This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents

►**B**

COUNCIL DIRECTIVE 92/46/EEC

of 16 June 1992

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

(OJ L 268, 14.9.1992, p. 1)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Council Directive 92/118/EEC of 17 December 1992	L 62	49	15.3.1993
►**M2**	Commission Decision 94/330/EC of 25 May 1994	L 146	23	11.6.1994
►**M3**	Council Directive 94/71/EC of 13 December 1994	L 368	33	31.12.1994

Amended by:

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

▼B

COUNCIL DIRECTIVE 92/46/EEC

of 16 June 1992

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

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposals from the Commission ([1]),

Having regard to the opinions of the European Parliament ([2]),

Having regard to the opinions of the Economic and Social Committee ([3]),

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

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

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

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

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

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

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

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

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

Whereas in order to ensure uniformity of checks at origin, it is necessary to provide for a procedure for the approval of establishments meeting the health conditions laid down in this Directive, to determine

---

([1]) OJ No C 84, 2. 4. 1990, pp. 112 and 130. OJ No C 306, 26. 11. 1991, p. 7. OJ No C 308, 28. 11. 1991, p. 14.
([2]) OJ No C 183, 15. 7. 1991, pp. 60 and 61.
([3]) OJ No C 332, 31. 12. 1990, pp. 91 and 102.
([4]) OJ No L 226, 24. 8. 1985, p. 13. Last amended by Commission Decision 89/165/EEC (OJ No L 61, 4. 3. 1989, p. 57).
([5]) Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ No L 395, 30. 12. 1989, p. 13). Last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).
([6]) Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries (OJ No L 373, 31. 12. 1990, p. 1). Amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

▼B

the requirements regarding conditions of hygienic production to be complied with by such establishments and to define the criteria to be met by the products covered by this Directive;

Whereas low-capacity establishments should be approved by means of simplified structure and infrastructure criteria, while complying with the rules of hygiene laid down in this Directive;

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

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

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

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

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

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

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

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

Whereas account should be taken of certain special cheesemaking techniques;

Whereas Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer [1] and Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs [2], are applicable;

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

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

---

[1] OJ No L 33, 8. 9. 1979, p. 1. Last amended by Commission Directive 91/72/EEC (OJ No L 42, 16. 2. 1991, p. 27).

[2] OJ No L 186, 30. 6. 1989, p. 21. Amended by Directive 91/238/EEC (OJ No L 107, 27. 4. 1991, p. 50).

[3] OJ No L 224, 18. 8. 1990, p. 1. Last amended by Commission Regulation (EEC) No 675/92 (OJ No L 73, 19. 3. 1992, p. 8).

▼B

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

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

HAS ADOPTED THIS DIRECTIVE:

CHAPTER ONE

General Rules

Article 1

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

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

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

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

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

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

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

Article 2

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

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

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

3. ‘heat-treated drinking milk’: either drinking milk intended for sale to the final consumer and to institutions, obtained by heat treat-

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

▼B

ment and presented in the forms defined in Annex C, Chapter I.A. 4 (a), (b), (c) and (d) or milk treated by pasteurization for sale in bulk at the request of the individual consumer;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

([1]) OJ No L 121, 29. 7. 1964, p. 1977/64. Last amended by Directive 91/499/EEC (OJ No L 268, 24. 9. 1991, p. 107).

▼B

— Article 2 of Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals ([1]),

— Article 3 of Regulation (EEC) No 1411/71 of 29 June 1971 laying down additional rules on the common organization of the market in milk and milk products falling within Common Customs Tariff heading 04-01 ([2]), and

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

CHAPTER II

Rules governing Community production

Article 3

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

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

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

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

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

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

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

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

Article 4

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

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

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

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

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

Article 5

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

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

   (i) comply with Article 3;

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

([1]) OJ No L 46, 19. 2. 1991, p. 19.
([2]) OJ No L 148, 3. 7. 1971, p. 4. Last amended by Regulation (EEC) No 222/88 (OJ No L 28, 1. 2. 1988, p. 1).

