# S.I. No. 506/2007 — European Communities (Food Supplements) Regulations 2007

S.I. No. 506 of 2007

EUROPEAN COMMUNITIES (FOOD SUPPLEMENTS) REGULATIONS 2007

*Notice of the making of this Statutory Instrument was published in*

*"Iris Oifigiúil" of* 20*th July*, 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 Directive 2002/46/EC [1] of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, and for the purpose of giving effect to Commission Directive 2006/37/EC [2] of 30 March 2006 amending Annex II to Directive 2002/46/EC [1] of the European Parliament and of the Council as regards the inclusion of certain substances, hereby make the following regulations—

PART 1 Preliminary

1. These Regulations may be cited as the European Communities (Food Supplements) 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 Deputy Public Analyst,

(*b*) an Executive Analytical Chemist, or

(*c*) a Public Analyst,

located at an official laboratory;

"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;

"Directive" means Directive 2002/46/EC 1 of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, as amended by Commission Directive 2006/37/EC 2 of 30 March 2006;

"food supplements" means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;

"General Food Law Regulation" means Regulation (EC) No. 178/2002 [3] 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;

"Minister" means the Minister for Health and Children;

"nutrients" means the following substances—

(*a*) vitamins,

(*b*) minerals;

"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 [4] 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, or

(*c*) the Public Analyst's Laboratory, Galway;

"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. (1) These Regulations concern food supplements marketed as foodstuffs and presented as such.

(2) These Regulations shall not apply to medicinal products as defined by Directive 2001/83/EC [5] of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

(3) Food supplements shall not be placed on the market unless they comply with the requirements of these Regulations.

(4) Food supplements shall be manufactured in accordance with the requirements of these Regulations.

4. (1) Subject to paragraph (4) of this Regulation, only vitamins and minerals listed in Schedule 1, in the forms listed in Schedule 2, may be used in the manufacture of food supplements.

(2) Purity criteria for substances listed in Schedule 2, specified by Community legislation for their use in the manufacture of foodstuffs for purposes other than those covered by these Regulations, shall apply.

(3) For those substances listed in Schedule 2 for which purity criteria are not specified by Community legislation, and until such specifications are adopted, generally acceptable purity criteria recommended by international bodies shall be applicable.

(4) By way of derogation from paragraph (1) of this Regulation, the use of vitamins and minerals not listed in Schedule 1, or in forms not listed in Schedule 2, is permitted provided that—

(*a*) the substance in question was used in one or more food supplements marketed in the Community on 12 July 2002, and

(*b*) the Authority, after consultation with the Minister, has either

— submitted a dossier, supporting use of the substance, or its use in that form, or

— indicated, in writing, its approval of a dossier submitted by another Member State,

and such dossier or written approval had been sent to the Commission by 12 July 2005, and where (*a*) and (*b*) are satisfied, the substance in question may be used until 31 December 2009, or until the European Food Safety Authority has given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements, whichever is the earliest.

5. (1) Food supplements shall be delivered to the ultimate consumer only in a pre-packaged form.

(2) For the purposes of Article 5(1) of Directive 2000/13/EC [6] , the name under which products covered by Directive 2002/46/EC1, as amended, are sold shall be ‘food supplement’.

(3) The labelling, presentation and advertising of food supplements shall not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.

(4) Without prejudice to Directive 2000/13/EC6, the labelling of food supplements shall bear the following particulars—

(*a*) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances,

(*b*) the portion of the product recommended for daily consumption,

(*c*) a warning not to exceed the stated recommended daily dose,

(*d*) a statement to the effect that food supplements should not be used as a substitute for a varied diet, and

(*e*) a statement to the effect that the products should be stored out of the reach of young children.

(5) The labelling, presentation and advertising of food supplements shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

(6) The amount of the nutrients or substances with a nutritional or physiological effect present in the product shall be declared on the labelling in numerical form. The units to be used for vitamins and minerals shall be those specified in Schedule 1.

(7) The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling.

(8) Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned, as the case may be, in the Annex to Directive 90/496/EEC [7] .

(9) The declared values mentioned in paragraphs (6) and (7) of this Regulation shall be average values based on the manufacturer's analysis of the product.

(10) The percentage of the reference values for vitamins and minerals mentioned in paragraph (8) of this Regulation may also be given in graphical form.

6. Any person placing a food supplement product on the market in the State, shall notify the Authority of that placing on the market by forwarding it a model of the label used for the product.

7. (1) The Minister, after consultation with the Authority, may by order temporarily suspend or restrict the application of the provisions of the Directive, or of one of the implementing Community acts, where, as a result of new information or of a reassessment of existing information made since Directive 2002/46/EC1 or the relevant implementing Community act was adopted, he or she has detailed grounds for establishing that a product referred to in Article 1 of the Directive endangers human health even though it complies with the Directive or the implementing Community acts.

(2) The Minister shall give notice of any such suspension or restriction in *Iris Oifigiúil*.

