

Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations
Official Journal L 368, 31/12/1994 pp. 0010 - 0031

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European 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 minced meat and meat preparations are included in the list of products in Annex II to the Treaty; whereas the production of and trade in minced meat and meat preparations constitute an important source of income for part of the farming population;

Whereas in order to ensure the rational development of the industry producing such meat and to increase productivity, public health rules for the production and placing on the market of such meat must be laid down at Community level;

Whereas the laying down of such rules improves the protection of public health and consequently facilitates the completion of the internal market;

Whereas, to achieve this purpose, it is necessary to repeal Council Directive 88/657/EEC of 14 December 1988 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 (4) , and to replace it by this Directive;

Whereas meat which has not undergone any treatment - other than cold treatment - is subject to the requirements of Directives 64/433/EEC (5) and 71/118/EEC (6) ; whereas products which have undergone treatment modifying the characteristics of fresh meat are regulated by Directive 77/99/EEC (7) ; whereas the production of other products, whether they are presented in the form of minced meat or meat preparations, should as a result be subject to the requirements of this Directive;

Whereas to take account of consumption habits in some Member States, and of the risk presented by some of those products if they are eaten lightly cooked, very strict requirements should be maintained for minced meat and preparations which may be traded;

Whereas the fundamental criterion which the Community must adopt as regards the functioning of the internal market is that of a high standard of consumer protection;

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 (8) and Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs (9) are applicable;

Whereas a system of approval should be introduced for the establishments which meet the health requirements laid down by this Directive, together with a Community inspection procedure to ensure that the conditions for such approval are observed;

Whereas that system should be based on the principle of self-monitoring by the establishments;

Whereas health marking of meat 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 the health certificate should be maintained for the purposes of verifying the destination of certain products;

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

Whereas, in the context of intra-Community trade, the rules laid down in Directive 89/662/EEC

(11) should also be applied;

Whereas the rules applicable to imports from third countries should be defined;

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

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Article 1

1. This Directive lays down rules for the production, placing on the market in the Union and importing of meat preparations and minced meat.

2. This Directive shall not apply to meat preparations and minced meat which are produced in retail shops or in premises adjacent to sales points, with a view to sale there directly to the final consumer, such operations remaining subject to the health checks required by national rules governing supervision of the retail trade.

3. This Directive shall not apply to mechanically recovered meat for industrial use which undergoes heat treatment in establishments approved in accordance with Directive 77/99/EEC.

4. National rules applicable to the production and placing on the market of minced meat intended for use as raw material for the manufacture of the products referred to in Article 21 (a) shall be unaffected by this Directive.

Article 2

For the purposes of this Directive:

1. the definitions contained in Article 2 of Directives 64/433/EEC, 71/118/EEC and 72/462/EEC (12) shall apply as necessary;

2. the following definitions shall apply;

(a) minced meat: meat which has been minced into fragments or passed through a spiral-screw mincer;

(b) meat preparations: meat within the meaning of Article 2 of Directives 64/433/EEC, 71/118/EEC and 92/45/EEC (13), and meat satisfying the requirements of Articles 3, 6 and 8 of Directive 91/495/EEC (14) which has had foodstuffs, seasonings or additives added to it or which has undergone a treatment insufficient to modify the internal cellular structure of the meat and thus to cause the characteristics of the fresh meat to disappear;

(c) seasonings: salt intended for human consumption, mustard, spices and aromatic spice extracts, aromatic herbs and aromatic extracts thereof;

(d) production plant: any plant in which minced meat or meat preparations are produced:

- which is located in a cutting plant and satisfies the requirements of Chapter I of Annex I to this Directive,

- which in the case of the production of meat preparations, is located in an establishment fulfilling the requirements of Chapter III of Annex I to this Directive,

- which, if it is not located on the premises of, or in an annex to, an establishment approved under Directives 64/433/EEC, 71/118/EEC or 77/99/EEC, fulfils the requirements of point 2 of Chapter I or point 2 of Chapter III of Annex I to this Directive;

(e) trade: trade between Member States within the meaning of Article 9 (2) of the Treaty;

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

CHAPTER II Placing on the market of minced meat

Article 3

1. Each Member State shall ensure that only fresh meat obtained from bovine animals, pigs, sheep or goats and presented in the form of minced meat, which meets the following requirements is traded:

(a) it must have been prepared from striated muscle (15) () - except heart muscle - which meets the requirements of:

(i) Article 3 of Directive 64/433/EEC; or

(ii) Directive 72/462/EEC;

and has been inspected in accordance with Directive 90/675/EEC.

In the case of fresh pigmeat, it must furthermore have been examined for trichinae in accordance with Article 2 of Directive 77/96/EEC (16) or have undergone cold treatment as referred to in Annex IV to that Directive;

(b) it must have been prepared, in accordance with the requirements of Chapter II of Annex I in a plant which:

(i) meets the requirements of points 1, 2 and 3 of Chapter I of Annex I, and

(ii) has been approved and is included on the list(s) drawn up in accordance with Article 8 (1) ;

(c) it must have been inspected in accordance with Chapter V of Annex I and with Article 8;

(d) it must be marked and labelled in accordance with Chapter VI of Annex I;

(e) it must have been wrapped, packaged and stored in accordance with the respective provisions of Chapters VII and VIII of Annex I;

(f) it must be transported in accordance with Chapter IX of Annex I;

(g) it must, during transport, be accompanied by:

(i) an accompanying commercial document which must:

- be drawn up by the dispatching establishment,

- bear the veterinary approval number of the approved production plant and in the case of frozen minced meat, the month and year of freezing in clear,

- for minced meat intended for Finland and Sweden, bear one of the indications provided for in the third indent of Part IV of Annex IV,

- be kept by the consignee so that it can be produced at the request of the competent authority.

