COMMISSION REGULATION (EC) No 1170/2009
of 30 November 2009
(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.


(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

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

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A (μg RE)</td>
<td>Calcium (mg)</td>
</tr>
<tr>
<td>Vitamin D (μg)</td>
<td>Magnesium (mg)</td>
</tr>
<tr>
<td>Vitamin E (mg a-TE)</td>
<td>Iron (mg)</td>
</tr>
<tr>
<td>Vitamin K (μg)</td>
<td>Copper (μg)</td>
</tr>
<tr>
<td>Vitamin B1 (mg)</td>
<td>Iodine (μg)</td>
</tr>
<tr>
<td>Vitamin B2 (mg)</td>
<td>Zinc (mg)</td>
</tr>
<tr>
<td>Niacin (mg NE)</td>
<td>Manganese (mg)</td>
</tr>
<tr>
<td>Pantothenic acid (mg)</td>
<td>Sodium (mg)</td>
</tr>
<tr>
<td>Vitamin B6 (mg)</td>
<td>Potassium (mg)</td>
</tr>
<tr>
<td>Folic acid (μg) (*)</td>
<td>Selenium (μg)</td>
</tr>
<tr>
<td>Vitamin B12 (μg)</td>
<td>Chromium (μg)</td>
</tr>
<tr>
<td>Biotin (μg)</td>
<td>Molybdenum (μg)</td>
</tr>
<tr>
<td>Vitamin C (mg)</td>
<td>Fluoride (mg)</td>
</tr>
</tbody>
</table>

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) dextanethanol
   (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
potassium chloride
potassium gluconate
potassium glycerophosphate
potassium lactate
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
potassium chloride
potassium gluconate
potassium glycerophosphate
potassium lactate
potassium hydroxide
potassium L-pidolate
potassium malate
potassium salts of orthophosphoric acid

(*) alpha-tocopherol < 20 %, beta-tocopherol < 10 %, gamma-tocopherol 50-70 % and delta-tocopherol 10-30 %
(**) Typical levels of individual tocophersols 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.

(****) 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

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>VITAMIN A</td>
<td>retinol, retinyl acetate, retinyl palmitate, beta-carotene</td>
</tr>
<tr>
<td>VITAMIN D</td>
<td>cholecalciferol, ergocalciferol</td>
</tr>
<tr>
<td>VITAMIN K</td>
<td>phylloquinone (phytomenadione), menaquinone (*)</td>
</tr>
<tr>
<td>VITAMIN B1</td>
<td>thiamin hydrochloride, thiamin mononitrate</td>
</tr>
<tr>
<td>VITAMIN B2</td>
<td>riboflavin, riboflavin 5′-phosphate, sodium</td>
</tr>
<tr>
<td>NIACIN</td>
<td>nicotinic acid, nicotinamide</td>
</tr>
<tr>
<td>PANTOTHENIC ACID</td>
<td>D-pantothenate, calcium, D-pantothenate, sodium dextranthenol</td>
</tr>
<tr>
<td>VITAMIN B6</td>
<td>pyridoxine hydrochloride, pyridoxine 5′-phosphate, pyridoxine dipalmitate</td>
</tr>
<tr>
<td>FOLIC ACID</td>
<td>pteroylmonoglutamic acid, calcium-L-methylfolate</td>
</tr>
<tr>
<td>VITAMIN B12</td>
<td>cyanocobalamin, hydroxocobalamin</td>
</tr>
<tr>
<td>BIOTIN</td>
<td>D-biotin</td>
</tr>
<tr>
<td>VITAMIN C</td>
<td>L-ascorbic acid, sodium-L-ascorbate, calcium-L-ascorbate, potassium-L-ascorbate, L-ascorbyl 6-palmitate</td>
</tr>
</tbody>
</table>

2. Mineral substances

<table>
<thead>
<tr>
<th>Mineral</th>
<th>Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>calcium carbonate</td>
<td>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</td>
</tr>
</tbody>
</table>
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.