## 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 food supplements or of another relevant article or substance.

(2) An authorised officer may, for the purpose of taking a sample of food supplements or of another relevant article or substance, open any receptacle.

(3) Where an authorised officer purchases, or takes without payment, with the intention of having it analysed, a sample of food supplements or of another relevant article or substance which are 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 seller, owner or person in apparent charge or control of such food supplements or other article or substance, prohibit the removal of the food supplements, article or substance, 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 detention of the sample.

(4) Where an authorised officer purchases or takes without payment a sample of food supplements or of another relevant article or substance with the intention of having it analysed, he or she shall after purchasing or taking the sample forthwith notify the seller, owner or person in apparent charge or control of the food supplements or other article or substance of his or her intention of having the sample analysed.

(5) Nothing in these Regulations shall authorise the examination or detention of food supplements or of another relevant article or substance without the consent of an officer of the Revenue Commissioners where the duties of such officer in relation to such item have not been wholly discharged.

10. (1) Where a sample of food supplements or of another relevant article or substance is taken pursuant to these Regulations for the purposes of analysis and where the division of the sample is reasonably practicable, the authorised officer concerned may divide the sample into three approximately equal parts 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 mark, seal and fasten each part in such a manner as its nature will permit, forward one part to an approved examiner in an official laboratory for analysis, give or send one part to the seller, owner or person in apparent charge or

control of the food supplements or other relevant article or substance, and retain the third part.

(2) Where an authorised officer takes a sample consisting of food supplements or of another relevant article or 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) of this Regulation 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) of this Regulation.

(3) In proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or report on a sample of food supplements or of another relevant article or 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 food supplements or of another relevant article or 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) of this Regulation shall be prima facie evidence of the matters contained therein until the contrary is proved.

12. Where a sample of food supplements or of another relevant article or substance is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, and where the certificate given in accordance with Regulation 11 indicates that there has been non-compliance with these Regulations, 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, and shall provide the seller, owner or person in apparent charge or control of the food supplements or other relevant article or substance, 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 food supplements.

14. (1) An authorised officer may, for the purposes of these Regulations, seize, remove, detain or direct the withdrawal from the market of any food supplement which

are suspected by him or her to fail to comply with the provisions of these Regulation.

(2) An authorised officer may, with the consent in writing of the seller, owner or person in apparent charge or control of such food supplements, 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 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, food supplements in pursuance of the provisions of this Regulation may, on giving notice in writing to the owner or person in apparent charge or control of such food supplements of his or her intention to do so, apply to a judge of the District Court for an order directing that such food supplements 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 food supplements 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.

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

16. (1) A person who fails to comply with these Regulations is guilty of an offence.

(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 who—

(*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,

is guilty of an offence.

17. 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 shall also be guilty of an offence and shall be liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

18. (1) Any person who 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 in this Regulation referred to as "a forged document"), is guilty of an offence.

(2) Any person who 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 in this Regulation referred to as "an altered document"), is guilty of an offence.

(3) Any person who, without lawful authority, has in his or her possession a forged document or an altered document is guilty of an offence.

(4) Any person who, with intent to defraud or deceive—

(*a*) tampers with any thing so as to procure that any 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

is guilty of an offence.

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

19. (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 of these Regulations.

(2) A person who is guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding €5,000 or at the discretion of the Court to imprisonment for a term not exceeding 6 months or both.

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

(*a*) the Authority, or

(*b*) an official agency,

or both.

## PART 4 Revocations

21. (1) The European Communities (Food Supplements) Regulations 2003 ( S.I. No. 539 of 2003 ) 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 VITAMINS AND MINERALS WHICH MAY BE USED IN THE MANUFACTURE OF FOOD SUPPLEMENTS

| **1. Vitamins** | **2. Minerals** |
|---|---|
| Vitamin A (g RE) | Calcium (mg) |
| Vitamin D (g) | Magnesium (mg) |
| Vitamin E (mg -TE) | Iron (mg) |
| Vitamin K (g) | Copper (g) |
| Vitamin B1 (mg) | Iodine (g) |
| Vitamin B2 (mg) | Zinc (mg) |
| Niacin (mg NE) | Manganese (mg) |
| Pantothenic acid (mg) | Sodium (mg) |
| Vitamin B6 (mg) | Potassium (mg) |
| Folic acid (g) | Selenium (g) |

| | |
|---|---|
| Vitamin B12 (g) | Chromium (g) |
| Biotin (g) | Molybdenum (g) |
| Vitamin C (mg) | Fluoride (mg) |
| | Chloride (mg) |
| | Phosphorus (mg) |

