

Statutory Instrument

S.I. No. 539 of 2003

EUROPEAN COMMUNITIES (FOOD SUPPLEMENTS) REGULATIONS 2003

I, Micheál Martin, 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 Regulation (EC) No. 178/2002¹ 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, and for the purpose of giving effect to Directive 2002/46/EC² 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, hereby make the following regulations:

² OJ L 183, 12.7.2002, p. 51.

¹ OJ L 31, 1.2.2002, p. 1.

1. These Regulations may be cited as the European Communities (Food Supplements) Regulations 2003.

2. (1) In these Regulations -

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

"approved examiner" in these Regulations means -

(a) the Public Analyst,

(b) a Deputy Public Analyst, or

(c) an Executive Analytical Chemist,

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/EC³ 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;

³ OJ L 183, 12.7.2002, p. 51.

"export" means exportation to a third country;

"food" or "foodstuff" means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans;

"food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC⁴ and without prejudice to the requirements of Directives 80/778/EEC⁵ and 98/83/EC⁶;

⁶ OJ L 330, 5.12.98, p. 32.

⁵ OJ L 229, 30.8.80, p. 11.

⁴ OJ L 330, 5.12.98, p. 32.

"food" shall not include -

(a) feed,

(b) live animals unless they are prepared for placing on the market for human consumption,

(c) plants prior to harvesting,

(d) medicinal products within the meaning of Council Directives 65/65/EEC⁷ and 92/73/EEC⁸,

⁸ OJ L 297, 13.10.1992, p. 8.

⁷ OJ 22, 9.2.1965, p. 369.

(e) cosmetics within the meaning of Council Directive 76/768/EEC⁹,

⁹ OJ L 262, 27.9.1976, p. 169.

(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC¹⁰,

¹⁰ OJ L 359, 8.12.1989, p. 1.

(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971, or

(h) residues and contaminants;

"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;

"import" means importation from a country other than a Member State, except in the context of paragraphs (7) and (8) of Regulation 3 where "import" means importation from a Member State into a third country;

"manufacture" includes the production and processing of food, other than primary production for private domestic use and domestic preparation, handling and storage of food for private domestic consumption, and cognate words shall be construed accordingly;

"Member State" means a Member State of the European Community and shall be construed as including reference to those States that are Contracting Parties to the EEA Agreement;

"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 laboratory" in these Regulations means -

(a) the Public Analyst's Laboratory, Cork

(b) the Public Analyst's Laboratory, Dublin, or

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

"place on the market" means -

(a) import

(b) sell,

(c) offer or expose for sale,

(d) invite the making by a person of an offer to purchase,

(e) distribute free of charge,

(f) supply for any of those purposes (whether or not for profit),

and cognate words shall be construed accordingly;

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

"third country" means a country which is not a Member State.

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

(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.

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/EC¹¹ of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

¹¹ OJ L 311, 28.11.2001, p. 67.

(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.

(5) Trade in products which do not comply with paragraphs (3) and (4) of this Regulation shall be prohibited from 1 August 2005.

(6) Trade in products complying with paragraphs (3) and (4) of this Regulation shall be permitted from the date of coming into effect of these Regulations.

(7) Subject to paragraphs (8) and (9), these Regulations shall also apply in respect of food supplements intended for export, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

(8) Notwithstanding paragraph (7), food supplements which are not in compliance with these Regulations may nonetheless be exported, provided that-

(a) the competent authorities of the importing country have expressly agreed to such importation, after having been fully informed of the reasons for which and the circumstances in which the food supplements concerned could not be placed on the market in the Community, and

(b) the food supplements in question are not injurious to health.

(9) Notwithstanding paragraph (7), where the provisions of a bilateral agreement concluded between the Community or the State and a third country are applicable, food supplements exported from the State to that third country shall comply with the said provisions.

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 even after 31 July 2005, 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 has 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,¹² the name under which products covered by Directive 2002/46/EC are sold shall be 'food supplement'.

¹² OJ L 109, 6.5.2000, p. 29.

(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/EC¹³, the labelling of food supplements shall bear the following particulars -

¹³ OJ L 109, 6.5.2000, p. 29.

(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.¹⁴

¹⁴ OJ L 276, 6.10.1990, p. 40.

(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 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 the Directive or the relevant implementing Community act was adopted, he 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*.

8. Control of the foodstuffs affected by these Regulations and the enforcement of these Regulations shall be carried out in accordance with the provisions of these Regulations.

9. These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998.

10. These Regulations shall be enforced by the Authority or by an official agency pursuant to a service contract with the Authority and without prejudice to Regulation 8, the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with these Regulations.

11. (1) A person who fails to comply with these Regulations shall be guilty of an offence.

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

12. 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.

13. (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of food supplements.

(2) An authorised officer may, for the purpose of taking a sample of food supplements, 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 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, prohibit the removal of the food supplements 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 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 of his or her intention of having the sample analysed.