Computer data must be printed out at the request of the aforesaid authority.

However, at the request of the competent authority in the Member State of destination, veterinary certification must be provided when meat is intended for export to a third country after mincing.

The cost of such certification shall be borne by the operators:

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

2. Minced meat must meet the following requirements in addition to those listed in paragraph 1:

(a) the fresh meat from which it is obtained must:

(i) where it has been frozen or deep-frozen, be obtained from fresh boned meat which has been stored for no longer than 18 months for beef and veal, 12 months for sheepmeat and six months for pigmeat, after freezing or deep-freezing, in a cold store approved in accordance with Article 10 of Directive 64/433/EEC. However, the competent authority may authorize the boning of pigmeat and sheepmeat on the spot immediately before mincing where this operation is carried out in satisfactory conditions of hygiene and quality;

(ii) where it has been chilled, be used:

- within no more than six days after slaughter of the animals, or

- within no more than 15 days after slaughter of the animals in the case of boned, vacuum-packed beef and veal;

(b) the minced meat must have undergone cold treatment within a period of not more than one hour after portioning and wrapping, except where processes requiring the lowering of the internal temperature of the meat during production are used;

(c) the minced meat must be packaged and presented in one of the following forms:

(i) chilled and in this case obtained from meat as described in (a) (ii) and cooled to an internal temperature below + 2°C in the shortest time possible.

However, the addition of a limited quantity of frozen meat satisfying the conditions laid down in

- (a) (i) shall be authorized to accelerate the refrigeration process provided that this addition is mentioned on the label. In such cases, the period referred to above must not exceed one hour;
 - (ii) deep-frozen, and in this case obtained from meat as described in (a) and cooled to an internal temperature below - 18°C as quickly as possible, in accordance with Article 1 (2) of Directive 89/108/EEC (17) () ;
 - (d) the minced meat must not have been subjected to ionizing radiation or ultraviolet treatment;
 - (e) the designations in Section 1 of Annex II, possibly combined with the name of the species of animal from which the meat was obtained, may be used on packages only if the requirements set out in Section 1 of Annex II are met for those designations.
3. Minced meat to which not more than 1 % salt has been added shall be subject to the requirements of paragraphs 1 and 2.

Article 4

1. In order to take account of particular habits of consumption and while ensuring that the health requirements of this Directive are observed, Member States may authorize the production and placing on the market of minced meat to be sold in their territory only obtained:

- a) from meat referred to in Article 2 (b) ;
- b) from production plants which are approved or registered and have the premises referred to in Annex I;
- c) by derogation from
 - i) point 4 of Chapter VI of Annex I;
 - ii) Article 3 (1) (f) and (g) and Article 3 (2) , except for the first, second and third indents of Annex II, point 1;

2. Minced meat obtained in accordance with this Article must not bear the health mark provided for in Chapter VI of Annex I.

3. A Member State which wishes to make use of the provisions of paragraph 1 shall notify the Commission of the nature of the derogations it intends to grant.

Should the Commission, after consulting the Member State concerned, consider that the derogations fail to guarantee the health standard provided for by the Directive, appropriate steps shall be taken in accordance with the procedure laid down in Article 20.

Otherwise, the Commission shall inform the other Member States of the measures notified to it.

CHAPTER III Placing on the market of meat preparations

Article 5

1. Meat preparations within the meaning of Article 2 (2) (b) may be traded only if:

- (a) they have been prepared from fresh meat, other than meat from solipeds, which:
 - (i) complies with Article 3 of the Directives referred to in Article 2 (2) (b) ;
 - (ii) in the case of imported meat, complies with Directive 72/462/EEC or Chapter III of Directives 71/118/EEC and 92/45/EEC and the requirements laid down in Articles 3, 6 and 8 of Directive 91/495/EEC, or Chapter 11 of Annex I to Directive 92/118/EEC (18) and be inspected in accordance with Directive 90/675/EEC. In the case of fresh meat from pigs, it must have been examined for trichinae in accordance with Article 2 of Directive 77/96/EEC or have undergone cold treatment in accordance with Annex IV to that Directive;
- (b) they have been prepared in one of the establishments referred to in Article 2 (2) (d) which:
 - (i) meets the requirements of Chapter III of Annex I; and
 - (ii) has been approved and is included on the list(s) drawn up in accordance with Article 8 (1) .
- (c) they have been obtained from meat which, if it has been deep-frozen, must be used within a maximum period after slaughter of 18 months for beef and veal, 12 months for sheepmeat and goatmeat, poultrymeat, rabbit meat and farmed game meat and six months for meat from other species;

However, the competent authority may authorize boning of pigmeat and sheepmeat on the spot immediately before preparation, provided this operation is carried out in satisfactory conditions

of hygiene and quality.

