therefor should be made known to the consignor or his representative and also, in certain cases, to the competent authorities of the exporting country;

Whereas, in the event of a dispute between himself and the authorities of the Member State of destination as to the justification for prohibition or restriction, the consignor should be enabled to obtain the opinion of an expert;

Whereas, in order to facilitate the implementation of the proposed measures, a procedure should be provided for close cooperation betwen the Member States and the Commission in the Standing Veterinary Committee,

HAS ADOPTED THIS DIRECTIVE:

▼M12

Article 1

1. This Directive lays down health rules for the production and placing on the market of meat products and other products of animal origin intended, after treatment, for human consumption or for the preparation of other foodstuffs.

2. This Directive shall not apply to the preparation and storage, in retail shops or in premises adjacent to sales points, of meat products and other products of animal origin intended for human consumption, where the preparation and storage are performed solely for the purpose of supplying the consumer directly.

Article 2

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

(a) meat products: products prepared from or with meat which has undergone treatment such that the cut surface shows that the product no longer has the characteristics of fresh meat.

However, the following shall not be regarded as meat products:

(i) meat which has undergone only cold treatment; such meat shall remain subject to the rules in the Directives referred to in (d);

(ii) products subject to Council Directive ►**M16** 94/65/EC ◄ of 14 December 1994 laying down the requirements for the production of, and trade in, minced meat, meat in pieces of less than 100 grams and meat preparations and amending Directives 64/433/EEC, 71/118/EEC and 72/462/EEC ([1]);

(b) other products of animal origin:

(i) meat extracts;

(ii) rendered animal fat: fat derived from rendering meat, including bones, and intended for human consumption;

(iii) greaves: the protein-containing residue of rendering, after partial separation of fat and water;

([1]) OJ No L 382, 31. 12. 1988, p. 3.

▼**M14**

▼**M12**

►**M14** (iv) ◄ meat powder, powdered rind, salted or dried blood, salted or dried blood plasma;

►**M14** (v) ◄ stomachs, bladders and intestines, cleaned, salted or dried, and/or heated;

(c) prepared meat meals; wrapped meat products corresponding to culinary preparations, cooked or pre-cooked and preserved by cold;

(d) meat: meat as defined in:

— Article 2 (a) of Directive 64/433/EEC,

— Article 2 of Directive 71/118/EEC,

— Article 2 of Directive 72/461/EEC,

— Article 2 of Directive 72/462/EEC,

— Article 2 of Directive ►**M16** 94/65/EC ◄,

— Article 2 (1) and (2) of Directive 91/495/EEC;

(e) raw material: any animal product used as an ingredient to obtain products referred to in (a) and (b) or used in the preparation of prepared meals;

(f) treatment: chemical or physical process such as heating, smoking, salting, marinating, curing or drying, intended to lengthen the preservation of meat or animal products whether or not associated with other foodstuffs, or a combination of these various processes;

(g) heating: use of dry or damp heat;

(h) salting: use of salt;

(i) curing: distribution of salts throughout the product;

(j) maturing: treatment of salted raw meat, applied under climatic conditions which, in the course of a slow and gradual reduction of humidity, are capable of generating natural fermentation or enzymatic processes, involving changes over a period of time which give the product typical organoleptic characteristics and ensure its preservation and wholesomeness at normal ambient temperature;

(k) drying: natural or artificial reduction of the water content;

(l) batch: a quantity of a meat product which is covered by the same accompanying commercial document or health certificate;

(m) 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 product concerned as well as the initial wrapper or initial container itself;

(n) 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;

(o) hermetically sealed container: container intended to protect the contents against the entry of microorganisms during and after heat treatment and which is impermeable to air;

(p) establishment: any undertaking manufacturing the products referred to in (a), (b) and (c);

(q) rewrapping centre: a workshop or depot where batches intended for placing on the market are reassembled and/or rewrapped;

(r) 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;

(s) competent authority: the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence.

▼**M12**

Article 3

A. Each Member State shall ensure — without prejudice to the conditions laid down in Article 4 — that meat products placed on the market:

1. have been prepared and stored in an establishment approved and supervised:

   — in accordance with Article 8, and meeting the requirements of this Directive, in particular those of Annex A and Chapters I and II of Annex B,

   or

   — ►**M16** in accordance with Article 9(1) ◄, in the case of establishments which do not have an industrial structure or production capacity;

▼**M16**

   or, which have been registered and inspected in accordance with Article 9(2);

▼**M13**

2. have been prepared from fresh meat as defined in Article 2 (d), on the understanding that meat imported from a third country must meet the minimum requirements of Chapter III of Directive 71/118/EEC and have been inspected in accordance with Directive 90/675/EEC.

▼**M12**

   Meat declared unfit for consumption in compliance with the requirements of Articles 5 and 6 of Directive 64/433/EEC ►**M13** and the third subparagraph of Article 4 (1), and Chapter IX of Annex I to Directive 71/118/EEC, and in general any meat declared unfit for human consumption under Community rules ◄ and the following items may not be used in the preparation of meat products:

   (a) genital organs of female or male animals, except testicles;

   (b) urinary organs, except the kidneys and the bladder;

   (c) the cartilage of the larynx, the trachea and the extralobular bronchi;

   (d) eyes and eyelids;

   (e) the external, auditory meatus;

   (f) corneous tissues;

   (g) in poultry, the head, — except the comb and the ears, the wattles and caruncles — the oesophagus, the crop, the intestines and the genital organs.

   Items may be added to or removed from this list in accordance with the procedure laid down in Article 20;

3. have been prepared in accordance with the requirements of Chapter III of Annex B and, in the case of pasteurized or sterilized products in hermetically sealed containers or of prepared meals, comply with the requirements of Annex B, Chapter VIII, or Chapter IX respectively;

4. have undergone the establishment's own checks provided for in Article 7 and are supervised by the competent authority in accordance with Chapter IV of Annex B;

5. if necessary, also meet the requirements laid down in Article 7 (2);

6. where wrapping, packaging or labelling take place, have been wrapped, packaged or labelled in accordance with Chapter V of Annex B on the spot or in wrapping centres specially approved by the competent authority for that purpose.

   However, pending the adoption of Community rules, the provisions of this Directive concerning the sales description of meat

▼M12

products shall not apply to products of designated origin or to typical products;

7. without prejudice to the marking requirements of Directive 80/215/EEC, have been marked, on the responsibility of the operator or manager of the establishment, with:

   — a national health mark, where the raw material used is marketed with that mark,

   — a mark to be determined in accordance with the procedure laid down in Article 20 where the meat used must, under Community law, be marketed locally,

   — in other cases, a health mark in accordance with Chapter VI of Annex B.

