

EUROPEAN COMMUNITIES (FOODS INTENDED FOR USE IN ENERGY-RESTRICTED DIETS FOR WEIGHT REDUCTION) REGULATIONS, 1998.

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S.I. No. 242 of 1998.

EUROPEAN COMMUNITIES (FOODS INTENDED FOR USE
IN ENERGY-RESTRICTED DIETS FOR WEIGHT REDUCTION) REGULATIONS,
1998.

I, BRIAN COWEN, Minister for Health and Children in exercise of the powers conferred on me by Section 3 of the European Communities Act, 1972 (No. 27 of 1972) having regard to Council Directive 89/398/EEC⁽¹⁾ of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses as amended by Directive 96/84/EC⁽²⁾ of the European Parliament and of the Council of 19 December 1996 and for the purposes of giving effect to Commission Directive 96/8/EC⁽³⁾ of the 26th of February, 1996, hereby make the following Regulations:—

⁽¹⁾O.J. No. L186, 30.6.1989, p. 27.

⁽²⁾O.J. No. L48, 19.2.1997, p. 20.

⁽³⁾O.J. No. L55, 6.3.1996, p. 22.

Title, Commencement and Interpretation

1. These Regulations may be cited as the European Communities (Foods Intended For Use In Energy-Restricted Diets For Weight Reduction) Regulations, 1998.

2. (1) These Regulations shall come into operation on the 17th day of July, 1998.

(2) Trade in products which do not comply with these Regulations is prohibited with effect from 31 March 1999.

3. (1) In these Regulations:

"advertising" means the making of any pronouncement in the course of a trade, business or profession for the purpose of promoting the supply of goods or services;

"authorised officer" means

(a) an officer of the Minister for Health and Children who is authorised in writing by the Minister for Health and Children to be an authorised officer for the purposes of these Regulations; or

(b) an officer of a health board who is authorised in writing by the Chief Executive Officer of the health board to be an authorised officer for the purposes of these Regulations.

"export" means to market a product in a country outside the European Union;

"foods for use in energy-restricted diets for weight reduction" means specially formulated foods which, when used as instructed by the manufacturer, replace the whole or part of the total daily diet;

"health board" means a health board established under Section 4(1) of the Health Act, 1970 (No. 1 of 1970);

"labelling" means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a product and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such product;

"to market" includes to supply, whether or not for profit, offer, expose for sale, and/or have in possession for sale and cognate words shall be construed accordingly;

"Minister" means the Minister for Health and Children;

"presentation" includes the shape, form, aspect, appearance or packaging of the product concerned, the packaging materials used, the way in which the product is arranged when it is exposed for sale and/or the setting in which the product is displayed with a view to sale, but does not include any form of labelling or advertising.

(2) In these Regulations, any reference to an article or Schedule shall be construed as a reference to an article contained in these Regulations, or, as the case may be, to a Schedule thereto and any reference in an article to a sub-article shall be construed as a reference to a sub-article of that article, unless otherwise stated.

(3) A word or expression that is used in these Regulations and is also used in Council Directive 89/398/EEC and/or Commission Directive 96/8/EC and/or Directive 96/84/EC of the European Parliament and of the Council has, unless the contrary intention appears, the meaning in these Regulations that it has in the Council, Commission and Parliament Directives.

Composition of Foods Intended for Use in Energy-Restricted Diets for Weight Reduction

4. For the purposes of these Regulations, foods for use in energy-restricted diets for weight reduction are divided into two categories:

(1) products presented as a replacement for the whole of the daily diet;

(2) products presented as a replacement for one or more meals of the daily diet.

5. Foods for use in energy-restricted diets for weight reduction must comply with the compositional criteria specified in Schedule I.

Conditions for the Marketing of Foods Intended for Use in Energy-Restricted Diets for Weight Reduction

6. (1) Foods for use in energy-restricted diets for weight reduction may be marketed only if they conform to the provisions laid down in these Regulations.

(2) The individual components which make up the products referred to in Article 4 (1), as marketed and/or sold, must be contained in the same package.

(3) The name under which the product is marketed and/or sold shall be:

(a) for products presented as a replacement for the whole of the daily diet — "Total diet replacement for weight control",

(b) for products presented as a replacement for one or more meals of the daily diet — "Meal replacement for weight control".