## SCHEDULE 2 VITAMIN AND MINERAL SUBSTANCES WHICH MAY BE USED IN THE MANUFACTURE OF FOOD SUPPLEMENTS

**A. Vitamins**

| | |
|---|---|
| 1. VITAMIN A | 8. PANTOTHENIC ACID |
| (*a*) retinol | (*a*) D-pantothenate, calcium |
| (*b*) retinyl acetate | (*b*) D-pantothenate, sodium |
| (*c*) retinyl palmitate | (*c*) dexpanthenol |
| (*d*) beta-carotene | 9. VITAMIN B6 |
| 2. VITAMIN D | (*a*) pyridoxine hydrochloride |
| (*a*) cholecalciferol | (*b*) pyridoxine 5'-phosphate |
| (*b*) ergocalciferol | 10. FOLATE |
| 3. VITAMIN E | (a) pteroylmonoglutamic acid |
| (*a*) D-alpha-tocopherol | (b) calcium-L-methylfolate |
| (*b*) DL-alpha-tocopherol | 11. VITAMIN B12 |
| (*c*) D-alpha-tocopheryl acetate | (a) cyanocobalamin |

(*d*) DL-alpha-tocopheryl acetate

(*e*) D-alpha-tocopheryl acid succinate

4. VITAMIN K

**(*a*)** phylloquinone (phytomenadione)

5. VITAMIN B1

(*a*) thiamin hydrochloride

(*b*) thiamin mononitrate

6. VITAMIN B2

(*a*) riboflavin

(*b*) riboflavin 5'-phosphate, sodium

7. NIACIN

(*a*) nicotinic acid

(*b*) nicotinamide

(b) hydroxocobalamin

12. BIOTIN

(a) D-biotin

13. VITAMIN C

(a) L-ascorbic acid

(b) sodium-L-ascorbate

(c) calcium-L-ascorbate

(d) potassium-L-ascorbate

(e) L-ascorbyl 6-palmitate

**B. Minerals**

calcium carbonate

calcium chloride

calcium salts of citric acid

zinc acetate

zinc chloride

zinc citrate

| | |
|---|---|
| calcium gluconate | zinc gluconate |
| calcium glycerophosphate | zinc lactate |
| calcium lactate | zinc oxide |
| calcium salts of orthophosphoric acid | zinc carbonate |
| calcium hydroxide | zinc sulphate |
| calcium oxide | manganese carbonate |
| magnesium acetate | manganese chloride |
| magnesium carbonate | manganese citrate |
| magnesium chloride | manganese gluconate |
| magnesium salts of citric acid | manganese glycerophosphate |
| magnesium gluconate | manganese sulphate |
| magnesium glycerophosphate | sodium bicarbonate |
| magnesium salts of orthophosphoric acid | sodium carbonate |
| magnesium lactate | sodium chloride |
| magnesium hydroxide | sodium citrate |
| magnesium oxide | sodium gluconate |
| magnesium sulphate | sodium lactate |
| ferrous carbonate | sodium hydroxide |

| | |
|---|---|
| ferrous citrate | sodium salts of orthophosphoric acid |
| ferric ammonium citrate | potassium bicarbonate |
| ferrous gluconate | potassium carbonate |
| ferrous fumarate | potassium chloride |
| ferric sodium diphosphate | potassium citrate |
| ferrous lactate | potassium gluconate |
| ferrous sulphate | potassium glycerophosphate |
| ferric diphosphate (ferric pyrophosphate) | potassium lactate |
| ferric saccharate | potassium hydroxide |
| elemental iron | potassium salts of orthophosphoric acid |
| (carbonyl+electrolytic+hydrogen reduced) | sodium selenate |
| ferrous bisglycinate | sodium hydrogen selenite |
| cupric carbonate | sodium selenite |
| cupric citrate | chromium (III) chloride |
| cupric gluconate | chromium (III) sulphate |
| cupric sulphate | ammonium molybdate |
| copper lysine complex | (molybdenum (VI)) |
| sodium iodide | sodium molybdate |

| | |
|---|---|
| sodium iodate | (molybdenum (VI)) |
| potassium iodide | potassium fluoride |
| potassium iodate | sodium fluoride |

SCHEDULE 3 *Form of official certificate to be given by an approved examiner to an authorised officer.*

EUROPEAN COMMUNITIES (FOOD SUPPLEMENTS) REGULATIONS 2007

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.....

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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.

GIVEN under my Official Seal,

16 July 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, which may be cited as the European Communities (Food Supplements) Regulations 2007, give further effect to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. They also give effect to Commission Directive 2006/37/EC of 30 March 2006 amending Annex II to Directive 2002/46/EC.

These Regulations set certain requirements in respect of the content and packaging of food supplements. The packaging of food supplement products is required to bear certain particulars and to be free from certain other claims or statements.

These Regulations revoke the European Communities (Food Supplements) Regulations 2003 ( S.I. No. 539 of 2003 ).

1 OJ L 183, 12.7.2002, p. 51.

2 OJ L 94, 1.4.2006, p. 32.

3 OJ L 31, 1.2.2002, p. 1.

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

5 OJ L 311, 28.11.2001, p. 67.

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

7 OJ L 276, 6.10.1990, p. 40.