   The mark must be printed on the label or affixed to the product or the wrapping, on the understanding that the printing or reprinting of labels or marks must be authorized by the competent authority;

8. have been handled, stored and transported in accordance with Chapter VII of Annex B and, if they are stored in a cold-storage plant separate from the establishment, this plant must have been approved and inspected in accordance with Article 10 of Directive 64/433/EEC;

9. are accompanied during transportation by:

▼M16

▼M12

►M16 (a) ◄ an accompanying commercial document which must:

   — in addition to the particulars provided for in Annex B, Chapter VI, point 4, bear a code number by which the competent authority responsible for supervising the establishment of origin 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,

   — until 31 December 1996, in the case of the meat products referred to in the second subparagraph of (b) below intended for the Hellenic Republic 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 meat products concerned meet the requirements of this Directive;

►M16 (b) ◄ a health certificate in accordance with Annex D, in the case of products referred to in Article 1 obtained from meat from a slaughterhouse situated in a region or area subject to a restriction on animal health grounds, or from meat referred to in Article 6 of Directive 64/433/EEC, or from products to be sent to another Member State, after transit through a third country in a sealed means of transport.

   This obligation shall not apply to meat products in hermetically sealed containers and having undergone one of the treatments referred to in Annex B, Chapter VIII, point B, first indent, if the health mark is indelibly marked on the container in accordance with the provisions to be drawn up under the procedure laid down in Article 20.

Detailed rules for applying (b), and in particular those concerning the allocation of code numbers and the compilation of one or more lists identifying the competent authorities, shall be adopted in accordance with the procedure laid down in Article 20.

B. Pending possible Community rules on ionization, meat products may not have been subjected to ionizing radiation.

▼M12

This provision shall not affect national rules applicable to ionization for medical purposes.

Article 4

Member States shall ensure that, in addition to the general requirements laid down in Article 3:

1. meat products:

   (a) have been prepared by heating, curing, marinating or drying, which processes may be combined with smoking or maturing, possibly under specific microclimatic conditions, and have been associated, in particular, with certain curing agents in compliance with Article 16 (2). The meat products may also be associated with other foodstuffs and condiments;

   (b) have, if appropriate, been obtained from a meat product or from a meat preparation;

2. until the expiry of the derogations provided for in Directive 71/118/EEC and Directive 91/498/EEC, premises, tools and equipment used for the preparation of meat products from or with meat bearing the EEC health mark may only be used for the preparation of meat products from or with meat which does not bear that mark following authorization from the competent authority and provided that all precautions are taken, to the satisfaction of that authority, to avoid any confusion between products from meat with and without the mark;

3. the meat products referred to in the first and second indents of Article 3 (7) cannot be sent to the territory of another Member State and their national or local marketing is strictly supervised.

Article 5

The Council, acting by a qualified majority on a proposal from the Commission, shall lay down the health and hygiene rules to be met by prepared meals, other than prepared meat meals, obtained from raw materials of animal origin not covered by this Directive. Pending the Council's decision, Member States shall ensure that, where they are manufactured in an establishment defined in Article 2 (p), the prepared meals in question comply with the hygiene rules laid down in Annex A, Chapter II, and that such meals also meet the specific requirements set out in Annex B, Chapter IX, and are supervised in accordance with Article 7.

Article 6

1. Member States shall ensure that other products of animal origin:

— have been obtained in establishments which meet the requirements of Article 7, have been authorized and registered in accordance with Article 11, meet the standards of Annex A and are inspected in accordance with Article 8,

— are manufactured in accordance with the specific conditions laid down in Annex C,

— are inspected as provided for in Chapter IV of Annex B,

— are accompanied, as provided for in Article 3 (9) (b) (i), by a commercial document specifying the origin of the products.

▼M14

2. Under the procedure laid down in Article 20, additional conditions may be set for the other products of animal origin so as to ensure the protection of public health.

▼M12

Article 7

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

▼M12

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

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

— establishment and implementation of methods for monitoring and checking such critical points,

— taking samples for analysis in a laboratory approved 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 the products referred to in paragraph 2 for which this period may be reduced to six months after the minimum conservation date of the product,

— guarantees as regards the administration of the health marking, particularly the labels bearing the health mark,

— 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,

— the requirements of the first and second indents must have been drawn up in conjunction with the competent authority, which must regularly monitor compliance therewith.

2. For inspection purposes, the operator or manager of the establishment or the rewrapping centre must ensure that the packaging of meat products which cannot be stored at ambient temperatures bears a clear and legible indication of the temperature at which the products must be transported and stored, as well as the minimum durability date or, in the case of microbiologically perishable products, the use-by date.

3. The operator or manager of the establishment must arrange or establish 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. This training programme may be of a specific type for the establishments referred to in Article 9.

The competent authority responsible for the establishment must be involved in the planning and implementation of the programme.

Article 8

1. Each Member State shall draw up a list of approved establishments, other than those referred to in Article 11, each establishment having an approval number. This list shall be sent to the other Member States and to the Commission.

A single approval number may be given to:

(i) an establishment or rewrapping centre processing or rewrapping products obtained from or with raw materials covered by several of the Directives referred to in Article 2 (d);

(ii) an establishment located on the same site as an establishment approved in accordance with one of the Directives referred to in Article 2 (d).

The competent authority shall not approve an establishment unless it is satisfied that it complies with this Directive with respect to the nature of its activities. However, if an establishment seeking approval pursuant to this Directive forms an integral part of an establishment

▼M12

approved under Directive 64/433/EEC, 71/118/EEC, 91/493/EEC or 91/495/EEC, the premises, equipment and installations for staff and all premises where there is no risk of contamination of raw materials or unwrapped products may be common to both establishments.

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

(i) it shall be empowered to act in respect of the use of equipment or premises and to take any requisite measures which may go as far as reducing the rate of production or temporarily suspending the production process;

(ii) where these measures or the measures provided for in the penultimate indent of Article 7 (1) have proved insufficient to remedy the situation, it shall temporarily suspend approval, if appropriate, for the type of production in question.

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

The competent authority in question shall in particular be obliged to comply with 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. Inspection and supervision of establishments shall be carried out by the competent authority.

The establishment 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 will depend on the size of the establishment, the type of product manufactured, risk assessment and the guarantees offered in accordance with the fifth and last indents of the second subparagraph of Article 7 (1).

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

The competent authority must regularly analyse the results of the checks provided for in Article 7 (1). It may, on the basisof these analyses, conduct further examinations at all stages of production or on the products.

The nature of these checks, their frequency and the methods of sampling and of carrying out microbiological examinations shall be established under the procedure laid down in Article 20.

The results of these 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, 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 arrangements for implementing this Article shall be adopted in accordance with the procedure laid down in Article 20.

