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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 1170/2009. (See end of Document for details)*

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)

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 1170/2009. (See end of Document for details)*

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 1170/2009. (See end of Document for details)*

(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