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Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (Text with EEA relevance)

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COMMISSION DIRECTIVE 1999/21/EC

of 25 March 1999

on dietary foods for special medical purposes

(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(1), as amended by Directive 96/84/EC of the European Parliament and of the Council(2), and in particular Article 4(1) thereof,

After consulting the Scientific Committee for food,

(1) Whereas dietary foods for special medical purposes are intended to meet the particular nutritional requirements of persons affected by or malnourished because of a specific disease, disorder or medical condition; whereas for this reason they must be used under medical supervision which may be applied with the assistance of other competent health professionals;

(2) Whereas such foods are numerous and their composition may differ substantially depending on the specific disease, disorder or medical condition of the patients for whom they are intended, the age of the patients and the place in which they receive health care support, on whether the foods are intended to be used as the sole source of nourishment or not, and possibly on other factors;

(3) Whereas, because of the wide diversity of such foods and the rapidly evolving scientific knowledge on which they are based, it is not appropriate to lay down detailed compositional rules;

(4) Whereas, however, some basic rules concerning vitamin and mineral substances content can be laid down for products considered to be nutritionally complete for covering the particular nutritional requirements of the intended user; whereas such rules for nutritionally incomplete foods can be laid down only for the maximum levels of these substances as appropriate;

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

(6) 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 manufacture of foods for special medical purposes should be laid down in a separate Commission directive;

(7) Whereas pursuant to Article 7 of Directive 89/398/EEC, the products covered by that 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(3), as last amended by Commission Directive 1999/10/EC(4); whereas the present Directive adopts and expands upon the additions and exceptions to those general rules, where appropriate;

(8) Whereas, in particular, in view of the nature and destination of dietary foods for special medical purposes, it is necessary to provide information concerning the energy value and principal nutrients contained in such foods;

(9) Whereas, given the particular nature of dietary foods for special medical purposes, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products;

(10) Whereas, in accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of approximating the laws of the Member States relating to foodstuffs intended for particular nutritional uses to lay down rules on foods for special medical purposes; whereas this Directive confines itself to what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 3b of the Treaty;

(11) 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(1) of Directive 89/398/EEC and lays down compositional and labelling requirements for dietary foods for special medical purposes as defined in paragraph 2 and presented as such.

2. For the purposes of this Directive:

(a) "infants" means children under the age of 12 months;

(b) "dietary foods for special medical purposes" means a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two.

3. Dietary foods for special medical purposes are classified in the following three categories:

(a) nutritionally complete foods with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;

(b) nutritionally complete foods with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;

(c) nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment.

The foods referred to in points (b) and (c) may also be used as a partial replacement or as a supplement to the patient's diet.

Article 2

Member States shall ensure that dietary foods for special medical purposes may be marketed within the Community only if they comply with the rules laid down in this Directive.

Article 3

The formulation of dietary foods for special medical purposes shall be based on sound medical and nutritional principles. Their use, in accordance with the manufacturer's instructions, shall be safe and beneficial and effective in meeting the particular nutritional requirements of the persons for whom they are intended, as demonstrated by generally accepted scientific data.

They must comply with the compositional criteria specified in the Annex.

Article 4

1. The name under which dietary foods for special medical purposes are sold shall be respectively:

- in Spanish:

"Alimento dietético para usos médicos especiales"

- in Danish:

"Levnedsmiddel/Levnedsmidler til særlige medicinske formål"

- in German:

"Diätetisches/Diätetische Lebensmittel für besondere medizinische Zwecke (Bilanzierte Diäten)"

- in Greek:

"Διαιτητικά τρόφιμα για ειδικούς ιατρικούς σκοπούς"

- in English:

"Food(s) for special medical purposes"

- in French:

"Aliment(s) diététique(s) destiné(s) a des fins médicales spéciales"

- in Italian:

"Alimento dietetico destinato a fini medici speciali"

- in Dutch:

"Dieetvoeding voor medisch gebruik"

- in Portuguese:

"Produto dietético de use clínico"

- in Finnish:

"Kliininen ravintovalmiste/kliinisiä ravintovalmisteita"

- in Swedish:

"Livsmedel för speciella medicinska ändamål".

