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
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THE COUNCIL OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100 thereof,
Having regard to the proposal from the Commission,
Having regard to the opinion of the European Parliament (1),
Having regard to the opinion of the Economic and Social Committee (2),
Whereas in order to contribute towards the establishment of a single market for preserved milk, to lay down conditions of production which take account of consumer requirements and to facilitate trade relations on the basis of fair competition, common rules must be adopted governing composition, use of reserved descriptions, manufacturing specification and labelling of the products concerned;
Whereas existing differences between national provisions governing these products constitute barriers to free movement and create unfair conditions of competition;
Whereas the determination of methods of analysis for checking the purity criteria of the additives and processing aids used in the manufacture of preserved milk, and the determination of the sampling procedure and the methods of analysis required for checking the composition and the manufacturing specifications of this milk, are implementing measures of a technical nature, the adoption of which should be left to the Commission so as to simplify and expedite the procedure;
Whereas, it is desirable that for all cases where the Council empowers the Commission to implement rules relating to foodstuffs, provision should be made for a procedure establishing close cooperation between the Member States and the Commission within the Standing Committee on Foodstuffs set up by the Council Decision of 13 November 1969 (3);
Whereas certain labelling rules laid down in this Directive cannot be implemented at present on account of the problems of understanding which this would create for the buyer;
Whereas in some cases it is sufficient to provide for a supplementary period after which the Directive would be applicable in its entirety;
Whereas in other cases national provisions must be maintained and a review clause applied;
Whereas pending the adoption of Community rules on indication of quality applicable to preserved milk, national provisions on this subject shall not be affected, but this situation must be reviewed if a Community system cannot be established within three years,
HAS ADOPTED THIS DIRECTIVE:

Article 1
1. This Directive concerns partly or wholly dehydrated preserved milk as defined in the Annex.
2. For the purposes of this Directive: (a) "partly dehydrated milk" means the liquid product obtained directly 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 (1)OJ No C 65, 5.6.1970, p. 47. (2)OJ No C 146, 11.12.1970, p. 26. (3)OJ No L 291, 29.11.1969, p. 9. dehydrated milk or of both, the addition of wholly dehydrated milk not to exceed, in the finished product, 25 % of total milk solids ; however, Member States may maintain in their territory any ban on the use of wholly dehydrated milk in the production and marketing of partly dehydrated milk, if the ban existed prior to 1 October 1974.
When adopting the quality criteria referred to in Article 11 (1) (d) and in any case not later than two years after notification of this Directive, the Council shall decide whether or not to continue to permit these prohibitions;

(b) "wholly dehydrated milk" means the solid product whose moisture content is not more than 5 % by weight in the finished product obtained directly by the removal of water from milk, wholly or partly skimmed milk, cream or from a mixture of these products.

3. The preservation of the products defined in the Annex shall be achieved as follows: (i) products in point 1 (a) to (d) by sterilization through heat treatment;
(ii) products in point 1 (e) to (g) by the addition of sucrose (semi-white sugar, sugar or white sugar or extra white sugar);
(iii) products in point 2 by dehydration.

Article 2
Member States shall take all measures necessary to ensure that the products defined in the Annex may be marketed only if they conform to the definitions and rules laid down in this Directive and the Annex thereto.

Article 3
1. The designations referred to in the Annex shall apply only to the products defined therein and must be used in trade to denote such products.
2. The use of the following designations may also be reserved, in their territory, by the Member States concerned: (a) "evaporated milk" in Ireland and the United Kingdom to denote unsweetened condensed milk containing, by weight, at least 9 % fat and 31 % total milk solids;
(b) "kondenseret kaffefløde" in Denmark, "kondensierte Kaffeesahne" in Germany and "panna da caffè" in Italy to denote the product defined in point 1 (d) of the Annex;
(c) "flødepulver" in Denmark, and "Rahmpulver" and "Sahnepulver" in Germany, to denote the product defined in point 2 (d) of the Annex.

3. Five years after the date of notification of this Directive, the Council, acting on a proposal from the Commission, may decide to modify or revoke paragraph 2.

Article 4
Without prejudice to provisions concerning health and hygiene to be adopted by the Community in relation to the basic materials referred to in Article 1 (2), such materials must be subjected to heat treatment at least equivalent to pasteurization where the process of manufacture of the products defined in Article 1 (1) does not include such treatment.