▼B

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9. in the case of cow's milk, it must have a freezing point not higher than − 0,520 ºC and a weight of not less than 1 028 grammes per litre, as determined in whole milk at 20 ºC, or the equivalent as determined in totally fat-free milk at 20 ºC, and contain a minimum of 28 grammes of protein per litre, obtained by multiplying the percentage total nitrogen content of the milk by 6,38, and a fat-free dry matter content of not less than 8,50 %. ►M2 However, a freezing point higher than − 0,52 ºC shall be acceptable subject to the checks provided for in Annex C, Chapter 1.A.3 (b) showing that there is no extraneous water present. ◄

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

▼B

Article 6

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

1. either raw milk that complies with the requirements set out in Article 3 and the standards and specifications laid down in Annex C, Chapter I, and if appropriate has passed through a milk-collection or a milk-standardization centre fulfilling the conditions laid down in Annex B, Chapters I, II, III, IV and VI;
2. or milk intended for the manufacture of milk-based products obtained from raw milk which meets the requirements of paragraph 1 and
   (a) comes from a treatment establishment which meets the requirements of Annex B, Chapters I, II, V and VI;
   (b) has been stored and transported in accordance with the requirements of Annex C, Chapter V.

Article 7

A. Milk-based products must:
   1. have been obtained from milk that meets the requirements of Article 6 or from milk-based products that satisfy the requirements of the present Article;
   2. be prepared in a processing establishment that meets the standards and specifications of Annex B, Chapters I, II, V and VI and has been checked in accordance with Article 10 (2) and Article 14;
   3. meet the standards laid down in Annex C, Chapter II;
   4. be wrapped and packaged in accordance with Annex C, Chapter III, and, if they are in liquid form and intended for sale to the final consumer, with point 3 of that Chapter;
   5. be labelled in accordance with Annex C, Chapter IV;
   6. be stored and transported in accordance with Annex C, Chapter V;
   7. be checked in accordance with Article 14 and with Annex C, Chapter VI;
   8. where appropriate, contain only substances, other than milk, that are fit for human consumption;
   9. have undergone heat treatment during the manufacturing process or be made from products that have undergone heat treatment or involve hygiene specifications that are sufficient to meet the guaranteed hygiene criteria for all finished products.

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

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

Article 8

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

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

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

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

General and particular requirements applicable to the manufacture of individual products and standards specific to this type of product shall

▼B

be adopted, as necessary in accordancy with the procedure laid down in Article 31.

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

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

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

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

Article 9

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

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

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

Article 10

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

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

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

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

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

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

([1]) See page 33 of this Official Journal.

▼B

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

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

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

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

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

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

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

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

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

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

Article 11

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

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

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

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

▼B

Article 12

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

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

Article 13

1. Member States shall ensure that:

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

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

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

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

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

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

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

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

Article 14

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

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

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

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

— taking samples for analysis in a laboratory recognized by the competent authority for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the standards established by this Directive,

— keeping a written or registered record of the information required in accordance with the preceding indents with a view to submitting it to the competent authority. The results of the different checks and tests shall in particular be kept for a period of at least two years, save in the case of milk-based products which cannot be stored at

▼B

ambient temperature, for which this period shall be reduced to two months after the use-by or minimum durability date,

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

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

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

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

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

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

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

Article 15

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

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

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

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

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

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

▼B

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

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

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

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

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

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

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

Article 16

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

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

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

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

Article 17

Experts from the Commission may, in so far as is necessary for the uniform application of this Directive and in cooperation with the competent authorities, make on-site checks. In particular, they may verify by checking a representative percentage of establishments whether the competent authorities are ensuring that approved establishments are complying with this Directive. The Commission shall inform the Member States of the results of the checks carried out.

A Member State in whose territory a check is being carried out shall give all the necessary assistance to the experts in carrying out their duties.

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

Article 18

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

Article 19

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

▼B

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

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

Article 20

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

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

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

— the reference methods and, where necessary, the criteria governing routine methods of analysis and testing to be used to monitor compliance with the requirements of this Directive, and the methods of sampling,

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

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

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

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

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

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

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

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

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

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

Article 21

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

▼B

CHAPTER III

Imports from third countries

Article 22

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

Article 23

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

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

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

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

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

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

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

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

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

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

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

The experts from the Member States responsible for these inspections shall be appointed by the Commission, acting on a proposal from the Member States.

These inspections shall be made on behalf of the Community, which shall bear the cost of any expenditure in this connection. The frequency of and procedure for these inspections, including those to be carried out in the event of a decision in accordance with paragraph 6, shall be determined in accordance with the procedure laid down in Article 31.

