STATUTORY INSTRUMENTS

S.I. No. 187 of 2009

EUROPEAN COMMUNITIES (DIETARY FOODS FOR SPECIAL MEDICAL PURPOSES) REGULATIONS 2009

(Prn. A9/0695)

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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 1999/21/EC[1] of 25 March 1999 on dietary foods for special medical purposes, as amended by Corrigendum[2] of 5 January 2000, and as amended by Commission Directive 2006/82/EC[3] of 23 October 2006 adapting Directive 91/321/EC on infant formulae and follow-on formulae and Directive 1999/21/EC on dietary foods for special medical purposes, by reason of the accession of Bulgaria and Romania, and for the purpose of giving effect to specific provisions of Commission Directive 2006/141/EC[4] of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, hereby make the following regulations—

PART I

Preliminary

1. These Regulations may be cited as the European Communities (Dietary Foods for Special Medical Purposes) Regulations 2009.

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, or

[1]OJ L 91, 7.4.1999, p. 29.
[2]OJ L 2, 5.1.2000, p. 79.
[3]OJ L 362, 20.12.2006, p. 94.
[4]OJ L 401, 30.12.2006, p. 1.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 22*nd May*, 2009.

(*f*) a person, or member of a class of persons, designated by the Minister pursuant to Regulation 21;

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

"Authority" means the Food Safety Authority of Ireland, established under section 9 of the Act of 1998;

"dietary foods for special medical purposes" means a category of foods for particular nutritional uses specifically 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;

"Directive" means Commission Directive 1999/21/EC[1] of 25 March 1999 on dietary foods for special medical purposes, as amended by Corrigendum[2] of 5 January 2000, and as amended by Commission Directive 2006/82/EC[3] of 23 October 2006 and Commission Directive 2006/141/EC[4] of 22 December 2006;

"General Food Law Regulation" means Regulation (EC) No. 178/2002[5] 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" (HSE) means the Health Service Executive, established under section 6 of the Health Act 2004 (No. 42 of 2004);

"infants" means children under the age of 12 months;

"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[6] 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,

[5]OJ L 31, 1.2.2002, p. 1, as amended.
[6]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, and by the further Corrigendum to Regulation (EC) No 882/2004, OJ L 204, 4.8.2007, p. 29.

(*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,

(*i*) the Public Heath Microbiology Laboratory, Limerick, or

(*j*) a laboratory designated by the Minister pursuant to Regulation 21;

"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.

(*d*) A reference in these Regulations to an Article is to an Article of the Directive, unless it is indicated that reference to some other instrument is intended.

PART 2

General Provisions

3. Dietary foods for special medical purposes may be placed on the market only if they comply with the provisions laid down in these Regulations and in the Directive.

4. (1) 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 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; and

(*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.

(2) The foods referred to in subparagraphs (*a*) and (*b*) of paragraph (1) may also be used as a partial replacement or as a supplement to the patient's diet.

5. (1) The formulation of dietary foods for special medical purposes shall be based on sound medical and nutritional principles.

(2) The use of dietary foods for special medical purposes, 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.

(3) Subject to paragraphs (4) and (5) dietary foods for special medical purposes shall comply with the compositional criteria specified in Schedule 1.

(4) Notwithstanding the provisions of point 4 of Schedule 1, the requirements of Regulation 4(4), (5) and (6) and Regulation 5(3) of the European Communities (Infant Formulae and Follow-On Formulae Regulations 2007 (S.I. No. 852 of 2007) shall not apply mandatorily to dietary foods for special medical purposes intended specifically for infants until 1 January 2012. Prior to that date, such foods shall, in the alternative, comply with the requirements of Regulations 4(3) and 5(3) of the European Communities (Infant Formulae and Follow-On Formulae Regulations 2004 (S.I. No. 242 of 2004).

(5) Notwithstanding the provisions of the second part of Table 1 of Schedule 1, concerning minerals, trade in products containing manganese at the following values will be permitted until 31 December 2009:

	Per 100 kJ		Per 100kcal	
	Minimum	Maximum	Minimum	Maximum
Manganese (mg)	0.012	0.05	0.05	0.2

6. (1) The name under which dietary foods for special medical purposes are sold shall be: "Food(*s*) for special medical purposes". The information required to be given by these Regulations shall be given in the English language and may, in addition, be given in the Irish language.

(2) The other names listed in Article 4 of the Directive, or any of them, may also be included in addition to the name indicated in paragraph (1).

