In any event, the product must be considered toxic or tainted when contamination reaches the microbic limit value S, which for general purposes is set at 10^3 m.

In the case of Staphylococcus aureus, the value of S must be allowed to exceed 5×10^4.

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

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

— 'Absence in': the result is considered satisfactory,

— 'Presence in': the result is considered unsatifactory.

2. The microbiological methods for examination will be established according to the procedure referred to in Article 9.

Proposal for a Council Regulation (EEC) adopting health rules for the production and placing on the market of heat-treated drinking milk

COM(89) 672 final

(Submitted by the Commission on 23 March 1990)

(90/C 84/12)

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 proposal of the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas heat-treated drinking milk is included in the list of products in Annex II to the Treaty; whereas the production of and trade in raw milk used for the preparation of heat-treated drinking milk constitute an important source of income for the farming population;

Whereas in order to ensure rational development of this sector and to increase productivity, public health rules governing the production and placing on the market of this product should be adopted at Community level;

Whereas the Community must adopt the measures intended to progressively establish the internal market over a period expiring on 31 December 1992;

Whereas the laying down of health rules promotes the protection of public health and completion of the internal market;

Whereas it is necessary to extend the principles laid down in Council Directive 85/397/EEC of 5 August 1985 on health and animal health problems affecting intra-Community trade in heat-treated milk [1], as last amended by Directive 89/165/EEC [2]; whereas this extension requires certain technical amendments to the said Directive;

Whereas it is possible that, due to certain circumstances, some establishments operating prior to 1 January 1992 will not be able to comply with all the rules laid down in this Regulation; whereas the question of whether limited or temporary derogations may be granted to such establishments within the general framework laid down in Council Decision . . ./ . . ./EEC of . . . on the conditions for granting temporary and limited derogations from specific Community health rules for certain products of animal origin [3] should be resolved;

Whereas it should be stressed that the granting of derogations from the health rules laid down in this Regulation is without prejudice to the submission of all operations of production and placing on the market of heat-treated milk to the general health rules laid down in Council Regulation (EEC) No . . . of . . . laying down general health rules for the production and placing on the market of products of animal origin and specific health rules for certain products of animal origin [4];

Whereas Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States

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[1] OJ No L 226, 24. 8. 1985, p. 13.
[2] OJ No L 61, 4. 3. 1989, p. 57.
[3] OJ No L . . .
[4] OJ No L . . .

relating to the labelling, presentation and advertising of foodstuffs [1], as last amended by Council Directive 89/395/EEC [2], and Council Directive 89/396/EEC of 14 June 1989 on indications or markings identifying the lot to which a foodstuff belongs [3] are applicable;

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

HAS ADOPTED THIS REGULATION:

Article 1

This Regulation lays down health rules for the production and placing on the market of heat-treated drinking milk.

Article 2

For the purposes of this Regulation:

1. *'raw milk'* means milk as produced by secretion from the mammary glands of one or more dairy cows which has not been heated beyond 40 °C or subjected to similar treatment;

2. *'production holding'* means an establishment at which one or more milk-producing cows are kept;

3. *'heat-treated drinking milk'* means prepacked drinking milk intended for sale to the final consumer and to institutions, obtained by heat treatment and presented in the form of pasteurized, UHT or sterilized milk ad defined in Annex B, Chapter VI (4), (6) and (7);

4. *'competent authority'* means the health authority designated by the Member State concerned;

5. *'milk treatment establishment'* means an establishment at which milk is heat-treated;

6. the definitions in 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 [4] and 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 tariff heading 04-01 [5] shall apply as necessary.

Article 3

Heat-treated milk must meet the following conditions:

1. It must have been obtained from raw milk:

   (a) from which nothing has been removed and to which nothing has been added, except as an inherent consequence of standardization and purification operations;

   (b) which meets the conditions laid down in Annex A, Chapter I;

   (c) which comes from production holdings which meet the general hygiene conditions laid down in Annex A, Chapter II;

   (d) in respect of which the standards of hygiene observed during milking, collection, handling and transport, and those of the staff carrying out those operations, satisfy the requirements of Annex A, Chapter III;

   (e) which comes from cows and production holdings which are checked at regular intervals by the competent authorities, in particular pursuant to Article 5 (1);

   (f) which has been checked in accordance with Article 7 (1) and which meets the standards set out in Annex A, Chapter IV;

   (g) which, if appropriate, has been channelled through a milk-collection centre fulfilling the conditions laid down in Annex B, Chapters I, III and V;

   (h) which, if appropriate, has been channelled through a milk-standardization centre fulfilling the conditions laid down in Annex B, Chapters I, IV and V;

   (i) which, if appropriate, has undergone an initial heat treatment in another establishment which fulfils the conditions laid down in paragraph 2.

