

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
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

Whereas:

- (1) There is an increasing number of products marketed in the Community as foods containing concentrated sources of nutrients and presented for supplementing the intake of those nutrients from the normal diet.
- (2) Those products are regulated in Member States by differing national rules that may impede their free movement, create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on those products marketed as foodstuffs.
- (3) An adequate and varied diet could, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities which meet those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for all nutrients and by all groups of the population across the Community.
- (4) Consumers, because of their particular lifestyles or for other reasons, may choose to supplement their intake of some nutrients through food supplements.
- (5) In order to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on to the market must be safe and bear adequate and appropriate labelling.
- (6) There is a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts.
- (7) As a first stage, this Directive should lay down specific rules for vitamins and minerals used as ingredients of food supplements. Food supplements containing vitamins or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in this Directive.
- (8) Specific rules concerning nutrients, other than vitamins and minerals, or other substances with a nutritional or physiological effect used as ingredients of food supplements should be laid down at a later stage, provided that adequate and appropriate scientific data about them become available. Until such specific Community rules are adopted and without prejudice to the provisions of the Treaty, national rules concerning nutrients or other substances with nutritional or physiological effect used as ingredients of food supplements, for which no Community specific rules have been adopted, may be applicable.
- (9) Only vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Controversy as to the identity of those nutrients that could potentially arise should be avoided. Therefore, it is appropriate to establish a positive list of those vitamins and minerals.
- (10) There is a wide range of vitamin preparations and mineral substances used in the manufacture of food supplements currently marketed in some Member States that have not been evaluated by the Scientific Committee on Food and consequently are not included in the positive lists. These should be submitted to the European Food Safety Authority for urgent evaluation, as soon as appropriate files are presented by the interested parties.

⁽¹⁾ OJ C 311 E, 31.10.2000, p. 207 and C 180 E, 26.6.2001, p. 248.

⁽²⁾ OJ C 14, 16.1.2001, p. 42.

⁽³⁾ Opinion of the European Parliament of 14 February 2001 (OJ C 276, 1.10.2001, p. 126), Council Common Position of 3 December 2001 (OJ C 90 E, 16.4.2002, p. 1) and Decision of the European Parliament of 13 March 2002. Council Decision of 30 May 2002.

- (11) The chemical substances used as sources of vitamins and minerals in the manufacture of food supplements should be safe and also be available to be used by the body. For this reason, a positive list of those substances should also be established. Such substances as have been approved by the Scientific Committee on Food, on the basis of the said criteria, for use in the manufacture of foods intended for infants and young children and other foods for particular nutritional uses can also be used in the manufacture of food supplements.
- (12) In order to keep up with scientific and technological developments it is important to revise the lists promptly, when necessary. Such revisions would be implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.
- (13) Excessive intake of vitamins and minerals may result in adverse effects and therefore necessitate the setting of maximum safe levels for them in food supplements, as appropriate. Those levels must ensure that the normal use of the products under the instructions of use provided by the manufacturer will be safe for the consumer.
- (14) When maximum levels are set, therefore, account should be taken of the upper safe levels of the vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data, and of intakes of those nutrients from the normal diet. Due account should also be taken of reference intake amounts when setting maximum levels.
- (15) Food supplements are purchased by consumers for supplementing intakes from the diet. In order to ensure that this aim is achieved, if vitamins and minerals are declared on the label of food supplements, they should be present in the product in a significant amount.
- (16) The adoption of the specific values for maximum and minimum levels for vitamins and minerals present in food supplements, based on the criteria set out in this Directive and appropriate scientific advice, would be an implementing measure and should be entrusted to the Commission.
- (17) General labelling provisions and definitions are contained in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs⁽¹⁾, and do not need to be repeated. This Directive should therefore be confined to the necessary additional provisions.
- (18) Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs⁽²⁾ does not apply to food supplements. Information relating to nutrient content in food supplements is essential for allowing the consumer who purchases them to make an informed choice and use them properly and safely. That information should, in view of the nature of those products, be confined to the nutrients actually present and be compulsory.
- (19) Given the particular nature of food supplements, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.
- (20) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽³⁾,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns food supplements marketed as foodstuffs and presented as such. These products shall be delivered to the ultimate consumer only in a pre-packaged form.
2. This Directive shall not apply to medicinal products as defined by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use⁽⁴⁾.

Article 2

For the purposes of this Directive:

- (a) 'food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;
- (b) 'nutrients' means the following substances:
 - (i) vitamins,
 - (ii) minerals.

⁽²⁾ OJ L 276, 6.10.1990, p. 40.

⁽³⁾ OJ L 184, 17.7.1999, p. 23.

⁽⁴⁾ OJ L 311, 28.11.2001, p. 67.

⁽¹⁾ OJ L 109, 6.5.2000, p. 29.

Article 3

Member States shall ensure that food supplements may be marketed within the Community only if they comply with the rules laid down in this Directive.

