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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,  
C(2009)

final

Draft

**COMMISSION REGULATION**

**of**

**amending Directive 2002/46/EC and Regulation (EC) No 1925/2006 as regards the lists  
of vitamins and minerals and their forms that can be added to foods, including food  
supplements**

**(Text with EEA relevance)**

Draft

## COMMISSION REGULATION

of

**amending Directive 2002/46/EC and Regulation (EC) No 1925/2006 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.

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<sup>1</sup> OJ L 183, 12.7.2002, p. 51.

<sup>2</sup> OJ L 404, 30.12.2006, p. 26.

- (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 twentieth day following that of 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,

*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 ( $\mu\text{g RE}$ )
  - Vitamin D ( $\mu\text{g}$ )
  - Vitamin E (mg  $\alpha$ -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 (µg)

Chromium (µg)

Molybdenum (µg)

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."

## 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\*
- (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\*\*\*\*\*

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\* 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

phylloquinone (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

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\*\*  
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

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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."