

COMMISSION REGULATION (EC) No 1170/2009**of 30 November 2009****amending Directive 2002/46/EC of the European Parliament and of 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****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard 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 ⁽¹⁾, and in particular Article 4(5) thereof,

Having regard to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods ⁽²⁾, and in particular Article 3(3) thereof,

After consulting the European Food Safety Authority,

Whereas:

- (1) Annexes I and II to Directive 2002/46/EC establish the lists of vitamins and minerals, and for each of them the forms, that may be used for the manufacture of food supplements. Modifications to these lists are to be adopted in compliance with the requirements laid down in Article 4 of that Directive and in accordance with the procedure referred to in its Article 13(3).
- (2) Annexes I and II to Regulation (EC) No 1925/2006 establish the lists of vitamins and minerals, and for each of them the forms, that may be added to food. Modifications to these lists are to be adopted in compliance with the requirements laid down in Article 3 of that Regulation and in accordance with the procedure referred to in its Article 14(3).
- (3) New vitamin and mineral forms have been evaluated by the European Food Safety Authority. The substances which have received a favourable scientific opinion and

for which the requirements laid down in Directive 2002/46/EC and in Regulation (EC) No 1925/2006 are complied with should be added to the respective lists in those acts.

- (4) Interested parties were consulted and the provided comments were taken into consideration.
- (5) Following the scientific evaluation by the European Food Safety Authority, it is appropriate to introduce specifications for some vitamin and mineral substances for their identification.
- (6) Directive 2002/46/EC and Regulation (EC) No 1925/2006 should therefore be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and II to Directive 2002/46/EC are replaced respectively by the texts in Annex I and II to this Regulation.

Article 2

Regulation (EC) No 1925/2006 is amended as follows:

- 1) In Annex I, the word 'Boron' is added in the list in point 2.
- 2) Annex II is replaced by the text in Annex III to this Regulation.

Article 3

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 30 November 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

⁽¹⁾ OJ L 183, 12.7.2002, p. 51.

⁽²⁾ OJ L 404, 30.12.2006, p. 26.

ANNEX I

ANNEX I

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

Vitamin A ($\mu\text{g RE}$)
Vitamin D (μg)
Vitamin E (mg a-TE)
Vitamin K (μg)
Vitamin B1 (mg)
Vitamin B2 (mg)
Niacin (mg NE)
Pantothenic acid (mg)
Vitamin B6 (mg)
Folic acid (μg) (*)
Vitamin B12 (μg)
Biotin (μg)
Vitamin C (mg)

2. Minerals

Calcium (mg)
Magnesium (mg)
Iron (mg)
Copper (μg)
Iodine (μg)
Zinc (mg)
Manganese (mg)
Sodium (mg)
Potassium (mg)
Selenium (μg)
Chromium (μg)
Molybdenum (μg)
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.

