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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,  
SANCO/2005/02485

Draft for a

**COMMISSION DIRECTIVE ..../.../EC**

**of [...]**

**amending the Annexes to Directive 2002/46/EC of the European Parliament and of the Council as regards the inclusion of certain substances**

**(Text with EEA relevance)**

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Draft

**COMMISSION DIRECTIVE ../.../EC**

**of [...]**

**amending the Annexes to Directive 2002/46/EC of the European Parliament and of the Council as regards the inclusion of certain substances**

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,

After consulting the European Food Safety Authority,

Whereas:

- (1) Directive 2002/46/EC specifies the vitamins and minerals, and for each of them the forms, that may be used for the manufacture of food supplements.
- (2) Those vitamin and mineral substances that have been evaluated by the European Food Safety Authority (hereafter “the Authority”) and have received a favourable scientific evaluation should be included in the Annexes to Directive 2002/46/EC.
- (3) Favourable scientific evaluation for some vitamins and minerals substances has been recently given and made public by the Authority.
- (4) Directive 2002/46/EC should therefore be amended accordingly.
- (5) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Annexes I and II to Directive 2002/46/EC are amended as set out in the Annex to this Directive.

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

## *Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [...] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

## *Article 3*

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

## *Article 4*

This Directive is addressed to the Member States.

Done at Brussels, [...]

*For the Commission*

[...]

*Member of the Commission*

*ANNEX*

(1) Annex I to Directive 2002/46/EC is amended as follows:

In Section 2. Minerals, the following line is added:

“Boron (mg)”

(2) Annex II to Directive 2002/46/EC is amended as follows:

(a) In Section A. Vitamins, the following line is added under the heading 10. FOLIC ACID:

“(b) calcium-L-methylfolate”

(b) In Section B. Minerals, the following lines are inserted before calcium carbonate:

“boric acid

sodium borate”