7. The labelling of dietary foods for special medical purposes shall bear, in addition to the particulars provided for in Article 3 of Directive 2000/13/EC[7] of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, 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 100g or per 100ml of the product as sold and where appropriate per 100g or per 100ml 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 Schedule 1 present in the product, expressed in numerical form per 100g or per 100ml of the product as sold and where appropriate per 100g or per 100ml 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 100g or per 100ml of the product as sold and where appropriate per 100g or per 100ml 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.

[7]OJ L 109, 6.5.2000, p. 29, as affected by the Corrigendum to Directive 2000/13/EC, OJ L 124, 25.5.2000, p. 66.

8. The labelling of dietary foods for special medical purposes 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.

9. The labelling of dietary foods for special medical purposes 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.

10. The labelling of dietary foods for special medical purposes shall bear instructions for the appropriate preparation, the use and the storage of the product after the opening of the container, as appropriate.

11. A food business operator placing a dietary food for special medical purposes on the market in the State, shall notify the Authority of that placing on the market by forwarding to it a model of the label used for that product.

PART 3

Enforcement

12. (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.

13. (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of dietary foods for special medical purposes or other relevant substance.

(2) An authorised officer may, for the purpose of taking a sample of dietary foods for special medical purposes or other relevant substance, open any receptacle.

(3) Where an authorised officer purchases or takes without payment a sample of dietary foods for special medical purposes 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 dietary foods for special medical purposes or other relevant 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 dietary foods for special medical purposes 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 working days from the date of the taking of the sample.

14. (1) Where a sample of dietary foods for special medical purposes 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 dietary foods for special medical purposes 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 dietary foods for special medical purposes 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.

15. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of dietary foods for special medical purposes 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 2 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.

16. (1) Where a sample of dietary foods for special medical purposes 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.

(2) Where the certificate given in accordance with Regulation 15 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 referred to in paragraph (1).

17. An authorised officer may, for the purposes of these Regulations, inspect and take copies, or samples, of labels used on dietary foods for special medical purposes or other relevant substance.

18. The provisions of Regulations 13, 14, 15, 16 and 17 shall also apply in respect of:

(*a*) products which are not dietary foods for special medical purposes, 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.

19. (1) An authorised officer may, for the purposes of these Regulations, seize, remove, detain or direct the withdrawal from the market of any dietary foods for special medical purposes 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 dietary foods for special medical purposes 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 dietary foods for special medical purposes 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.

20. 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.

21. 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.

22. (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, an address or corroborative evidence which is false or misleading.

23. Where a body corporate, or a person acting on behalf of a body corporate, commits an offence under these Regulations and the offence is committed with the consent, connivance or approval of, or is attributable to any neglect or default on the part of, any director, manager, secretary or any other officer of such body, or a person 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.

24. (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 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.

25. (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.

26. 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.

PART 4

Revocations

27. (1) The following are revoked:

(*a*) the European Communities (Dietary Foods for Special Medical Purposes) Regulations 2001 (S.I. No. 64 of 2001),

(*b*) the European Communities (Dietary Foods for Special Medical Purposes) (Amendment) Regulations 2002 (S.I. No. 150 of 2002), and

(*c*) the European Communities (Dietary Foods for Special Medical Purposes) (Amendment) Regulations 2007 (S.I. No. 241 of 2007).

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

Regulation 5(3).

SCHEDULE 1

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 Regulation 4(1)(*a*) intended specifically for infants will contain the vitamins and mineral substances as specified in Table 1.

2. Products referred to in Regulation 4(1)(*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 Regulation 4(1)(*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, dietary 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 the European Communities (Infant Formulae and Follow-on Formulae Regulations 2007 (S.I. No. 852 of 2007) and its subsequent modifications.

5. Products referred to in Regulation 4(1)(*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 Regulation 4(1)(*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 Regulation 4(1)(*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:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg RE)	14	43	60	180
Vitamin D (µg)	0.25	0.75	1	3
Vitamin K (µg)	1	5	4	20
Vitamin C (mg)	1.9	6	8	25
Thiamin (mg)	0.01	0.075	0.04	0.3
Riboflavin (mg)	0.014	0.1	0.06	0.45
Vitamin B6 (mg)	0.009	0.075	0.035	0.3
Niacin (mg NE)	0.2	0.75	0.8	3
Folic acid (µg)	1	6	4	25
Vitamin B_{12} (µg)	0.025	0.12	0.1	0.5
Pantothenic acid (mg)	0.07	0.5	0.3	2
Biotin (µg)	0.4	5	1.5	20
Vitamin E (mg α-TE)	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1mg per 100 available kJ	0.75	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.5mg per 100 available kcal	3