ANNEX II

ANNEX II

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

- | | |
|---------------------------------------|--|
| 1. VITAMIN A | (c) inositol hexanicotinate (inositol hexaniacinate) |
| (a) retinol | 8. PANTOTHENIC ACID |
| (b) retinyl acetate | (a) D-pantothenate, calcium |
| (c) retinyl palmitate | (b) D-pantothenate, sodium |
| (d) beta-carotene | (c) dexpanthenol |
| 2. VITAMIN D | (d) pantethine |
| (a) cholecalciferol | 9. VITAMIN B6 |
| (b) ergocalciferol | (a) pyridoxine hydrochloride |
| 3. VITAMIN E | (b) pyridoxine 5'-phosphate |
| (a) D-alpha-tocopherol | (c) pyridoxal 5'-phosphate |
| (b) DL-alpha-tocopherol | 10. FOLATE |
| (c) D-alpha-tocopheryl acetate | (a) pteroylmonoglutamic acid |
| (d) DL-alpha-tocopheryl acetate | (b) calcium-L-methylfolate |
| (e) D-alpha-tocopheryl acid succinate | 11. VITAMIN B12 |
| (f) mixed tocopherols (*) | (a) cyanocobalamin |
| (g) tocotrienol tocopherol (**) | (b) hydroxocobalamin |
| 4. VITAMIN K | (c) 5'-deoxyadenosylcobalamin |
| (a) phylloquinone (phytomenadione) | (d) methylcobalamin |
| (b) menaquinone (***) | 12. BIOTIN |
| 5. VITAMIN B1 | (a) D-biotin |
| (a) thiamin hydrochloride | 13. VITAMIN C |
| (b) thiamin mononitrate | (a) L-ascorbic acid |
| (c) thiamine monophosphate chloride | (b) sodium-L-ascorbate |
| (d) thiamine pyrophosphate chloride | (c) calcium-L-ascorbate (***) |
| 6. VITAMIN B2 | (d) potassium-L-ascorbate |
| (a) riboflavin | (e) L-ascorbyl 6-palmitate |
| (b) riboflavin 5'-phosphate, sodium | (f) magnesium L-ascorbate |
| 7. NIACIN | (g) zinc L-ascorbate |
| (a) nicotinic acid | B. Minerals |
| (b) nicotinamide | calcium acetate |
| | calcium L-ascorbate |

calcium bisglycinate	ferric sodium diphosphate
calcium carbonate	ferrous lactate
calcium chloride	ferrous sulphate
calcium citrate malate	ferric diphosphate (ferric pyrophosphate)
calcium salts of citric acid	ferric saccharate
calcium gluconate	elemental iron (carbonyl + electrolytic + hydrogen reduced)
calcium glycerophosphate	ferrous bisglycinate
calcium lactate	ferrous L-pidolate
calcium pyruvate	ferrous phosphate
calcium salts of orthophosphoric acid	iron (II) taurate
calcium succinate	cupric carbonate
calcium hydroxide	cupric citrate
calcium L-lysinate	cupric gluconate
calcium malate	cupric sulphate
calcium oxide	copper L-aspartate
calcium L-pidolate	copper bisglycinate
calcium L-threonate	copper lysine complex
calcium sulphate	copper (II) oxide
magnesium acetate	sodium iodide
magnesium L-ascorbate	sodium iodate
magnesium bisglycinate	potassium iodide
magnesium carbonate	potassium iodate
magnesium chloride	zinc acetate
magnesium salts of citric acid	zinc L-ascorbate
magnesium gluconate	zinc L-aspartate
magnesium glycerophosphate	zinc bisglycinate
magnesium salts of orthophosphoric acid	zinc chloride
magnesium lactate	zinc citrate
magnesium L-lysinate	zinc gluconate
magnesium hydroxide	zinc lactate
magnesium malate	zinc L-lysinate
magnesium oxide	zinc malate
magnesium L-pidolate	zinc mono-L-methionine sulphate
magnesium potassium citrate	zinc oxide
magnesium pyruvate	zinc carbonate
magnesium succinate	zinc L-pidolate
magnesium sulphate	zinc picolinate
magnesium taurate	zinc sulphate
magnesium acetyl taurate	manganese ascorbate
ferrous carbonate	manganese L-aspartate
ferrous citrate	manganese bisglycinate
ferric ammonium citrate	manganese carbonate
ferrous gluconate	manganese chloride
ferrous fumarate	manganese citrate

