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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
►M4	Council Directive 96/23/EC of 29 April 1996	L 125	10	23.5.1996
►M5	Council Regulation (EC) No 806/2003 of 14 April 2003	L 122	1	16.5.2003
►M6	Council Directive 2003/85/EC of 29 September 2003	L 306	1	22.11.2003

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
►A2	Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded	L 236	33	23.9.2003

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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

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([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).

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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;

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[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).

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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).

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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).