

**COMMISSION DIRECTIVE 96/8/EC**  
**of 26 February 1996**  
**on foods intended for use in energy-restricted diets for weight reduction**  
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses<sup>(1)</sup>, and in particular Article 4 thereof,

Whereas the Community measures envisaged by this Directive do not exceed what is necessary for the attainment of the objectives already provided for by Directive 89/398/EEC;

Whereas the products covered by this Directive are varied and are generally distinguished as those intended to replace the whole of the daily diet and those intended to replace part of the daily diet;

Whereas the composition of such products should be such as to fulfil the daily nutritional requirements for essential nutrients, such as to provide a significant part of those requirements, as the case may be, of the persons for whom they are intended;

Whereas a number of products have been recently developed to be used as a replacement for snacks and to supply certain quantities of selected essential macronutrients and micronutrients; whereas the essential composition of those products will be adopted at a later date;

Whereas, in addition, the energy provided by the products covered by this Directive must be restricted;

Whereas the energy content of some products intended to replace the whole of the daily diet is very low; whereas specific rules for these very low energy products will be adopted at a later date;

Whereas this Directive reflects current knowledge about these products; whereas any modification to allow innovation based on scientific and technical progress will be decided by the procedure laid down in Article 13 of Directive 89/398/EEC;

Whereas pursuant to Article 4 (2) of Directive 89/398/EEC, the provisions relating to the substances with specific nutritional purposes to be used in the manu-

facture of the products should be laid down in a separate Commission Directive;

Whereas the provisions relating to the use of additives in the manufacture of the products should be laid down in the relevant Council Directives;

Whereas pursuant to Article 7 of Directive 89/398/EEC, the products covered by this Directive are subject to the general rules laid down by 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<sup>(2)</sup>, as last amended by Commission Directive 93/102/EC<sup>(3)</sup>; whereas this Directive adopts and expands upon the additions and exceptions to those general rules, where it is appropriate;

Whereas, in particular, the nature and destination of the products covered by this Directive require nutritional labelling for the energy value and principal nutrients they contain;

Whereas the Scientific Committee for Food, in accordance with Article 4 of Directive 89/398/EEC, has been consulted on the provisions liable to affect public health;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

1. This Directive is a 'specific Directive' within the meaning of Article 4 of Directive 89/398/EEC and lays down compositional and labelling requirements for foods for particular nutritional uses intended for use in energy restricted diets for weight reduction and presented as such.

2. Foods for use in energy-restricted diets for weight reduction are specially formulated foods which, when used as instructed by the manufacturer, replace the whole or part of the total daily diet. They are divided in two categories:

<sup>(1)</sup> OJ No L 186, 30. 6. 1989, p. 27.

<sup>(2)</sup> OJ No L 33, 8. 2. 1979, p. 1.

<sup>(3)</sup> OJ No L 291, 29. 11. 1993, p. 14.

- (a) products presented as a replacement for the whole of the daily diet;
- (b) products presented as a replacement for one or more meals of the daily diet.

#### Article 2

Member States shall ensure that the products referred to in Article 1 may be marketed within the Community only if they conform to the rules laid down in this Directive.

#### Article 3

Foods covered by this Directive shall comply with the compositional criteria specified in Annex 1.

#### Article 4

All individual components making up the products referred to in point (a) of Article 1 (2), as sold, shall be contained in the same package.

#### Article 5

1. The name under which the product is sold shall be:

- (a) for products covered by point (a) of Article 1 (2), 'Total diet replacement for weight control';
- (b) for products covered by point (b) of Article 1 (2), 'Meal replacement for weight control'.

2. The labelling of the products concerned shall bear, in addition to those provided for in Article 3 of Council Directive 79/112/EEC, the following mandatory particulars:

- (a) the available energy value expressed in kJ and kcal, and the content of proteins, carbohydrates and fat, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;
- (b) the average quantity of each mineral and each vitamin for which mandatory requirements are stipulated in paragraph 5 of Annex 1, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption. In addition, for products mentioned in point (b) of Article 1 (2), information on vitamins and minerals listed in the Table of point 5 of Annex I shall also be expressed as a percentage of the values as defined in the Annex to Council Directive 90/496/EEC<sup>(1)</sup>;
- (c) instructions for appropriate preparation, when necessary and a statement as to the importance of following those instructions;
- (d) if a product, when used as instructed by the manufacturer, provides a daily intake of polyols in excess of

20 g per day, there shall be a statement to the effect that the food may have a laxative effect;

- (e) a statement on the importance of maintaining an adequate daily fluid intake;
- (f) for products mentioned in point (a) of Article 1 (2):
  - (i) a statement that the product provides adequate amounts of all essential nutrients for the day;
  - (ii) a statement that the product should not be used for more than three weeks without medical advice;
- (g) for products mentioned in point (b) of Article 1 (2), a statement to the effect that the products are useful for the intended use only as part of an energy-restricted diet and that other foodstuffs should be a necessary part of such diet.

