

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 5 August 1985

on health and animal-health problems affecting intra-Community trade in heat-treated milk

(85/397/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⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Whereas, so long as intra-Community trade is hindered by differences between the health requirements of Member States concerning milk, the harmonious functioning of the common market and in particular of the relevant common organization of markets will not have the desired effect;

Whereas, to eliminate such differences, the health provisions of the Member States must be approximated;

Whereas, in view of the magnitude of the dairy sector and the diversity of the problems to be resolved, initial action should be limited to the fixing of standards to apply to heat-treated milk provisionally excluding other products derived from milk except, by way of derogation and in view of the special use made of that

product, concentrated pasteurized milk delivered in tankers;

Whereas the milk must come from cattle which are free from diseases which are dangerous to human health; whereas account should nevertheless be taken of the differences which still persist between Member States as regards the state of health of their cattle;

Whereas production holdings must themselves be equipped in such a way as to ensure that cattle are kept and milk is obtained under hygienically satisfactory conditions; whereas provision should be made for the preparation of a code of hygiene laying down those conditions;

Whereas it is necessary to establish rules of hygiene regarding the collection and transport of milk to collection or standardization centres or treatment establishments, and to lay down the health requirements for staff engaged in those operations;

Whereas the untreated milk from each production holding must undergo periodic analysis or testing in order to ensure that it complies with the standards introduced; whereas it must also be possible to carry out inspections, at holdings, of the hygiene of milk production and of the general state of health of dairy cattle; whereas the arrangement for carrying out such inspections must be adopted at Community level;

Whereas the principle of sampling inspections for the presence of residues of substances likely to affect adversely the wholesomeness of milk should be adopted;

⁽¹⁾ OJ No C 36, 12. 4. 1972, p. 12.

⁽²⁾ OJ No C 4, 20. 1. 1972, p. 5.

Whereas countries of destination should be enabled to carry out non-discriminatory checks and inspections, subject to compliance with the general provisions of the Treaty, as to whether consignments are complying with the requirements of this Directive ;

Whereas heat-treated milk must be produced, stored and transported under conditions which give every guarantee of hygiene ; whereas the necessity for collection and standardization centres and treatment establishments to be registered or approved is likely to facilitate checking on the observance of these conditions ; whereas a procedure should be introduced for the settlement of disputes which might arise between Member States over the justification for the approval of a treatment establishment or a centre ;

Whereas Community surveillance should be introduced to verify whether the standards laid down are being applied in a uniform manner in all the Member States ; whereas it should be laid down that the manner in which that surveillance is carried out must be specified following a Community procedure within the Standing Veterinary Committee ;

Whereas, in the case of intra-Community trade, the issue of a certificate drawn up by the competent authority of the exporting country is the most appropriate means of giving the competent authorities of the country of destination the assurance that a consignment of heat-treated milk complies with the requirements of this Directive ;

Whereas a Member State must be able to refuse entry into free circulation within its territory in the case of heat-treated milk from another Member State where it has been found that that milk does not satisfy the provisions of this Directive ; whereas, however, the return of such milk should be permitted, provided that there are no health reasons why that should not be done and if the consignor or his representative so requests ; whereas, moreover, in order that those concerned may be aware of the reasons for a ban or a restriction, the grounds for importing it must be communicated to the consignor or his representative and, in certain cases, to the competent authorities of the exporting country ;

Whereas the consignor should have the possibility of seeking expert opinion in the event of a dispute between himself and the authorities of the Member State of destination over the justification for a ban or a restriction ;

Whereas it should be open to the Member States to prohibit the introduction, into their territory, of milk from a Member State in which an epizootic disease has broken out ; whereas, depending on the nature and characteristics of the disease, such a ban either must extend only to milk from a region of the territory of the exporting country, or may cover milk from the whole of that territory ; whereas, in the event of an outbreak of an infectious disease in the territory of a Member State, it is necessary that the appropriate

measures to combat the disease be taken swiftly ; whereas the dangers of such diseases and the defensive measures which they render necessary should be assessed in the same way throughout the Community ; whereas to that end an emergency Community procedure should be introduced, within the Standing Veterinary Committee referred to above, for the purpose of taking the necessary measures ;

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

HAS ADOPTED THIS DIRECTIVE :

Article 1

This Directive lays down health and animal-health requirements for heat-treated milk intended for intra-Community trade.

Pending the entry into force of Community provisions on this matter, and subject to compliance with the general provisions of the Treaty, intra-Community trade in products derived from milk other than heat-treated milk shall not be affected by this Directive. By derogation from the definitions laid down in Article 2, however, concentrated, pasteurized milk imported into a Member State in tankers for marketing there with or without further processing shall be subject to the requirements of this Directive.

Article 2

For the purposes of this Directive, the definitions which appear in Article 2 of Directive 64/432/EEC ⁽¹⁾ as last amended by Directive 85/320/EEC ⁽²⁾ and in Article 3 of Regulation (EEC) No 1411/71 ⁽³⁾ shall apply as necessary.

In addition :

- (a) 'untreated milk' shall mean milk as produced by secretion from the mammary glands of one or more dairy cows ;
- (b) 'production holding' shall mean an establishment situated within the territory of a Member State at which one or more milk-producing cows are kept ;
- (c) 'heat-treated milk' shall mean milk fit for human consumption obtained directly and exclusively from untreated milk as defined in (a) by heat treatment and presented in the form of pasteurized, UHT or sterilized milk as defined in Annex A, Chapter VII, paragraphs 2, 3, 4, 5 and 6 ;

⁽¹⁾ OJ No 121, 29. 7. 1964, p. 2012/64.

⁽²⁾ OJ No L 168, 28. 6. 1985, p. 36.

⁽³⁾ OJ No L 148, 3. 7. 1971, p. 4.