manganese gluconate	L-selenomethionine
manganese glycerophosphate	selenium enriched yeast (*****)
manganese pidolate	selenious acid
manganese sulphate	sodium selenate
sodium bicarbonate	sodium hydrogen selenite
sodium carbonate	sodium selenite
sodium chloride	chromium (III) chloride
sodium citrate	chromium (III) lactate trihydrate
sodium gluconate	chromium nitrate
sodium lactate	chromium picolinate
sodium hydroxide	chromium (III) sulphate
sodium salts of orthophosphoric acid	ammonium molybdate (molybdenum (VI))
potassium bicarbonate	potassium molybdate (molybdenum (VI))
potassium carbonate	sodium molybdate (molybdenum (VI))
potassium chloride	calcium fluoride
potassium citrate	potassium fluoride
potassium gluconate	sodium fluoride
potassium glycerophosphate	sodium monofluorophosphate
potassium lactate	boric acid
potassium hydroxide	sodium borate
potassium L-pidolate	choline-stabilised orthosilicic acid
potassium malate	silicon dioxide
potassium salts of orthophosphoric acid	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.'

ANNEX III

ANNEX II

Vitamin formulations and mineral substances which may be added to foods**1. Vitamin formulations**

VITAMIN A

retinol

retinyl acetate

retinyl palmitate

beta-carotene

VITAMIN D

cholecalciferol

ergocalciferol

VITAMIN E

D-alpha-tocopherol

DL-alpha-tocopherol

D-alpha-tocopheryl acetate

DL-alpha-tocopheryl acetate

D-alpha-tocopheryl acid succinate

VITAMIN K

phyloquinone (phytomenadione)

menaquinone (*)

VITAMIN B1

thiamin hydrochloride

thiamin mononitrate

VITAMIN B2

riboflavin

riboflavin 5'-phosphate, sodium

NIACIN

nicotinic acid

nicotinamide

PANTOTHENIC ACID

D-pantothenate, calcium

D-pantothenate, sodium

dexpanthenol

VITAMIN B6

pyridoxine hydrochloride

pyridoxine 5'-phosphate

pyridoxine dipalmitate

FOLIC ACID

pteroylmonoglutamic acid

calcium-L-methylfolate

VITAMIN B12

cyanocobalamin

hydroxocobalamin

BIOTIN

D-biotin

VITAMIN C

L-ascorbic acid

sodium-L-ascorbate

calcium-L-ascorbate

potassium-L-ascorbate

L-ascorbyl 6-palmitate

2. Mineral substances

calcium carbonate

calcium chloride

calcium citrate malate

calcium salts of citric acid

calcium gluconate

calcium glycerophosphate

calcium lactate

calcium salts of orthophosphoric acid

calcium hydroxide

calcium malate

calcium oxide

calcium sulphate

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 potassium citrate

magnesium sulphate

ferrous bisglycinate

ferrous carbonate	manganese gluconate
ferrous citrate	manganese glycerophosphate
ferric ammonium citrate	manganese sulphate
ferrous gluconate	sodium bicarbonate
ferrous fumarate	sodium carbonate
ferric sodium diphosphate	sodium citrate
ferrous lactate	sodium gluconate
ferrous sulphate	sodium lactate
ferric diphosphate (ferric pyrophosphate)	sodium hydroxide
ferric saccharate	sodium salts of orthophosphoric acid
elemental iron (carbonyl + electrolytic + hydrogen reduced)	selenium enriched yeast (**)
cupric carbonate	sodium selenate
cupric citrate	sodium hydrogen selenite
cupric gluconate	sodium selenite
cupric sulphate	sodium fluoride
copper lysine complex	potassium fluoride
sodium iodide	potassium bicarbonate
sodium iodate	potassium carbonate
potassium iodide	potassium chloride
potassium iodate	potassium citrate
zinc acetate	potassium gluconate
zinc bisglycinate	potassium glycerophosphate
zinc chloride	potassium lactate
zinc citrate	potassium hydroxide
zinc gluconate	potassium salts of orthophosphoric acid
zinc lactate	chromium (III) chloride and its hexahydrate
zinc oxide	chromium (III) sulphate and its hexahydrate
zinc carbonate	ammonium molybdate (molybdenum (VI))
zinc sulphate	sodium molybdate (molybdenum (VI))
manganese carbonate	boric acid
manganese chloride	sodium borate
manganese citrate	

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

(**) 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.