3. The labelling, advertising and presentation of the products concerned shall not make any reference to the rate or amount of weight loss which may result from their use or to a reduction in the sense of hunger or an increase in the sense of satiety.

#### Article 6

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 September 1997. They shall forthwith inform the Commission thereof.

Those laws, regulations and administrative provisions shall be applied in such a way as to:

- permit trade in products complying with this Directive, by 1 October 1997,
- prohibit trade in products which do not comply with this Directive, with effect from 31 March 1999.

When Member States adopt these provisions, 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 7

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

#### Article 8

This Directive is addressed to the Member States.

Done at Brussels, 26 February 1996.

For the Commission

Martin BANGEMANN

Member of the Commission

<sup>(1)</sup> OJ No L 276, 6. 10. 1990, p. 40.

## ANNEX I

**ESSENTIAL COMPOSITION OF FOODS FOR ENERGY RESTRICTED DIETS**

The specifications refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

**1. Energy**

- 1.1. The energy provided by a product mentioned in Article 1 (2) (a) shall not be less than 3 360 kJ (800 kcal) and shall not exceed 5 040 kJ (1 200 kcal) for the total daily ration.
- 1.2. The energy provided by a product mentioned in Article 1 (2) (b) shall not be less than 840 kJ (200 kcal) and shall not exceed 1 680 kJ (400 kcal) per meal.

**2. Protein**

- 2.1. The protein contained in products mentioned in Article 1 (2) (a) and (b) shall provide not less than 25 % and not more than 50 % of the total energy of the product. In any case the amount of protein of products mentioned in Article 1 (2) (a) shall not exceed 125 g.
- 2.2. The abovementioned provisions on protein refer to a protein the chemical index of which is equal to that of the FAO/WHO (1985) reference protein given in Annex 2. If the chemical index is lower than 100 % of the reference protein, the minimum protein levels shall be correspondingly increased. In any case the chemical index of the protein shall at least be equal to 80 % of that of the reference protein.
- 2.3. The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein in and the quantity of each corresponding amino acid of the reference protein.
- 2.4. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

**3. Fat**

- 3.1. The energy derived from fat shall not exceed 30 % of the total available energy of the product.
- 3.2. For products mentioned in Article 1 (2) (a), the linoleic acid (in the form of glycerides) shall not be less than 4,5 g.
- 3.3. For products mentioned in Article 1 (2) (b), the linoleic acid (in the form of glycerides) shall not be less than 1 g.

**4. Dietary fibre**

The dietary fibre content of products mentioned in Article 1 (2) (a) shall not be less than 10 g and shall not exceed 30 g for the daily ration.

**5. Vitamins and minerals**

- 5.1. The products mentioned in Article 1 (2) (a) shall provide for the whole of the daily diet at least:  
100 % of the amounts of vitamins and minerals specified in Table 1.

- 5.2. The products mentioned in Article 1 (2) (b) shall provide at least 30 % of the amounts of vitamins and minerals specified in the Table per meal; however, the amount of potassium per meal provided by these products shall be at least 500 mg.

TABLE

Vitamin A	( $\mu\text{g}$ RE)	700
Vitamin D	( $\mu\text{g}$ )	5
Vitamin E	(mg-TE)	10
Vitamin C	(mg)	45
Thiamin	(mg)	1,1
Riboflavin	(mg)	1,6
Niacin	(mg-NE)	18
Vitamin B <sub>6</sub>	(mg)	1,5
Folate	( $\mu\text{g}$ )	200
Vitamin B <sub>12</sub>	( $\mu\text{g}$ )	1,4
Biotin	( $\mu\text{g}$ )	15
Pantothenic acid	(mg)	3
Calcium	(mg)	700
Phosphorus	(mg)	550
Potassium	(mg)	3 100
Iron	(mg)	16
Zinc	(mg)	9,5
Copper	(mg)	1,1
Iodine	( $\mu\text{g}$ )	130
Selenium	( $\mu\text{g}$ )	55
Sodium	(mg)	575
Magnesium	(mg)	150
Manganese	(mg)	1

## ANNEX II

AMINO ACID REQUIREMENT PATTERN<sup>(1)</sup>

	g/100 g protein
Cystine + methionine	1,7
Histidine	1,6
Isoleucine	1,3
Leucine	1,9
Lysine	1,6
Phenylalanine + tyrosine	1,9
Threonine	0,9
Tryptophan	0,5
Valine	1,3

<sup>(1)</sup> World Health Organisation. Energy and protein requirements. Report of a Joint FAO/WHO/UNU Meeting. Geneva: World Health Organisation, 1985. (WHO Technical Report Series, 724).