(d) they have been packaged and where they are to be placed on the market:

(i) chilled, they must be cooled as quickly as possible to an internal temperature below + 2°C for meat preparations obtained from minced meat, + 7°C for preparations obtained from fresh meat, + 4°C for preparations of poultry meat and + 3°C for preparations containing offal;

(iii) deep-frozen, they must be cooled to an internal temperature below - 18°C as quickly as possible, in accordance with Article 1 (2) of Directive 89/108/EEC.

2. Meat preparations must fulfil the following requirements in addition to those laid down in paragraph 1:

(a) they must have been prepared in accordance with Chapter IV of Annex I;

(b) they must have been inspected in accordance with Article 8 and Chapter V of Annex I;

(c) they must be marked and labelled in accordance with Chapter VI of Annex I;

(d) they must be wrapped and packaged in accordance with the requirements of Chapter VII of Annex I and stored in accordance with Chapter VIII of Annex I;

(e) they must be transported in accordance with Chapter IX of Annex I;

(f) they must during transport be accompanied by a health certificate in accordance with Annex V, which must be kept by the consignee for a period of not less than one year for presentation on request to the competent authority.

3. With the exception of fresh sausages and sausage meat, meat preparations obtained from minced meat of slaughter animals may be traded only if they fulfil the requirements of Article 3.

4. Pending the possible introduction of Community rules on ionization, meat preparations must not have been subjected to ionizing radiation. This provision shall not affect national rules applicable to ionization for medical purposes.

5. Member States may, for the purpose of their approval, grant manufacturing plants manufacturing meat preparations without an industrial structure or production capacity derogations from the requirements of Chapter I of Annex I to this Directive and from those of Chapter I of Annex B to Directive 77/99/EEC and of Chapter I (2) (a) (as regards taps) and point 11 (as regards lockers) of Annex A to Directive 64/433/EEC.

Moreover, derogations may be granted from point 7 of Chapter I of Annex B to Directive 77/99/EEC as regards rooms where raw materials and finished products are stored. However, in this case, the establishment must have at least:

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

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

Article 6

1. In order to take account of particular habits of consumption and while ensuring that the health requirements of this Directive are observed, Member States may authorize the production and placing on the market of minced meat to be sold in their territory only obtained:

(a) from meat referred to in Article 2 (b) ;

(b) from production plants which are approved or registered and have the premises referred to in Annex III;

(c) by derogation from:

- points (b) and (d) of Chapter IV of Annex I,

- Article 5 (1) (c) and (d) ,

- point 4 of Chapter VI of Annex I,

- Article 5 (2) (e) and (f) and Article 5 (3) .

2. Meat preparations obtained in accordance with paragraph 1 must not bear the health mark provided for in Chapter VI of Annex I.

3. A Member State which wishes to make use of the provisions of paragraph 1 shall notify the Commission of the nature of the derogations it intends to grant.

Should the Commission, after consulting the Member State concerned, consider that the derogations fail to guarantee the health standard provided for by the Directive, appropriate steps shall be taken in accordance with the procedure laid down in Article 20.

Otherwise, the Commission shall inform the other Member States of the measures notified to it.

CHAPTER IV Common provisions

Article 7

1. Member States shall ensure that the operator or manager of the production plant takes all necessary measure to ensure that, at all stages of production, the provisions of this Directive are complied with.

To that end, the said persons must comply with the requirements of Articles 3 and 6 of Directive 93/43/EEC (19) and, in addition, constantly carry out their own checks in compliance with the following principles:

- checking raw materials entering the establishment to ensure compliance with the criteria in Annexes II and IV in respect of the final product,
- checking cleaning and disinfection methods,
- taking samples for analysis in a laboratory recognized by the competent authority,
- keeping written or recorded track of the information required in accordance with the preceding indent 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 chilled products for which this period may be reduced to six months after the use-by date of the product,
- providing guarantees for the competent authority 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 health risk, informing the competent authority thereof,
- in the event of an immediate human health risk, withdrawing 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.

2. For inspection purposes, the operator or manager of the establishment must ensure that the packaging of the products bears a clear and legible indication of the temperature at which the products must be transported and stored, as well as the use-by date for deep-frozen products or the minimum conservation date for chilled products.

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

3. Microbiological tests must be carried out on minced meat as referred to in Article 3 and minced-meat preparations as referred to in Article 5 on a daily basis and at least weekly on other minced meat and meat preparations. These tests must be carried out either in the production plant, if it is recognized by the competent authority, or in an approved laboratory.

The sample taken for analysis must comprise five units and be representative of daily production. Samples of meat preparations must be taken from deep in the muscle after the skin has been cauterized.

The microbiological checks must be carried out in accordance with proven methods which are scientifically recognized, in particular those laid down in Community directives or other international standards.

The results of the microbiological checks must be assessed using the criteria for interpretation laid down in Annex II in the case of minced meat and meat preparations obtained from minced meat of slaughter animals, except for fresh sausages and sausage meat, in accordance with the

criteria in Annex IV in the case of other meat preparations.

In the event of disputes arising in trade, Member States shall recognize the EN methods as reference methods.

