



STATUTORY INSTRUMENTS

**S.I. No. 784 of 2007**

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EUROPEAN COMMUNITIES (FOODS INTENDED FOR USE IN  
ENERGY-RESTRICTED DIETS FOR WEIGHT REDUCTION)  
REGULATIONS 2007

**(Prn. A7/2177)**

EUROPEAN COMMUNITIES (FOODS INTENDED FOR USE IN  
ENERGY-RESTRICTED DIETS FOR WEIGHT REDUCTION)  
REGULATIONS 2007

I, MARY HARNEY, 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), and for the purpose of giving further effect to Commission Directive 96/8/EC<sup>1</sup> of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction, and for the purpose of giving effect to Commission Directive 2007/29/EC<sup>2</sup> of 30 May 2007, amending Directive 96/8/EC<sup>1</sup> as regards labelling, advertising or presenting foods intended for use in energy-restricted diets for weight reduction, hereby make the following regulations:—

PART 1

PRELIMINARY

1. These Regulations may be cited as the European Communities (Foods Intended for Use in Energy-Restricted Diets for Weight Reduction) Regulations 2007.

2. (1) In these Regulations—

“Act of 1998” means the Food Safety Authority of Ireland Act 1998 (No. 29 of 1998);

“approved examiner” means—

- (a) a Chief Medical Scientist located at an official laboratory,
- (b) a Consultant Microbiologist located at an official laboratory,
- (c) a Deputy Public Analyst located at a Public Analyst’s Laboratory,
- (d) an Executive Analytical Chemist located at a Public Analyst’s Laboratory,
- (e) a Public Analyst located at a Public Analyst’s Laboratory,
- (f) a person designated by the Minister pursuant to Regulation 17;

“authorised officer” means an authorised officer appointed under section 49 of the Act of 1998;

<sup>1</sup> OJ L 55, 6.3.1996, p. 22.

<sup>2</sup> OJ L 139, 31.5.2007, p. 22.

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 7th December, 2007.*

“Authority” means the Food Safety Authority of Ireland established under section 9 of the Act of 1998;

“Directive” means Commission Directive 96/8/EC<sup>1</sup> of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction, as amended by Commission Directive 2007/29/EC<sup>2</sup> of 30 May 2007 as regards labelling, advertising or presenting foods intended for use in energy-restricted diets for weight reduction;

“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;

“General Food Law Regulation” means Regulation (EC) No 178/2002<sup>3</sup> of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety;

“Health Service Executive” or “HSE” means the Health Service Executive established under section 6 of the Health Act 2004 (No. 42 of 2004);

“Minister” means the Minister for Health and Children;

“official agency” means an official agency carrying out functions under a service contract and acting on behalf of the Authority pursuant to section 48 of the Act of 1998;

“Official Controls Regulation” means Regulation (EC) No 882/2004<sup>4</sup> of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

“official laboratory” means—

- (a) the Public Analyst’s Laboratory, Cork,
- (b) the Public Analyst’s Laboratory, Dublin,
- (c) the Public Analyst’s Laboratory, Galway,
- (d) the Public Health Laboratory, HSE, Dublin Mid-Leinster,
- (e) the Public Health Laboratory, Sligo,
- (f) the Public Health Laboratory, Waterford,
- (g) the Public Health Microbiology Laboratory, Cork,
- (h) the Public Health Microbiology Laboratory, Galway,

<sup>3</sup> OJ L 31, 1.2.2002, p. 1, as amended.

<sup>4</sup> OJ L 165, 30.4.2004, p. 1, as affected by the Corrigendum to Regulation (EC) No 882/2004, OJ L 191, 28.5.2004, p. 1.

(i) the Public Health Microbiology Laboratory, Limerick, or

(j) a laboratory designated by the Minister pursuant to Regulation 17;

“service contract” means a contract entered into between the Authority and an official agency pursuant to section 48 of the Act of 1998.

(2) A word or expression which is used in these Regulations and which is also used in the Directive or in the General Food Law Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directive or in the General Food Law Regulation.

(3) (a) A reference in these Regulations to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other Regulations is intended.

(b) A reference in these Regulations to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

(c) A reference in these Regulations to a Schedule is to a Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.

## PART 2

### GENERAL PROVISIONS

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

(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.

4. Foods for use in energy-restricted diets for weight reduction shall comply with the compositional criteria specified in Schedule 1.

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

(2) The individual components which make up the products referred to in Regulation 3(a), as sold, shall be contained in the same package.

(3) The name under which the product is sold shall be—

(a) for products presented as a replacement for the whole of the daily diet: “Total diet replacement for weight control”, and

- (b) for products presented as a replacement for one or more meals of the daily diet: “Meal replacement for weight control”.