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

▼B

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

Article 24

The principles and general rules laid down in Directive 90/675/EEC shall apply, with particular reference to the organization of and follow up to the inspections to be carried out by the Member States and the safeguard measures to be implemented.

Article 25

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

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

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

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

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

Article 26

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

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

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

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

CHAPTER IV

Final provisions

Article 27

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

([1]) Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (OJ No L 268, 24. 9. 1991, p. 56).

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

▼B

These laboratories shall be responsible for:

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

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

— periodically organizing comparative tests,

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

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

Article 28

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

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

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

Article 29

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

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

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

Article 30

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

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

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

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

‘— Council Directive 85/397/EEC of 5 August 1985 on health and animal health problems affecting intra-Community trade in heat-treated milk (OJ No L 226, 24. 8. 1985, p. 13), as last

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

▼B

amended by Regulation (EEC) No 3768/85 of 20 December 1985 (OJ No L 362, 31. 12. 1985, p. 8).';

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

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

Article 31

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

2. The representatives of the Commission, after consulting the Management Committee for Milk and Milk Products established by Regulation (EEC) No 804/68 where matters of chemistry or technology are involved, shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on such measures within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. Within the Committee the votes of the representatives of the Member States shall be weighted in the manner set out in Article 148 (2) of the Treaty. The Chairman shall not vote.

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

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

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

Article 32

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1994 ►A1 , except for Sweden, where the date to be adopted shall be 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 a reference shall be laid down by the Member States.

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

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

Article 33

This Directive is addressed to the Member States.

[1] OJ No L 225, 18. 10. 1968, p. 23.

▼B

ANNEX A

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

CHAPTER I

Animal health requirements for raw milk

1. Raw milk must originate as follows:

(a) from cows or buffaloes:

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

— officially tuberculosis-free,

— brucellosis-free or officially brucellosis-free;

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

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

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

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

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

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

(b) from sheep and goats:

(i) belonging to a sheep and goat holding officially free or free of brucellosis (*Brucella melitensis*) within the meaning of Article 2 (4) and (5) of Directive 91/68/EEC ►**M3** , except where the milk is intended for the manufacture of cheese with a maturation period of at least two months ◄;

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

▼M3

Milk and milk-based products must not come from a surveillance zone established under Directive 85/511/EEC [1], unless the milk has undergone, under the supervision of the competent authority, initial pasteurization (71,7 ºC for 15 seconds) followed by:

(a) a second heat treatment resulting in a negative reaction to the peroxidase test; or

(b) a drying procedure including heating having an effect equivalent to the heat treatment provided for in (a); or

(c) a second treatment whereby pH is reduced and kept for at least one hour at less than 6.

[1] Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease (OJ No L 315, 26. 11. 1985, p. 11). Directive as last amended by Commission Decision 92/380/EEC (OJ No L 198, 17. 7. 1992).

▼B

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

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

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

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

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

CHAPTER II

Hygiene of the holding

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

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

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

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

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

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

   (c) adequate ventilation and lighting;

   (d) an appropriate and sufficient supply of potable water, complying with the parameters laid down in Annexes D and E to Directive 80/778/EEC [3], for use in milking and in cleaning the equipment and instruments referred to in Chapter III B of this Annex;

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

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

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

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

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

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

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

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

---

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

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

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

▼B

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

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

CHAPTER III

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

A. *Hygiene in milking*

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

▼M3

2. Immediately after milking, the milk must be placed in a clean place which is so equipped as to avoid adverse effects on the quality of the milk. If the milk is not collected within two hours of milking, it must be cooled to a temperature of 8 ºC or lower in the case of daily collection or 6 ºC if collection is not daily. While the milk is being transported to the treatment and/or processing establishment, the temperature of the cooled milk must not exceed 10 ºC unless the milk has been collected within two hours of milking.

   For technological reasons concerning the manufacture of certain milk-based products, the competent authorities may authorize derogations from the temperatures laid down in the first subparagraph provided the end product meets the standards set out in Chapter II of Annex C.

▼B

B. *Hygiene of premises, equipment and tools*

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

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

C. *Staff hygiene*

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

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

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

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

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

   Any person performing milking or handling raw milk shall be required to show that there is no medical impediment to such employment. The medical supervision of such a person shall be governed by the national legislation in force in the Member State concerned or in the case of third countries by specific guarantees to be fixed under the procedure laid down in Article 31 of this Directive.