Article 9

1. Member States may, for the purpose of their approval, grant establishments manufacturing meat products without an industrial structure or production capacity derogations from the requirements of Chapter I of Annex B and from those of Annex A, Chapter I, point 2

▼M12

(g) (as regards taps) and point 11 (to substitute lockers for changing rooms).

Moreover, derogations may be granted from point 3 of Annex A, Chapter I, as regards rooms where the raw materials and finished products are stored. However, in this case, the establishment must have at least:

(i) a room or a secure place, where appropriate refrigerated, for the storage of raw materials, if such storage takes place;

(ii) a room or a secure place, where appropriate refrigerated, for the storage of finished products, if such storage takes place.

▼M16

2. Member States may extend the derogation provided for in paragraph 1 to the establishments referred to in Article 4, section A, point (a)(i), and sections C, D and E of Directive 64/433/EEC, on the understanding that the processing of products in those establishments must meet the other requirements of this Directive.

▼M12

3. The provisions of Annex B, Chapter VII shall not apply to storage operations in the establishments referred to in paragraph 1, nor to the transporting of products other than those referred to in Article 7 (2).

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

If after examination of these criteria or following the checks carried out in accordance with Article 12, the Commission considers that the criteria adopted might jeopardize the uniform application of this Directive, such criteria may be amended or supplemented, for the first time before 1 January 1993, in accordance with the procedure laid down in Article 20. The conditions under which the competent authorities of the Member State shall reclassify such establishments shall also be laid down by the same procedure.

5. On the basis of the information collected by the Commission in accordance with the first subparagraph of paragraph 4, uniform criteria for the application of this Article shall be laid down before 1 January 1993 in accordance with the procedure laid down in Article 20.

Article 10

Establishments currently benefiting from national approval must apply to the competent authority before 1 October 1992 for classification either under Article 8 or under Article 9.

Until such time as a decision has been taken by the competent authority of the Member State and until 1 January 1996 ►A2 except for: ◄

▼A2

— Sweden, where the date to be adopted shall be 1 January 1997,

— Austria and Finland, where the date to be adopted shall be 1 January 1998,

▼M12

at the latest, all products coming from an establishment which has not been classified must still bear the national health mark.

As regards the establishments referred to in Article 8, at the request of a Member State accompanied by appropriate justification, an additional period expiring on 1 January 1996 ►A2 except for: ◄

▼A2

— Sweden, where the date to be adopted shall be 1 January 1997,

— Austria and Finland, where the date to be adopted shall be 1 January 1998,

▼M12

may be granted in accordance with the procedure laid down in Article 20 for compliance with the requirements of Annex B, Chapter I, 1 (a). Products from such an establishment must bear the national health mark.

Article 11

1. By way of derogation from Article 8, and where the products concerned are not produced in an establishment approved in accordance with Article 8, Member States shall authorize and register all establishments producing other products of animal origin defined in Article 2 (b) and give each of them a specific official number for inspection purposes and in order to be able to trace the establishment of origin of the products concerned.

However, where production takes place in premises adjacent to an approved slaughterhouse, this approval shall, provided the requirements of this Directive are complied with, be extended to cover the premises in question.

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

3. If such inspections reveal that the requirements of this Directive are not being met, the competent authority shall take appropriate action, up to and including the measures provided for in Article 8 (1), third and fourth subparagraphs.

4. The analyses and tests must be carried out in accordance with proven and scientifically recognized methods, in particular those laid down in Community provisions or international standards.

The Commission shall establish the reference methods in accordance with the procedure laid down in Article 20.

Article 12

1. 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. To do this, they may verify by checking a representative percentage of establishments whether the competent authorities are verifying 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 general provisions for implementing this Article shall be adopted in accordance with the procedure laid down in Article 20.

2. Before 1 January 1995 the Council shall review this Article on the basis of a report from the Commission, which may be accompanied by proposals.

Article 13

1. By way of derogation from the conditions stipulated in Article 3, it may be decided, in accordance with the procedure laid down in Article 20, that some provisions of this Directive shall not apply to meat products which contain other foodstuffs and only a small percentage of meat, meat product or meat preparation.

These derogations shall relate only to:

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

(b) the inspection requirements described in Annex B, Chapter IV;

(c) the marking requirements laid down in Annex B, Chapter VI ►M16 ——— ◄.

▼**M12**

When considering whether to grant derogations such as those provided for under this Article, both the nature and the composition of the product shall be taken into account.

Notwithstanding the provisions of this Article, Member States shall ensure that all meat products placed on the market are wholesome products prepared from fresh meat, meat products or products covered by Directive ►**M16** 94/65/EC ◄.

2. Until such time as a decision is taken in accordance with paragraph 1, Directive 82/201/EEC shall continue to apply.

Article 14

The provisions of Council Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the internal market 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 applied.

Article 15

After obtaining the opinions of the Member States in the Standing Veterinary Committee, the Commission may, if it deems necessary, draw up recommendations containing guidelines on good manufacturing practices applicable at the different stages of the production and placing on the market of the products referred to in Article 1.

Article 16

1. Pending the adoption of Community regulations on health rules applicable to the placing on the market of wild game, the national rules on the use of such meat in the establishments referred to in this Directive and to the placing on the market of meat products containing such meat shall continue to apply, in compliance with the general provisions of the Treaty.

2. Pending compilation, in the context of Community legislation on additives, of the list of foodstuffs to which the additives authorized for use may be added and establishment of the conditions under which they may be added and, where appropriate, a limit on the technological purpose of their use, the national rules and the bilateral arrangements existing on the date on which Directive 88/658/EEC was brought into effect restricting the use of additives in the products covered by this Directive shall remain applicable, with due regard for the general provisions of the Treaty, provided that they apply without distinction to domestic production and to trade.

Until that list is drawn up, the national rules and the bilateral arrangements governing the use of additives for the products referred to in this Directive shall remain in force, in compliance with the general provisions of the Treaty and the Community rules in force in the field of additives.

Article 17

In accordance with the procedure laid down in Article 20, the following may be established:

— special conditions for the approval of establishments situated in wholesale markets and of rewrapping centres,

— rules for the marking of products from a rewrapping centre and supervision procedures enabling the establishment of origin of the raw materials to be traced,

— at the request of a Member State or on the Commission's initiative the relevant requirements in this Directive which would apply 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 containers referred to in Chapter VIII, point 1 (f), of Annex B are correctly sealed,

▼M12

— microbiological standards including sampling plans and methods of analysis for the products referred to in Article 7 (2).

Article 18

1. Without prejudice to the specific provisions of this Directive, the competent authority shall, where it is suspected that the provisions of this Directive have not been 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.