6. The labelling of foods for use in energy-restricted diets for weight reduction shall bear the following particulars, in addition to general Community 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 paragraph 5 of Schedule 1, 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 20g per day, 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 paragraph (b) above, information on vitamins and minerals listed in the Table in Schedule 1, expressed as a percentage of the values as defined in the Annex to Council Directive 90/496/EEC<sup>5</sup> of 24 September 1990 on nutrition labelling for foodstuffs.

<sup>5</sup> OJ L 276, 6.10.1990, p. 40.

7. The labelling, advertising and presentation of foods for use in energy-restricted diets for weight reduction shall not make any reference to the rate or amount of weight loss which may result from their use.

### PART 3

#### ENFORCEMENT

8. (1) The enforcement of these Regulations and of the Directive shall be carried out in accordance with the provisions of these Regulations.

(2) These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998.

(3) These Regulations shall be enforced by the Authority or by an official agency acting pursuant to a service contract with the Authority, or by both, and, without prejudice to paragraph (1), the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with the requirements of these Regulations.

9. (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of foods for use in energy-restricted diets for weight reduction or other relevant substance.

(2) An authorised officer may, for the purpose of taking a sample of foods for use in energy-restricted diets for weight reduction or other relevant substance, open any receptacle.

(3) Where an authorised officer purchases or takes without payment a sample of foods for use in energy-restricted diets for weight reduction or other relevant substance with the intention of having it analysed, he or she shall after purchasing or taking the sample forthwith notify the food business operator, or the person in apparent charge or control of the foods for use in energy-restricted diets for weight reduction or other substance of his or her intention of having the sample analysed.

(4) Where an authorised officer purchases or takes without payment, with the intention of having it analysed, a sample of foods for use in energy-restricted diets for weight reduction or other relevant substance which is suspected by him or her to fail to comply with the provisions of these Regulations, he or she may, by notice in writing to the food business operator, or the person in apparent charge or control of such foods or other substances, prohibit their removal except to any place which may be specified in the notice, during such period as may be specified in the notice, but not exceeding 15 days from the date of the taking of the sample.

10. (1) Where a sample of foods for use in energy-restricted diets for weight reduction or other relevant substance is taken pursuant to these Regulations, for the purposes of official analysis and where the division of the sample is reasonably practicable, the authorised officer concerned may divide the sample into three approximately equal parts, (enforcement, trade (defence) and

referee), each of which he or she shall mark in such a way as to identify it as a part of the sample taken by the officer. The authorised officer shall, in the presence of the food business operator, or the person in apparent charge or control of such food—

- (a) mark, seal and fasten each part in such a manner as its nature will permit, and in such a way that the integrity of the sample is not compromised;
- (b) forward one part to the approved examiner in an official laboratory for analysis;
- (c) give or send one part to the food business operator, and
- (d) retain the third part.

(2) Where an authorised officer takes a sample consisting of foods for use in energy-restricted diets for weight reduction or other relevant substance contained in unopened containers and its division into parts—

- (a) is not reasonably practicable, or
- (b) might affect the composition or impede the proper analysis of the sample,

the provisions of paragraph (1) as regards the division of samples into parts shall be deemed to be complied with if the authorised officer divides the containers into three lots and deals with each lot as if it were a sample as specified under paragraph (1).

(3) In proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or report on a sample of foods for use in energy-restricted diets for weight reduction or other relevant substance taken pursuant to these Regulations, shall not be adduced unless before the proceedings were instituted the sample was divided as specified in paragraphs (1) and (2) of this Regulation. The part, package or container retained by the authorised officer shall be produced at the hearing.

11. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of foods for use in energy-restricted diets for weight reduction or other relevant substance submitted to him or her in pursuance of these Regulations and the approved examiner shall certify to the person who submitted the sample to him or her the result of such analysis. The form of certificate set out in Schedule 3 to these Regulations or a certificate in like form shall be used.

(2) An official certificate given in accordance with paragraph (1) shall be *prima facie* evidence of the matters contained therein until the contrary is proved.

12. Where a sample of foods for use in energy-restricted diets for weight reduction or other relevant substance is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, the Authority, or an official agency as the case may be, shall draw up a report in accordance with Article 9 of the Official Controls Regulation, where the certificate given in accordance with Regulation 11 indicates that there has been non-compliance with these Regulations, the Authority, or the official agency, as the case may be, shall provide the food business operator with a copy of the report.

13. An authorised officer may, for the purposes of these Regulations, inspect and take copies, or samples, of labels used on foods for use in energy-restricted diets for weight reduction or other relevant substance.