2. It must come from a milk-treatment establishment which meets the conditions laid down in Annex B, Chapters I, II and V.

3. It must have been treated there in accordance with the requirements laid down in Annex B, Chapter VI;

4. It must have been packaged in accordance with Annex B, Chapter VII, at a milk-treatment establishment where the milk has been subjected to final treatment.

5. It must have been stored in accordance with Annex B, Chapter VIII.

6. It must be transported under satisfactory conditions of hygiene in accordance with Annex B, Chapter IX.

7. It must have a weight of not less than 1 030 grams per litre, as recorded in whole milk at 20 °C, or the equivalent as recorded in totally fat-free milk at 20 °C, and contain a minimum of 28 grams of protein (total nitrogen minus non-protein nitrogen) per litre and a fat-free dry matter content of not less than 8,5 %.

(1) OJ No L 33, 8. 2. 1979, p. 1.
(2) OJ No L 186, 30. 6. 1989, p. 17.
(3) OJ No L 186, 30. 6. 1989, p. 21.
(4) OJ No 121, 29. 7. 1964, p. 1977/64.
(5) OJ No L 148, 3. 7. 1971, p. 4.

Article 4

1. The reference methods and, where necessary, routine methods of analysis and testing to be used to monitor compliance with the conditions laid down in Article 3 (1) (f), and (3), shall be adopted in accordance with the procedure laid down in Article 16. If necessary, the sampling methods shall be defined in accordance with the same procedure.

2. The reference methods and, where necessary routine methods to be used to monitor compliance with the conditions laid down in Article 3 (7) shall be adopted in accordance with the procedure laid down in Article 16.

In accordance with the same procedure, limits and methods shall be established to enable a distinction to be made between different types of heat-treated milk as defined in Annex B, Chapter VI.

3. However, pending the decisions referred to in paragraphs 1 and 2, any internationally accepted analysis and test methods shall be recognized as reference methods.

Article 5

1. Production holdings shall undergo periodic inspection by the competent authority in order to ensure that hygiene requirements are fulfilled.

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

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

2. The detailed arrangements for the inspection referred to in paragraph 1 and the general hygiene conditions to be complied with by milk 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 16.

Article 6

1. Each Member State shall draw up a list of milk-treatment establishments approved by it and a list of approved collecition centres and standardization centres. Each such establishment or centre shall have an approval number.

A Member State shall not approve an establishment or centre unless compliance with this Regulation is assured. A Member State shall withdraw approval if the conditions for approval cease to be met.

2. Regular inspection of approved establishments and centres shell be carried out by the competent authority. The inspection and supervision of establishments and of collection and standardization centres shall be carried out under the responsibility of the competent authority.

The competent authority must at all times have free access to all parts of establishments or centres involved in the production of heat-treated drinking milk in order to ensure that this Regulation is being complied with.

3. The detailed rules for the application of this Article shall be determined in accordance with the procedure laid down in Article 17.

Article 7

1. Raw milk and heat-treated drinking milk shall undergo checks carried out by milk-treatment establishments, under the supervision and responsibility of the competent authority, with periodic inspection by the latter, in order to ensure that the milk complies with the requirements of this Regulation.

2. Where there are reasonable grounds for suspecting that the requirements of this Regulation are not being satisfied, the competent authority shall carry out the necessary checks and, if that suspicion is confirmed, take appropriate measures, in particular the suspension of approval.

3. The detailed rules for the application of this Article shall, if necessary, be determined in accordance with the procedure laid down in Article 17.

Article 8

1. The competent authority shall carry out checks to detect any residues of substances having a pharmacological or hormonal action, and of antibiotics, pesticides, detergents and other substances which are harmful or which might alter the organoleptic characteristics of milk or make its consumption dangerous or harmful to human health, in so far as those residues exceed the permitted tolerance limits.

2. If the milk examined shows traces of residues which exceed the permitted tolerances, the heat-treated milk must be excluded from human consumption.

3. Examinations for residues must be carried out in accordance with proven methods which are scientifically recognized, in particular those laid down in Community provisions or other international standards.

4. In accordance with the procedure laid down in Article 16, the Commission shall adopt the detailed arrangements for and the frequency of the checks, and, if necessary, the tolerances provided for in paragraph 1 and the reference methods provided for in paragraph 3.

