

EN

EN

EN



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 supplements¹, 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 foods², 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.

¹ OJ L 183, 12.7.2002, p. 51.

² 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 (μg)
 - Vitamin E ($\text{mg } \alpha\text{-TE}$)
 - 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
 - (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."

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

* 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."