Labelling, Advertising and Presentation of Foods Intended for Use in Energy-Restricted Diets for Weight Reduction

7. (1) The labelling of the foods intended for use in energy-restricted diets for weight reduction shall bear the following particulars, in addition to general EU and national food labelling requirements:

(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 article 5 of Schedule I, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;

(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 must 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 presented as a replacement for the whole of the daily diet:

(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 presented as a replacement for one or more meals of the daily diet:

(i) 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,

(ii) in addition to the information required in sub-article (b) above, information on vitamins and minerals as listed in Table I of Schedule I must also be expressed as a percentage of the values as defined in the Annex to Council Directive 90/496/EEC⁽⁴⁾ on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses.

⁽⁴⁾O.J. No. L276, 6.10.1990, p. 40.

8. The labelling, advertising and presentation of the foods intended for use in energy-restricted diets for weight reduction may 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.

Enforcement

9. These Regulations shall be enforced and executed by each health board in respect of its functional area through its authorised officers and/or the officers of the Minister for Health and Children who are authorised officers for the purposes of these Regulations.

10. For the purposes of ensuring compliance with these Regulations, the provisions of the European Communities (Official Control of Food) Regulations, 1998 (S.I. No. 85 of 1998) shall apply.

Offences

11. (1) A person shall not, in respect of foods for use in energy-restricted diets for weight reduction, manufacture, prepare, import, distribute, market, advertise and/or label any product or promotional material which does not comply with these Regulations.

(2) Any person who contravenes any article or sub-article of these Regulations shall be guilty of an offence.

(3) A person guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding £1,000 or, at the discretion of the Court, to imprisonment for a term not exceeding six months or to both.

(4) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of a director, secretary or other officer of the body corporate, the director, secretary or other officer or any person purporting to act in such capacity shall, as well as the body corporate, be guilty of an offence and shall be liable to be proceeded against and punished accordingly.

(5) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act, 1851, proceedings for an offence under these Regulations may be instituted within twelve months from the date of the offence or at any time within twelve months from the date on which knowledge of the commission of the offence came to the attention of an authorised officer.

12. An offence under these Regulations may be prosecuted by—

(a) the Minister, or

(b) a health board within whose functional area the offence was committed.

13. (1) An authorised officer shall be furnished with a certificate of his appointment as an authorised officer and when exercising any power conferred on an authorised officer by these Regulations shall, if so requested by a person affected, produce the certificate for the inspection of the person.

(2) It shall be an offence for a person falsely to represent himself to be an authorised officer.

14. A health board shall

(a) forward to the Minister such information as he may request in respect of the exercise of the functions conferred on it by or under these Regulations;

(b) comply with any directions given by the Minister from time to time as the exercise of its powers or the performance of its functions and duties under these Regulations.

SCHEDULE 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 4(1) shall not be less than 3,360kJ (800kcal) and shall not exceed 5,040kJ (1, 200 kcal) for the total daily ration.

1.2 The energy provided by a product mentioned in Article 4(2) 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 4(1) and 4(2) 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 in products mentioned in Article 4(1) 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 Schedule II. 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 be at least 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 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 4(1), the linoleic acid (in the form of glycerides) shall not be less than 4.5 g.

3.3 For products mentioned in Article 4(2), the linoleic acid (in the form of glycerides) shall not be less than 1 g.

4. Dietary Fibre

4.1 The dietary fibre content of products mentioned in Article 4(1) 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 4(1) 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 4(2) shall provide at least 30% of the amounts of vitamins and minerals specified in Table I per meal; however, the amount of potassium per meal provided by these products shall be at least 500 mg.

Table I

Vitamin A

(µg RE) 700.0

Vitamin D

(µg) 5.0

Vitamin E

(mg-TE) 10.0

Vitamin C

(mg) 45.0

Thiamin

(mg) 1.1

Riboflavin

(mg) 1.6

Niacin

(mg-NE) 18.0

Vitamin B6

(mg) 1.5

Folate

(µg) 200.0

Vitamin B12

(μg) 1.4

Biotin

(μg) 15.0

Pantothenic acid

(mg) 3.0

Calcium

(mg) 700.0

Phosphorus

(mg) 550.0

Potassium

(mg) 3,100

Iron

(mg) 16.0

Zinc

(mg) 9.5

Copper

(mg) 1.1

Iodine

(µg) 130.0

Selenium

(µg) 55.0

Sodium

(mg) 575.0

Magnesium

(mg) 150.0

Manganese

(mg) 1.0

SCHEDULE II

Amino Acid Requirement Pattern ¹

¹ 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).

g/100g protein

Cystine + methionine

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

GIVEN under the Official Seal of the Minister for Health and Children, this 16th day of July, 1998.

BRIAN COWEN, T.D.

Minister for Health and Children.

EXPLANATORY NOTE.

These Regulations give effect to Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction.

These Regulations lay 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.

These Regulations come into effect on the 17th of July, 1998.