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

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

Article 9

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

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

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

4. In accordance with the procedure laid down in Article 16, the Commission shall adopt the detailed rules for the application of this Article, and in particular the conditions relating to washing, cleaning and disinfecting before re-use, and the conditions of transport.

Such rules may include an exclusion of certain types of foodstuffs, if the conditions are not adequate for these products.

Article 10

1. Veterinary experts from the Commission may make on-the-spot checks in so far as it is necessary for ensuring uniform application of this Regulation; they may, in particular, verify whether establishments are actually complying with this Regulation. The Commission shall inform the Member States of the results of the inspections.

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

2. If necessary, the general provisions in paragraph 1 of this Article shall be determined in accordance with the procedure laid down in Article 17.

In accordance with the same procedure, a code containing the rules to be followed for the purpose of the checks referred to in paragraph 1 may be established.

Article 11

1. In accordance with the procedure laid down in Article 16, derogations from the provisions of Annex B, Chapters I, II, III and IV may be granted for establishments with limited production.

2. In examining the derogations referred to in paragraph 1, the Commission shall take into consideration the information and criteria laid down in Articles 2 and 3 of Decison .../.../EEC of ... (on the conditions for granting temporary and limited derogations from specific health rules for the production and placing on the market of certain products of animal origin).

3. When granting the derogations referred to in paragraph 1, the Commission shall set the general and particular terms applicable to the implementation of each derogation in accordance with the procedure laid down in Article 16.

Article 12

The rules laid down in Council Regulation (EEC) No ... of ... concerning veterinary checks in intra-Community trade with a view to the completion of the internal market [1] shall apply, in particular with respect to the organization and the action to be taken following the checks carried out by the Member State of destination and the safeguard measures to be applied.

Article 13

The Commission may, in accordance with the procedure laid down in Article 17, draw up recommendations containing guidelines on good manufacturing practices applicable at the different stages of production and placing on the market.

Article 14

The Annexes shall be amended, in particular with a view to adapting them to take account of scientific and technological progress, by the Commission in accordance with the procedure laid down in Article 16.

Article 15

The Commission shall be assisted by the Standing Veterinary Committee set up by Council Decision 68/361/EEC [2], hereinafter referred to as 'the Committee'.

Article 16

Where the procedure laid down in this Article is to be followed, the following provisions shall apply:

The representative of the Commission, after consulting the Management Committee for Milk and Milk Products set up by Council Regulation (EEC) No 804/68 [3] in cases where aspects of chemistry or technology are involved, shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case

[1] OJ No L
[2] OJ No L 255, 18. 10 1968, p 23
[3] OJ No L 148, 28 9 1968, p 13

of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

The Commission shall adopt the proposed measures if they are in accordance with the opinion of the Committee.

If the proposed measures 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, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 17

Where the procedure laid down in the Article is to be followed, the following provisions shall apply:

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter, if necessary, by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account.

Article 18

Until Community rules concerning the importation of heat-treated drinking milk from third countries are implemented, Member States shall apply to such imports conditions at least equivalent to those laid down in this Regulation.

Article 19

1. Directive 85/397/EEC is hereby repealed with effect from 1 January 1993.

2. However, the implementing provisions adopted under Directive 85/397/EEC shall remain valid for the purposes of this Regulation.

Article 20

This Regulation shall enter into force on the 30th day following its publication in the *Official Journal of the European Communities*.

It shall apply from 1 January 1993.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX A

REQUIREMENTS RELATING TO THE ADMISSION OF RAW MILK TO TREATMENT ESTABLISHMENTS

CHAPTER I

Conditions for raw milk

1. The raw milk must come from cows:

   (a) belonging to a bovine herd which is officially tuberculosis-free and free or officially free from brucellosis;

   (b) not showing any symptoms of infectious diseases communicable to human beings through milk or likely to give the milk abnormal organoleptic characteristics;

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

   (d) not showing any udder wound likely to affect the milk;

   (e) yielding at least two litres of milk a day;

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

2. Raw milk must be excluded from treatment if it:

(a) comes from animals which are treated with unauthorized substances referred to in Directives 81/602/EEC [1] and 88/146/EEC [2];

(b) contains residues of the substances referred to in Article 8 (1), in so far as those residues exceed the permitted tolerance levels

CHAPTER II

Hygiene of the holding

1. Raw milk must come from production holdings which are registered and checked in accordance with Article 5. The premises so used must be designed, constructed, maintained and managed in such a way as to ensure:

(i) good conditions of housing, hygiene, cleanliness and health of the cows; and

(ii) good hygienic conditions for milking, the handling and the storage of milk.