Article 5
1. In the manufacture of the products defined in point 1 (a) to (d) of the Annex, only the use of the following shall be authorized:
>PIC FILE= "T9000919"> >PIC FILE= "T9000921"> - provided that the total quantity by weight of these added substances in the finished product is not greater than: - 0 72 % for products with a total dry matter content not exceeding 28 %,
- 0 73 % for products with a total dry matter content exceeding 28 %;

- provided that the total triphosphate and linear polyphosphate content by weight expressed as P2O5, in ultra heat treated (UHT) unsweetened partly dehydrated milk, is not greater than 0 71 %;

- provided that the total added phosphate content expressed as P2O5 is not greater than 0 71 % for products whose total dry matter content does not exceed 28 %, and is not greater than 0 715 % for products whose total dry matter content exceeds 28 %.

2. In the manufacture of the products defined in point 1 (e) to (g) of the Annex, only the use of the following shall be authorized: (a) the substances listed in paragraph 1, provided that their total quantity by weight in the finished product is not greater than 0 72 % and that the total added phosphate content expressed as P2O5 does not exceed 0 71 %;
(b) a quantity of lactose that is not greater than 0 702 % by weight of the finished product with the addition, where appropriate, of tricalcium phosphate, the quantity of which must not exceed 10 % of the lactose added.

3. In the manufacture of the products defined in point 2 of the Annex, only the use of the following shall be authorized: (a) the substances listed in paragraph 1: - provided that their total quantity, by weight, in the finished product is not greater than 0 75 % of which the maximum content of sodium and potassium bicarbonate is 0 72 %. The latter quantity may be a maximum of 0 73 % in the case of wholly dehydrated milk of the "Hatmaker" or "Roller" types other than that intended for retail sale and for the manufacture of which none of the other substances listed in paragraph 1 is used ; however, the United Kingdom may authorize the retail sale of this milk in its territory;
- provided that the total added phosphate content expressed as P2O5 does not exceed 0 725 %;

(b) L-ascorbic acid (E 300), sodium L-ascorbate (E 301) and ascorbyl palmitate (E 304), singly or mixed at a maximum level, by weight, of the finished product, of 0 705 % expressed as ascorbic acid.

4. Where the designation of the products defined in point 2 (a), (c) and (d) of the Annex refers to instant solubility, the use of lecithins (E 322) shall also be authorized for their manufacture at a maximum level, by weight, of 0.5 %.
5. Where this Article refers to the percentage of an additive, the anhydrous substance is meant.
6. Member States may authorize in their territory the use of additional additives for wholly dehydrated milk used in vending machines and clearly labelled as such.
7. Notwithstanding paragraphs 1 to 3, Member States may authorize in their territory the addition of vitamins to the products defined in the Annex.

Article 6
Without prejudice to the provisions adopted under Article 11 (1), the lactate content of the products defined in the Annex shall not be greater than 300 mg per 100 g of milk solids not fat.

Article 7
1. The only information which is compulsory on the packages, containers or labels of the products defined in the Annex, and which must be conspicuous, clearly legible and indelible, shall be the following: (a) one of the designations reserved for such products in accordance with Article 3;
(b) the word "instant" and a reference to the use of lecithin immediately following the designation where the authorization referred to in Article 5 (4) has been used;

(c) the percentage of milk fat expressed as a proportion of the finished product by weight, except for those products defined in point 1 (b) and (f) and point 2 (b) of the Annex, and the percentage of milk solids not fat derived from milk for products defined in point 1 of the Annex;
(d) further particulars indicating the dehydration process for the products defined in point 2 of the Annex;
(e) for products defined in point 1 of the Annex, intended for retail sale, a statement as to the method of use ; this statement may be replaced by meaningful information on the use of the product if the product is intended for consumption unaltered ; until the expiry of the transitional period referred to in (h), Member States may stipulate that if such statements relate to quantities expressed by weight or by volume, they must also be expressed in equivalent imperial units of measurement;
(f) for products defined in point 2 of the Annex, intended for retail sale, recommendations on the method of dilution or reconstitution, including a statement of the fat content of the products obtained after dilution or reconstitution except for those products defined under point 2 (b) of the Annex ; until the expiry of the transitional period referred to in (h), Member States may stipulate that if such recommendations relate to quantities expressed by weight or by volume, they must also be expressed in equivalent imperial units of measurement;
(g) the words "UHT" or "ultra heat treated" for the products defined in point 1 (a) to (d) of the Annex, where these products are obtained as a result of such treatment and aseptically packed;
(h) the nominal weight, expressed in grammes or kilogrammes and, for liquid and semi-liquid products contained in bottles, the nominal volume expressed in litres, centilitres or millilitres ; pending the entry into force of Community provisions in the matter, national provisions on the measuring and marking of nominal volume and of nominal weight shall apply.
Until the expiry of the transitional period during which the use of the imperial units of measurement appearing in Annex II to Council Directive 71/354/EEC (1), as last amended by the Act of Accession (2), is authorized in the Community, the indication of the nominal weight or nominal volume of the contents expressed in SI units of measurement shall, if the United Kingdom or Ireland so desire for products put up for sale on their national territories, be accompanied by an indication of the nominal weight or nominal volume of the contents expressed in equivalent imperial units of measurement calculated on the basis of the following conversion factors: >PIC FILE= "T0009068">
(i) the name or trade name and address or registered office of the manufacturer or packer, or of a seller established within the Community.

