

# **S.I. No. 355/2010 — European Communities (Food Supplements) (Amendment) Regulations 2010.**

S.I. No. 355/2010 — European Communities (Food Supplements) (Amendment) Regulations 2010. 2010 355

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

*“Iris Oifigiúil” of 20th July, 2010.*

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 of the European Parliament and of the Council of 10 June 2002<sup>1</sup> on the approximation of the laws of the Member States relating to food supplements, and for the purpose of giving partial effect to Commission Regulation (EC) No. 1170/2009 of 30 November 2009<sup>2</sup> amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No. 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements, hereby make the following regulations:

1. (1) These Regulations may be cited as the European Communities (Food Supplements) (Amendment) Regulations 2010.

(2) The Principal Regulations and these Regulations may be cited together as the European Communities (Food Supplements) Regulations 2007 and 2010 and shall be construed together as one.

2. In these Regulations, “Principal Regulations” means European Communities (Food Supplements) Regulations 2007 (S.I. No. 506 of 2007).

3. The Principal Regulations are amended—

(a) in Regulation 2(1), by substituting for the definition of “Directive” the following—

“Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 1 on the approximation of the laws of the Member States relating to food supplements, as amended by Commission Directive 2006/37/EC of 30 March 2006 2 and Commission Regulation (EC) No. 1170/2009 of 30 November 2009 2A ”

And by the addition of the following footnote to the definition of “Directive”—

“ 2A OJ L 314, 1.12.2009, p. 36”

(b) in Regulation 19, by substituting for paragraph (2) the following—

“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 6 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.”

(c) in Regulation 19 by inserting after paragraph (2) the following—

“(3) Where a person is convicted of an offence under these Regulations, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Authority or the official agency, as the case may be, the costs and expenses, measured by the court, incurred by the Authority or official agency in relation to the investigation, detection and prosecution of the offence, including costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisors engaged by the Authority or official agency.

(4) An order for costs and expenses under subsection (3) is in addition to, and not instead of, any fine or penalty the court may impose under subsection (2).”

(d) by substituting for Regulation 20 the following—

“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.”

(e) by substituting for Schedule 1 the Schedule set out in Schedule 1 to these Regulations.

(f) by substituting for Schedule 2 the Schedule set out in Schedule 2 to these Regulations.

Schedule 1 Vitamins and minerals which may be used in the manufacture of food supplements

**1. Vitamins**

Vitamin A (g RE)

Vitamin D (g)

Vitamin E (mg -TE)

Vitamin K (g)

Vitamin B1 (mg)

Vitamin B2 (mg)

Niacin (mg NE)

**2. Minerals**

Calcium (mg)

Magnesium (mg)

Iron (mg)

Copper (g)

Iodine (g)

Zinc (mg)

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)
	Boron (mg)
	Silicon (mg)

(\*) Folic acid is the term included in Annex I of Commission Directive 2008/100/EC of 28 October 2008 amending Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions for nutrition labelling purposes and covers all forms of folates.

Schedule 2 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
- (f) mixed tocopherols (\*)

(g) tocotrienol tocopherol (\*\*)

#### 4. VITAMIN K

(a) phylloquinone (phytomenadione)

(b) menaquinone (\*\*\*)

#### 5. VITAMIN B1

(a) thiamin hydrochloride

(b) thiamin mononitrate

(c) thiamine monophosphate chloride

(d) thiamine pyrophosphate chloride

#### 6. VITAMIN B2

(a) riboflavin

(b) riboflavin 5-phosphate, sodium

#### 7. NIACIN

(a) nicotinic acid

(b) nicotinamide

(c) inositol hexanicotinate (inositol hexaniacinate)

#### 8. PANTOTHENIC ACID

(a) D-pantothenate, calcium

(b) D-pantothenate, sodium

(c) dexpanthenol

(d) pantethine

#### 9. VITAMIN B6

(a) pyridoxine hydrochloride

(b) pyridoxine 5-phosphate

(c) pyridoxal 5-phosphate

#### 10. FOLATE

(a) pteroylmonoglutamic acid

(b) calcium-L-methylfolate

11. VITAMIN B12

- (a) cyanocobalamin
- (b) hydroxocobalamin
- (c) 5-deoxyadenosylcobalamin
- (d) methylcobalamin

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
- (f) magnesium L-ascorbate
- (g) zinc L-ascorbate