4. The requirements as regards self-monitoring must have been drawn up in conjunction with the competent authority, which must regularly monitor compliance therewith.

5. The arrangements for implementing this Article, in particular in cases where paragraph 1 applies, shall be detailed in accordance with the procedure laid down in Article 20.

Article 8

1. Each Member State shall draw up a list of establishments producing minced meat or meat preparations, making a distinction between those approved under Articles 3 and 5 and those registered under Articles 4 and 6. It shall send a list of the production plants approved under Articles 3 and 5 to the other Member States and to the Commission.

It shall assign to each production plant the approval number of the establishment approved in accordance with Directives 64/433/EEC, 71/118/EEC, 77/99/EEC, 91/495/EEC or 92/45/EEC with an indication that it has been approved for the production of minced meat or meat preparations, and to each independent production unit an individual approval number.

A single approval number may be given to:

(i) an establishment making preparations obtained from or with raw materials covered by more than one of the Directives referred to in the following subparagraph:

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

Production plants thus approved shall be entered either for the production of minced meat or for that of meat preparations in a separate column in the list of establishments referred to in Article 10 of Directive 64/433/EEC, Article 6 of Directive 71/118/EEC, Article 8 of Directive 77/99/EEC or that referred to in Article 7 of Directive 92/45/EEC and, in the case of an independent production unit, on a separate list drawn up according to the same criteria.

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 approved under Directives 64/433/EEC, 71/118/EEC, 79/99/EEC or 92/45/EEC, the premises, equipment and installations for staff and, generally, all premises where there is no risk of contamination of raw materials or unwrapped products may be common to both establishments.

2. Production plants must remain under the control of the competent authority, which shall inspect and monitor them with the following frequency:

- for production plants attached to cutting plants: same frequency as for the said cutting plants,

- for approved production plants producing the products referred to in Article 3: at least once a day during the production of minced meat,

- for other production plants: 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 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 establishment of origin of the raw material to be traced and, as regards compliance with the criteria laid down in Annexed II and IV, to the results of the self-monitoring provided for in Article 7, including the result of checks on raw materials. In the case of computer data, they must be printed out at the request of the competent authority.

The competent authority must regularly analyse the results of the checks provided for in Article 7. It may, on the basis of 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 set out in a report, the conclusions or recommendations of which shall be notified to the operator or manager of the establishment, who shall be obliged to rectify the shortcomings noted with a view to improving hygiene.

The competent authority may, when carrying out the said checks, be helped by assistants who hold the professional qualifications specified in Annex III to Directive 64/433/EEC or in Annex III to Directive 71/118/EEC.

3. Where the competent authority finds, in the course of checks carried out in accordance with Chapter V of Annex I, that there is repeated non-compliance during self-monitoring with the criteria laid down in Annexes II and IV, it shall intensify the measures for monitoring the production of the establishment in question, and may seize the labels and other items bearing the health mark referred to in Chapter VI of Annex I.

If, after the expiry of 15 days, the output from production plants still fails to meet the above standards, the competent authority shall take all appropriate measures to make good the shortcomings noted and shall if necessary require products from the establishment in question to undergo heat treatment. If these measures are not adequate, the establishment's approval shall be suspended.

4. 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 final 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 9.

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

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

6. The arrangements for implementing this Article, in particular details of help by assistants, shall be adopted in accordance with the procedure laid down in Article 20.

Article 9

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 production plants, whether the competent authorities are, in a uniform manner, ensuring that such plants are complying with the provisions of this Directive, and in particular with Article 7 (self-monitoring).

These checks may be carried out when other checks are being made by Commission experts pursuant to Community legislation.

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 applying this Article - in particular those aimed at regulating procedures for cooperation with national authorities - shall be adopted in accordance with the

procedure laid down in Article 20.

Article 10

The provisions 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 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 11

Any addition of additives to the minced meat or meat preparations covered by this Directive shall take place in compliance with Directive 94/36/EEC (20) .

Article 12

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. Each Member State shall determine the penalties to be applied in the event of infringement of the provisions of this Directive.

CHAPTER V Provisions applicable to imports into the Community of meat preparations and minced meat

Article 13

I. Member States shall ensure that imports of minced meat satisfying the requirements of Article 3 which has been deep-frozen at the production plant of origin and preparations satisfying the requirements of Article 5 which have been deep-frozen at the production plant of origin are not authorized unless they meet the requirements of this chapter.

A. The guarantees provided by the production plant of origin and confirmed by the competent authority of the third country regarding compliance with the requirements laid down for the placing on the market of products of Community origin obtained in accordance with Articles 3 and 5 must be approved in accordance with the procedure laid down in Article 20.

B. For the purposes of uniform application of A, the provisions of the following paragraphs shall apply.

1. In order to be imported into the Community, deep-frozen minced meat as referred to in Article 3 and deep-frozen meat preparations as referred to in Article 5 must:

(a) come from third countries or parts of third countries from which imports are not prohibited on animal health grounds in accordance with Directive 91/494/EEC (21) , 92/118/EEC, 72/462/EEC and 92/45/EEC;

(b) come from a third country on the lists drawn up in accordance with the Directives governing health and animal health aspects to be complied with for imports of meat used in meat preparations and offering the guarantees provided for in this Directive;

(c) be accompanied by the animal and public health certificate which is to be drawn up in accordance with the procedure laid down in Article 20 supplemented by a declaration signed by the official veterinarian to the effect that this minced meat and these preparations fulfil respectively the requirements laid down in Articles 3 and 5, come from establishments offering the guarantees provided for in Annex I, and have been deep-frozen at the production plant of origin.