▼B

D. *Production hygiene*

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

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

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

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

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

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

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

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

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

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

CHAPTER IV

▼M3

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

For compliance with these standards, a separate test shall be carried out on a representative sample of the raw milk collected from each production holding.

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

▼B

A. *Raw cow's milk*

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

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

Plate counti 30 ºC (per ml)	≤ 100 000 (a)
Somatic cell count (per ml)	≤ 400 000 (b)

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

►M3 (b) Geometric average over a period of three months, with at least one sample a month. Where production levels vary considerably according to season, Member States may be authorized, in accordance with the procedure laid down in Article 31 of this Directive, to apply a different method of calculating results during the low lactation period. ◄

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

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

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

►M3 (b) Geometric average over a period of three months, with at least one sample a month. Where production levels vary considerably according to season, Member States may be authorized, in accordance with the procedure laid down in Article 31 of this Directive, to apply a different method of calculating results during the low lactation period. ◄

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

(a) meet the standards of point 1;

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

Staphylococcus aureus (per ml):

n = 5

m = 500

M = 2 000

c = 2.

B. *Raw buffalo milk*

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

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

	from 1. 1. 1994
Plate count 30 ºC (per ml)	≤ 1 000 000 (a)
Somatic cell count (per ml)	≤ 500 000 (b)

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

▼B

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

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

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

plate count 30 ºC (per ml): ≤ 500 000

somatic cell count (per ml): ≤ 400 000

staphylococcus aureus: as for cow's milk.

▼M3

C. Raw goat's, sheep's and buffalo's milk must meet the following standards:

1. if it is intended for the manufacture of heat-treated drinking milk or heat-treated milk-based products:

	From 1. 1. 995	From 1. 2. 1999
Plate count at 30 ºC (per ml)	≤ 3 000 000	< 1 500 000 (a)

(a) without prejudice to the result of the re-examination to be carried out in accordance with Article 21.

2. if it is intended for the manufacture of products made with raw milk by a process which does not involve any heat treatment:

	From 1. 1. 1995	From 1. 1. 1999
Plate count at 30 ºC (per ml)	≤ 1 000 000	< 500 000

▼B

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

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

▼B

ANNEX B

CHAPTER I

General conditions for approval of treatment establishments and processing establishments

Treatment establishments and processing establishments shall have at least:

1. working areas of sufficient size for work to be carried out under adequate hygienic conditions. Their design and layout shall be such as to preclude contamination of the raw materials and products covered by this Directive.

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

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

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

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

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

   (d) doors in non-corrodible materials which are easy to clean;

   (e) adequate ventilation and, where necessary, good steam and water-vapour extraction facilities;

   (f) adequate natural or artificial lighting;

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

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

▼M3

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

▼B

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

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

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

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

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

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

5. appropriate arrangements for protection against pests;

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

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

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

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

▼B

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

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

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

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

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

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

CHAPTER II

General conditions of hygiene in treatment establishments and processing establishments

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

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

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

▼M3

3. Working areas, instruments and working equipment must be used only for work on products for which approval has been granted.

   However, following authorization by the competent authority, they may be used at the same time or other times for work on other foodstuffs fit for human consumption or other products based on milk for human consumption but intended for use other than human consumption, provided they do not create contamination of the products for which approval has been given.

▼B

4. Potable water, within the meaning of Directive 80/778/EEC, must be used for all purposes. However, by way of exception, non-potable water may be used for the cooling of equipment, steam production and fire-fighting, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the raw materials and products covered by this Directive.

5. Disinfectants and similar substances must be approved by the competent authority and used in such a way that they do not have adverse effects on the machinery, equipment, raw materials and products covered by this Directive.

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

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

▼B

B. *General conditions of hygiene applicable to staff*

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

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

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

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

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

   When recruited, any person working on and handling the products covered by this Directive shall be required to prove, by a medical certificate, that there is no medical impediment to such employment. The medical supervision of such a person shall be governed by the national legislation in force in the Member State concerned or, in the case of third countries, by specific guarantees to be fixed under the procedure laid down in Article 31 of this Directive.

CHAPTER III

▼M3

Special requirements for approval of collection centres

▼B

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

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

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

CHAPTER IV

▼M3

Special requirements for approval of standardization centres

▼B

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

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

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

CHAPTER V

Special requirements for the approval of treatment establishments and processing establishments

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

▼M3

(a) equipment for the mechanical filling and proper automatic sealing of containers which are to be used for packaging heat-treated drinking milk and milk-based products in liquid form, after filling, in so far as such operations are carried out there. This requirement does not apply to churns, tanks and bulk packaging of more than 4 litres.