2. The details referred to in paragraph 1 (a) to (d) and (h) shall appear on one of the main surfaces of the packaging or container and in the same field of vision.
3. By way of derogation from paragraph 1, the Member States may: (a) retain national provisions which require the indication of - a list of ingredients,
- a list of additives,
- the date,
- the factory or packaging plant ; this information may, however, appear in code only,
- the country of origin, although this information may not be required for products manufactured within the Community,
- subject to paragraph 8, a specific recommendation on the use of partly or wholly skimmed-milk products for infants where such products are sold retail;

(b) retain or lay down national provisions requiring the indication of the date of the products under point 1 (a) to (d) of the Annex where these products are obtained as a result of ultra heat treatment (UHT) and aseptically packed.

4. By way of derogation from paragraph 1, and without prejudice to the provisions to be adopted by the Community with regard to dietetic foodstuffs, the Member States may retain or lay down national (1)OJ No L 243, 29.10.1971, p. 29. (2)OJ No L 73, 27.3.1972, p. 14.
provisions which require indication of the quantity of added vitamins.
5. Where the products defined in the Annex are made up in packages or containers of a nominal weight of more than 20 kg and are not sold retail, the information required under paragraph 1 (b) to (h) need appear only on the accompanying documents.
6. Where products weighing less than 20 g per unit are packed in an outer package, the information required under paragraph 1 (b) to (h) need appear only on that outer package.
7. For a period of four years from the notification of this Directive and by way of derogation from paragraph 1 (a), Member States may allow the designation herein adopted to be accompanied on the packages, containers or labels by the designation previously used according to the national practices or provisions current at the time of notification of this Directive.
8. Within three years of the notification of this Directive the Council shall re-examine the derogation provided for in paragraph 3 (a), last indent, on the basis of a report from the Commission, accompanied by suitable proposals, where appropriate.
As regards partly skimmed-milk products, this derogation shall in any case cease to apply five years after the notification of this Directive.
9. Member States shall refrain from stating, apart from what is laid down in paragraph 1, how the information referred to in that paragraph is to be given.
However, Member States may forbid trade in their territory in the products defined in the Annex if the details referred to in paragraph 1 (a) to (g) are not shown in their national language or languages on one of the main surfaces of the package, container or label, or as provided for in paragraph 5, on the accompanying documents.
10. Paragraphs 1 to 9 shall apply without prejudice to the provisions to be adopted by the Community on labelling.

Article 8
The products referred to in Article 1 and destined for retail sale shall be packaged by the manufacturer or packer in sealed containers which protect the product from harmful influence and which must be delivered intact to the consumer.

Article 9
1. Member States shall adopt all the measures necessary to ensure that trade in products referred to in Article 1 which comply with the definitions and rules laid down in this Directive and the Annex cannot be impeded by the application of non-harmonized national provisions governing the composition, manufacturing specifications, packaging or labelling of these products or foodstuffs in general.
2. Paragraph 1 shall not be applicable to non-harmonized provisions justified on grounds of: - protection of public health,
- prevention of frauds unless such provisions are liable to impede the application of the definitions and rules laid down by this Directive,
- protection of industrial and commercial property, indications of source, registered designation and prevention of unfair competition.

Article 10

1. Where a Member State, as a result of new information or of a re-assessment of existing information made since the Directive was adopted, has detailed grounds for establishing that the use, in the products referred to in the Annex, of one of the substances listed in Article 5, or where the maximum level which may be employed endangers human health although it complies with the provisions of this Directive, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.
2. The Commission shall examine as soon as possible the grounds given by the Member State concerned and consult the Member States within the Standing Committee for Foodstuffs, and shall then deliver its opinion forthwith and take the appropriate measures.
3. If the Commission considers that amendments to the Directive are necessary in order to resolve the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 12, with a view to adopting these amendments ; the Member State which has adopted safeguard measures may in that event retain them until the amendments enter into force.

Article 11
1. The Council, acting on a proposal from the Commission, shall lay down: (a) as far as is necessary, the purity criteria for the additives or products used as additives referred to in Article 5;
(b) the hygienic, chemical and physical criteria for the products defined in the Annex;
(c) the microbiological criteria for the products defined in the Annex;
(d) the quality criteria for wholly dehydrated milk which may be used in the production of partly dehydrated milk in accordance with Article 1 (2) (a).