14. The provisions of Regulations 9, 10, 11, 12 and 13 shall also apply in respect of—

- (a) products which are not foods for use in energy-restricted diets for weight reduction, as defined in Regulation 2(1), but which are being placed on the market as such, and
- (b) any other products which the authorised officer suspects are being treated, manufactured or placed on the market in contravention of these Regulations.

15. (1) An authorised officer may, for the purposes of these Regulations, seize, remove, detain or direct the withdrawal from the market of any foods for use in energy-restricted diets for weight reduction, or other products, which are suspected by him or her to fail to comply with the provisions of these Regulations.

(2) An authorised officer may, with the consent in writing of the food business operator, or the person in apparent charge or control of such foods for use in energy-restricted diets for weight reduction or other products or in accordance with an order of a judge of the District Court under paragraph (4) of this Regulation, destroy or otherwise dispose of same so as to prevent them being used for human consumption.

(3) An authorised officer who has seized, removed, detained or directed the withdrawal from the market of foods for use in energy-restricted diets for weight reduction or other products in pursuance of the provisions of this Regulation may, on giving notice in writing to the food business operator of his or her intention to do so, apply to a judge of the District Court for an order directing that such products be destroyed or otherwise disposed of.

(4) A judge of the District Court, to whom an application is made for an order under paragraph (3), may, if satisfied that such foods or products fail to comply with these Regulations, order that they be destroyed or otherwise disposed of, after such period, not exceeding 14 days, as may be specified in such order, and an authorised officer shall destroy or dispose of them accordingly.



16. Where an authorised officer has reasonable grounds for believing that a person has contravened any provision of these Regulations and so informs that person, the authorised officer may require that person to state his or her name and address and, if the authorised officer thinks it necessary, to produce corroborative evidence of same.

17. The Minister may, for the purposes of these Regulations designate, by notice in writing published in *Iris Oifigiúil*—

- (a) a laboratory as a laboratory at which samples taken under these Regulations may be analysed, and testing and verification may be carried out, and
- (b) a person as being a person who, or a class of persons the members of which, may, at a designated laboratory, engage in analysis, testing and verification for the purposes of these Regulations.

18. (1) A person is guilty of an offence if he or she fails to comply with these Regulations.

(2) Paragraph (1) shall not apply to an authorised officer or an approved examiner acting in the course of his or her duties pursuant to these Regulations.

(3) A person is guilty of an offence if he or she—

- (a) obstructs or interferes with an authorised officer in the exercise of the officer's powers under these Regulations,
- (b) fails or refuses to state his or her name or address in compliance with a request under these Regulations,
- (c) fails to comply with a request or notice from an authorised officer under these Regulations,
- (d) makes a statement to an authorised officer which the person knows is false or misleading, or
- (e) gives in purported compliance with a request under these Regulations a name, address or corroborative evidence which is false or misleading.

19. Where an offence under these Regulations is committed by a body corporate or by a person acting on behalf of a body corporate and is proved to have been so committed with the consent, connivance or approval of, or to be attributed to any neglect or default on the part of, any director, manager, secretary or any other officer of such body, or a person who was purporting to act in any such capacity, such person is also guilty of an offence and is liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

20. (1) A person is guilty of an offence if he or she forges, or utters knowing it to be forged, a certificate of analysis or other document purporting to be issued, granted or given under these Regulations or required for the purposes of these Regulations, (hereafter referred to as “a forged document”).

(2) A person is guilty of an offence if he or she alters with intent to defraud or deceive, or who utters knowing it to be so altered, a certificate of analysis or other document issued, granted or given under these Regulations, or required for the purposes of these Regulations (hereafter referred to as “an altered document”).

(3) A person is guilty of an offence if he or she without lawful authority, has in his or her possession a forged document or an altered document, knowing it to be a forged or altered document as the case may be.

(4) A person is guilty of an offence if he or she with the intent to defraud or deceive—

(a) tampers with any substance or thing with the result that a sample taken pursuant to these Regulations does not correctly represent the substance sampled, or

(b) tampers or interferes with any sample taken under these Regulations.

(5) A person is guilty of an offence if he or she falsely represents himself or herself to be an authorised officer.

21. (1) For the purposes of these Regulations, every contravention of a Regulation shall be deemed a separate contravention and every contravention of a paragraph or a subparagraph shall also be deemed to be a separate contravention and shall carry the same penalty as for a single contravention of any Regulation.

(2) A person who is guilty of an offence under these Regulations is liable—

(a) on summary conviction to a fine not exceeding €5,000 or at the discretion of the Court to imprisonment for a term not exceeding 3 months or both, or,

(b) on conviction on indictment, to a fine not exceeding €500,000, or imprisonment for a term not exceeding 3 years, or both.

22. Notwithstanding section 57 of the Act of 1998, a summary offence under these Regulations may be prosecuted by—

(a) the Authority, or

(b) an official agency or both.