2. Premises where cows are milked or milk is stored, handled and cooled must be so sited and constructed as to avoid risk of contamination of the milk. They must be easy to wash and disinfect and have at least:

(a) walls and flooring capable of being readily cleansed in those areas liable to soiling or infection;

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

(c) adequate ventilation and lighting;

(d) an adequate and sufficient supply of potable water within the meaning of Directive 80/778/EEC [3] for use in milking, cleansing and cooling operations;

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

(f) fittings and equipment which are capable of being readily and properly washed, cleansed and disinfected.

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

3. If a movable milking bail is used, the requirements in 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. A milking parlour or milking area, adequately separated from the housing area, is obligatory when the cows are loose housed.

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

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

(1) OJ No L 222, 1. 8. 1981, p. 32.
(2) OJ No L 70, 16. 3. 1988, p. 16.
(3) OJ No L 229, 30. 8. 1980, p. 11.

CHAPTER III

Hygiene in milking, in collecting raw milk and in its transport from the production holding to the collection or standardization centre or to the milk-treatment establishment – hygiene of staff

1. Milking must be carried out hygienically and under the general conditions of hygiene referred to in Article 5 (2) of this Regulation.

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

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

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

5. Where chemicals are used for the disinfection operations laid down in point 4, such chemicals must have been approved for that purpose by the competent authority.

6. The tanks used in the collection of milk must be used in accordance with Article 9 and Annex B, Chapter IX.

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

CHAPTER IV

Standards to be met on admission

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

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

Plate count 30 °C (per ml)	≤ 100 000 (1)
Somatic cell count (per ml)	≤ 400 000 (2)
Antibiotics (per ml)	
— penicillin	< 0,004 µg
— other	undetectable

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

When the maximum standards are exceeded the competent authority shall take appropriate measures.

2. A control system shall be established under the supervision of the competent authority to prevent the presence of extraneous water in milk. This system shall in particular include regular checks on the freezing point of milk from each production holding. When extraneous water is detected the competent authority shall take appropriate measures.

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

4. If, within three months after notification of the measures referred to in points 1, 2 and 3, milk from the holding in question does not meet the standards laid down, the holding must temporarily be excluded from supplying raw milk for the production of heat-treated drinking milk, until such time as it meets the standards again.

However, milk containing residues of antibiotics which exceed the permitted levels must be excluded from human consumption.

ANNEX B

CHAPTER I

General approval requirements

The general requirements for establishments and cold stores laid down in Chapter I of the Annex to Council Regulation (EEC) No . . . (general hygiene rules) shall apply to collection centres, standardization centres and treatment establishments.

CHAPTER II

Special requirements for the approval of treatment establishments

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

(a) equipment for the mechanical filling and proper automatic sealing of containers which are to be used for packaging heat-treated drinking milk, after filling, excluding churns and tanks in so far as such an operation is carried out there;

(b) equipment for the cooling and cold storage of heat-treated milk and, in the cases provided for in Chapters III, IV and VII (1), raw milk. Cold stores must be equipped with temperature-measuring apparatus;

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

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

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

(e) centrifuges or any other suitable means for purifying milk;

(f) 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 pasteurized or sterilized milk with incompletely heated milk,

— an automatic safety recording device preventing the aforementioned mixture.

CHAPTER III

Special requirements for registration of collection centres

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

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

(b) if milk is purified at the milk collection centre, purification must be carried out by means of centrifuges or by any other suitable mechanical means.

CHAPTER IV

Special requirements for registration of standardization centres

In addition to the general requirements laid down in Chapter I, milk 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 suitable mechanical means for purifying milk.

CHAPTER V

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

The general requirements laid down in Chapter II of the Annex to Council Regulation (EEC) No . . . (general hygiene rules) shall apply. In addition:

1. the treatment premises must be cleaned at least once each working day;

2. equipment, containers and installations which come into contact with milk, milk products or other foodstuffs must be washed, cleaned and disinfected at the end of each work phase and at least once each working day;

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

CHAPTER VI

Requirements relating to heat treatment

1. Upon admission to a treatment establishment, milk must, unless treated within four hours of its arrival, be cooled to a temperature not exceeding + 6 °C and maintained at that temperature until heat-treated.

2. The manufacture of heat-treated milk shall include all necessary measures, in particular by means of random sampling checks, to ensure that:

   (a) raw milk, if it is not treated within 36 hours of its arrival, has, immediately before heat-treatment, a plate count of 30 °C not exceeding 200 000 per ml;

   (b) milk which has been subjected to a previous pasteurization has, immediately before the second heat treatment, a plate count at 30 °C not exceeding 100 000 per ml.

