

Council Directive 2001/114/EC of 20 December 2001 relating to certain partly or wholly dehydrated preserved milk for human consumption

COUNCIL DIRECTIVE 2001/114/EC  
of 20 December 2001

relating to certain partly or wholly dehydrated preserved milk for human consumption

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the European Parliament<sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(3)</sup>,

Whereas:

- (1) Certain vertical Directives relating to foodstuffs should be simplified to take account only of the essential requirements to be met by the products they cover so as to allow those products to move freely within the internal market, in accordance with the conclusions of the European Council held in Edinburgh on 11 and 12 December 1992, as confirmed by those of the European Council in Brussels on 10 and 11 December 1993.
- (2) 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<sup>(4)</sup> was justified by the fact that differences between national laws concerning preserved milk could result in conditions of unfair competition likely to mislead consumers, and thereby have a direct effect on the establishment and functioning of the common market.
- (3) Directive 76/118/EEC was consequently designed to lay down definitions and common rules governing the composition, manufacturing specifications and labelling of certain preserved milk, so as to ensure its free movement within the Community.
- (4) Directive 76/118/EEC should be brought into line with general Community legislation on foodstuffs, particularly legislation on labelling, authorised additives, hygiene and the health rules laid down in Council Directive 92/46/EEC<sup>(5)</sup>.
- (5) For the sake of clarity, Directive 76/118/EEC should be recast in order to make the rules on the conditions for the production and marketing of certain partly or wholly dehydrated preserved milk for human consumption more accessible.
- (6) The general food-labelling rules laid down in Directive 2000/13/EC of the European Parliament and of the Council<sup>(6)</sup> should apply subject to certain conditions.

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- (7) Subject to Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs<sup>(7)</sup>, the addition of vitamins to the products defined in this Directive is authorised in certain Member States. However, no decision can be taken to extend such authorisation to the Community as a whole. Member States are therefore free to authorise or prohibit the addition of vitamins to their national products although the free movement of goods within the Community is, in any case, to be guaranteed in accordance with the rules and principles deriving from the Treaty.
- (8) For products intended for infants, Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae<sup>(8)</sup> applies.
- (9) In accordance with the principles of subsidiarity and proportionality established by Article 5 of the Treaty, the objective of laying down common definitions and rules for the products concerned and bringing the provisions into line with general Community legislation on foodstuffs cannot be sufficiently achieved by the Member States and can therefore, by reason of the nature of this Directive, be better achieved by the Community. This Directive does not go beyond what is necessary in order to achieve the said objective.
- (10) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(9)</sup>.
- (11) To avoid creating new barriers to free movement, Member States should refrain from adopting, for the products in question, national provisions not provided for by this Directive,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

This Directive shall apply to partly or wholly dehydrated preserved milk defined in Annex I.

*F1 Article 2*

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**Textual Amendments**

- F1** Deleted by [Council Directive 2007/61/EC of 26 September 2007 amending Directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption.](#)

*Article 3*

Directive 2000/13/EC shall apply to the products defined in Annex I, subject to the following conditions.

1. (a) The product names listed in Annex I shall apply only to the products referred to therein and shall, without prejudice to subparagraph (b), be used in trade to designate them;

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- (b) as an alternative to the product names referred to in subparagraph (a), Annex II provides a list of particular designations. These designations may be used in the language and under the conditions laid down in Annex II.
2. The labelling must state the percentage of milk fat, expressed by weight in relation to the finished product, except in the case of the products defined in Annex I(1)(d) and (g) and Annex I(2)(d), and the percentage of fat-free dried milk extract in the case of the products defined in Annex I(1). These particulars shall appear near the trade name.
  3. In the case of the products defined in Annex I(2), the label must state the recommendations as to the method of dilution or reconstitution, including details of the fat content of the product thus diluted or reconstituted.
  4. Where products weighing less than 20 g per unit are packed in an outer packaging, the particulars required by this Article need appear on the outer packaging only, except for the designation required by point 1(a).
  5. The labelling of the products defined in Annex I(2) shall state that the product is ‘not intended as a food for infants under 12 months’.