2. 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 19

The Annexes to this Directive shall be amended by the Council acting by a qualified majority on a proposal from the Commission, in particular to adapt them to advances in technology.

Article 20

1. Where the procedure laid down in this Article is to be followed, matters shall without delay be referred to the Standing Veterinary Committee by its chairman, either on his own initiative or at the request of the representative of a Member State.

▼A2

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.

▼M12

3. The Commission shall adopt the measures and implement them immediately where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall adopt the measures by a qualified majority.

If, within three months from the date on which a proposal was submitted to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately, save where the Council has rejected these measures by a simple majority.

▼M16

▼B

Article 22

The Member States shall bring into force the laws, regulations and administrative provisions necessary for them to comply with this Directive on 1 July 1979.

▼**M3**

▼**B**

Article 23

This Directive is addressed to the Member States.

▼**M10**

Article 24

The Rules laid down in Directive 89/662/EEC ([1]) concerning veterinary checks applicable in intra-Community trade, with a view to the completion of the internal market, shall apply in particular to checks at origin, to the organization of and follow-up to the checks to be carried out by the Member State of destination, and to the protective measures to be implemented.

([1]) OJ No L 395, 30. 12. 1989, p. 13.

▼M12

ANNEX A

GENERAL CONDITIONS

CHAPTER I

General conditions for approval of establishments

Establishments shall afford at least the following facilities:

1. working areas of sufficient size for work to be carried out under adequate hygienic conditions. Their design and layout shall be such as to preclude contamination of the raw materials and the products referred to in this Directive;
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 the water or 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, washable coating up to a height of at least two metres, or at least storage height in refrigeration and storage rooms;
   (c) ceilings or roof linings which are easy to clean;
   (d) doors in non-corrodible materials which are easy to clean;

▼M15

   (e) adequate ventilation and, where necessary, good steam and water-vapour extraction facilities in order to eliminate as far as possible condensation on surfaces such as walls and ceilings or roof linings;

▼M12

   (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 utensils;
3. in rooms where the raw materials and the products covered by this Directive are stored, the same conditions as those at 2 apply, except in:
   — chilling and refrigeration rooms, where a floor which is easy to clean and disinfect, laid in such a way as to facilitate the draining of water is sufficient,
   — freezing and deep-freezing rooms, where waterproof and rotprof flooring which is easy to clean is sufficient,

   in that case, 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 does not constitute grounds for withdrawing approval provided they were built before 1 January 1983.

   The capacity of the store rooms must be adequate to store the raw materials used and the products referred to in 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 such as insects, rodents, birds, etc.;
6. instruments and working equipment such as cutting tables, containers, conveyor belts, saws and knives, 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, with lids and fasteners to prevent unauthorized persons from removing things from them, in which to put raw materials or products not intended for human consumption, or a lockable room for such purposes if the quantities are large enough to necessitate this or if they are not removed or destroyed at the end of each stage of work. 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;

▼M12

8. appropriate facilities for the cleaning and disinfecting of equipment and utensils; ►M15 for disinfecting equipment and utensils, water of a temperature of not less than 82º C, or other disinfection methods approved by the competent authority, must be used; ◄

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

10. a supply of potable water only, within the meaning of Council Directive 80/778/EEC of 15 July 1980 on the quality of water intended for human consumption [1]. However, the use 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 inspection service; ►M15 where the competent authority is not required to be present at all times, a lockable device of sufficient capacity for storage of equipment and materials is sufficient; ◄

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;

▼M15

15. adequate facilities for cleaning and desinfecting means of transport; unless, with the agreement of the competent authority, facilities not situated in the establishment may be used;

16. where the treatment applied requires the absence of water for manufacture of the products, certain requirements of this Chapter, in particular those laid down in points 2 (a) and (g), may be adjusted. Should recourse be had to such a derogation, cleaning and disinfecting processes which do not make use of water may, with the authorization of the competent authority, be applied in the parts of the establishment concerned.

▼M12

CHAPTER II

General conditions of hygiene

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

1. Equipment and instruments used for working on raw materials and products, floors, walls and partitions, ceilings or roof linings, 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. ►M15 Cleaning and disinfecting must be performed with a frequency and by means of processes which are in line with the principles set out in Article 7 of the Directive. ◄

2. No animals may enter the establishments. Rodents, insects and any other vermin must be systematically exterminated in the premises or on the equipment; rodenticides, insecticides, disinfectants and any other potentially toxic substances must be stored in premises or cupboards which can be locked; their use must not present any risk of contamination of the products.

3. Working areas, instruments and working equipment must be used only for work on 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. This restriction does not apply to transport equipment used in premises where no work is done on raw materials or products covered by this Directive.

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 steam production, fire-fighting and the cooling of equipment, provided that the pipes installed for the purpose preclude the use of such

[1] OJ No L 229, 30. 8. 1980, p. 11.

▼M12

water for other purposes and present no risk of contamination of the raw materials and products.

▼M15

5. Detergents, disinfectants and similar substances must be used in accordance with the manufacturers' instructions in such a way that they do not have adverse effects on the machinery, equipment, raw materials and products. Their use must be followed by thorough rinsing of such instruments and working equipment with potable water except where the directions for use of such substances render such rinsing unnecessary.

   Products for maintenance and cleaning must be kept in the room or facility provided for in Chapter I (14) of this Annex.

▼M12

6. The spreading of sawdust or any other similar substance on the floor of the workrooms and storage rooms for the raw materials and products referred to in this Directive is prohibited.

B. *General conditions of hygiene applicable to staff*

1. Absolute cleanliness is required of staff. Specifically:

   (a) staff must wear suitable clean working clothes and headgear which completely encloses the hair. This applies particularly to persons handling exposed, non-packaged raw materials and products;

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

   (c) smoking, spitting, eating and drinking in rooms where raw materials and products are worked on or stored is prohibited.

2. The employer shall take all the requisite measures to prevent persons liable to contaminate raw materials and products from handling them, until there is evidence that such persons can do so without risk.

   When recruited, any person working on and handling raw materials and products shall be required to prove, by a medical certificate, that there is no impediment to such employment. The medical supervision of such a person shall be governed by the national legislation in force in the Member State concerned or in the case of third countries by specific guarantees to be fixed under the procedure laid down in Article 20.

