

**Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements**

(2000/C 311 E/13)

(Text with EEA relevance)

COM(2000) 222 final — 2000/0080(COD)

*(Submitted by the Commission on 10 May 2000)*

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,

Having regard to the Opinion of the Economic and Social Committee,

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

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, may 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 as 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 onto 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 plant and herbal extracts. However, as a first stage, this Directive should only cover food supplements containing vitamins and minerals.

- (7) Only vitamins and minerals normally found in and consumed as part of the diet and considered essential nutrients 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 essential nutrients that could potentially arise should be avoided. Therefore it is appropriate to establish a positive list of those vitamins and minerals.
- (8) 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 for 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.
- (9) 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.
- (10) For vitamins and minerals excessive intakes 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.
- (11) For that reason, when setting those maximum safe levels, account should be taken of the upper safe levels of the vitamins or minerals, as established by scientific risk assessment based on generally acceptable scientific data, of intakes of those nutrients from the normal diet and of the fact that for some nutrients upper safe levels may be close to the level that may be recommended for consumption. The latter consideration is of particular importance where generally acceptable scientific data prove that excess intake of the vitamins and minerals concerned cause adverse effects.

- (12) 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.
- (13) 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.
- (14) General labelling provisions and definitions are contained in Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer <sup>(1)</sup>, as last amended by Directive 97/4/EC of the European Parliament and of the Council <sup>(2)</sup>, and do not need to be repeated. This Directive can therefore be confined to the necessary additional provisions.
- (15) Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs <sup>(3)</sup> 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.
- (16) 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.
- (17) Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(4)</sup>, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

HAVE ADOPTED THIS DIRECTIVE:

#### Article 1

1. This Directive concerns food supplements marketed in pre-packaged form as foodstuffs and presented as such.

<sup>(1)</sup> OJ L 33, 8.2.1979, p. 1.

<sup>(2)</sup> OJ L 43, 14.2.1997, p. 21.

<sup>(3)</sup> OJ L 276, 6.10.1990, p. 40.

<sup>(4)</sup> OJ L 184, 17.7.1999, p. 23.

2. This Directive does not apply to:

- (a) foods for particular nutritional uses covered by Council Directive 89/398/EEC <sup>(5)</sup>;
- (b) medicinal products covered by Council Directive 65/65/EEC <sup>(6)</sup>.

#### Article 2

For the purposes of this Directive:

- (a) 'food supplements' means foodstuffs that are concentrated sources of nutrients as specified in (b), alone or in combination, marketed in dose form, whose purpose is to supplement the intake of those nutrients in the normal diet;
- (b) 'nutrients' means the following substances:
- (i) vitamins listed in point 1 of Annex I,
- (ii) minerals listed in point 2 of Annex I;
- (c) 'dose form' means forms such as capsules, tablets, pills and other similar forms, sachets of powder, ampoules of liquids and drop dispensing bottles.

#### Article 3

Member States shall ensure that the food supplements containing the nutrients listed in Article 2(b) may be marketed within the Community only if they comply with the rules laid down in this Directive.

#### Article 4

1. Only the vitamins and minerals listed in Annex I and the vitamin formulations and the permitted mineral substances listed in Annex II may be used for the manufacture of food supplements.

2. The criteria of purity for the substances, referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 13(2).

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

<sup>(5)</sup> OJ L 186, 30.6.1989, p. 27.

<sup>(6)</sup> OJ 22, 9.2.1965, p. 369/65.

*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 acceptable scientific data;
- (b) reference intakes of vitamins and minerals for the population, where these are close to the upper safe levels;
- (c) intakes of vitamins and minerals from other dietary sources.

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

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

*Article 6*

1. The name under which products covered by this Directive are sold shall include the word 'supplement' and the name of the category of the nutrient(s) characterising the product. The name of the category of the nutrient(s) may be completed or replaced by the specific name of the nutrient(s) characterising the product.

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 the requirements of Directive 79/112/EEC, the labelling shall bear the following mandatory particulars:

- (a) the portion of the product recommended for daily consumption;
- (b) a warning as to the possible health risks, as the case may be, in exceeding the recommended portion for daily consumption;
- (c) a statement to the effect that food supplements should not be used as a substitute for a diversified diet.

4. When the form of presentation is similar to a pharmaceutical form as defined by pharmacopoeias, the statement 'This is not a medicinal product' shall appear on the label.

*Article 7*

The labelling of food supplements shall not include any mention stating or implying that an adequate and diversified diet cannot provide appropriate quantities of nutrients.

*Article 8*

1. The amount of the nutrient(s) listed in Article 2(b) present in the product shall be declared in the labelling in numerical form. The units to be used shall be those specified in Annex I.