*Article 4*

For the products defined in Annexes I and II, Member States shall not adopt national provisions not provided for by this Directive.

*F<sup>2</sup> Article 5*

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**Textual Amendments**

- F2** Deleted by [Regulation \(EU\) No 1021/2013 of the European Parliament and of the Council of 9 October 2013 amending Directives 1999/4/EC and 2000/36/EC of the European Parliament and of the Council and Council Directives 2001/111/EC, 2001/113/EC and 2001/114/EC as regards the powers to be conferred on the Commission \(Text with EEA relevance\).](#)

*F<sup>2</sup> Article 6*

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**Textual Amendments**

- F2** Deleted by [Regulation \(EU\) No 1021/2013 of the European Parliament and of the Council of 9 October 2013 amending Directives 1999/4/EC and 2000/36/EC of the European Parliament and of the Council and Council Directives 2001/111/EC, 2001/113/EC and 2001/114/EC as regards the powers to be conferred on the Commission \(Text with EEA relevance\).](#)

*Article 7*

Directive 76/118/EEC is hereby repealed with effect from 17 July 2003.

References to the repealed Directive shall be construed as references to this Directive.

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#### *Article 8*

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 17 July 2003. They shall forthwith inform the Commission thereof.

The measures shall be applied so as to:

- authorise the marketing of the products defined in Annex I if they conform to the definitions and rules laid down in this Directive, with effect from 17 July 2003,
- prohibit the marketing of products which fail to conform to this Directive, with effect from 17 July 2004.

However, the marketing of products which fail to conform to this Directive but which were labelled before 17 July 2004 in accordance with Directive 76/118/EEC shall be permitted until stocks run out.

When Member States adopt these measures these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

#### *Article 9*

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

#### *Article 10*

This Directive is addressed to the Member States.

## ANNEX I

## DEFINITIONS OF PRODUCTS AND PRODUCT NAMES

## 1. Partly dehydrated milk

[<sup>F3</sup>This means the liquid product, whether or not sweetened, obtained by the partial removal of water from milk, from wholly or partly skimmed milk or from a mixture of these products, which may have an admixture of cream or of wholly dehydrated milk or both, the addition of wholly dehydrated milk not to exceed, in the finished products, 25 % of total milk solids.]

**Textual Amendments**

**F3** Substituted by [Council Directive 2007/61/EC of 26 September 2007 amending Directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption.](#)

## — Types of unsweetened condensed milk

## (a) Condensed high-fat milk

Partly dehydrated milk containing, by weight, not less than 15 % fat, and not less than 26,5 % total milk solids.

## (b) Condensed milk

Partly dehydrated milk containing, by weight, not less than 7,5 % fat and not less than 25 % total milk solids.

## (c) Condensed, partly skimmed milk

Partly dehydrated milk containing, by weight, not less than 1 % and less than 7,5 % fat, and not less than 20 % total milk solids.

## (d) Condensed skimmed milk

Partly dehydrated milk containing, by weight, not more than 1 % fat and not less than 20 % total milk solids.

## — Types of sweetened condensed milk

## (e) Sweetened condensed milk

Partly dehydrated milk with an admixture of sucrose (semi-white sugar, white sugar or extra-white sugar) and containing, by weight, not less than 8 % fat and not less than 28 % total milk solids.

## (f) Sweetened condensed, partly skimmed milk

Partly dehydrated milk with an admixture of sucrose (semi-white sugar, white sugar or extra-white sugar) and containing, by weight, not less than 1 % and less than 8 % fat, and not less than 24 % total milk solids.

## (g) Sweetened condensed skimmed milk

Partly dehydrated milk with an admixture of sucrose (semi-white sugar, white sugar or extra-white sugar) and containing, by weight, not more than 1 % fat and not less than 24 % total milk solids.

## 2. Totally dehydrated milk

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[<sup>F3</sup>This means the solid product, where the water content does not exceed 5 % by weight of the finished product, obtained by the removal of water from milk, from wholly or partly skimmed milk, from cream or from a mixture of these products.]