▼**M12**

ANNEX B

SPECIAL CONDITIONS FOR MEAT PRODUCTS

CHAPTER I

Special conditions for approval of establishments preparing meat products

1. In addition to the general requirements laid down in Annex A, Chapter I, establishments manufacturing, handling and wrapping meat products shall have at least:

   (a) suitable rooms large enough for the separate storage:

      (i) of raw materials, under refrigeration; and

      (ii) of meat products at ambient temperature or, where appropriate, depending on the nature of the products, under refrigeration;

   on the understanding that non-packaged raw materials, meat products and other products of animal origin must be stored separately from packaged raw materials and products;

   (b) one or more appropriate rooms large enough for the manufacture and wrapping of meat products. Provided these operations constitute a single production cycle complying with the requirements of this Directive and guaranteeing the safety of the raw materials and finished products, and provided the design and dimensions of the manufacturing room allow, they may be carried out in the same room;

   (c) a room or a secure place for the storage of certain ingredients such as food additives;

   (d) a room for packaging, unless the conditions laid down for packaging in Chapter V, point 3 are fulfilled, and for dispatch;

   (e) a room for the storage of wrapping and packaging materials;

   (f) a room for cleaning equipment and instruments, such as hooks and containers.

2. Depending on the type of product involved, the establishment must have:

   (a) a room or — of there is no danger of contamination — an area where packaging is removed;

   (b) a room or — if there is no danger of contamination — an area for thawing raw materials;

   (c) a cutting room;

   (d) a room or equipment for drying or maturing;

   (e) a room or equipment for smoking;

   (f) a room for desalting, soaking and any other treatment, particularly of natural guts, where these raw materials have not undergone such operations in the establishment of origin;

   (g) a room for the prior cleaning of the raw materials needed to prepare meat products;

   (h) a room for salting, if necessary with air-conditioning facilities to maintain the temperature provided for in Chapter II (4);

   (i) a room for the prior cleaning, if necessary, of meat products to be sliced or cut and wrapped;

   (j) a room, if necessary with air-conditioning facilities, for slicing or cutting and packaging of meat products intended for sale in pre-packed form;

   (k) the specific rooms provided for in Annex C, where the products referred to therein are manufactured in the establishments referred to in this Chapter;

   (l) where the conditions laid down in 1 (b) are met, it may be decided following agreement by the competent authority, that some of these operations may be carried out in the same room.

   Where the conditions laid down in 1 (b) are not met, operations which might constitute a health risk in the case of certain products manufactured simultaneously and operations associated with excessive heat production must be carried out in a separate room.

▼**M12**

CHAPTER II

Special conditions of hygiene for establishments preparing meat products

1. Rooms used for storing or working on foodstuffs other than meat or meat products, liable to form part of the composition of meat products, must be subject to the general rules on hygiene laid down in this Directive.

2. Raw materials and the ingredients forming part of the composition of meat products as well as the products themselves and products of animal origin and their containers shall not come into direct contact with the ground and shall be handled under conditions which preclude any risk of contamination. Care must be taken to ensure that there is no contact between raw materials and finished products.

3. The use of wood is permitted in rooms in which meat products are smoked, cured, matured, pickled, stored or dispatched, when essential for technological reasons, provided there is no risk of the products being contaminated. Wooden pallets may be brought into the said rooms solely for transporting packaged meat or meat products and for no other purposes. In addition, the use of galvanized metals may be authorized for the drying of hams and sausages, provided that they are not corroded and do not come into contact with the meat products.

4. The temperature in rooms or parts of rooms where work on meat, minced meat used as a raw material, meat products and meat preparations is carried out must ensure hygienic production; if necessary, such rooms or parts of rooms must be provided with air-conditioning facilities.

   During cutting, slicing and curing operations rooms for cutting and curing must be kept at a temperature not exceeding 12º C, except in the case of the establishments referred to in Article 9.

   However, in the case of other establishments the competent authority may derogate from this requirement where it considers such a derogation justified in the light of the technology used in preparing the meat product.

CHAPTER III

Requirements for raw materials to be used for the manufacture of meat products

1. Meat which is to be used for the manufacture of meat products must:

   — come from an establishment approved in accordance with the Directives referred to in Article 2 (d) and have been transported under satisfactory hygiene conditions in accordance with the said Directives,

   — from the time of its arrival in the processing establishment until the time of its use, be kept in accordance with the requirements of the Directives referred to in Article 2 (d).

   However, until 31 December 1995, meat obtained from establishments granted derogations under Directive 91/498/EEC may be held in approved establishments. Until that date, meat which does not comply with the conditions set out in the Directives referred to in Article 2 (d) may be held in approved establishments only if stored in separate places; it must not be used in the same place or at the same time as meat which does comply with these conditions. Meat products obtained from such meat must bear the national mark.

2. Minced meat and meat preparations, unless produced in the manufacturing room referred to in Chapter I (1) (b), must:

   — come from an establishment approved in accordance with Directive ►**M16** 94/65/EC ◄ and have been transported under satisfactory health conditions in accordance with that Directive,

   — from the time of their arrival in the processing establishment until the time of their use, be kept in accordance with the requirements of Directive ►**M16** 94/65/EC ◄.

▼**M15**

3. The presence of products of animal origin, other than meat as defined in Article 2 (d) of the Directive contained in the meat products, is authorized only if these products comply with the requirements laid down in the relevant Community legislation.

▼M12

CHAPTER IV

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 put by the establishment, in accordance with Article 7, notably by examining the results and taking samples;

      (iii) the microbiological and hygienic condition of the products of animal origin;

      (iv) the efficacy of the treatment of the meat products;

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

      (vi) the appropriate health marking of the meat products and identification of products declared unfit for human consumption and what is done with the latter;

      (vii) the 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;

   (d) establish whether a meat product has been made from meat in which other foodstuffs, additives or condiments have been incorporated, by submitting it to an appropriate inspection and establishing whether it complies with the production criteria laid down by the producer and especially whether the composition of the product truly corresponds to the information on the label, in particular where the sales description referred to in Chapter V (4) is used.

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

CHAPTER V

Wrapping, packaging and labelling

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

   Without prejudice to 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 [1], wrapping and packaging must comply with all the rules of hygiene, and be strong enough to protect the meat products effectively.

2. Wrapping or packaging may not be re-used for meat products, with the exception of certain special types of containers such as earthenware, glass or plastic containers which may be re-used after thorough cleaning and disinfecting.

3. Manufacture of meat products and packaging operations may take place in the same room if the packaging is as described in 2 or subject to the following conditions:

   (a) the room must be sufficiently large and so equipped 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 room intended for that purpose;

   (c) the rooms for storing the packaging material must be free from dust and vermin and have no atmospheric connection with rooms containing substances which might contaminate meat, minced meat, meat preparations or meat 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

[1] OJ No L 40, 11. 2. 1989, p. 38.