   However, in the case of limited production of liquid milk intended for drinking, the competent authorities may authorize alternative methods using means of filling and sealing which are not automatic, provided that such methods carry equal assurances with regard to hygiene;

▼B

(b) equipment for the cooling and cold storage of heat-treated milk, liquid milk-based products and, ►M3 in the cases provided for in Chapters II and IV ◄, raw milk, in so far as such operations are carried out there. Cold stores must be equipped with correctly calibrated temperature-measuring apparatus;

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

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

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

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

▼M3

(f) 1. in the case of treatment establishments, heat-treatment equipment approved or authorized by the competent authority, fitted with:

— an automatic temperature control,

— a recording thermometer,

— an automatic safety device preventing insufficient heating,

— an adequate safety system preventing the mixture of heat-treated milk with incompletely heated milk,

— an automatic recording device for the safety system referred to in the preceding indent or a procedure for monitoring the system's effectiveness.

However, when approving establishments, the competent authorities may authorize different equipment with equivalent performance guarantees and equal assurances with regard to hygiene.

2. in the case of processing establishments, in so far as such operations are carried out there, equipment and methods for heating, thermization or heat treatment, meeting the hygiene requirements;

▼B

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

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

CHAPTER VI

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

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

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

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

▼M3

3. Equipment, containers and installations which come into contact with milk or milk-based products or other perishable raw materials during production must be cleaned and if necessary disinfected according to a frequency and procedures consistent with the principles referred to in Article 14 (1).

4. The treatment premises must be cleaned according to a frequency and procedures consistent with the principles referred to in Article 14 (1).

▼B

5. For the cleaning of other equipment, containers and installations which come into contact with microbiologically stable milk-based products and with rooms in which such substances are placed, the operator or manager of the establishment shall draw up a cleaning programme based on the risk analysis referred to in Article 14 of this Directive. This programme must meet the requirement referred to in point 1 of this Chapter and must also ensure that

▼B

there is no health risk to products covered by this Directive as a result of inadequate cleaning methods.

▼B

ANNEX C

CHAPTER I

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

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

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

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

   If raw ►M3 cow's ◄ milk is not treated within 36 hours of acceptance, a further test must be carried out on that milk before it is heat-treated. If it is found by means of a direct or indirect method that the plate count of that milk at 30 ºC exceeds 300 000 per ml the milk in question must not be used for the production of heat-treated drinking milk.

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

   (a) the plate count, to ensure that:

▼M3

   — raw milk, if it is not treated within 36 hours of acceptance, does not exceed immediately before heat treatment a plate count at 30 ºC of 300 000 per ml in the case of cow's milk,

▼B

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

   (b) the presence of extraneous water in the milk

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

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

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

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

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

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

4. (a) *Pasteurized milk* must:

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

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

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

   (b) *UHT milk* must:

   — have been obtained by applying to the raw milk a continuous flow of heat entailing the application of a high temperature for a short

▼B

time (not less than + 135 ºC for not less than a second) — the aim being to destroy all residual spoilage micro-organisms and their spores — using aseptic opaque containers, or containers made opaque by the packaging, but so that the chemical, physical and organoleptic changes are minimal,

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

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

(c) *Sterilized milk* must:

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

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

(d) Pasteurized milk which has been subjected to high-temperature pasteurization, UHT milk and sterilized milk may be produced from raw milk which has undergone thermization or an initial heat treatment in another establishment. In this case the time-temperature set must be lower than or equivalent to pasteurization and the milk must show a positive reaction to the peroxidase test before the second treatment. Recourse to this practice must be brought to the attention of the competent authority. Mention of the first treatment must be made on the document provided for in Article 5 (8) of this Directive. ►M3 Pasteurized milk may be produced in the same conditions from raw milk which has undergone only initial thermization. ◄

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

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

5. *Heat-treated drinking milk* must:

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

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

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

▼M3

1. The operator or manager of the processing establishment must take all necessary steps to ensure that the raw milk is heat treated or used, in the case of products made with raw milk

— as soon as possible after acceptance if the milk has not been refrigerated,

— within 36 hours of acceptance if the milk is kept at a temperature not exceeding 6 ºC,

— within 48 hours of acceptance if the milk is kept at a temperature not exceeding 4 ºC,

— within 72 hours for buffalo's, sheep's and goat's milk.