- (d) 'exporting country' shall mean the Member State from which heat-treated milk is sent to another Member State ;
- (e) 'country of destination' shall mean the Member State to which heat-treated milk from another Member State is sent ;
- (f) 'official department' shall mean the veterinary department or any other equivalent department designated by the Member State concerned to monitor the implementation of this Directive ;
- (g) 'milk treatment establishment' shall mean an establishment situated within the territory of a Member State at which milk is heat-treated.

Article 3

A. The Member States shall ensure that only the following milk is exported to another Member State :

1. heat-treated milk which satisfies the following general conditions :

- (a) it must have been obtained from untreated milk within the meaning of Article 2 (a)
 - (i) from which nothing has been removed or to which nothing has been added, except as an inherent consequence of fat-content standardization operations ;
 - (ii) which comes from cows which fulfil the conditions imposed in Annex A, Chapter VI, Section A ;
 - (iii) which comes from production holdings which meet the general hygiene conditions laid down in Annex A, Chapter VI, Section B ;
 - (iv) in respect of which the standards of hygiene observed during milking, collection, handling and transport, and those of the staff carrying out those operations, satisfy the requirements of Annex A, Chapter VI, Section C ;
 - (v) which comes from cows and production holdings which are checked at regular intervals by the competent national authorities in application of Article 11 (1) in particular ;
 - (vi) which has been checked in accordance with Article 11 (2) and which meets the standards set in Annex A, Chapter VI, Section D ;

- (b) it must come from a milk-treatment establishment which fulfils the conditions laid down in Annex A, Chapters I, II and V ; in addition if the untreated milk has been channelled through a milk-collection centre, that collection centre must fulfil the condi-

tions laid down in Annex A, Chapters I, III and V and if the untreated milk has been channelled through a milk-standardization centre, that standardization centre must fulfil the conditions laid down in Annex A, Chapters I, IV and V ;

- (c) it must have been treated there in accordance with the requirements laid down in Annex A, Chapter VII ;
- (d) if it is packaged, it must have been packaged in accordance with Annex A, Chapter VIII, at a milk-treatment establishment where the milk has been treated ;
- (e) it must have been stored in accordance with Annex A, Chapter IX ;
- (f) when being transported to a country of destination it must, in accordance with Annex A, Chapter X, be accompanied by a health certificate which conforms to the model in Annex B ;
- (g) it must be transported under satisfactory conditions of hygiene in accordance with Annex A, Chapter XI ;

2. pasteurized milk which fulfils the requirements laid down in paragraph 1 and has undergone one pasteurization process only ;

3. heat-treated milk intended for direct human consumption which, moreover, has a weight of not less than 1 030 grammes per litre established from milk at 15 °C or the equivalent from totally fat-free milk at 20 °C and contains a minimum of 28 grammes of protein per litre and a fat-free dry matter content of not less than 8,50 %, on the understanding that, without prejudice to the provisions adopted in the context of the common organization of the market in milk and milk products, stricter requirements may not be set for milk intended for industry.

B. Those Member States which grant approved establishments situated within their territories one of the derogations provided for in Article 4 (2) and Annex A, Chapter VII, paragraph 6 may not prohibit or limit the introduction into their territories of heat-treated milk from a treatment establishment in another Member State covered by the same derogation.

Article 4

Member States shall ensure that :

- milk tankers are used exclusively for the transport of milk, milk products and potable water ;
- premises, installations and working equipment are not used for purposes other than the collection, treatment and storage of milk and milk products.

Where an establishment makes products obtained in whole or in part from milk and milk products, the foodstuffs used in the manufacture of these products must, if they have not previously undergone heat treatment or another kind of treatment which does not adversely affect milk or milk products, be stored and treated in separate premises specially provided for this purpose.

2. Member States which, by way of derogation from paragraph 1, authorize the use of tankers and working equipment for the transport and manufacture of other liquid foodstuffs at different times, shall ensure that all appropriate measures are taken to prevent contamination or deterioration of the products covered by this Directive.

Member States shall inform the Commission and the other Member States of the derogations granted and provide a list of the establishments covered by these derogations.

3. The list of foodstuffs intended for human consumption which are referred to in paragraph 2 and which may form the subject of the derogation concerning transport shall be drawn up by the Council, acting on a proposal from the Commission.

The conditions to be complied with when reassigning tankers to milk transport after their use for transporting the foodstuffs referred to in the first subparagraph shall be adopted in accordance with the same procedure.

4. Member States shall ensure that :

- (a) the tankers covered by the derogation provided for in paragraph 2 may not be used for the transport of heat-treated milk intended for a Member State which does not grant such a derogation. At its request, the competent authority of the exporting Member State shall supply the Member State of designation with a list of tankers not covered by this derogation ;
- (b) the health certificate contains a clear indication whereby tankers used for the exclusive transport of heat-treated milk can be identified.

Article 5

1. Each Member State shall draw up a list of its approved milk-treatment establishments and, in so far as they are concerned with intra-Community trade in heat-treated milk, a list of approved collection centres and standardization centres, each such establishment

or centre having an approval number. The Member States shall send those lists to the other Member States and to the Commission.

No Member State shall approve an establishment or centre unless compliance with this Directive is assured. A Member State shall withdraw approval if the conditions for granting it cease to be fulfilled. The other Member States and the Commission shall be informed of the withdrawal of approval.

2. Regular inspection of approved establishments and centres shall be carried out by the official department. The supervision and continuous checking of establishments and of collection and standardization centres shall be carried out under the responsibility of the official department.

The staff of the official department may be assisted by staff specially trained for the purpose. The staff of the official department must at all times have free access to all parts of establishments or centres involved in the production of heat-treated milk in order to ensure compliance with this Directive.

3. Where a Member State considers, in particular after carrying out a check or inspection provided for in Article 7 (1) and (2), that the provisions governing approval are not being, or have ceased to be, observed in an establishment or centre in another Member State, it shall inform the competent central authority of that State accordingly. That authority shall take all necessary measures, which may include the withdrawal of approval, and notify the competent central authority of the first Member State of the decisions taken and the reasons for such decisions.

