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)

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

ANNEX I

‘ANNEX I

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

1. **Vitamins**

Vitamin A (µg 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)[3]

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)

ANNEX II

ANNEX II

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[(4)]

(g) tocotrienol tocopherol[(5)]

4. VITAMIN K

(a) phylloquinone (phytomenadione)

(b) menaquinone[(6)]

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[7]

(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[(8)]

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[9]

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

phylloquinone (phytomenadione)

menaquinone[(10)]
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

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 bisglycinate

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 citrate

sodium gluconate

sodium lactate

sodium hydroxide

sodium salts of orthophosphoric acid

selenium enriched yeast[11]

sodium selenate

sodium hydrogen selenite

sodium selenite

sodium fluoride

potassium fluoride

potassium bicarbonate

potassium carbonate

potassium chloride

potassium citrate

potassium gluconate

potassium glycerophosphate

potassium lactate

potassium hydroxide

potassium salts of orthophosphoric acid

chromium (III) chloride and its hexahydrate

chromium (III) sulphate and its hexahydrate

ammonium molybdate (molybdenum (VI))

sodium molybdate (molybdenum (VI))

boric acid

sodium borate

(**1**) OJ L 183, 12.7.2002, p. 51.

(**2**) OJ L 404, 30.12.2006, p. 26.

(**3**) 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.'

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

(**5**) 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),

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

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

(**8**) 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.

(**9**) In the form of gel.'

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

(**11**) 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.'

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 1170/2009.