2. The following shall be established in accordance with the procedure laid down in Article 20:

(a) a Community list of establishments which satisfy the requirements in (b) . Pending the compilation of that list, Member States are authorized to maintain the controls provided for in Article 11 (2) of Directive 90/675/EEC and the national health certificate required for establishments which have been the subject of national approval;

(b) the specific conditions relating to the requirements of this Directive, other than those enabling meat to be excluded from human consumption in accordance with Directive 64/433/EEC and 71/118/EEC. Such conditions and guarantees may not be less stringent than those laid down in Articles 3 and 5.

Pending the decisions referred to in (a) and (b), imports from establishments approved under Directive 72/462/EEC with respect to which the competent authorities are able to guarantee that the requirements of this Directive are complied with, may be authorized as from the date laid down in Article 22.

3. Experts from the Commission shall, in cooperation with the competent authorities of the Member States, carry out on-the-spot inspections to check:

(a) the guarantees given by the third country regarding the conditions of production and placing on the market;

(b) whether the conditions of paragraphs 1 and 2 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 20.

4. Pending the organization of the inspections referred to in paragraph 3, 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.

II. Under the procedure laid down in Article 19, derogations may be made from the requirements of this Article.

Article 14

The lists provided for in Article 13 (I) (B) (2) may include only third countries or parts of third countries:

(a) from which imports are not prohibited pursuant to Articles 9 to 12 of Directive 91/494/EEC and Articles 14, 17 and 20 of Directive 72/462/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) of Article 9 (2) of Directive 91/494/EEC, as capable of guaranteeing and supervising the implementation of their legislation in force, or the veterinary services of which are able to guarantee that health requirements at least equivalent to those laid down in Articles 3 and 5 are being complied with.

Article 15

1. Member States shall ensure that deep-frozen minced meat as referred to in Article 3 and deep-frozen meat preparations as referred to in Article 5 are imported into the Community only if they:

- are accompanied by the certificate provided for in Article 13 (1) (B) (1) (c),
- have satisfied the checks required by Directive 90/675/EEC.

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

- the import of minced meat remains prohibited,
- the national rules applicable to imports of meat preparations from third countries for which such requirements have not been adopted at Community level shall continue to apply, provided that they are not more favourable than those laid down in Article 5,
- imports must take place under the conditions laid down in Article 11 of Directive 90/675/EEC.

Article 16

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) of Directive 90/675/EEC, imports must take place in accordance with Article 11 (2) that Directive.

CHAPTER VI Final provisions

Article 17

1. The following paragraph 3 shall be added to Article 5 of Directive 71/118/EEC:

' 3. Member States shall ensure that mechanically recovered meat may be traded only if it has previously undergone heat treatment in accordance with Directive 77/99/EEC in the establishment of origin or any other establishment designated by the competent authority.'

2. The following paragraph 4 shall be added to Article 6 of Directive 91/495/EEC:

' 4. Member States shall ensure that mechanically recovered meat may be traded only if it has previously undergone heat treatment in accordance with Directive 77/99/EEC in the establishment of origin or any other establishment designated by the competent authority.'

Article 18

1. The provisions of the Annexes shall not apply to production plants situated on certain islands of the Hellenic Republic or in certain French Overseas Departments and territories where the production of such establishments remains exclusively reserved for local consumption.

2. The arrangements for applying paragraph 1 shall be adopted in accordance with the procedure provided for in Article 20.

Under the same procedure it may be decided to amend paragraph 1 with a view to the progressive extension of Community standards to all production plants situated in the abovementioned islands and parts of territories.

Article 19

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 technological and scientific progress.

Article 20

1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay to the Standing Veterinary Committee (hereinafter referred to as ' the Committee') set up by Decision 68/361/EEC (22) 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 the time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

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

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

If, 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 21

The Council, acting by a qualified majority on a proposal from the Commission, shall before 1 January 1996 lay down the health rules applicable to:

- (a) the production and placing on the market of sausage meat intended for the subsequent production of a meat-based product;
- (b) the production and use of mechanically recovered meat.

Article 22

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1996. 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 reference shall be laid down by Member States.

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

Article 23

Directive 88/657/EEC shall be repealed with effect from 1 January 1996.

Article 24

This Directive is addressed to the Member States.

Done at Brussels, 14 December 1994.

For the Council

The President

J. BORCHERT

ANNEX I

CHAPTER I Special conditions for the approval of establishments producing minced meat

1. Production plants within the meaning of Article 2 (2) (d) .

Over and above compliance with the conditions laid down in Annex I, Chapters I and III, to Directive 64/433/EC, production plants must have at least:

(a) a room for mincing and wrapping separate from the cutting room and equipped with a recording thermometer or recording telethermometer.

However, the competent authority may authorize the mincing of meat in the cutting room provided that the mincing is carried out in specific area that is clearly separate;

(b) a room for packaging, unless the conditions laid down in point 63 of Chapter XII of Annex I to Directive 64/433/EEC are fulfilled;

(c) a room or cabinets for storing salt;

(d) refrigeration equipment enabling the temperatures laid down in this Directive to be adhered to.

2. Over and above the general conditions laid down in Chapter I of Annex A to Directive 77/99/EEC, independent production units must have at least:

(a) rooms in accordance with point 1 of Chapter I of Annex B to Directive 77/99/EEC; and

(b) rooms as described in point 1.a of this chapter.

3. The rules laid down in Chapter V of Annex I to Directive 64/433/EEC shall apply as regards the hygiene of the staff, premises and equipment in the establishments.

Staff engaged in the manual preparation of minced meat must in addition wear masks covering the mouth and nose. The competent authority may also oblige staff to wear smooth, moisture-proof gloves, either for once-only use or capable of being cleaned and disinfected.

CHAPTER II Conditions for the production of minced meat

1. Meat must be examined before mincing or cutting up, in accordance with Article 7. All soiled and suspect parts shall be removed and condemned before the meat is minced.

2. Minced meat may not be obtained from scrap cuttings, scrap trimmings or from mechanically recovered meat.

In particular, it may not be prepared from the meat referred to in Article 5 of Directive 64/433/EEC or from meat from the following parts of bovine animals, pigs, sheep or goats: muscles from the head, with the exception of the masseters, and the non-muscular part of the linea alba, the carpus and tarsus region and bone scrapings. The muscles of the diaphragm - after removal of serosa - and of the masseters may be used only after an investigation for cysticercosis has been carried out. The fresh meat must not contain any bone fragments.

Where the operations carried out from the time when the meat enters the room referred to in Chapter I to the time when the finished product undergoes the chilling or deep-freezing process are performed within a maximum period of one hour, the internal temperature of the meat must be no higher than +7 °C and the temperature of the production premises must be no higher than +12 °C. The competent authority may authorize a longer time limit in individual cases where the addition of salt justifies this on technical grounds, provided that health rules are not affected by that derogation.

Where the duration of these operations is over one hour or over the period authorized by the competent authority in accordance with the preceding subparagraph, the fresh meat may not be used until the internal temperature of the meat has been reduced to a maximum of +4 °C.

3. Minced meat may be deep-frozen only once.

4. Immediately after production the minced meat must be hygienically wrapped and, after packaging, be cooled to and stored at the temperatures laid down in Article 3 (2) (c) .

CHAPTER III Special conditions for the approval of establishments producing meat preparations

1. Production plants within the meaning of Article 2 (2) (d) must have premises which at least meet the requirements of:

- (a) Chapters I and III of Annex I to Directive 64/433/EEC; or
- (b) Chapters I and III of Annex I to Directive 71/118/EEC; or
- (c) Chapters I and IV, point 1, of Annex I to Directive 92/45/EEC;

as well as having:

- a room separate from the cutting room for the production of meat preparations, the addition of other foodstuffs and wrapping, equipped with a recording thermometer or recording telethermometer.

However, the competent authority may authorize the production of meat preparations in the cutting room provided that the production is carried out on a specific area that is clearly separate. The addition of seasonings to whole poultry carcasses may be authorized in a specific room that is clearly separate from the slaughter premises,

- a room for packaging, unless the conditions laid down in point 63 of Chapter XII of Annex I to Directive 64/433/EEC or point 74 of Chapter XIV of Annex I to Directive 71/118/EEC or point 5 of Chapter VIII of Annex I to Directive 92/45/EEC are fulfilled,

- a room for storing seasonings and other cleaned foodstuffs ready for use,

- refrigerated rooms for the storage of:

- fresh meat as referred to in Article 5 (1) (a) ,

- meat preparations,

- refrigeration equipment enabling the temperatures laid down in this Directive to be adhered to.

2. Independent production units must meet the requirements of Chapter I of Annex A and Chapter I of Annex B to Directive 77/99/EEC.

3. The rules laid down in Chapter V of Annex I to Directives 64/433/EEC or 71/118/EEC or those of Chapter II of Directive 92/45/EEC shall apply by analogy as regards the hygiene of the staff, premises and equipment in the establishments.

Staff engaged in the manual production of meat preparations must also wear masks covering their noses and mouths. The competent authority may also require such staff to wear smooth, moisture-proof gloves, either or once-only use or capable of being cleaned and disinfected.

CHAPTER IV Special requirements for the production of meat preparations

Over and above compliance with the general requirements of Chapter III, and depending on the type of production concerned:

- (a) the production of meat preparations must take place under conditions of temperature control;
- (b) meat preparations must be wrapped in dispatch units in such a way as to obviate any risk of contamination;
- (c) meat preparations may be deep-frozen only once and may be traded only within a period not exceeding 18 months;
- (d) meat preparations must, immediately after the production process, be wrapped in accordance with Chapter VII and, after packaging, be cooled to the relevant temperature laid down in Article 5 (1) (d) .