- (a) Dried high-fat milk or high-fat milk powder  
Dehydrated milk containing, by weight, not less than 42 % fat.
- (b) Dried whole milk or whole milk powder  
Dehydrated milk containing, by weight, not less than 26 % and less than 42 % fat.
- (c) Dried partly skimmed milk or partly skimmed-milk powder  
Dehydrated milk with a fat content of more than 1,5 % and less than 26 % by weight.
- (d) Dried skimmed milk or skimmed-milk powder  
Dehydrated milk containing, by weight, not more than 1,5 % fat.

### 3. Treatments

- (a) An additional quantity of lactose not greater than 0,03 % by weight of the finished product is authorised for the manufacture of the products defined in 1(e) to (g).
- (b) [<sup>F3</sup>Without prejudice to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin<sup>(10)</sup>, the preservation of the products referred to in paragraphs 1 and 2 shall be achieved:]
  - by heat-treatment (sterilisation, UHT, etc.), for the products referred to in 1(a) to (d),
  - by the addition of sucrose, for the products referred to in 1(e) to (g),
  - by dehydration, for the products referred to in 2.
- (c) [<sup>F4</sup>Without prejudice to the compositional requirements of points 1 and 2 of this Annex the protein content of milk may be adjusted to a minimum content of 34 % by weight (expressed on fat free dry matter), by the addition and/or withdrawal of milk constituents in such a way as not to alter the whey protein to casein ratio of the milk being adjusted.]

#### Textual Amendments

- F4** Inserted by [Council Directive 2007/61/EC of 26 September 2007 amending Directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption.](#)

### [<sup>F3</sup>4. Authorised additions and raw materials

- (a) Vitamins and minerals in accordance with Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 of December 2006, on the addition of vitamins and minerals and of certain other substances to foods<sup>(11)</sup>.
- (b) Authorised raw materials for protein adjustment purposes referred to in point 3(c) shall be as follows:
  - (i) Milk retentate

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Milk retentate is the product obtained by concentrating milk protein by ultra filtration of milk, partly skimmed milk, or skimmed milk;

(ii) Milk permeate

Milk permeate is the product obtained by removing milk proteins and milk fat from milk, partly skimmed milk, or skimmed milk by ultra filtration; and

(iii) Lactose

Lactose is a natural constituent of milk normally obtained from whey with an anhydrous lactose content of not less than 99,0 % m/m on a dry basis. It may be anhydrous or contain one molecule of water of crystallisation or be a mixture of both forms.]

## ANNEX II

### PARTICULAR DESIGNATIONS FOR CERTAIN PRODUCTS LISTED IN ANNEX I

- (a) The English term ‘evaporated milk’ means the product defined in Annex I(1)(b) containing, by weight, at least 9 % fat and 31 % total milk solids.
- (b) The French terms ‘lait demi-écrémé concentré’ and ‘lait demi-écrémé concentré non sucré’, the Spanish term ‘leche evaporada semidesnatada’, the Dutch terms ‘geëvaporeerde halfvolle melk’ or ‘halfvolle koffiemelk’ and the English term ‘evaporated semi-skimmed milk’ mean the product defined in Annex I(1)(c) containing, by weight, between 4 % and 4,5 % fat and not less than 24 % total solids.
- (c) The Danish term ‘kondenseret kaffebløde’ and the German term ‘kondensierte Kaffeesahne’ mean the product defined in Annex I(1)(a).
- (d) The Danish term ‘flødepulver’, the German terms ‘Rahmpulver’ and ‘Sahnepulver’, the French term ‘crème en poudre’, the Dutch term ‘roompoeder’, the Swedish term ‘gräddpulver’ and the Finnish term ‘kermajauhe’ mean the product defined in Annex I(2)(a).
- (e) The French term ‘lait demi-écrémé concentré sucré’, the Spanish term ‘leche condensada semidesnatada’ and the Dutch term ‘gecondenseerde halfvolle melk met suiker’ mean the product defined in Annex I(1)(f) containing, by weight, between 4 % and 4,5 % fat and not less than 28 % total milk solids.
- (f) The French term ‘lait demi-écrémé en poudre’, the Dutch term ‘halfvolle melkpoeder’ and the English terms ‘semi-skimmed milk powder’ or ‘dried semi-skimmed milk’ mean the product defined in Annex I(2)(c) with a fat content of between 14 % and 16 %.
- (g) The Portuguese term ‘leite em pó meio gordo’ means the product defined in Annex I(2)(c) with a fat content of between 13 % and 26 %.
- (h) The Dutch term ‘koffiemelk’ means the product defined in Annex I(1)(b).
- (i) The Finnish term ‘rasvaton maitojauhe’ means the product defined in Annex I(2)(d).
- (j) The Spanish term ‘leche en polvo semidesnatada’ means the product defined in Annex I(2)(c) with a fat content of between 10 % and 16 %.