▼M12

granted in the case of the automatic assembly of packaging, provided there is no risk of contamination of the meat products;

(e) packaging must be brought to the room under hygienic conditions and used without delay. It may not be handled by staff handling unwrapped meat, minced meat, meat preparations or meat products;

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

4. In addition to the requirements of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer [1], the following information [2] must be visible and legibly displayed on the wrapping or on the label of meat products:

— where it is not clear from the sales description of the product or from the list of ingredients in accordance with Directive 79/112/EEC, the species from which the meat was obtained,

— a reference permitting identification of a quantity of products obtained in technologically similar conditions and likely to present the same risk,

▼M15

— for packaging not intended for the final consumer, the date of preparation or a code which can be interpreted by the recipient and by the competent authority allowing the identification of that date,

▼M12

— the sales description followed by a reference to the national standard or legislation [3] authorizing it,

▼M16

— where the legislation of a Member State authorises the use of starch or of proteins of animal or vegetable origin for other than technological purposes, a reference to such use in connection with the sales description.

▼M15

CHAPTER VI

HEALTH MARK

1. Meat products must carry a health mark. Marking must be carried out during or immediately after manufacture in the establishment or wrapping centre, in an easily visible place in legible and indelible characters which are easy to distinguish. The health mark may be applied directly to the product or to its wrapping if the meat product is individually wrapped, or to a label affixed to the wrapping, in accordance with point 4 (b). However, where a meat product is wrapped and packaged individually, a health mark applied to the packaging is sufficient.

2. Where meat products carrying a health mark in accordance with point 1 are then packaged, the health mark must also be applied to the packaging.

3. By way of derogation from points 1 and 2, the health marking of meat products is not necessary:

(a) where the health mark, in compliance with point 4, is applied to the external surface of each sales unit containing them;

(b) where, for meat products in consignments intended for further processing or wrapping in an approved establishment:

— the said consignments bear the health mark of the approved establishment consigning them in a visible place on the external surface, together with a clear indication of the intended destination,

— the recipient establishment maintains a record of the quantities, type and origin of meat products received in accordance with this point and stores that record for the period laid down in the fourth indent of the second subparagraph of Article 7 (1) of the Directive. However, meat products in large packagings which are intended for

(1) OJ No L 33, 8. 2. 1979, p. 1. Directive as last amended by Directive 89/395/EEC (OJ No L 186, 30. 6. 1989, p. 17).

(2) This information must accompany the meat products up to the final consumer stage, except in the case referred to in the third indent.

(3) The words 'national standard or legislation' cover:

(a) the conditions of production or preparation authorized under national law;
(b) the particular rules of national law imposing specific constraints on conditions of production or preparation for certain products;
(c) all sales descriptions which, in the absence of national standards limiting them, are permitted by the law of a Member State or in a Member State where that description has been confirmed by usage.

▼M15

immediate sale without further processing or wrapping must bear a health mark in compliance with point 1, 2 or 3 (a);

(c) where, for meat products which are not wrapped or packaged but sold in bulk by the manufacturer directly to a retailer:

— the health mark, in compliance with point 1, is applied to the container carrying them,

— the manufacturer maintains a record of the quantities and type of the meat products consigned in accordance with this point and of the name of the recipient and stores that record for the period laid down in the fourth indent of the second subparagraph of Article 7 (1) of the Directive.

4. (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 printed capitals, i.e. B — DK — D — EL — E — F — IRL — I — L — N L — AT — P — FI — S — UK, followed by the approval number of the establishment or, the rewrapping centre, in accordance with Decision 94/837/EC, if necessary accompanied by a code number stating the type of product for which the establishment is approved,

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

(ii) or:

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

— in the centre: the approval number of the establishment or the rewrapping centre, in accordance with Decision 94/837/EC, if necessary accompanied by a code number stating the type of product for which the establishment is approved,

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

(b) the health mark may be applied directly to the product by authorized means or be pre-printed on its wrapping or packaging, or to a label affixed to the product, its wrapping or packaging. Where it is applied to the wrapping, the stamp must be destroyed when the wrapping is opened. Failure to destroy the stamp can be tolerated only where the wrapping is destroyed by opening it. In the case of products in hermetically sealed containers, the stamp must be applied indelibly on either the lid or the can;

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

5. Where a meat product contains other foodstuffs of animal origin such as fishery products, dairy products or egg products, only one health mark must be applied.

▼M12

CHAPTER VII

Storage and transport

▼M15

1. Meat products must be stored in the rooms provided for in Annex B, Chapter I, point 1(a).

However, meat products may also be stored outside the rooms provided for in that point on the following conditions:

(a) meat products which cannot be kept at ambient temperatures may be stored in cold storage plant as referred to in Article 3 (A) (8) of the Directive or in cold storage plant approved in accordance with the other relevant Directives;

(b) meat products which can be kept at ambient temperatures may be stored in stores of solid construction, easy to clean and disinfect, and approved by the competent authority.

▼M12

2. Meat products for which certain storage temperatures are indicated in accordance with Article 7 (2) must be maintained at those temperatures.

3. Meat products must be dispatched in such a way that they are protected during transportation from anything which might contaminate or adversely

▼M12

affect them. For this purpose account shall be taken of the length of the journey, the means of transport employed and the weather conditions.

4. Meat products must, if the product so requires, be transported in vehicles equipped to ensure that they can be transported at the required temperatures and in particular that the temperatures indicated in accordance with Article 7 (2) are not exceeded.

▼M15

5. The commercial document referred to in Article 3 A (9) (b) (i) of the Directive must accompany meat products during the first stage of marketing.

For transport and marketing at subsequent stages, the products must be accompanied by a commercial document bearing the approval number of the consigning establishment identifying the competent authority responsible for control.

▼M12

CHAPTER VIII

Special conditions for pasteurized or sterilized products in hermetically sealed containers

A. In addition to the conditions laid down in Annex A, establishments manufacturing pasteurized or sterilized products in hermetically sealed containers

1. must have:

(a) a device for conveying empty cans hygienically to the work room;

(b) equipment enabling cans to be thoroughly cleaned immediately before filling;

(c) equipment for washing containers in potable water hot enough to remove grease after they have been hermetically sealed and before retorting;

(d) a suitable room, area or installation for cooling and drying containers after heat treatment;

(e) facilities for the incubation of samples taken from meat products packed in hermetically sealed containers;

(f) adequate facilities for checking whether containers are hermetically sealed and undamaged;

2. must ensure that:

(a) hermetically sealed containers are removed from the heating equipment at a sufficiently high temperature to ensure rapid evaporation of humidity and are not touched by hand until completely dry;

(b) containers in which gas appears to be present undergo a further examination;

(c) the thermometers of heating equipment are checked against calibrated thermometers;

(d) containers are:

— rejected if damaged or badly made,

— rejected or cleaned if they are dirty and, in the case of cans, thoroughly cleaned immediately before filling, by means of the cleaning equipment referred to in 1 (b); the use of stagnant water is not authorized,

— if necessary, drained for a sufficiently long time after cleaning and before filling,

— if necessary, washed in potable water, sufficiently hot to remove grease if appropriate, after they have been hermetically sealed and before retorting, by means of the equipment referred to in 1 (c),

— cooled, after heating, in water meeting the requirements in the fifth indent of B,

— handled, before and after heat treatment, in such a way that any damage or contamination is avoided.