CHAPTER V Inspection

1. Production plants which produce minced meat and meat preparations shall be subject to monitoring by the competent authority, which must ensure that the requirements of this Directive are met and in particular must:

- (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 of this Directive, in particular by examining the results and taking samples;
 - (iii) the microbiological and hygienic condition of the minced meat and the meat preparations;
 - (iv) the appropriate health marking of the minced meat and the meat preparations;
 - (v) storage and transport conditions;
- (b) within the framework of the official checks, take any samples required for laboratory tests to confirm the results of the self-monitoring;
- (c) make any other checks it considers necessary to ensure compliance with this Directive, it being understood that the results of the microbiological tests must be evaluated by the competent authority on the basis of the criteria laid down in Annex II for minced meat and in Annex IV for meat preparations.

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 VI Marking and labelling

1. Minced meat and meat preparations must be marked on the wrapping or packaging with a health mark.

2. Only minced meat obtained in accordance with Article 3 and meat preparations obtained in accordance with Article 5 and produced in a production plant approved in accordance with Article 8, may be given the Community health mark. That health mark must correspond:

- (a) to point 50 of Chapter XI of Annex I to Directive 64/433/EEC for minced meat;
- (b) for meat preparations:
 - (i) of fresh meat of slaughter animals or farmed game meat, to point 50 of Chapter XI of Annex I to Directive 64/433/EEC;
 - (ii) of poultrymeat or small feathered or furred farmed game, to point 66 of Chapter XII of Annex I to Directive 71/118/EEC;
 - (iii) of killed game, to point 2 of Chapter VII of Annex I to Directive 92/45/EEC.

3. Where minced meat or meat preparations are produced in an independent production unit, the health mark must include the approval number assigned by the competent authority pursuant to Article 8 (1) .

4. Without prejudice to Directive 79/112/EEC, in the case of meat preparations the following information must be visibly and legibly displayed for inspection purposes on the packaging,

where it is not clear from the sales description or from the list of ingredients in accordance with Directive 79/112/EEC: the species from which the meat was obtained and, in the case of a mixture, the percentage of each species and, for packaging not intended for the final consumer, the date of preparation.

In the case of minced meat and meat preparations made from minced meat except for fresh sausages and sausage meat bearing the healthmark provided for in this chapter, the labelling must also display the following words:

- 'percentage of fat under ...',
- 'Collagen: meat protein ratio under ...'.

CHAPTER VII Wrapping and packaging

1. Packaging (for example packing cases, paperboard boxes) must fulfil all rules of hygiene, and in particular:

- must not alter the organoleptic characteristics of the minced meat or meat preparations,
- must not be capable of transmitting to the minced meat or meat preparations substances harmful to human health,
- must be strong enough to ensure effective protection of the minced meat or meat preparations during transport and handling.

2. Packaging must not be reused for minced meat or meat preparations unless it is made of corrosion-resistant materials which are easy to clean and has been previously cleaned and disinfected.

3. Wrapped minced meat or meat preparations 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 point 1 above are fulfilled.

CHAPTER VIII Storage

1. Minced meat and meat preparations must be chilled immediately after wrapping and/or packaging. Minced meat must be stored at the temperatures indicated in Article 3 (2) (c) and meat preparations at the temperatures indicated in Article 5 (1) (d) .

2. Minced meat and meat preparations may be deep-frozen only in rooms of the production establishment or independent production unit or in approved cold stores.

3. In cold stores, minced meat and meat preparations may be stored together with other foodstuffs only if it is ensured by means of packaging that the minced meat or meat preparations cannot be affected unfavourably.

CHAPTER IX Transport

1. Minced meat and meat preparations must be dispatched in such a way that during transport they are protected from anything liable to contaminate them or to affect them unfavourably, having regard to the duration and conditions of transport and to the means of transport employed. In particular, vehicles used to transport minced meat and meat preparations must be equipped in such a way as to ensure that the temperatures laid down in this Directive are not exceeded during transport and they must be equipped with a recording thermometer to record that the latter requirement is fulfilled.

2. Member States may, by way of derogation from paragraph 1, authorize the transport of meat preparations originating in the establishments referred to in Article 5 (5) at temperatures higher than those laid down in this Directive from a production plant or independent production unit to nearby retail premises or local communities, provided that such transportation takes not more than one hour.

3. In the case of transit through a third country and where the production plant is situated in an area subject to restrictions for animal health reasons, the means of transport must remain sealed.

ANNEX II

COMPOSITION CRITERIA AND MICROBIOLOGICAL CRITERIA I. Composition criteria

checked on the basis of a daily average

" 1" - lean minced meat - minced pure beef - minced meat containing pigmeat - minced meat of other species 25 % II. Microbiological criteria

Production plants and independent production units must ensure that, during the checks provided for in Article 7 (3) and in accordance with the methods of interpretation set out below, minced meat complies with the following criteria:

Aerobic mesophile bacteria n Escherichia coli n Salmonella " absence in 10 Staphylococcus aureus n 103/g 102/g(a) acceptability threshold, above which results are no longer considered satisfactory where M equals 10 m where the count is made in a solid medium and M equals 30 M where the count is made in a liquid medium.

(b) threshold below which all results are considered satisfactory.

(c) number of units making up the sample.

(d) number of units in the sample giving values between m and M.