If the first Member State fears that such measures are not being taken or are inadequate, the two Member States shall together seek ways and means of remedying the situation ; if appropriate, that may involve a visit. In the event of a dispute over the application of provisions of this Directive which are not covered by Article 10, a solution shall be sought on the basis of a reference method and/or reference standards approved, after the Scientific Veterinary Committee has delivered its opinion, in accordance with the procedure laid down in Article 14.

The Member States concerned shall inform the Commission of disputes and of the solutions reached.

4. If those Member States cannot reach agreement, one of them shall, within a reasonable time, bring the matter before the Commission, which shall instruct one or more experts to give an opinion.

Pending that opinion, the exporting Member State must, for serious public-health reasons, at the request of the Member State of destination, intensify checks on heat-treated milk coming from the establishment in question.

The Member State of destination may, for its part, intensify checks on heat-treated milk coming from the same establishment and, if a positive result is obtained, take the measures laid down in Article 7 (4).

At the request of one of the two Member States concerned, the Commission shall immediately instruct an expert to go to the place where the consignment under dispute is stored and/or the consignor establishment, in order to propose appropriate interim protective measures.

In the light of the opinion provided for in the first subparagraph, the Member States may be authorized, under the procedure laid down in Article 13, to prohibit provisionally the introduction into their territories of heat-treated milk from that establishment.

Such authorization may be withdrawn under the procedure laid down in Article 13 in the light of a further opinion delivered by one or more experts.

An expert must be a national of a Member State other than those involved in the dispute.

5. The general rules for the application of this Article shall be adopted in accordance with the procedure set out in Article 14.

Article 6

1. Veterinary experts from the Commission may, in cooperation with the competent authorities of the Member States, make on-the-spot checks in so far as that is indispensable for ensuring uniform application of the Directive; they may verify whether approved establishments and centres are actually complying with the Directive, particularly with Annex A.

A Member State within the territory of which a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the Member State concerned of the results of the investigation.

The Member State concerned shall take any measures required to take account of the results of the investigation. If the Member State does not take those measures, the Commission may, after the situation has been examined by the Standing Veterinary Committee, have recourse to the provisions of the fifth and sixth subparagraphs of Article 5 (4).

2. Before the checks referred to in paragraph 1 are carried out, in accordance with the procedure laid down in Article 14, the general provisions for applying this Article shall be determined and a vade-mecum shall be established, containing the rules to be followed for the purpose of the checks provided for in paragraph 1.

3. Before 1 July 1990 the Council shall review this Article on the basis of a report from the Commission, which may also submit proposals in this connection.

Article 7

1. Without prejudice to Articles 5 and 6, a country of destination may check that all consignments of heat-treated milk as defined in Article 2 are accompanied by the prescribed health certificate.

2. If irregularities are seriously suspected, the country of destination may carry out non-discriminatory checks to verify whether the requirements of this Directive have been met.

3. As a general rule, checks and inspections shall be carried out at the place of destination of the goods or at another suitable place, provided that in the latter case the place chosen interferes as little as possible with the routing of the goods.

The checks and inspections referred to in paragraphs 1 and 2 may not unduly delay the passage of the goods and their placing on the market, or cause delays which might adversely affect the quality of the milk.

4. If, during a check carried out on the basis of paragraph 2, it is found that the milk does not comply with this Directive, the competent authority in the country of destination may, provided that health considerations so permit, give the consignor, the consignee or their representatives, at their expense, the choice of whether the consignment is to be turned back, the milk used for other purposes or destroyed or, if health considerations do not so permit, order destruction of the milk. In any event, precautionary measures shall be taken to prevent improper use of such milk, and the certificate must bear a clear indication of the purpose for which that milk is intended.

5. (a) Such decisions, and the grounds for taking them, must be communicated to the consignor or his representative. Should such person so request, they must be communicated forthwith in writing, together with an indication of the channels of appeal provided for under current legislation, their forms and the time-limits within which they are open.

- (b) If such decisions are based on the diagnosis of a contagious or infectious disease, or a deterioration dangerous to human or animal health, or a serious infringement of this Directive, they shall be communicated forthwith to the competent central authority of the producing Member State and to the Commission.
- (c) Following that communication, appropriate measures may be taken in accordance with the procedure laid down in Article 13, in particular for the purpose of coordinating the measures taken in other Member States with regard to the milk involved.

6. Before 1 July 1990 the Council shall review this Article on the basis of a report from the Commission, which may also submit proposals in this connection.

Article 8

1. This Directive shall not affect any channels of appeal available under current legislation in the Member States against decisions taken by the competent authorities and provided for in this Directive.

2. Each Member State shall grant consignors of milk the marketing of which is prohibited pursuant to Article 7 the right to obtain the opinion of an expert. Each Member State shall ensure that, before the competent authorities take any other measures such as destroying the milk, the experts have an opportunity of determining whether the conditions of Article 7 (4) were in fact fulfilled.

An expert must be a national of a Member State other than the exporting country or the country of destination.

Acting on proposals from the Member States, the Commission shall draw up a list of the experts who may be instructed to formulate such opinions.

The general rules for applying this Article, in particular as regards the procedure for formulating such opinions, shall be adopted in accordance with the procedure laid down in Article 14.

Article 9

Amendments to the Annexes to this Directive for the purpose of adapting them to technological developments shall be decided on by the Council acting by a qualified majority on a proposal from the Commission.

Article 10

1. The Member States shall ensure that, without prejudice to the additional requirements laid down in Article 3 (A) (3), only heat-treated milk from milk-treatment establishments satisfying the standards laid

down in Annex A, Chapters VI and VII for step 1 may be exported to another Member State.

However, a Member State which, from the date laid down in Article 16, applies to heat-treated milk intended for home consumption the microbiological standards laid down for step 2 may, after such application has been established in accordance with the procedure in Article 14, make the entry of sterilized and UHT milk into its territory subject to the standards laid down in that step for the finished product, and the entry of pasteurized milk subject to the standards laid down for both untreated milk and pasteurized milk.