14. (1) Where a sample of food supplements is taken pursuant to these Regulations and where the division of the sample is reasonably practicable, the authorised officer concerned may divide the sample into not more than 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 the 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, and retain the third part.

(2) Where an authorised officer takes a sample consisting of food supplements 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 provision 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 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 food supplements 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.

16. Where a sample of food supplements is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, and where the

seller, owner or person in apparent charge or control of the food supplements requests in writing the results of such analysis the request shall be made to -

- (a) the Authority, where the officer was appointed by the Authority, or
- (b) the official agency, where the officer was appointed by an official

agency

and the Authority, or the official agency (as the case may be) shall comply with such request.

17. An authorised officer may, for the purposes of these Regulations, inspect and take copies, or samples, of labels used on food supplements.

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

19. (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.

20. (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 €3,000 or at the discretion of the Court to imprisonment for a term not exceeding 12 months or both.

21. An offence under these Regulations may be prosecuted by -

- (1) the Authority, or
- (2) an official agency.

Vitamins and Minerals which may be used in the Manufacture of Food

Supplements

1. Vitamins

2. Minerals

Vitamin A ($\mu\text{g RE}$)

Calcium (mg)

Vitamin D (μg)

Magnesium (mg)

Vitamin E (mg α -TE)

Iron (mg)

Vitamin K (μg)

Copper (μg)

Vitamin B1 (mg)

Iodine (μg)

Vitamin B2 (mg)

Zinc (mg)

Niacin (mg NE)

Manganese (mg)

Pantothenic acid (mg)

Sodium (mg)

Vitamin B6 (mg)

Potassium (mg)

Folic acid (μg)

Selenium (μg)

Vitamin B12 (μg)

Chromium (μg)

Biotin (μg)

Molybdenum (μg)

Vitamin C (mg)

Fluoride (mg)

Chloride (mg)

Phosphorus (mg)

**Vitamin and mineral substances which may be used in the
manufacture of food supplements**

A. Vitamins

1. VITAMIN A

- (a) retinol
- (b) retinyl acetate
- (c) retinyl palmitate
- (d) beta-carotene

2. VITAMIN D

- (a) cholecalciferol
- (b) ergocalciferol

3. VITAMIN E

- (a) D-alpha-tocopherol
- (b) DL-alpha-tocopherol
- (c) D-alpha-tocopheryl acetate
- (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

8. PANTOTHENIC ACID

(a) D-pantothenate, calcium

(b) D-pantothenate, sodium

(c) dexpanthenol

9. VITAMIN B6

(a) pyridoxine hydrochloride

(b) pyridoxine 5'-phosphate

10. FOLIC ACID

(a) pteroylmonoglutamic acid

11. VITAMIN B12

(a) cyanocobalamin

(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

calcium gluconate

calcium glycerophosphate

calcium lactate

calcium salts of orthophosphoric acid

calcium hydroxide

calcium oxide

magnesium acetate

magnesium carbonate

magnesium chloride

magnesium salts of citric acid

magnesium gluconate

magnesium glycerophosphate

magnesium salts of orthophosphoric acid

magnesium lactate

magnesium hydroxide

magnesium oxide

magnesium sulphate

ferrous carbonate

ferrous citrate

ferric ammonium citrate

ferrous gluconate

ferrous fumarate

ferric sodium diphosphate

ferrous lactate

ferrous sulphate

ferric diphosphate (ferric pyrophosphate)

ferric saccharate

elemental iron

(carbonyl+electrolytic+hydrogen reduced)

cupric carbonate

cupric citrate

cupric gluconate

cupric sulphate

copper lysine complex

sodium iodide

sodium iodate

potassium iodide

potassium iodate

zinc acetate

zinc chloride

zinc citrate

zinc gluconate

zinc lactate

zinc oxide

zinc carbonate

zinc sulphate

manganese carbonate

manganese chloride

manganese citrate

manganese gluconate

manganese glycerophosphate

manganese sulphate

sodium bicarbonate

sodium carbonate

sodium chloride

sodium citrate

sodium gluconate

sodium lactate

sodium hydroxide

sodium salts of orthophosphoric acid

potassium bicarbonate

potassium carbonate

potassium chloride

potassium citrate

potassium gluconate

potassium glycerophosphate

potassium lactate

potassium hydroxide

potassium salts of orthophosphoric acid

sodium selenate

sodium hydrogen selenite

sodium selenite

chromium (III) chloride

chromium (III) sulphate

ammonium molybdate

(molybdenum (VI))

sodium molybdate

(molybdenum (VI))

potassium fluoride

sodium fluoride

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

European Communities (Food Supplements) Regulations 2003

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 in 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 the Official Seal of the Minister for Health and Children this 11 day of November, 2003.

Micheál Martin,
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 effect to Directive 2002/46/EC¹⁵ 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 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.

¹⁵ OJ L 183, 12.7.2002, p. 51.

These Regulations may be cited as the European Communities (Food Supplements) Regulations 2003, and they come into effect on the day they are signed by the Minister.

DEPARTMENT OF HEALTH AND CHILDREN

November, 2003.