PART 4

REVOCATION

23. (1) The European Communities (Foods Intended for Use in Energy-Restricted Diets for Weight Reduction) Regulations 1998 (S.I. No. 242 of 1998) are revoked.

(2) References in any other instrument to the Regulations revoked under paragraph (1) shall be construed as references to these Regulations, as appropriate.

## SCHEDULE 1

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 Regulation 3(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 Regulation 3(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 Regulation 3(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 Regulation 3(a) shall not exceed 125g.
- 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 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 Regulation 3(a), the linoleic acid (in the form of glycerides) shall not be less than 4.5g.
- 3.3 For products mentioned in Regulation 3(b), the linoleic acid (in the form of glycerides) shall not be less than 1g.

#### 4. Dietary fibre

The dietary fibre content of products mentioned in Regulation 3(a) shall not be less than 10g and shall not exceed 30g for the daily ration.

#### 5. Vitamins and minerals

5.1 The products mentioned in Regulation 3(a) shall provide for the whole of the daily diet at least: 100% of the amounts of vitamins and minerals specified in the Table.

5.2 The products mentioned in Regulation 3(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 500mg.

TABLE

Vitamin A	(µg RE)	700
Vitamin D	(µg)	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	(µg)	200
Vitamin B <sub>12</sub>	(µg)	1.4
Biotin	(µg)	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	(µg)	130
Selenium	(µg)	55
Sodium	(mg)	575
Magnesium	(mg)	150
Manganese	(mg)	1

## SCHEDULE 2

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

	g/100g 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).

SCHEDULE 3

*Form of official certificate to be given by an approved examiner to an authorised officer.*

**European Communities  
(Foods Intended for Use in Energy-Restricted Diets for Weight Reduction)  
Regulations 2007  
Certificate of Analysis**

To <sup>(1)</sup>.....

I, the undersigned <sup>(2)</sup>.....

being an Approved Examiner for the purpose of the above Regulations certify that on the.....day of..... 20.....

a sample marked <sup>(3)</sup>.....

Date.....

Number.....

Weight or Measure.....

was submitted to me by you and I certify that the sample was prepared and analysed/examined by me or under my direction<sup>(4)</sup>

and as a result I am of the opinion that<sup>(5)</sup>

Observations:<sup>(6)</sup>

I further certify that the sample has undergone no change which would affect my opinion/observations expressed above.

Certified by me this..... day of..... 20.....

at<sup>(7)</sup>.....

Name in BLOCK LETTERS.....

Status.....

Signature.....

\_\_\_\_\_  
Official Stamp

## NOTES

- (1) Insert the name and address of the person submitting the sample for analysis.
- (2) Insert description (e.g. Executive Analytical Chemist located at a Public Analyst Laboratory).
- (3) Insert particulars of marking (e.g. name, date etc.) and the weight or measure (this may be left unanswered if the sample cannot be conveniently weighed or measured or if the weight or measurement is not material to the result of analysis).
- (4) Indicate whether the approved examiner carried out the analysis himself or herself or whether it was carried out by another under the direction of the approved examiner.
- (5) Here the approved examiner should specify the result of the analysis having regard to the provisions of the relevant legislation.
- (6) Here the approved examiner may insert, at his or her discretion, his or her opinion whether the analysis indicates any addition, abstraction, deficiency or the presence of foreign matter or other defect and whether the composition or quality is thereby affected; any physical, chemical or other properties bearing on the composition or quality of the article; whether the article is injurious to health or unfit for human consumption; whether and in what respect a label and description relating to the sample is incorrect or misleading; and he or she may add any other observations as he or she may consider relevant.
- (7) Insert the name and address of the laboratory carrying out the analysis/examination.



GIVEN under my Official Seal,  
29 November 2007

MARY HARNEY.  
Minister for Health and Children



## EXPLANATORY NOTE

*(This note is not part of the instrument and does not purport to be a legal interpretation.)*

These Regulations give further 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 also give effect to Commission Directive 2007/29/EC of 30 May 2007 amending Directive 96/8/EC as regards labelling, advertising or presenting foods intended for use in energy-restricted diets for weight reduction.

These Regulations revoke the European Communities (Foods Intended for Use in Energy-Restricted Diets for Weight Reduction) Regulations 1998 (S.I. No. 242 of 1998).

These Regulations may be cited as the European Communities (Foods Intended for Use in Energy-Restricted Diets for Weight Reduction) Regulations 2007.

BAILE ÁTHA CLIATH  
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR  
Le ceannach díreach ón  
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,  
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2  
nó tríd an bpost ó  
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,  
51 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2  
(Teil: 01 - 6476834/35/36/37; Fax: 01 - 6476843)  
nó trí aon díoltóir leabhar.

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