However, for technological reasons concerning the manufacture of certain milk-based products, the competent authorities may authorize the times and temperatures referred to in the above indents to be exceeded.

▼M3

They shall inform the Commission of these derogations, and of the technical reasons for them.

▼B

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

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

(a) *thermized milk* must:

▼M3

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

▼B

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

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

(b) *pasteurized milk* must

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

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

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

CHAPTER II

Microbiological criteria for milk-based products and drinking milk

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

1. Compulsory criteria: Pathogenic micro-organisms

Type of micro-organism	Product	Standard (ml, g) (a)
— Listeria monocytogenes	— Cheese, other than hard cheese	Absent in 25 g (c) n = 5, c = 0
	— Other products (b)	Absent in 1 g
— Salmonella spp.	— All except milk powder	►M3 Absent in 1g ◄ n = 5, c = 0
	— Milk powder	►M3 Absent in 1g ◄ n = 10, c = 0

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

▼B

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

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

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

2. Analytical criteria: organisms indicating poor hygiene

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

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

▼M3

In addition, whenever the standard M is exceeded in the case of cheese made from raw milk and from thermized milk and soft cheese, testing must be carried out for the possible presence of strains of enterotoxinogenic S. aureus or E. coli that are presumed to be pathogenic and also, if necessary, the possible presence of staphylococcal toxins in such products by means of methods to be determined in accordance with the procedure laid down in Article 31 of this Directive. If the abovementioned strains are identified and/or staphylococcal enterotoxins are found, all the batches involved shall be withdrawn from the market. In this case, the competent authority shall be informed of the findings, pursuant to the fifth indent of the second subparagraph of Article 14 (1) of this Directive, and of the action taken to withdraw the suspect batches and the corrective procedures introduced into the production monitoring system.

▼B

3. Indicator organisms: guidelines

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

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

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

4. ►M3 In addition, milk-based products in liquid or gel form which have undergone UHT treatment or sterilization which are intended for conservation at room temperature must meet the following standards after incubation for 15 days at 30 ºC: ◄

(a) plate count at 30 ºC (per 0,1 ml): ≤ 10,

(b) organoleptic test: normal.

B. *Microbiological criteria for drinking milk*

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

Plate count at 30 ºC (per ml) ≤ 50 000 (a)

— *Staphylococcus aureus* (per ml)

m = 100,

M = 500,

n = 5,

c = 2

— Salmonella: absent in 25 g

n = 5,

c = 0

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

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

▼B

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

Pathogenic micro-organisms:	absent in 25 g
	n = 5, c = 0, m = 0, M = 0
Coliforms (per ml):	n = 5, c = 1, m = 0, M = 5

After incubation at 6 ºC for five days

Plate count at 21 ºC (per ml):	n = 5, c = 1, m = 5×10^4, M = 5×10^5.

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

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

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

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

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

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

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

CHAPTER III

Wrapping and packaging

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

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

3. Bottling, filling of containers with heat-treated milk and liquid milk-based products and sealing of containers and of packaging must be carried out automatically. ►M3 However, in the case of limited production, the competent authorities may authorize non-automatic sealing methods provided that these provide equal assurances with regard to hygiene. ◄

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

▼M3

Sealing must be carried out in the establishment in which the last heat treatment of drinking milk and/or milk-based products in liquid form has been

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

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

▼M3

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

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

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

   — an indication, in code or not, whereby the date of the last heat treatment may be established,

   — in the case of pasteurized milk, the temperature at which the product must be stored.

   However, these details need not appear on the reusable glass bottles referred to in Article 11 (6) of Directive 79/112/EEC.