The Member States shall ensure that no later than 1 January 1993 the standards laid down in Annex A, Chapters VI and VII for step 2 are applicable to intra-Community trade unless the Council, on the basis of a Commission report together with any proposals, decides by a qualified majority to postpone that deadline by up to two years.

Furthermore, as from 1 April 1990, the standards of step 2 shall apply to milk intended for direct human consumption.

2. The methods of analysis and testing to be used to monitor compliance with the standards referred to in paragraph 1 shall be adopted in accordance with the procedure laid down in Article 14 before 1 January 1989.

In accordance with the same procedure, a method shall be established, following an opinion from the Scientific Veterinary Committee, which replaces the modified Aschaffenburg turbidity test and enables a distinction to be made between sterilized milk and UHT milk.

Pending those decisions, however, the Member States shall, during the application period of step 1, recognize as reference methods any analysis and test methods accepted internationally.

Article 11

1. The Member States shall ensure that production holdings undergo periodic inspection in order to ensure that hygiene requirements are fulfilled.

In addition, if there are reasonable grounds for suspecting that the animal health requirements laid down in Annex A, Chapter VI, are not being fulfilled, they shall ensure that the official veterinarian checks the general state of health of the dairy animals and, should it prove necessary, has a clinical examination of the udders of those animals carried out.

If the inspection or inspections referred to in the first or second subparagraphs show that not all hygiene requirements are being fulfilled, the official department shall take appropriate steps.

2. The Member States shall ensure that untreated milk and heat-treated milk undergo checks carried out by milk-treatment establishments, under the supervision and responsibility of the official department and with periodic inspection by the official department, in order to ensure that the milk complies with the requirements of this Directive.

3. The Member States shall ensure that checks are effected to detect any residues of substances having a pharmacological or hormonal action, and of antibiotics, pesticides, detergents and other substances which are harmful or which might alter the organoleptic characteristics of milk or make its consumption dangerous or harmful to human health, in so far as those residues exceed the tolerance limits permitted or, where no tolerance is laid down, the quantity which has been proved harmless in accordance with scientific knowledge and on which the Scientific Veterinary Committee has given its opinion.

4. If the milk examined does not comply with this Directive and in particular shows traces of residues which exceed the permitted tolerances, the heat-treated milk must be excluded from intra-Community trade.

Such examinations for residues 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.

It must be possible to assess the results of the examination for residues using reference methods laid down pursuant to Article 10.

For the purpose of inspecting producing holdings and in accordance with the procedure laid in Article 14, a general code of hygiene shall be drawn up which shall specify the general conditions of hygiene to be complied with in production holdings, in particular the conditions for the upkeep of premises and those relating to milking operations. The Commission will effect the publication of that code.

5. Where there is good reason to suspect that the requirements of this Directive are not being satisfied, the official department shall carry out the necessary checks and, if that suspicion is confirmed, take appropriate measures, in particular the suspension of approval.

6. Acting by a qualified majority on a proposal from the Commission, within two years of the notification of this Directive the Council shall lay down the detailed arrangements for and the frequency of the

checks provided for in paragraphs 1 and 2 and the tolerances provided for in paragraph 3.

In accordance with the same procedure, a decision may be taken to extend the examinations to substances other than those referred to in paragraph 3.

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

Article 12

1. A Member State may take the following measures with due regard for the general provisions of the Treaty:

- (a) in the event of an outbreak of foot-and-mouth disease in another Member State, it may temporarily prohibit or restrict the introduction into its territory of pasteurized milk obtained in an approved establishment which collects untreated milk in the protection area, to be determined pursuant to Directive 64/432/EEC, or which is situated in that area;
- (b) if that epizootic disease becomes widespread or if there is an outbreak of a further infectious animal disease of a serious nature, it may temporarily prohibit or restrict the introduction into its territory of pasteurized milk and UHT milk from the whole of the territory of that State.

2. Every Member State must immediately inform the other Member States and the Commission of any outbreak within its territory of a disease covered by paragraph 1 (b) and not covered by Directive 82/894/EEC⁽¹⁾ and of the measures which it has taken to combat it. It must also notify them without delay of the disappearance of the disease.

3. The measures taken by the Member States under paragraph 1 and the repeal of any such measures must be communicated without delay to the other Member States and to the Commission, together with the reasons for such action.

It may be decided, in accordance with the procedure laid down in Article 13, that the measures should be amended, in particular in order to ensure their coordination with those adopted by the other Member States, or abolished.

4. If the situation provided for in paragraph 1 arises and if it appears necessary for other Member States also to take measures under that paragraph, possibly amended in accordance with paragraph 3, the appropriate measures shall be decided on in accordance with the procedure defined in Article 14.

⁽¹⁾ OJ No L 378, 31. 12. 1982, p. 58.

Article 13

1. Where the procedure laid down in this Article is to be followed, matters shall without delay be referred to the Standing Veterinary Committee set up by the Council Decision of 15 October 1968 (hereinafter referred to as 'the Committee') by its Chairman, either on his own initiative or at the request of a Member State.

2. Within the Committee the votes of the Member States shall be weighted as provided for in Article 148 (2) of the Treaty. The Chairman shall not vote.

3. The Commission representative shall submit a draft of the measures to be taken. The Committee shall deliver its opinion on those measures within two days. Opinions shall be delivered by a majority of 45 votes.

4. The Commission shall adopt the measures and implement them immediately where they are in accordance with the opinion of the Committee. If they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall forthwith submit to the Council a proposal concerning the measures to be taken. The Council shall adopt the measures by a qualified majority.

If 15 days after the proposal was submitted to it the Council has not adopted any measures, the Commission shall adopt the measures proposed and implement them immediately unless the Council has rejected those measures by a simple majority.

Article 14

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

2. Within the Committee the votes of the Member States shall be weighted as provided for in Article 148 (2) of the Treaty. The Chairman shall not vote.