Article 4

1. Only vitamins and minerals listed in Annex I, in the forms listed in Annex II, may be used for the manufacture of food supplements, subject to paragraph 6.

2. The purity criteria for substances listed in Annex II shall be adopted in accordance with the procedure referred to in Article 13(2), except where they apply pursuant to paragraph 3.

3. Purity criteria for substances listed in Annex II, specified by Community legislation for their use in the manufacture of foodstuffs for purposes other than those covered by this Directive, shall apply.

4. For those substances listed in Annex II for which purity criteria are not specified by Community legislation, and until such specifications are adopted, generally acceptable purity criteria recommended by international bodies shall be applicable and national rules setting stricter purity criteria may be maintained.

5. Modifications to the lists referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 13(2).

6. By way of derogation from paragraph 1 and until 31 December 2009, Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that:

- (a) the substance in question is used in one or more food supplements marketed in the Community on the date of entry into force of this Directive,
- (b) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State not later than 12 July 2005.

7. Notwithstanding paragraph 6, Member States may, in compliance with the rules of the Treaty, continue to apply existing national restrictions or bans on trade in food supplements containing vitamins and minerals not included in the list in Annex I or in the forms not listed in Annex II.

8. Not later than 12 July 2007, the Commission shall submit to the European Parliament and the Council a report on the advisability of establishing specific rules, including, where appropriate, positive lists, on categories of nutrients or of

substances with a nutritional or physiological effect other than those referred to in paragraph 1, accompanied by any proposals for amendment to this Directive which the Commission deems necessary.

Article 5

1. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:

- (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;

- (b) intake of vitamins and minerals from other dietary sources.

2. When the maximum levels referred to in paragraph 1 are set, due account should also be taken of reference intakes of vitamins and minerals for the population.

3. To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily portion of consumption as recommended by the manufacturer shall be set, as appropriate.

4. The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with the procedure referred to in Article 13(2).

Article 6

1. For the purposes of Article 5(1) of Directive 2000/13/EC, the name under which products covered by this Directive are sold shall be 'food supplement'.

2. The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.

3. Without prejudice to Directive 2000/13/EC, the labelling shall bear the following particulars:

- (a) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances;

- (b) the portion of the product recommended for daily consumption;

- (c) a warning not to exceed the stated recommended daily dose;

- (d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;

- (e) a statement to the effect that the products should be stored out of the reach of young children.

Article 7

The labelling, presentation and advertising of food supplements shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

Rules for implementing this Article may be specified in accordance with the procedure referred to in Article 13(2).

Article 8

1. The amount of the nutrients or substances with a nutritional or physiological effect present in the product shall be declared on the labelling in numerical form. The units to be used for vitamins and minerals shall be those specified in Annex I.

Rules for implementing this paragraph may be specified in accordance with the procedure referred to in Article 13(2).

2. The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling.

3. Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned, as the case may be, in the Annex to Directive 90/496/EEC.

Article 9

1. The declared values mentioned in Article 8(1) and (2) shall be average values based on the manufacturer's analysis of the product.

Further rules for implementing this paragraph with regard in particular to the differences between the declared values and those established in the course of official checks shall be decided upon in accordance with the procedure referred to in Article 13(2).

2. The percentage of the reference values for vitamins and minerals mentioned in Article 8(3) may also be given in graphical form.

Rules for implementing this paragraph may be adopted in accordance with the procedure referred to in Article 13(2).

Article 10

To facilitate efficient monitoring of food supplements, Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product.

Article 11

1. Without prejudice to Article 4(7), Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and, where appropriate, with Community acts adopted in implementation of this Directive.

2. Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, paragraph 1 shall not affect national provisions which are applicable in the absence of Community acts adopted under this Directive.

Article 12

1. Where a Member State, as a result of new information or of a reassessment of existing information made since this Directive or one of the implementing Community acts was adopted, has detailed grounds for establishing that a product referred to in Article 1 endangers human health though it complies with the said Directive or said acts, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the grounds adduced by the Member State concerned and shall consult the Member States within the Standing Committee on the Food Chain and Animal Health, and shall then deliver its opinion without delay and take appropriate measures.

3. If the Commission considers that amendments to this Directive or to the implementing Community acts are necessary in order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure referred to in Article 13(2) with a view to adopting those amendments. The Member State that has adopted safeguard measures may in that event retain them until the amendments have been adopted.

Article 13

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002⁽¹⁾ (hereinafter referred to as 'the Committee').

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

Article 14

Provisions that may have an effect upon public health shall be adopted after consultation with the European Food Safety Authority.

Article 15

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 July 2003. They shall forthwith inform the Commission thereof.

Those laws, regulations and administrative provisions shall be applied in such a way as to:

- (a) permit trade in products complying with this Directive, from 1 August 2003 at the latest;
- (b) prohibit trade in products which do not comply with the Directive, from 1 August 2005 at the latest.