▼B

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

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

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

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

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

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

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

CHAPTER IV

Conditions governing health marking and labelling

A. *Conditions governing health marking*

1. The products covered by this Directive must carry a health mark. Marking must be carried out during or immediately after manufacture in the establishment, in an easily visible place. The mark shall be legible,indelible and its characters easily distinguishable. The health mark may be applied to the product or to the wrapping, if the product is individually wrapped, or to a label affixed to this wrapping. ►M3 However, where small products are individually wrapped and then packaged together or where such small individually wrapped portions are supplied to the final consumer, it will suffice for the health mark to be applied to their collective packaging. ◄

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

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

   (i) either:

   — above: the initial letter or letters of the consigning country in capitals, i.e. for the Community, the letters, B — DK — D — EL — E — F — IRL — I — L — N L — P — UK ►A1 — AT — FI — SE ◄, followed by the approval number of the establishment,

▼B

— below: one of the following sets of initials: CEE — EØF — EWG — EOK — EEC — EEG ►A1 — ETY ◄;

(ii) or:

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

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

— below, one of the following sets of initials: CEE — EØF — EWG — EOK — EEC — EEG ►A1 — ETY ◄;

▼M3

(iii) or

— above: the name or initial letter or letters of the consigning country in capitals, i.e. for the Community, the letters,

B - DK - D - EL - E - F - IRL - I - L - NL - P - UK,

— in the centre: a reference to where the approval number of the establishment is shown,

— below: one of the following sets of initials:

CEE - EØF - EWG - EOK - EEC - EEG.

In the case of the bottles, packaging and containers referred to in Article 11 (4) and (6) of Directive 79/112/EEC, the health mark may indicate only the initials of the consigning country and the approval number of the establishment.

▼B

(b) the health mark may be applied to the product, wrapping or packaging by an ink stamp or by branding, or it may be printed on or applied to a label ►M3 ——————— ◄;

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

▼M3

4. To take account of the disposal of existing packaging, application of the health mark on packaging shall be compulsory only from 1 January 1996. However, the information to be given on the health mark must be shown on the accompanying commercial document provided for in Article 5 (8) and the last subparagraph of Article 7 (A) (9) of this Directive.

▼B

B. *Conditions governing labelling*

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

1. the words ‘raw milk’ for raw milk intended for direct human consumption;
2. the words ‘made with raw milk’ for milk-based products manufactured from raw milk whose manufacturing process does not include any heat treatment, including thermization;
3. for other milk-based products the nature of any heat treatment applied at the end of the manufacturing process;
4. for milk-based products in which growth of micro-organisms can occur, the use-by or minimum durability date.

CHAPTER V

Storage and transport requirements

1. Products covered by this Directive which cannot be stored at ambient temperature must be stored at the temperatures established by the manufacturer to ensure their durability. In particular, the maximum temperature at which pasteurized milk may be kept until it leaves the establishment and during transport must be 6 ºC. When stored under cooled conditions the storage temperatures must be registered and the cooling rate must be such that the product reaches the required temperature as quickly as possible.
2. Tanks, churns and other containers which are used for the transport of pasteurized milk must comply with all the rules of hygiene and in particular the following:

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

▼B

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

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

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

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

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

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

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

7. During transport, the temperature of pasteurized milk transported in tanks or packed in small containers and in churns must not exceed 6 ºC. However, the competent authorities may grant a derogation from this requirement for door-step deliveries ►**M3** and authorize a tolerance of +2 ºC during deliveries to retail establishments ◄.

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

CHAPTER VI

Health checks and supervision of production

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

   (a) check:

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

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

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

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

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

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

      (vii) storage and transport conditions;

   (b) take any samples required for laboratory tests;

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

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

▼B

ANNEX D

CHAPTER I

Community reference laboratory

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

CHAPTER II

Duties and tasks of the Community reference laboratory

1. The Community reference laboratory for the analysis and testing of milk and milk products shall be responsible for:
   - providing national reference laboratories with details of analytical methods and comparative testing,
   - coordinating the application, by national reference laboratories, of the methods referred to in the first indent, in particular by organizing comparative testing,
   - coordinating research into new analytical methods and informing national reference laboratories of advances in this field,
   - conducting initial and further training courses for the benefit of staff from national reference laboratories,
   - providing scientific and technical assistance to the Commission, including the Community Bureau of References, especially in cases where the results of analyses are contested between Member States.
2. The Community reference laboratory shall ensure that the following operating conditions are maintained.

   It must:
   - have suitably qualified staff with adequate training in the techniques applied to the analysis and testing of milk and milk products,
   - possess the equipment and substances needed to carry out the tasks provided for in paragraph 1,
   - have an appropriate administrative infrastructure,
   - ensure that its staff respect the confidential nature of certain subjects, results or communications,
   - have sufficient knowledge of international standards and practices,
   - have available, if appropriate, an updated list of reference substances held by the Community Bureau of References and an updated list of the manufacturers and suppliers of such substances.