Minerals:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	5	14	20	60
Chloride (mg)	12	29	50	125
Potassium (mg)	15	35	60	145
Calcium (mg)	12	60	50	250
Phosphorus (mg)[1]	6	22	25	90
Magnesium (mg)	1.2	3.6	5	15
Iron (mg)	0.12	0.5	0.5	2
Zinc (mg)	0.12	0.6	0.5	2.4
Copper (µg)	4.8	29	20	120
Iodine (µg)	1.2	8.4	5	35
Selenium (µg)	0.25	0.7	1	3
Manganese (µg)[2]	0.25	25	1	100
Chromium (µg)	-	2.5	-	10
Molybdenum (µg)	-	2.5	-	10
Fluoride (mg)	-	0.05	-	0.2

[1] The calcium/phosphorus ratio shall not be less than 1.2 nor greater than 2.0.
[2] See Regulation 5(5).

TABLE 2

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

Vitamins:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg RE)	8.4	43	35	180
Vitamin D (µg)	0.12	0.65/0.75[(1)]	0.5	2.5/3[(1)]
Vitamin K (µg)	0.85	5	3.5	20
Vitamin C (mg)	0.54	5.25	2.25	22
Thiamin (mg)	0.015	0.12	0.06	0.5
Riboflavin (mg)	0.02	0.12	0.08	0.5
Vitamin B6 (mg)	0.02	0.12	0.08	0.5
Niacin (mg NE)	0.22	0.75	0.9	3
Folic acid (µg)	2.5	12.5	10	50
Vitamin B_{12} (µg)	0.017	0.17	0.07	0.7
Pantothenic acid (mg)	0.035	0.35	0.15	1.5
Biotin (µg)	0.18	1.8	0.75	7.5
Vitamin E (mg α-TE)	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1mg per 100 available kJ	0.75	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.5mg per 100 available kcal	3

[(1)] For products intended for children of 1 to 10 years of age.

Minerals:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	7.2	42	30	175
Chloride (mg)	7.2	42	30	175
Potassium (mg)	19	70	80	295
Calcium (mg)	8.4/12[(1)]	42/60[(1)]	35/50[(1)]	175/250[(1)]
Phosphorus (mg)	7.2	19	30	80
Magnesium (mg)	1.8	6	7.5	25
Iron (mg)	0.12	0.5	0.5	2.0
Zinc (mg)	0.12	0.36	0.5	1.5
Copper (µg)	15	125	60	500
Iodine (µg)	1.55	8.4	6.5	35
Selenium (µg)	0.6	2.5	2.5	10
Manganese (mg)	0.012	0.12	0.05	0.5
Chromium (µg)	0.3	3.6	1.25	15
Molybdenum (µg)	0.72	4.3	3.5	18
Fluoride (mg)	-	0.05	-	0.2

[(1)] For products intended for children of 1 to 10 years of age.

SCHEDULE 2

Regulation 15(1).

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

European Communities

(Dietary Foods for Special Medical Purposes) Regulations 2009

Certificate of Analysis

To[1].....

I, the undersigned[2].....

being an approved examiner for the purpose of the above Regulations certify that on

the.....day of..... 20.....

a sample marked[3].....

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[4]

and as a result I am of the opinion that[5]

Observations:[6]

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[7].....

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's 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.

L.S.

GIVEN under my Official Seal,
18 May 2009

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 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes, as amended by Corrigendum of 5 January 2000, and as amended by Commission Directive 2006/82/EC of 23 October 2006. These Regulations also give effect for the first time to certain provisions relating to dietary foods for special medical purposes of Commission Directive 2006/141/EC of 22 December 2006.

These Regulations revoke the European Communities (Dietary Foods for Special Medical Purposes) Regulations 2001 (S.I. No. 64 of 2001), the European Communities (Dietary Foods for Special Medical Purposes) (Amendment) Regulations 2002 (S.I. No. 150 of 2002), and the European Communities (Dietary Foods for Special Medical Purposes) (Amendment) Regulations 2007 (S.I. No. 241 of 2007).

These Regulations may be cited as the European Communities (Dietary Foods for Special Medical Purposes) Regulations 2009.

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