**B. Minerals**

calcium acetate

calcium L-ascorbate

calcium bisglycinate

calcium carbonate

calcium chloride

calcium citrate malate

calcium salts of citric acid

calcium gluconate

calcium glycerophosphate

calcium lactate

calcium pyruvate

calcium salts of orthophosphoric acid

calcium succinate  
calcium hydroxide  
calcium L-lysinate  
calcium malate  
calcium oxide  
calcium L-pidolate  
calcium L-threonate  
calcium sulphate  
magnesium acetate  
magnesium L-ascorbate  
magnesium bisglycinate  
magnesium carbonate  
magnesium chloride  
magnesium salts of citric acid  
magnesium gluconate  
magnesium glycerophosphate  
magnesium salts of orthophosphoric acid  
magnesium lactate  
magnesium L-lysinate  
magnesium hydroxide  
magnesium malate  
magnesium oxide  
magnesium L-pidolate  
magnesium potassium citrate  
magnesium pyruvate  
magnesium succinate  
magnesium sulphate  
magnesium taurate

magnesium acetyl taurate

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)

ferrous bisglycinate

ferrous L-pidolate

ferrous phosphate

iron (II) taurate

cupric carbonate

cupric citrate

cupric gluconate

cupric sulphate

copper L-aspartate

copper bisglycinate

copper lysine complex

copper (II) oxide

sodium iodide

sodium iodate

potassium iodide

potassium iodate

zinc acetate  
zinc L-ascorbate  
zinc L-aspartate  
zinc bisglycinate  
zinc chloride  
zinc citrate  
zinc gluconate  
zinc lactate  
zinc L-lysinate  
zinc malate  
zinc mono-L-methionine sulphate  
zinc oxide  
zinc carbonate  
zinc L-pidolate  
zinc picolinate  
zinc sulphate  
manganese ascorbate  
manganese L-aspartate  
manganese bisglycinate  
manganese carbonate  
manganese chloride  
manganese citrate  
manganese gluconate  
manganese glycerophosphate  
manganese pidolate  
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 L-pidolate  
potassium malate  
potassium salts of orthophosphoric acid  
L-selenomethionine  
selenium enriched yeast (\*\*\*\*\*)  
selenious acid  
sodium selenate  
sodium hydrogen selenite  
sodium selenite  
chromium (III) chloride  
chromium (III) lactate trihydrate  
chromium nitrate  
chromium picolinate  
chromium (III) sulphate

ammonium molybdate (molybdenum (VI))

potassium molybdate (molybdenum (VI))

sodium molybdate (molybdenum (VI))

calcium fluoride

potassium fluoride

sodium fluoride

sodium monofluorophosphate

boric acid

sodium borate

choline-stabilised orthosilicic acid

silicon dioxide

silicic acid (\*\*\*\*\*)

(\*) alpha-tocopherol < 20 %, beta-tocopherol < 10 %, gamma-tocopherol 50-70 % and delta-tocopherol 10-30 %

(\*\*) Typical levels of individual tocopherols and tocotrienols:

— 115 mg/g alpha-tocopherol (101 mg/g minimum),

— 5 mg/g beta-tocopherol (< 1 mg/g minimum),

— 45 mg/g gamma-tocopherol (25 mg/g minimum),

— 12 mg/g delta-tocopherol (3 mg/g minimum),

— 67 mg/g alpha-tocotrienol (30 mg/g minimum),

— < 1 mg/g beta-tocotrienol (< 1 mg/g minimum),

— 82 mg/g gamma-tocotrienol (45 mg/g minimum),

— 5 mg/g delta-tocotrienol (< 1 mg/g minimum),

(\*\*\*) Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.

(\*\*\*\*) May contain up to 2 % of threonate.

(\*\*\*\*\*) Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2,5 mg Se/g. The predominant organic selenium species present in the yeast is selenomethionine (between 60 and 85 % of the total extracted selenium in the product). The content of other organic

selenium compounds including selenocysteine shall not exceed 10 % of total extracted selenium. Levels of inorganic selenium normally shall not exceed 1 % of total extracted selenium.

(\*\*\*\*\*) In the form of gel.’



GIVEN under my Official Seal,

15 July 2010.

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 partial effect to Commission Regulation (EC) No. 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No. 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements.

These Regulations contain enforcement provisions to 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 Member States relating to food supplements and amend the European Communities (Food Supplements) Regulations 2007 (S.I. No. 506 of 2007) in the manner specified in these Regulations.

These Regulations may be cited as the European Communities (Food Supplements) (Amendment) Regulations 2010.

1 OJ L 183, 12.7.2002, p. 51.

2 OJ L 314, 1.12.2009, p. 36

(\*) Folic acid is the term included in Annex I of Commission Directive 2008/100/EC of 28 October 2008 amending Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions for nutrition labelling purposes and covers all forms of folates.