3. The Commission representative shall submit a draft of the measures to be taken. The Committee

shall deliver its opinion on those measures within a time limit which the Chairman may set according to the urgency of the matter submitted. Opinions shall be delivered by a majority of 45 votes.

4. The Commission shall adopt the measures and implement them immediately where they are in accordance with the opinion of the Committee. If they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall forthwith submit a proposal to the Council concerning the measures to be taken.

The Council shall adopt the measures by a qualified majority.

If three months after the proposals was submitted to it the Council has not adopted any measures, the Commission shall adopt the measures proposed and implement them immediately unless the Council has rejected those measures by a simple majority.

Article 15

Pending the adoption of a Community system governing the importation of heat-treated milk from non-member countries, the provisions of national law applicable to such imports must not be more favourable than those governing intra-Community trade.

Article 16

The Member States shall bring into force the laws, regulations and administrative provisions necessary for them to comply with this Directive no later than 1 January 1989.

Article 17

This Directive is addressed to the Member States.

Done at Brussels, 5 August 1985.

For the Council

The President

J. POOS

ANNEX A

CHAPTER I

General approval requirements

Treatment establishments and collection and standardization centres must be located in premises such that the milk can have no adverse effects on human health and its natural characteristics cannot be altered, and have at least:

1. in rooms where heat-treated milk is processed or stored :
 - (a) flooring which is easy to clean and disinfect and laid in such a way as to facilitate the draining of liquids ;
 - (b) smooth, durable, impermeable walls, with a light-coloured, washable coating up to a height of at least two metres, and in chilling or refrigeration rooms and in stores to at least storage height, unless the milk is stored in hermetically closed tanks. Wall-to-floor junctions must be rounded or similarly finished except in stores and chilling or refrigeration rooms ;
 - (c) doors in hard-wearing, non-corrodible material and, if of wood, with a smooth and impermeable covering on both sides ;
 - (d) insulation materials which are rot-proof and odourless ;
 - (e) adequate ventilation and, if necessary, good extraction of steam ;
 - (f) adequate natural or artificial lighting ;
 - (g) As near as possible to the work stations, a sufficient number of facilities for cleaning and disinfecting hands and for cleaning tools with hot water. Taps must not be hand-operable. For washing hands, these facilities must have hot and cold running water or water premixed to a suitable temperature, cleaning and disinfecting products and hand towels which can be used once only ;
2. an adequate number of changing rooms with smooth, waterproof, washable walls and floors, washbasins, showers and flush lavatories. The latter must not open directly onto

the work rooms. The washbasins must have hot and cold running water or water premixed to a suitable temperature, materials for cleaning and disinfecting the hands and hand towels which can be used once only ; the washbasin taps must not be hand-operable. There must be a sufficient number of such washbasins near the lavatories ;

3. a special area and adequate facilities for cleaning and disinfecting containers and tanks. However, this area and these facilities are not compulsory if there are provisions requiring containers and tanks to be cleaned and disinfected by other centres situated near the treatment establishment ;
4. equipment supplying exclusively potable water within the meaning of Directive 80/778/EEC ⁽¹⁾.

However, the use of non-potable water is authorized as an exception for steam production, firefighting and for cooling purposes in refrigeration equipment, provided that the pipes installed for this purpose preclude the use of this water for other purposes and present no risk of contaminating the milk. The steam and the water concerned must neither come into direct contact with the milk nor be used to clean or disinfect containers, plant or equipment which come into contact with the milk. Pipes carrying non-potable water must be clearly distinguished from those carrying potable water ;

5. appropriate equipment for protection against pests such as insects and rodents ;
6. equipment, piping and instruments or their surfaces which are intended to come into contact with milk must be made of smooth material which is easy to wash, clean and disinfect, resists corrosion and does not transfer substances to the milk in such quantities as to endanger human health, cause deterioration in the composition of the milk or adversely affect its organoleptic characteristics.

CHAPTER II

Special requirements for the approval of treatment establishments

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

- (a) equipment for the mechanical filling and proper automatic sealing of containers which are to be used for pack-

aging heat-treated milk, after filling, excluding churns and tanks in so far as such an operation is carried out there ;

- (b) equipment for the cooling and cold storage of heat-treated milks and, in the case provided for in Chapters III, IV and VII (1), untreated milk. Coldstores must be

⁽¹⁾ OJ No L 229, 30. 8. 1980, p. 11.

- equipped with temperature-measuring apparatus ;
- (c) — in the case of packaging in disposable containers, an area for the storage of such containers and for storage of the raw materials intended for their manufacture ;
 - in the case of packaging in re-usable containers, a special area for their storage and equipment designed to clean and disinfect them mechanically ;
 - (d) containers for storing untreated milk, standardization equipment and containers for storing standardized milk ;
 - (e) centrifuges or any other means, approved or authorized for purifying milk ;
 - (f) heat-treatment equipment approved or authorized by the official department, fitted with :
 - an automatic temperature control,
 - a recording thermometer,
 - an automatic safety device preventing insufficient heating,
 - an adequate safety system preventing the mixture of pasteurized or sterilized milk with incompletely heated milk,
 - an automatic safety recording device preventing the aforementioned mixture ;
 - (g) the treatment establishment must have its own laboratory or make use of the services of a laboratory equipped with the necessary facilities for carrying out essential analyses and tests on milk.

CHAPTER III

Special requirements for registration of collection centres

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

- (a) cooling equipment or appropriate means for cooling milk and, if milk is stored at the collection centre, an installation for cold-storing milk ;
- (b) if milk is purified at the milk collection centre, purification must be carried out by means of centrifuges or by any other means approved or authorized by the official department.

CHAPTER IV

Special requirements for the registration of standardization centres

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

- (a) containers for the cold storage of untreated milk, standardization equipment and containers for the storage of standardized milk ;
- (b) centrifuges or any other means approved or authorized by the official department for purifying milk.