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

(a) the available energy value expressed in kJ and kcal, and the content of protein, carbohydrate and fat, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(b) the average quantity of each mineral substance and each vitamin mentioned in the Annex present in the product, expressed in numerical form per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(c) selectively the content of components of protein, carbohydrate and fat and/or of other nutrients and their components the declaration of which would be necessary for the appropriate intended use of the product, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(d) information on the osmolality or the osmolarity of the product where appropriate;

(e) information on the origin and the nature of the protein and/or protein hydrolysates contained in the product.

3. The labelling shall in addition bear the following mandatory particulars, preceded by the words "important notice" or their equivalent:

(a) a statement that the product must be used under medical supervision;

(b) a statement whether the product is suitable for use as the sole source of nourishment;

(c) a statement that the product is intended for a specific age group, as appropriate;

(d) where appropriate a statement that the product poses a health hazard when consumed by persons who do not have the diseases, disorders or medical conditions for which the product is intended.

4. The labelling shall also include:

(a) the statement "For the dietary management of..." where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended;

(b) where appropriate a statement concerning adequate precautions and contra-indications;

(c) a description of the properties and/or characteristics that make the product useful in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product;

(d) where appropriate a warning that the product is not for parenteral use.

5. The labelling shall bear instructions for the appropriate preparation, the use and the storage of the product after the opening of the container, as appropriate.

Article 5

1. To facilitate efficient official monitoring of dietary foods for special medical purposes, when a product is placed on the market, the manufacturer, or where a product is manufactured in a third country, the importer, shall notify the competent authority of the Member States where the product is being marketed by forwarding to it a model of the label used for the product. Member

States may, if they can demonstrate that notification is not necessary in order to monitor those products efficiently in their territory, not impose that obligation.

2. The competent authorities within the meaning of this Article are those referred to in Article 9(4) of Directive 89/398/EEC.

Article 6

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 April 2000 at the latest. 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 with effect from 1 May 2000,

- prohibit trade in products which do not comply with this Directive with effect from 1 November 2001.

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 twentieth day following that of its publication in the Official Journal of the European Communities.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 25 March 1999.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ L 186, 30.6.1989, p. 27.

(2) OJ L 48, 19.2.1997, p. 20.

(3) OJ L 33, 8.2.1979, p. 1.

(4) OJ L 69, 16.3.1999, p. 22.

ANNEX

ESSENTIAL COMPOSITION OF FOODS FOR SPECIAL MEDICAL PURPOSES

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

1. Products referred to in Article 1(3)(a) intended specifically for infants will contain the vitamins and mineral substances as specified in Table 1.

2. Products referred to in Article 1(3)(b) intended specifically for infants will contain the vitamins and mineral substances as specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

3. Maximum levels of vitamins and mineral substances present in products referred to in Article 1(3)(c) intended specifically for infants shall not exceed those specified in Table 1, without

prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

4. Where this is not contrary to the requirements dictated by the intended use, foods for special medical purposes intended specifically for infants shall comply with the provisions relating to other nutrients applicable to infant formulae and follow-on formulae, as the case may be, laid down in Directive 91/321/EEC and its subsequent modifications.

5. Products referred to in Article 1(3)(a), other than those specifically intended for infants will contain the vitamins and mineral substances as specified in Table 2.

6. Products referred to in Article 1(3)(b) other than those specifically intended for infants will contain the vitamins and mineral substances as specified in Table 2 without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

7. Maximum levels of vitamins and mineral substances present in products referred to in Article 1(3)(c) other than those intended specifically for infants shall not exceed those specified in Table 2, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

TABLE 1

Values for vitamins, mineral and trace elements in nutritionally complete foods intended for use by infants

Vitamins:

>TABLE>

Minerals:

>TABLE>

TABLE 2

Values for vitamins, minerals and trace elements in nutritionally complete foods other than those intended for use by infants

Vitamins:

>TABLE>

Minerals:

>TABLE>