3. Pasteurized milk which has been subjected to high-temperature pasteurization, UHT milk and sterilized milk may be produced from milk which has undergone, in another establishment, an initial heat treatment. 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.

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

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

   A. **Microbiological standards**

   Pathogens: absent in 25 grams: n = 5, c = 0, m = 0, M = 0

   Coliform (per ml): n = 5, c = 1, m = 0, m = 5

   After incubation at 6 °C in five days:

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

   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 the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other sample units is m or less.

   In accordance with the procedure laid down in Article 16 the Commission may establish microbiological standards applicable to the labelled 'use by' date and the necessary implementing measures.

   B. **Other standards**

   (a) Pasteurized milk must 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'.

   (b) Antibiotics (per ml): may not exceed permitted levels.

6. UHT milk must satisfy the following conditions:

   — it must have been obtained by applying a continuous flow of heat entailing the application of a high temperature for a short time (not less than 135 °C for not less than a second) with the aim of destroying all residual spoilage microorganisms and their spores, and the use of aseptic opaque containers for packaging, but so that the chemical, physical and organoleptic changes are minimal,

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

   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.

7. Sterilized milk must:

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

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

8. 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 °C for 15 days:

   — plate count (30 °C): ≤ 10 (per 0,1 ml),

   — organoleptic check: normal,

   — antibiotics: not exceeding permitted levels.

9. For checks on the presence of extraneous water in milk the following provisions apply:

   (a) heat-treated drinking milk shall be subjected to regular checks on 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 adequate measures;

   (b) 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 IV (2), and in particular their variation and average;

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

   (c) the Member States shall communicate to the Commission all details of the control system which they apply and its justification before 1 June 1993.

10. 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 respected shall be established in accordance with the procedure laid down in Article 16.

11. Heating processes, the temperatures and duration of heating in respect of pasteurized, sterilized and UHT milk, the types of heating equipment, the flow-diversion valve and the types of temperature controlling and recording devices shall be approved or authorized by the competent central authorities of the Member States.

12. After pasteurization, milk must be cooled immediately, in order to comply with the temperatures laid down in Chapters VIII and IX as soon as possible.

13. The graphs produced by recording thermometers must be dated and kept for two years so that they can be shown upon request to the officials appointed by the competent authorities to inspect the establishment.

CHAPTER VII

Packaging at the treatment establishment of heat-treated drinking milk in containers intended for sale to the final consumer

1. Without prejudice to Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs [1], wrapping and packaging shall comply with all the rules of hygiene and be strong enough to protect the heat-treated milk effectively.

2. Bottling, filling, sealing of containers and packaging must be carried out automatically.

3. Sealing must be carried out in the treatment establishment in which the heat treatment has been carried out immediately after filling, by means of a sealing device which ensures that the milk is protected from any adverse effects of external origin on its characteristics and that the seal cannot be re-used after opening.

4. The producer must ensure for control purposes that in addition to the information required by Directive 79/112/EEC [2] the following information is visibly and legibly displayed on the packaging of the product:

   (a) the nature of the heat treatment which the milk has undergone;

   (b) a batch identification and, in the case of pasteurized milk, the temperature at which the product must be stored;

   (c) the initials (in latin script) of the country of production, i.e. B, DK, D, EL, ESP, F, IRL, I, L, NL, P or UK, followed by the approval number of the treatment establishment and one of the following sets of initials: CEE — EEG — EWG — EØF — EEC — EOK.

(1) OJ No L 40, 11. 2. 1989, p. 38.
(2) OJ No L 33, 8. 2. 1979, p. 1.

CHAPTER VIII

The storage of pasteurized milk in the treatment establishment

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

The storage temperature of the storage rooms must be recorded.

CHAPTER IX

Transport of heat-treated milk

1. 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, cause deterioration in the composition of the milk or adversely affect its organoleptic characteristics,

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

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

   — they must be hermetically sealed shut before and during transportation by means of a watertight closure.

2. Vehicles and containers used for transporting pasteurized milk must be designed and equipped in such a way that the temperatures laid down in paragraph 5 can be maintained throughout the period of transport.

3. Vehicles used for transporting heat-treated 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 indluences and may not be used to transport animals.

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

5. During transport, the temperature of pasteurized milk transported in tanks or packed in small containers and in churns must not exceed 6 °C. However, the competent authorities may grant a derogation from this requirement for door-step deliveries.

6. When heat-treated drinking milk is transported in tanks the information referred to in point 4 (a), (b) and (c) of Chapter VII shall be given in accompanying documents.