When Member States adopt these measures, they shall contain a reference to this Directive or be accompanied by such a refer-

ence on the occasion of their official publication. The methods of making such reference shall be adopted by the Member States.

Article 16

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 17

This Directive is addressed to the Member States.

Done at Luxembourg, 10 June 2002.

For the European Parliament

The President

P. COX

For the Council

The President

J. PIQUÉ I CAMPS

 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 α-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)

ANNEX II

Vitamin and mineral substances which may be used in the manufacture of food supplements

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| <p>A. Vitamins</p> <p>1. VITAMIN A</p> <p>(a) retinol</p> <p>(b) retinyl acetate</p> <p>(c) retinyl palmitate</p> <p>(d) beta-carotene</p> <p>2. VITAMIN D</p> <p>(a) cholecalciferol</p> <p>(b) ergocalciferol</p> <p>3. VITAMIN E</p> <p>(a) D-alpha-tocopherol</p> <p>(b) DL-alpha-tocopherol</p> <p>(c) D-alpha-tocopheryl acetate</p> <p>(d) DL-alpha-tocopheryl acetate</p> <p>(e) D-alpha-tocopheryl acid succinate</p> <p>4. VITAMIN K</p> <p>(a) phyloquinone (phytomenadione)</p> <p>5. VITAMIN B1</p> <p>(a) thiamin hydrochloride</p> <p>(b) thiamin mononitrate</p> <p>6. VITAMIN B2</p> <p>(a) riboflavin</p> <p>(b) riboflavin 5'-phosphate, sodium</p> <p>7. NIACIN</p> <p>(a) nicotinic acid</p> <p>(b) nicotinamide</p> <p>8. PANTOTHENIC ACID</p> <p>(a) D-pantothenate, calcium</p> <p>(b) D-pantothenate, sodium</p> <p>(c) dexpanthenol</p> <p>9. VITAMIN B6</p> <p>(a) pyridoxine hydrochloride</p> <p>(b) pyridoxine 5'-phosphate</p> <p>10. FOLIC ACID</p> <p>(a) pteroylmonoglutamic acid</p> <p>11. VITAMIN B12</p> <p>(a) cyanocobalamin</p> <p>(b) hydroxocobalamin</p> | <p>12. BIOTIN</p> <p>(a) D-biotin</p> <p>13. VITAMIN C</p> <p>(a) L-ascorbic acid</p> <p>(b) sodium-L-ascorbate</p> <p>(c) calcium-L-ascorbate</p> <p>(d) potassium-L-ascorbate</p> <p>(e) L-ascorbyl 6-palmitate</p> <p>B. Minerals</p> <p>calcium carbonate</p> <p>calcium chloride</p> <p>calcium salts of citric acid</p> <p>calcium gluconate</p> <p>calcium glycerophosphate</p> <p>calcium lactate</p> <p>calcium salts of orthophosphoric acid</p> <p>calcium hydroxide</p> <p>calcium oxide</p> <p>magnesium acetate</p> <p>magnesium carbonate</p> <p>magnesium chloride</p> <p>magnesium salts of citric acid</p> <p>magnesium gluconate</p> <p>magnesium glycerophosphate</p> <p>magnesium salts of orthophosphoric acid</p> <p>magnesium lactate</p> <p>magnesium hydroxide</p> <p>magnesium oxide</p> <p>magnesium sulphate</p> <p>ferrous carbonate</p> <p>ferrous citrate</p> <p>ferric ammonium citrate</p> <p>ferrous gluconate</p> <p>ferrous fumarate</p> <p>ferric sodium diphosphate</p> <p>ferrous lactate</p> <p>ferrous sulphate</p> <p>ferric diphosphate (ferric pyrophosphate)</p> <p>ferric saccharate</p> <p>elemental iron (carbonyl+electrolytic+hydrogen reduced)</p> <p>cupric carbonate</p> <p>cupric citrate</p> <p>cupric gluconate</p> <p>cupric sulphate</p> <p>copper lysine complex</p> |
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sodium iodide	sodium gluconate
sodium iodate	sodium lactate
potassium iodide	sodium hydroxide
potassium iodate	sodium salts of orthophosphoric acid
zinc acetate	potassium bicarbonate
zinc chloride	potassium carbonate
zinc citrate	potassium chloride
zinc gluconate	potassium citrate
zinc lactate	potassium gluconate
zinc oxide	potassium glycerophosphate
zinc carbonate	potassium lactate
zinc sulphate	potassium hydroxide
manganese carbonate	potassium salts of orthophosphoric acid
manganese chloride	sodium selenate
manganese citrate	sodium hydrogen selenite
manganese gluconate	sodium selenite
manganese glycerophosphate	chromium (III) chloride
manganese sulphate	chromium (III) sulphate
sodium bicarbonate	ammonium molybdate (molybdenum (VI))
sodium carbonate	sodium molybdate (molybdenum (VI))
sodium chloride	potassium fluoride
sodium citrate	sodium fluoride
