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;

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[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 conditions 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 our 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.