2. The following shall be determined in accordance with the procedure laid down in Article 12:
(a) the methods of analysis necessary for checking the above purity criteria;
(b) the sampling procedures and methods of analysis necessary for checking the composition and manufacturing specifications of the products defined in the Annex.

Article 12
1. Where the procedure laid down in this Article is to be followed, the matter shall be referred to the Standing Committee on Foodstuffs set up by the Council Decision of 13 November 1969 (hereinafter called "the committee") by its chairman, either on his own initiative or at the request of a representative of a Member State.
2. The Commission representative shall submit to the committee a draft of the measures to be taken. The committee shall give its opinion on this draft within a time limit set by the chairman having regard to the urgency of the matter. Opinions shall be delivered by a majority of 41 votes, the votes of the Member States being weighted in accordance with Article 148 (2) of the Treaty. The chairman shall not vote.
3. (a) Where the measures envisaged are in accordance with the opinion of the committee, the Commission shall adopt them.
(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 on the measures to be taken. The Council shall act by a qualified majority.
(c) If, within three months of the proposals having been submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 13
The provisions of Article 12 shall apply for a period of 18 months from the date on which the matter was first referred to the committee under Article 12 (1).

Article 14
This Directive shall not affect the laws of the Member States concerning indications of quality applicable to products referred to in the Annex and manufactured in their territory.
In the absence of relevant Community provisions within a period of three years from notification of this Directive, the Council shall re-examine the provisions of this Article on the basis of a report from the Commission with any appropriate proposals.

Article 15
This Directive shall not apply: - without prejudice to any provisions to be adopted by the Community, to dietetic products or products specifically prepared for babies and young children; - to products intended for export outside the Community.

Article 16
Within a period of one year from notification of this Directive, the Member States shall, where necessary, amend their laws to comply with the provisions of this Directive. They shall immediately inform the Commission of these amendments and of those exceptions laid down by this Directive of which they avail themselves. Not later than two years after notification of this Directive the laws thus amended shall apply to the products put on the market for the first time in the Member States.

Article 17
This Directive is addressed to the Member States.

Done at Brussels, 18 December 1975.
For the Council
The President
M. TOROS

ANNEX DESIGNATIONS AND DEFINITIONS OF PRODUCTS
1. Partly dehydrated milk to which this Directive is applicable (a) Unsweetened condensed milk
Partly dehydrated milk containing, by weight, not less than 7 75 % fat and 25 % total milk solids.
(b) Unsweetened condensed skimmed milk
Partly dehydrated milk containing, by weight, not more than 1 % fat and not less than 20 % total milk solids.
(c) Unsweetened condensed partly skimmed milk
Partly dehydrated milk containing, by weight, not less than 1 % and not more than 7 75 % fat, and not less than 20 % total milk solids. Partly dehydrated milk containing, by weight, between 4 and 4 75 % fat and not less than 24 % total milk solids is the only milk which may be sold retail with this designation.
(d) Unsweetened condensed high-fat milk

Partly dehydrated milk containing, by weight, not less than 15 % fat and not less than 26 75 % total milk solids.
(e) Sweetened condensed milk
Partly dehydrated milk with an admixture of sucrose (semi-white sugar, sugar or white sugar or extra white sugar) and containing, by weight, not less than 8 % fat and 28 % total milk solids.
Partly dehydrated milk with an admixture of sucrose (semi-white sugar, sugar or white sugar or extra white sugar) and containing, by weight, not less than 9 % fat and 31 % total milk solids is the only milk which may be sold retail with this designation.
(f) Sweetened condensed skimmed milk
Partly dehydrated milk with an admixture of sucrose (semi-white sugar, sugar or white sugar or extra white sugar) and containing, by weight, not more than 1 % fat and not less than 24 % total milk solids.
(g) Sweetened condensed partly skimmed milk Partly dehydrated milk with an admixture of sucrose (semi-white sugar, sugar or white sugar or extra white sugar) and containing by weight not less than 1 % and not more than 8 % fat and not less than 24 % total milk solids. Partly dehydrated milk with an admixture of sucrose (semi-white sugar, sugar or white sugar or extra white sugar) and containing, by weight, between 4 and 4 75 % fat and not less than 28 % total milk solids is the only milk which may be sold retail with this designation.

2. Wholly dehydrated milk to which this Directive is applicable (a) Dried whole milk or whole milk powder
Dehydrated milk containing, by weight, not less than 26 % fat.
(b) Dried skimmed milk or skimmed-milk powder
Dehydrated milk containing, by weight, not more than 1 75 % fat.
(c) Dried partly skimmed milk or partly skimmed-milk powder
Dehydrated milk with a fat content not less than 1 75 % and not more than 26 % by weight.
(d) Dried high-fat milk or high-fat milk powder
Dehydrated milk containing, by weight, not less than 42 % fat.