▼M15

B. The operator or manager of an establishment manufacturing meat products in hermetically sealed containers must also check by sampling that:

(1) a heat treatment is applied to meat products intended for storing at ambient temperature which is capable of destroying or inactivating pathogenic germs and the spores of pathogenic micro-organisms. A register of manufacturing parameters such as duration of heating, temperature, filling, size of containers, etc. must be kept.

▼M15

The heat treatment apparatus must be fitted with control devices making it possible to check that containers have undergone effective heat treatment;

(2) the material used for the containers meets Community requirements relating to materials intended to come into contact with foodstuffs;

(3) checks on the daily output are carried out at intervals determined in advance, to ensure the efficacy of the sealing. To this end, suitable equipment must be available for examining perpendicular sections and the seams of the sealed containers;

(4) additional checks by sampling are carried out by the manufacturer to ensure that:

(a) sterilized products have undergone effective treatment, by means of:

— incubation tests. Incubation must be performed at a least 37º C for seven days or at at least 35º C for 10 days, or any other time/temperature combination recognized as equivalent by the competent authority,

— microbiological examination of the contents and the containers in the establishment's laboratory or in another approved laboratory;

(b) pasteurized products in hermetically sealed containers satisfy criteria recognized by the competent authority,

(5) the necessary checks are carried out to ensure that the cooling water contains a residual level of chlorine after use. Member States may, however, grant a derogation from this requirement if the water fulfils the requirements of Directive 80/778/EEC.

▼M12

C. The competent authority may authorize the addition of certain substances to the water used in retorts in order to prevent corrosion of cans and to soften and disinfect the water. A list of these substances will be drawn up in accordance with the procedure laid down in Article 20.

The competent authority may allow the use of recirculated water for cooling heat-processed containers. Such water must be purified and have either been treated with chlorine or undergone some other treatment approved in accordance with the procedure laid down in Article 20. The purpose of such treatment is to make the recirculated water comply with the standards laid down in Annex I (E) to Directive 80/778/EEC so that it cannot contaminate the products and does not constitute a hazard to human health.

The recirculated water shall circulate in closed circuit so that it cannot be used for other purposes.

Where there is no risk of contamination, the water used for cooling containers and water from retorts may be used at the end of a working period for cleaning floors.

CHAPTER IX

Special conditions for meat-based prepared meals

In addition to the general conditions in Annex A and in Chapters I, II and III of this Annex:

1. establishments manufacturing prepared meals must have a separate room for the preparation and wrapping of prepared meals; a separate room is not required where meat products and meat are handled at separate times, provided the rooms used for these operations are cleaned and disinfected between use for each type of product;

▼M15

2. (a) The meat product contained in the prepared meal must, as soon as it has been cooked:

(i) either be mixed with the other ingredients as soon as practically possible; in that event the time during which the temperature of the meat products is between 10º C and 60º C must be kept to a maximum of two hours;

(ii) or be refrigerated to 10º C or less before being mixed with the other ingredients.

Where other preparation methods are applied, these must be approved by the competent authority, which shall inform the Commission accordingly;

▼M12

(b) the meat product and the prepared meal must be refrigerated to an internal temperature of + 10 ºC or less within a period of not more than two hours after the end of cooking and to the storage temperature as soon

▼**M12**

as possible. However, the competent authority may authorize the establishment to derogate from the two-hour period where a longer period is justified for reasons connected with the production technology employed, provided that the safety of the end product is guaranteed;

(c) the prepared meal must, where appropriate, be frozen or quick-frozen immediately after cooling;

3. labelling of prepared meals must comply with Directive 79/112/EEC. The list of ingredients shall, for the purpose of this Directive, include an indication of the animal species.

   Prepared meals shall bear the date of manufacture very clearly on one of the outer surfaces of the wrapping in addition to the information already specified;

4. the results of the various checks to be carried out by the operator or manager must be kept, so that they can be shown on receipt of any request from the competent authority, for a minimum period to be specified by the competent authority according to the durability of the product concerned.

▼M12

ANNEX C

SPECIFIC HYGIENE STANDARDS FOR THE MANUFACTURE OF OTHER PRODUCTS OF ANIMAL ORIGIN

CHAPTER I

General conditions

The premises may be used for the production of products not intended for human consumption only under the following conditions:

(a) raw materials unfit for human consumption must be stored in a completely separate room or separate reception area;

(b) they must be processed in separate rooms using separate installations and equipment, except where the processing takes place in completely enclosed installation or equipment used exclusively for this purpose;

(c) the final products from these raw materials must be stored in a different room or separate tanks which are labelled appropriately and must not go for human consumption.

CHAPTER II

Special conditions for rendered animal fats, greaves and by-products

In addition to the conditions in Annex A, the following conditions apply:

A. *Standards applicable to establishments collecting or processing raw materials*

1. Centres for the collection of raw materials and further transport to processing establishments must be equipped with a cold store to store raw materials at a temperature of 7 ºC or less, unless the raw materials are collected and rendered within the time limits laid down in B (3) (b) and (c).

2. The processing establishment must have at least:

▼M15

(a) a cold store, unless the raw materials are collected and rendered within the time limits laid down in B (3) (b) and B (3) (c);

▼M12

(b) a room or place to receive raw materials;

(c) an installation to facilitate the visual inspection of raw materials;

(d) if appropriate, an installation to crush raw materials;

(e) equipment for the rendering of raw materials by heat or pressure or other appropriate method;

(f) containers or tanks in which the fat can be kept in liquid state;

(g) apparatus for plastification or crystallization of the fat to facilitate market preparation and packaging, unless the establishment dispatches liquid rendered animal fat only;

(h) a dispatch room, unless the establishment dispatches melted animal fat only by means of tankers;

(i) watertight containers for the disposal of raw materials unfit for human consumption;

(j) if appropriate, suitable equipment for the preparation of products consisting of rendered animal fat mixed with other foodstuffs and/or seasonings;

(k) if greaves are intended for human consumption, suitable facilities ensuring hygienic collection, wrapping and packaging and storage under the conditions laid down in B (9).

B. *Additional hygiene requirements relating to the preparation of rendered animal fat, greaves and by-products*

1. Raw materials shall originate from animals which, after ante and post mortem inspection, have been found fit for human consumption.