CHAPTER V

Hygiene requirements relating to the premises, equipment and staff of establishments

1. The highest degree of cleanliness shall be required of staff, premises, installations and equipment :
 - (a) staff who treat or handle the milk must in particular wear clean working clothes and headgear ; they must also have clean hands. Smoking shall be forbidden in the areas where milk is handled and stored ;
 - (b) no animals may enter the establishments. Any rodents, insects or other vermin found must be systematically destroyed ;
 - (c) the equipment and installations used in treating the milk must be kept clean and in a good state of repair ;
 - (i) the treatment premises must be cleaned at least once each working day ;
 - (ii) equipment, containers and installations which come into contact with milk, milk products or other foodstuffs must be washed, cleaned and disinfected at the end of each work phase and at least once each working day.
2. As soon as possible after each journey, or after each series of journeys where there is only a very short space of time between unloading and the following loading, but in any event at least once a day, containers and tanks used for transporting untreated milk to the milk collection or stan-

- standardization centre or to the milk treatment establishment must be washed, cleaned and disinfected before re-use.
3. Where untreated milk is not piped from the milk collection or standardization centre to the treatment establishment, the containers required for transporting it must satisfy the requirements laid down in paragraph 1 (c).
 4. Where chemicals are used for the disinfection laid down in paragraph 1, such chemicals must have been approved for that purpose by the official department.
 5. Persons who might transmit infectious diseases or any other kind of disease through the milk shall be prohibited from working with, treating, handling or transporting the milk.
 6. Any person employed to work with or handle milk shall be required to show by a medical certificate that there is no impediment to such employment. The medical certificate shall be renewed every year, unless another staff medical check-up scheme offering equivalent guarantees is recognized in accordance with the procedure laid down in Article 14.

CHAPTER VI

Requirements relating to the admission of untreated milk to treatment establishments

A. Originating herd

1. The untreated milk must come from cows :
 - (a) belonging to a bovine herd which is officially tuberculosis-free and free or officially free from brucellosis ;
 - (b) not showing any symptoms of infectious diseases communicable to human beings through milk ;
 - (c) whose general state of health is not impaired by any visible disorder and which must not be suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognizable inflammation affecting the udder or the skin of the udder ;
 - (d) not showing any udder wound likely to affect the milk ;
 - (e) yielding at least two litres of milk a day ;
 - (f) which have not been treated with substances that are transmissible to milk and that are dangerous or likely to be dangerous to human health, unless the milk has complied with an official waiting period. The official waiting periods shall be set by the Council, acting on a proposal from the Commission.
2. Untreated milk must be excluded from treatment if it :
 - (a) comes from animals which do not fulfil the requirements laid down in Directive 81/602/EEC ⁽¹⁾ ;
 - (b) contains residues of the substances referred in Article 11 (3) of this Directive.

B. Hygiene of the holding

1. Untreated milk must come from production holdings which are registered and checked in accordance with Article 11 of this Directive. The premises so used must be designed, constructed, maintained and managed in such a way as to ensure :
 - (i) good conditions of housing, hygiene, cleanliness and health of the cows ; and
 - (ii) good hygienic conditions for milking, the handling and the storage of milk.

Premises used for particular purposes must meet the conditions in the following paragraphs.

2. Premises where cows are milked or milk is stored, handled or cooled must be so sited and constructed as to avoid risk of contamination of the milk. They must be easy to wash and disinfect and have at least :
 - (a) walls and flooring capable of being readily cleansed in those areas liable to soiling or infection ;
 - (b) flooring laid in such a way as to facilitate the draining of liquids and satisfactory means of disposing of waste ;
 - (c) adequate ventilation and lighting ;
 - (d) an adequate and sufficient supply of potable water within the meaning of Directive 80/778/EEC for use in milking, cleansing and cooling operations ;
 - (e) adequate separation from all sources of contamination such as lavatories and dung heaps ;
 - (f) fittings and equipment which are capable of being readily and properly washed, cleansed and disinfected ;

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

3. If a movable milking bail is used, the requirements in paragraph 2 (d) and (f) must be satisfied and in addition the bail must :
 - (a) be sited on fresh ground which is free from any accumulation of excreta or other waste matter ;
 - (b) provide protection for the milk during the whole period in which it is in use ;
 - (c) be so constructed and finished as to permit the interior surfaces to be kept clean.
4. A milking parlour or milking area, adequately separated from the housing area, is obligatory where cows are loose housed.
5. The isolation of animals which are infected, or suspected of being infected, with any of the diseases referred to in A (1) (b) or the separation of the animals referred to in A (1) (c) from the rest of the herd must be both possible and effective.

⁽¹⁾ OJ No L 222, 1. 8. 1981, p. 32.

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

C. *Hygiene in milking, in collecting untreated milk and in its transport from the production holding to the collection or standardization centre or to the milk treatment establishment — Hygiene of staff*

1. Milking must be carried out hygienically and under conditions to be laid down in the code of hygiene referred to in Article 11 (4) of the Directive.

2. Immediately after milking, the milk must be placed in a clean place which is so equipped as to avoid adverse effects on the milk. If it is not collected within two hours of milking, the milk must be cooled to a temperature of 8 °C at least in the case of daily collection or 6 °C if collection is not daily; while the milk is being transported to the treatment establishment, its temperature must not exceed 10 °C.

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

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

5. Where chemicals are used for the disinfection operations laid down in paragraph 4, such chemicals must have been approved for that purpose by the official department.

6. The tanks used in the collection of milk must be used only for the transport of milk, milk products and potable water.

7. Persons who might transmit infectious diseases or any other kind of disease through the milk shall be prohibited from milking and from handling and collecting milk.

D. *Standards to be met on admission*

In order to be able to receive heat treatment and to meet the requirements of this Directive, untreated milk from each holding must satisfy the following minimum standards.

Compliance with the standards must be checked either by means of random samples taken during collection at the farm, or when the untreated milk is admitted to the treatment establishment, or at the milk collection centre or milk-standardization centre.