2. The amounts of the nutrient(s) declared shall be those per portion of the product as recommended for daily consumption on the labelling and per unit dose form, as appropriate. The amounts declared shall be those of the product as sold.

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.

The 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, when a product is placed on the market the manufacturer or, where a product is manufactured in a third country, the importer, shall notify the competent authority of each Member State where the product is being marketed by forwarding it a model of the label used for the product.

Member States may not impose this requirement, if they can demonstrate to the Commission that notification is not necessary in order to monitor those products efficiently in their territory.

#### Article 11

1. 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 relevant provisions of the EC 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 in implementation of 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 those provisions, 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 for Foodstuffs, 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 for Foodstuffs instituted by Decision 69/414/EEC <sup>(1)</sup>.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

#### Article 14

Provisions that may have an effect upon public health shall be adopted after consultation with the Scientific Committee for Food.

#### Article 15

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 May 2002. 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 June 2002 at the latest;
- (b) prohibit trade in products which do not comply with the Directive, from 1 June 2004 at the latest.

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.

#### Article 16

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

#### Article 17

This Directive is addressed to the Member States.

<sup>(1)</sup> OJ L 291, 19.11.1969, p. 9.

## 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 ( $\mu\text{g}$ )  
 Vitamin E (mg  $\alpha\text{-TE}$ )  
 Vitamin K ( $\mu\text{g}$ )  
 Vitamin B1 (mg)  
 Vitamin B2 (mg)  
 Niacin (mg NE)  
 Pantothenic acid (mg)  
 Vitamin B6 ( $\mu\text{g}$ )  
 Folic acid ( $\mu\text{g}$ )  
 Vitamin B12 ( $\mu\text{g}$ )  
 Biotin ( $\mu\text{g}$ )  
 Vitamin C (mg)

2. *Minerals*

Calcium (mg)  
 Magnesium (mg)  
 Iron (mg)  
 Copper ( $\mu\text{g}$ )  
 Iodine ( $\mu\text{g}$ )  
 Zinc (mg)  
 Manganese (mg)  
 Sodium (mg)  
 Potassium (mg)  
 Selenium ( $\mu\text{g}$ )  
 Chromium ( $\mu\text{g}$ )  
 Molybdenum ( $\mu\text{g}$ )  
 Fluoride (mg)  
 Chloride (mg)  
 Phosphorus (mg)

## ANNEX II

**Vitamin and mineral substances which may be used in the manufacture of food supplements**1. *Vitamins*

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  
 — phyloquinone (phytomenadione)  
 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  
 FOLIC ACID  
 — pteroylmonoglutamic acid  
 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. *Minerals*

calcium carbonate  
 calcium chloride  
 calcium salts of citric acid  
 calcium gluconate  
 calcium glycerophosphate  
 calcium lactate

calcium salts of orthophosphoric acid	zinc lactate
calcium hydroxide	zinc oxide
calcium oxide	zinc carbonate
magnesium acetate	zinc sulphate
magnesium carbonate	manganese carbonate
magnesium chloride	manganese chloride
magnesium salts of citric acid	manganese citrate
magnesium gluconate	manganese gluconate
magnesium glycerophosphate	manganese glycerophosphate
magnesium salts of orthophosphoric acid	manganese sulphate
magnesium lactate	sodium bicarbonate
magnesium hydroxide	sodium carbonate
magnesium oxide	sodium chloride
magnesium sulphate	sodium citrate
ferrous carbonate	sodium gluconate
ferrous citrate	sodium lactate
ferric ammonium citrate	sodium hydroxide
ferrous gluconate	sodium salts of orthophosphoric acid
ferrous fumarate	potassium bicarbonate
ferric sodium diphosphate	potassium carbonate
ferrous lactate	potassium chloride
ferrous sulphate	potassium citrate
ferric diphosphate (ferric pyrophosphate)	potassium gluconate
ferric saccharate	potassium glycerophosphate
elemental iron (carbonyl + electrolytic + hydrogen reduced)	potassium lactate
cupric carbonate	potassium hydroxide
cupric citrate	potassium salts of orthophosphoric acid
cupric gluconate	sodium selenate
cupric sulphate	sodium hydrogen selenite
copper lysine complex	sodium selenite
sodium iodide	chromium (III) chloride
sodium iodate	chromium (III) sulphate
potassium iodide	ammonium molybdate (molybdenum (VI))
potassium iodate	potassium molybdate (molybdenum (VI))
zinc acetate	potassium fluoride
zinc chloride	sodium fluoride
zinc citrate	
zinc gluconate	

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