

**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 <sup>(1)</sup>, 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 <sup>(2)</sup>, 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*<sup>(1)</sup> OJ L 183, 12.7.2002, p. 51.<sup>(2)</sup> 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 ( $\mu\text{g}$ )  
Vitamin E (mg a-TE)  
Vitamin K ( $\mu\text{g}$ )  
Vitamin B1 (mg)  
Vitamin B2 (mg)  
Niacin (mg NE)  
Pantothenic acid (mg)  
Vitamin B6 (mg)  
Folic acid ( $\mu\text{g}$ ) (\*)  
Vitamin B12 ( $\mu\text{g}$ )  
Biotin ( $\mu\text{g}$ )  
Vitamin C (mg)

**2. Minerals**

Calcium (mg)  
Magnesium (mg)  
Iron (mg)  
Copper ( $\mu\text{g}$ )  
Iodine ( $\mu\text{g}$ )  
Zinc (mg)  
Manganese (mg)  
Sodium (mg)  
Potassium (mg)  
Selenium ( $\mu\text{g}$ )  
Chromium ( $\mu\text{g}$ )  
Molybdenum ( $\mu\text{g}$ )  
Fluoride (mg)  
Chloride (mg)  
Phosphorus (mg)  
Boron (mg)  
Silicon (mg)

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(\*) 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.

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## 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>B. Minerals</b>                                   |
| (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

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|                                                             |                                             |
|-------------------------------------------------------------|---------------------------------------------|
| 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                                           |                                             |

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(\*) 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.

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