	Step 1	Step 2
Plate count 30 °C (per ml)	≤ 300 000 ⁽¹⁾	< 100 000 ⁽¹⁾
Cell count (per ml)	≤ 500 000 ⁽²⁾	< 400 000 ⁽²⁾
Freezing point (°C)	≤ -0,520	< -0,520
Antibiotics (per ml)		
— penicillin	< 0,004 µg	< 0,004 µg
— other	undetectable	undetectable

⁽¹⁾ Average recorded over a period of two months, with at least two samples a month.

⁽²⁾ Average recorded over a period of three months, with at least one sample a month.

In addition, untreated milk must be subjected to a pyruvic test or any system giving equivalent results and in that test satisfy the standards to be laid down before 1 January 1989 in accordance with the procedure laid down in Article 14 of the Directive and after the Scientific Veterinary Committee's opinion has been obtained. Pending that decision, Article 10 (2), third subparagraph shall apply.

The treatment establishment shall inform the official veterinarian as soon as the maximum standards fixed for the cell count have been achieved. The official veterinarian shall take the appropriate measures.

If after one month milk from the holding in question does not meet the standards laid down, it must be treated at a different time from milk intended for intra-Community trade and excluded from that trade.

CHAPTER VII

Requirements relating to heat treatment

1. Upon admission to a treatment establishment, untreated milk must, unless treated within four hours of its arrival, be cooled to a temperature not exceeding +5 °C and maintained at that temperature until heat-treated.

If untreated milk is not treated within 36 hours of its arrival, a further test must be carried out on that milk before it is heat-treated. If it is found by means of a direct or indirect method that the plate count of that milk at

30 °C exceeds 600 000 per ml for step 1 and 200 000 for step 2, the untreated milk in question must be treated at a different time from that which is intended for intra-Community trade.

2. Pasteurized milk must have been obtained by means of a treatment involving a high temperature for a short time (at least 71,7 °C for 15 seconds or any equivalent combination).

In the random sampling checks carried out in a treatment establishment, pasteurized milk must also satisfy the following standards :

	Step 1	Step 2
Pathogens	none	none
Coliform (per ml)	< 5	< 1
Plate count 30 °C (per ml)	≤ 50 000	≤ 30 000
<i>After incubation 6 °C in 5 days :</i>		
Plate count 21 °C (per ml)	≤ 250 000	≤ 100 000
Phosphatase	—	—
Peroxydase	+	+
Antibiotics (per ml)	Undetectable	Undetectable
Freezing point (°C)	≤ 0,520	≤ 0,520

In addition, pasteurized milk must be subjected to a pyruvic test or any system giving equivalent results and in that test satisfy the standards to be laid down in accordance with the procedure laid down in Article 14 of the Directive and after the Scientific Veterinary Committee's opinion has been obtained.

3. UHT milk must satisfy the following conditions :

- it must have been obtained by applying a continuous flow of heat during one unbroken period entailing the application of a high temperature for a short time (not less than + 135 °C for not less than a second) and the use of aseptic opaque containers for packaging ;
- its preservability must be such that no deterioration can be observed by means of random sampling checks after it has spent 15 days in a closed container at a temperature of +30 °C ; where necessary, provision can also be made for a period of seven days in a closed container at a temperature of +55 °C ;
- it must show a positive reaction to the modified Aschaffenburg turbidity test or to any other test to be worked out before the entry into force of the Directive, in accordance with the procedure laid down in Article

14 following an opinion from the Scientific Veterinary Committee ;

- it must have a freezing-point depression figure of not more than —0,520 °C. However, for milk which has been treated by the steam-injection process, a maximum figure of —0,515 °C shall apply for two years.

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

4. Sterilized milk must :

- have been heated and sterilized in hermetically sealed packagings or containers, the seal of which must remain intact ;
- in the event of random sampling, have a preservability such that no deterioration can be observed after it has spent 15 days in a closed container at a temperature of +30 °C ; where necessary, provision can also be made for a period of seven days in a closed container at a temperature of +55 °C ;
- show a negative reaction to the modified Aschaffenburg turbidity test or to any other test to be worked out before the entry into force of this Directive, following an opinion from the Scientific Veterinary Committee in accordance with the procedure laid down in Article 14 ;
- have a freezing-point depression figure of not more than —0,520 °C.

5. In the random sampling checks carried out in the treatment establishment, sterilized milk and UHT milk must meet the following standards :

	Step 1	Step 2
<i>After incubation for 15 days at 30 °C</i>		
(a) Plate count 30 °C (per 0,1 ml)	≤ 10	≤ 10
(b) Organoleptic check	normal	normal
Antibiotics (per ml)	undetectable	undetectable

In addition, milk must be subjected to an LPS test or any system giving equivalent results and in that test satisfy standards to be laid down in accordance with the procedure laid down in Article 14 of the Directive and after the Scientific Veterinary Committee's opinion has been obtained.

6. Pasteurized milk, UHT milk and sterilized milk may be produced from untreated milk which has undergone, in another establishment, an initial heat treatment the 'time-temperature' set of which must be lower than that used for pasteurization and which must therefore have positive phosphatase. The competent authorities must be informed of recourse to this derogation. Reference to this initial heat treatment must be made on the certificate.
7. Heating processes, the temperatures and duration of heating in respect of pasteurized, sterilized and UHT milk, the types of heating equipment, the flow-diversion valve and the types of temperature controlling and recording devices will be approved or authorized by the competent central authorities of the Member States.
8. After pasteurization, milk must be cooled immediately, in order to comply with the temperatures laid down in Chapters IX and XI as soon as possible.
9. The graphs produced by recording thermometers must be dated and kept for two years so that they can be shown upon request to the officials appointed by the official department to inspect the establishment.

