STATUTORY INSTRUMENTS.

S.I. No. 355 of 2010

EUROPEAN COMMUNITIES (FOOD SUPPLEMENTS) (AMENDMENT) REGULATIONS 2010

(Prn. A10/1032)

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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 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, and for the purpose of giving partial effect to Commission Regulation (EC) No. 1170/2009 of 30 November 2009[2] 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"

[1] OJ L 183, 12.7.2002, p. 51.
[2] OJ L 314, 1.12.2009, p. 36

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 20*th July*, 2010.

(*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**	2. **Minerals**
Vitamin A (µg 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)
	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.'

L.S.

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.

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