The results of the microbiological analyses must be interpreted according to:

A. Three categories of contamination for aerobic mesophile bacteria, Escherichia coli and Staphylococcus aureus, viz.:

- up to and including the criterion m,

- between the criterion m and the threshold M,

- above the threshold M.

1. The quality of the consignment shall be considered:

(a) satisfactory, where all the values observed are equal to or less than 3 m where a solid medium has been used or 10 m where a liquid medium has been used;

(b) acceptable, where all the values observed are between:

(i) 3 m and 10 m (= M) in a solid medium;

(ii) 10 m and 30 m (= M) in a liquid medium;

and where c/n is equal to or less than 2/5 where n = 5 and c = 2 or any other figures of equivalent or greater reliability to be recognized by the Council, acting in accordance with the procedure laid down in Article 19.

2. The quality of the consignment shall be considered unsatisfactory;

- in all cases where values in excess of M are observed,

- when c/n is 2/5.

However, where this latter threshold has been exceeded for aerobic micro-organisms at + 30 °C while all the other criteria have been fulfilled, this exceeding of the threshold must be the subject of a further interpretation, in particular in the case of raw products.

In any event, the product must be considered toxic or tainted when contamination reaches the microbic limit value S, which for general purposes is set at 10³ m.

In the case of Staphylococcus aureus, the value of S must never be allowed to exceed 5 × 10⁴.

Tolerances related to analytical techniques shall not apply to the values M and S.

B. Two categories for salmonella, with no category tolerance permitted:

- ' Absence in' : the result is considered satisfactory.

- ' Presence in' : the result is considered unsatisfactory.

ANNEX III

HEALTH CERTIFICATE FOR MINCED MEAT (1) No .

Exporting country: .

Ministry: .

Department concerned: .

Reference (2) : .

I. Identification of minced meat

Products prepared with meat from: .

(Animal species)

Nature of products (3) : .

Nature of packaging: .

Number of individual items or packages: .

Storage and transport temperature: .

Storage life: .

Net weight: .

II. Origin of minced meat

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

.

.

If necessary:

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

.

.

.

III. Destination of minced meat

The minced meat is to be sent

from: .

(Place of dispatch)

to: .

(Country of destination)

by the following means of transport: (4) .Name and address of consignor: .

.

.

Name and address of consignee: .

.

.

IV. Health attestation

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

(a) was manufactured from fresh meat under the specific conditions laid down in Directive 94/65/EC;

(b) is intended for the Hellenic Republic (5) .

Done at ., on .

(place) (date)

.

(Stamp and signature of official veterinarian)

(Name in capital letters)

(1) Within the meaning of Article 2 of Directive 94/65/EC.(2) Optional.(3) To be completed with the words provided for in Article 3 (2) (e) of Directive 94/65/EC.(4) Indicate the number or registration number (railway wagons and lorries) , the flight number (aircraft) or the name (ship) . This information must be updated in the event of transshipment.(5) If appropriate.

ANNEX IV

MICROBIOLOGICAL CRITERIA Production plants and independent production units must ensure that, during the checks provided for in Article 7 (3) and in accordance with the methods of interpretation specified in Annex II, meat preparations comply with the following criteria:

(1) (2) " 1" Escherichia coli $n = 5$; $c = 2$ " 2" $5 \times 10^3/g$ " 3" $5 \times 10^2/g$ " 1" Staphylococci aurei $n = 5$; $c = 1$ " 2" $5 \times 10^3/g$ " 3" $5 \times 10^2/g$ " 1" Salmonella $n = 5$; $c = 0$ " 2" absence in 1 g
The Council acting on a Commission proposal shall, before 31 December 1995, review the criteria applicable to meat preparations as regards the absence of salmonella.

(1) M = acceptability threshold, above which results are no longer considered satisfactory where M equals 10 m where the count is made in a solid medium and M equals 30 m where the count is made in a liquid medium. (2) m = threshold below which all results are considered satisfactory.

ANNEX V

HEALTH CERTIFICATE FOR MEAT PREPARATIONS (1) No .

Exporting country: .

Ministry: .

Department concerned: .

Reference (2) : .

I. Identification of meat preparations

Products prepared with meat from: .

(Animal species)

Nature of products (3) : .

Nature of packaging: .

Number of individual items or of packages: .

Storage and transport temperature: .

Storage life: .

Net weight: .

II. Origin of meat preparations

Address(es) and approval number(s) of approved production plant(s) : .

.

.

If necessary:

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

.

.

.

III. Destination of meat preparations

The preparations are to be sent

from: .

(Place of dispatch)

to: .

(Country of destination)

by the following means of transport (4) .Name and address of consignor: .

.

.

Name and address of consignee: .

.

.

IV. Health attestation

I, the undersigned, certify at the meat preparations described above

a) were manufactured from fresh meat under the specific conditions laid down in Directive 94/65/EC;

b) are intended for the Hellenic Republic (5) .

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

.
(Stamp and signature of official veterinarian)
(Name in capital letters)

(1) Within the meaning of Article 2 of Directive 94/65/EC.(2) Optional.(3) Mention any ionizing radiation for medical reasons.(4) Indicate the number or registration number (railway wagons and lorries) , the flight number (aircraft) or the name (ship) . This information must be updated in the event of transshipment.(5) If appropriate.