CHAPTER VIII

Packaging at the treatment establishment of heat-treated milk in containers intended for direct sale to consumers

1. Containers intended for direct sale to consumers must comply with all the rules of hygiene. In particular, they must not transfer substances to the milk in such quantities as to endanger human health, cause deterioration in the composition of the milk or adversely affect its organoleptic characteristics in view of the standards laid down by the Community rules or in their absence by the national rules in force on the date of notification of the Directive. Re-usable containers must be so designed as to be easily washed, cleaned and disinfected.

Washing, cleaning and disinfection must be carried out in accordance with Chapter XI, paragraph 1, third indent.
2. Bottling, filling, sealing of containers and packaging must be carried out automatically.
3. Sealing must be carried out in the treatment establishment in which the heat treatment has been carried out immediately after filling, by means of a sealing device which ensures that the milk is protected from any adverse effects of external origin on its characteristics and that the seal cannot be re-used after opening.
4. The producer must ensure for control purposes that in addition to the information required by Directive 79/112/EEC⁽¹⁾ the following information is visibly and legibly displayed on the packaging of the product:
 - (a) the nature of the heat treatment which the milk has undergone;
 - (b) any information whereby the date of heat treatment may be established and, in the case of pasteurized milk, the temperature at which the product must be stored;
 - (c) the approval number of the treatment establishment and one of the following sets of initials: CEE — EEG — EWG — EØF — EEC — EOK.

CHAPTER IX

The storage of pasteurized milk in the treatment establishment

After cooling, the maximum temperature of pasteurized milk must be +6 °C until it leaves the treatment establishment.

The storage temperature of the storage rooms must be recorded.

CHAPTER X

Health certificate

The original of the health certificate which must accompany heat-treated milk during transport to the country of destination must be issued at the time of loading by the official veterinarian or any other competent authority of an equivalent level appointed by the competent central authority.

The health certificate must correspond in form and content to the model reproduced in Annex B. It must be drawn up in at least the official language or languages of the country of destination and must include the particulars provided for in the model reproduced in Annex B.

⁽¹⁾ OJ No L 33, 8. 2. 1979, p. 1.

CHAPTER XI

Transport of heat-treated milk

1. Tanks, churns and other containers which are to be used for the transport of pasteurized milk must comply with all the rules of hygiene and in particular the following:
 - their inside surfaces and any other part which may come into contact with the milk must be made of smooth material which is easy to wash, clean and disinfect, resists corrosion and does not transfer substances to the milk in such quantities as to endanger human health, cause deterioration in the composition of the milk or adversely affect its organoleptic characteristics;
 - they must be designed so that the milk can drain away completely; if they are fitted with taps, these must be easy to remove, dismantle, wash, clean and disinfect;
 - they must be washed, cleaned and disinfected immediately after each use and as necessary before further use; cleaning and disinfection must be carried out in accordance with Chapter V, paragraph 1 (c);
 - they must be hermetically sealed shut before and during transportation by means of a watertight closure.
2. Vehicles and containers used for transporting pasteurized milk must be designed and equipped in such a way that the temperatures laid down in paragraph 5 can be maintained throughout the period of transport.
3. Vehicles used for transporting heat-treated milk and milk in small containers or in churns must be in good condition. They may not be used to transport any other product or object likely to cause the milk to deteriorate. Their internal surfaces must be smooth and easy to wash, clean and disinfect. The interiors of vehicles intended for transport must comply with all the rules of hygiene. Vehicles intended for the transport of heat-treated milk in small containers or in churns must be so designed as to give the containers or churns adequate protection against all contamination and atmospheric influences and may not be used to transport animals.
4. (a) Each tank used for the transport of pasteurized milk intended for intra-Community trade must have been approved by the official department and be fitted, during transport, with a lead seal affixed when the competent authority signs the certificate.

(b) To that end, the competent authority must ensure before dispatch that the means of transport and loading conditions meet the hygiene requirements of this chapter.
5. During transport, the temperature of pasteurized milk transported in tanks or packed in small containers and in churns must not exceed 6 °C.

ANNEX B

HEALTH CERTIFICATE FOR HEAT-TREATED MILK INTENDED FOR ANOTHER MEMBER STATE

No (Optional)

Exporting country :

Ministry :

Department

Ref. : (optional)

I. Identification of product

Nature of product :

The product has been/has not been (1) obtained from untreated milk which has undergone, in another establishment, an initial heat treatment the 'time-temperature' set of which was lower than that used for pasteurization ; this milk therefore has positive phosphatase.

Date and nature of heat-treatment : (temperature/time)

The UHT milk-treatment process has been/has not been (1) applied by direct contact of milk and steam.

Nature of packaging :

Number of containers :

Quantity of product by volume or weight :

No of consignment :

II. Origin of product

Address and approval number of treatment establishment :

III. Destination of product

The product was sent from : (place of dispatch)

Name and address of consignor :

to (country and place of destination)

Name and address of consignee :

By the following means of transport (2) :

The milk tanker which served for the transport referred to in this certificate was used/was not (1) used exclusively for the transport of heat-treated milk.

(1) Delete the inappropriate alternative. (2) For railway wagons or goods vehicles, the registration number should be given, for aircraft, the flight number and for ships, the name.

IV. Attestation

I, the undersigned, certify that the milk referred to above has been produced under production conditions and subject to checking as provided for in Council Directive 85/397/EEC of 5 August 1985 on health and animal-health problems affecting intra-Community trade in heat-treated milk.

I certify further that the milk referred to above satisfies :

- the microbiological standards provided for in the abovementioned Directive for step 2 ⁽¹⁾ ⁽²⁾ ;
- the standards of step 2 for milk intended for direct human consumption ⁽³⁾.

Stamp

Done at , on
(place) (date)

.....
(signature)

.....
(name in capital letters)



⁽¹⁾ Attestation to be issued for milk intended for a Member State which may subject the introduction of heat-treated milk on to its territory to compliance with this condition.

⁽²⁾ Delete the inappropriate alternative.

⁽³⁾ For the period 1 April 1990 to 1 January 1993.