2. The raw materials shall consist of adipose tissues or bones found fit for human consumption and which are reasonably free from blood and impurities. They must not show signs of deterioration and must be obtained under hygienic conditions.

▼**M12**

3. (a) For the preparation of rendered animal fat, only adipose tissues or bones, collected at slaughterhouses, cutting plants or meat processing establishments shall be used. Raw materials shall be transported and stored until rendering in hygienic conditions and at an internal temperature of 7 ºC or less;

   (b) by way of derogation from (a), raw materials may be stored and transported unrefrigerated provided that they are rendered within twelve hours after the day on which they were obtained;

   (c) by way of derogation from (a), raw materials collected at retail shops or in premises adjacent to sales points, where the cutting and the storage of meat or poultrymeat is performed for the sole purpose of supplying the final consumer directly, may be used for the preparation of rendered animal fat, provided they are in satisfactory hygienic condition and properly packed. When the raw materials are collected daily the temperature requirements laid down in (a) and (b) must be complied with. If the raw materials are not collected daily, they must be refrigerated immediately after they have been obtained.

4. Vehicles and containers for the collection and transport of raw materials must have smooth internal surfaces, easy to wash, dean and disinfect and vehicles must be adequately covered. Vehicles for refrigerated transport must have been designed in such a way that the temperature required can be maintained throughout the period of transport.

5. Before rendering, raw materials shall be inspected for the presence of raw materials unfit for human consumption, or extraneous matter. When present these must be removed.

6. Raw materials shall be rendered by heat, pressure or other appropriate method, followed by separation of the fat by decantation, centrifugation, filtration or other appropriate method. The use of dissolvents is prohibited.

7. Rendered animal fat which is prepared in accordance with points 1, 2, 3, 5 and 6 may ►**M15** ——————— ◄ be refined in the same or another establishment to improve its physico-chemical quality when the fat for refining satisfies the standards laid down in point 8.

▼**M15**

8. Rendered animal fat, depending on type, must meet the following standards:

	Bovines			Pigs			Other animal fat	
	Edible tallow		Tallow for refining	Edible pig fat		Lard and other pork fat for refining	Edible	For refining
	Premier jus (1)	Other		Lard (2)	Other fat			
FFA (m/m % oleic acid) maximum	0,75	1,25	3,0	0,75	1,25	2,0	1,25	3,0
Maximum peroxide	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	6 meq/kg	6 meq/kg	4 meq/kg	10 meq/kg
Moisture and impurities	*max* 0,5 %							
Odour, taste, colour	normal							

(1) Rendered animal fat obtained by the low-temperature rendering of fresh fat from the heart, caul, kidneys and mesentery of bovine animals, and fat from cutting rooms.
(2) Melted fat obtained from rendering the adipose tissues of swine.

▼**M12**

9. Greaves intended for human consumption shall be stored:

   (i) when rendered at a temperature of 70 ºC or less: at a temperature of less than 7 ºC for a period not exceeding 24 hours or at − 18 ºC or lower;

▼M12

(ii) when rendered at a temperature of more than 70 ºC and having a moisture content of 10 % (m/m) or more:

— at a temperature of less than 7 ºC for a period not exceeding 48 hours or at a time/temperature ratio offering an equivalent guarantee,

— at − 18 ºC or lower;

(iii) when rendered at a temperature of more than 70 ºC and having a moisture content of less than 10 % (m/m): no specific requirement.

▼M16

CHAPTER III

Conditions governing the production, placing on the market and import of cleaned, salted or dried and/or heated stomachs, bladders and intestines

In addition to the conditions in Annex A and Chapter II of Annex B, establishments treating stomachs, bladders and intestines must comply with the following conditions:

1. raw materials must come from animals which, following ante-mortem and post-mortem inspection have been judged suitable for human consumption;
2. products which cannot be kept at ambient temperature must be stored until their dispatch in premises intended for that purpose. In particular, products which are not salted or dried must be kept at a temperature of less than 3 ºC;
3. raw materials must be transported from the slaughterhouse of origin to the establishment under satisfactory hygiene conditions and, where appropriate in the light of the period between slaughter and the collection of the raw materials, refrigerated. Vehicles and containers for transporting such materials must have smooth internal surfaces that are easy to wash, clean and disinfect. Vehicles for refrigerated transport must be designed in such a way that the required temperature can be maintained throughout the period of transport;
4. premises must be provided for the storage of wrapping and packaging materials;
5. wrapping and packaging must take place under hygienic conditions in a room or in a place intended for that purpose;
6. the use of wood is forbidden; however, the use of wooden pallets is authorised for the transport of the containers of the products concerned.

▼M12

ANNEX D

HEALTH CERTIFICATE FOR MEAT PRODUCTS (1)

No (2) .....

Exporting country: .....

Ministry: .....

Department concerned: .....

Reference (2): .....

I. Identification of meat products

Products manufactured with meat from: .....
(Animal species)

Nature of products (3): .....

Nature of packaging: .....

Number of individual items or of packages: .....

Storage and transport temperature (3): .....

Storage life (4): .....

Net weight: .....

II. Origin of meat products

Address(es) and approval number(s) of approved processing establishment(s) .....

.....

.....

If necessary:

Address(es) and approval number(s) of approved cold store(s): .....

.....

.....

.....

III. Destination of meat products

The meat products are to be sent

from: .....
(Place of dispatch)

to: .....
(Country of destination)

by the following means of transport (5): .....

Name and address of consignor: .....

.....

Name and address of consignee: .....

.....

(1) Within the meaning of Article 2 of Directive 77/99/EEC.
(2) Optional.
(3) Mention any ionizing radiation for medical reasons.
(4) To be completed where an indication is given in accordance with Article 7 of the Directive 77/99/EEC.
(5) Indicate the number or registration number (railway wagons and lorries), the flight number (aircraft) or the name (ship).

▼M12

IV. **Health attestation**

I, the undersigned, certify that the meat products described above:

(a) were manufactured from fresh meat or meat products under the specific conditions laid down in Directive 77/99/EEC (1);

(b) were prepared with meat from animal species other than those referred to in Article 2 (d) of Directive 77/99/EEC (1);

(c) are intended for the Hellenic Republic (1).

V. **If necessary:**

In the event of unloading and reloading in an approved establishment or approved cold store, indicate:

(a) the place of unloading and reloading (address and approval number):

.....

.....

.....

(b) the means of transport (2):

.....

.....

Done at ....., on .....
(place) (date)

Stamp

.....
(Signature of competent authority)
(Name in capital letters)

(1) Delete as appropriate .
(2) Indicate the number or registration number (railway wagons and lorries), the flight number (aircraft) or the name (ship).