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- (k) [<sup>F5</sup>The Maltese term ‘Ħalib evaporat’ means the product defined in Annex I(1)(b).
- (l) The Maltese term ‘Ħalib evaporat b'kontenut baxx ta' xaħam’ means the product defined in Annex I(1)(c).
- (m) The Estonian term ‘koorepulber’ means the product defined in Annex I(2)(a).
- (n) The Estonian term ‘piimapulber’ means the product defined in Annex I(2)(b).
- (o) The Estonian term ‘väherasvane kondenspiim’ means the product defined in Annex I(1)(c).
- (p) The Estonian term ‘magustatud väherasvane kondenspiim’ means the product defined in Annex I(1)(f).
- (q) The Estonian term ‘väherasvane piimapulber’ means the product defined in Annex I(2)(c).
- (r) The Czech term ‘zahuštěná neslazená smetana’ means the product defined in Annex I (1)(a).
- (s) The Czech term ‘zahuštěné neslazené plnotučné mléko’ means the product defined in Annex I (1)(b).
- (t) The Czech term ‘zahuštěné neslazené polotučné mléko’ means the product defined in Annex I (1)(c) containing, by weight, between 4 % and 4,5 % fat.
- (u) The Czech term ‘zahuštěné slazené plnotučné mléko’ means the product defined in Annex I (1)(e).
- (v) The Czech term ‘zahuštěné slazené polotučné mléko’ means the product defined in Annex I (1)(f) containing, by weight, between 4 % and 4,5 % fat.
- (w) The Czech term ‘sušená smetana’ means the product defined in Annex I (2)(a).
- (x) The Czech term ‘sušené polotučné mléko’ means the product defined in Annex I (2) (c) containing, by weight, between 14 % and 16 % fat.]

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#### **Textual Amendments**

- F5** Inserted by 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.



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- (1) OJ C 231, 9.8.1996, p. 20.
- (2) OJ C 279, 1.10.1999, p. 95.
- (3) OJ C 56, 24.2.1997, p. 20.
- (4) OJ L 24, 30.1.1976, p. 49. Directive as last amended by the 1994 Act of Accession.
- (5) OJ L 268, 14.9.1992, p. 1. Directive as last amended by Directive 94/71/EC (OJ L 368, 31.12.1994, p. 33).
- (6) OJ L 109, 6.5.2000, p. 29.
- (7) OJ L 276, 6.10.1990, p. 40.
- (8) OJ L 175, 4.7.1991, p. 35. Directive as last amended by Directive 1999/50/EC (OJ L 139, 2.6.1999, p. 29).
- (9) OJ L 184, 17.7.1999, p. 23.
- (10) [<sup>F3</sup>OJ L 139, 30.4.2004, p. 55. Corrected by OJ L 226, 25.6.2004, p. 22.]
- (11) [<sup>F3</sup>OJ L 404, 30.12.2006, p. 26.]

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#### **Textual Amendments**

- F3** Substituted by Council Directive 2007/61/EC of 26 September 2007 amending Directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption.