COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 19.03.2001 COM(2001) 159 final

2000/0080(COD)

Amended 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

(presented by the Commission pursuant to Article 250 (2) of the EC-Treaty)

# EXPLANATORY MEMORANDUM

## A. Introduction

On 10 May 2000, the Commission submitted a proposal for a Directive of the European Parliament and the Council on food supplements (COM(2000)222 final - 2000/0080 (COD)) for adoption by the co-decision procedure laid down in Article 251 of the Treaty establishing the European Community.

The Economic and Social Committee delivered its opinion on 19 October 2000.

On 14 February 2001, the European Parliament adopted a report on the proposal at first reading (Report A5-0025/2001). The report proposes 38 amendments to the proposal.

In the light of these developments the Commission is submitting this amended proposal based on the amendments adopted by the European Parliament that the Commission accepted in full or in principle with drafting changes.

## **B.** Explanation on the amendments

The Commission can accept amendments 2, 4, 17, 19, 33 and 44 as they constitute an improvement and clarification of the Commission's initial proposal. The Commission accepts those for the following reasons:

- Amendments 2 and 4 constitute technical and factual corrections to the text.
- Amendments 33 and 44 are identical and clarify in the definition given in Article 2 what is explained in recital 6 of the proposal, namely that ingredients of food supplements may be some substances that have nutritional function (e.g. vitamins, minerals, amino acids, fatty acids) or physiological one (e.g. fibre and various plant and herbal extracts).
- Amendment 17 proposes to include on the label a statement to the effect that food supplements should be stored out of the reach of children. Such a statement would provide additional safeguards for avoiding accidental ingestion of these products.
- Amendment 19 proposes to delete Article 6(4) that would result in the vast majority of food supplements bearing the statement "This is not a medicinal product". The Commission accepts the argument that this is not an appropriate statement to appear on the label of a food product.

The Commission can accept in principle amendments 7, 9, 12, 20, 30, 34, 37, 38, 42, and 46 with the understanding that further changes will improve the text and ensure the necessary coherence. The Commission accepts in principle these amendments for the following reasons:

- The Commission agrees with the principle of the clarifications that are proposed by amendment 37 for inclusion in recital 6. The specific rules on vitamins and minerals laid down in the future directive should be applicable to food supplements containing vitamins, minerals and other ingredients. Otherwise it would be very easy to avoid applying these rules by adding just a small quantity of another ingredient to a food supplement containing vitamins or minerals. On the other hand in the absence of specific Community rules concerning other ingredients relevant national rules may continue to apply, without prejudice to the provisions of the Treaty. Therefore the Commission can accept amendment 37 with some editorial changes.

- Amendments 30, 38 and 42 are identical. They propose to state in a recital that priority should be given to the evaluation by the Scientific Committee for Food of substances that are not included in Annex II of the proposal but which are used in the manufacture of products currently marketed in some Member States. It should be noted that Annex II includes only vitamin preparations and mineral salts. It does not include other ingredients. It should also be noted that the reference to the procedure of Article 13 is not appropriate here. That procedure is not applicable to the evaluation of the substances in question by the Scientific Committee for Food. Therefore these amendments can be accepted provided that the drafting reflect the above points.
- Amendments 34 and 46 are identical and would stem from the change to Article 2 introduced by amendments 33 and 44. However the proposed added text should be separate from the provisions of Article 2(b) that concern nutrients. Further there can be no reference to Annex I because that Annex lists exclusively vitamins and minerals. Finally there can neither be reference to Article 4(3a) because that Article does not exist in the original proposal and the Commission cannot accept amendment 47 that proposes its addition. Therefore amendments 34 and 46 can be accepted with the necessary drafting changes to take into account the above points.
- Amendment 7 proposes to modify the definition of "dose form" provided in Article 2(c). The Commission accepts the principle of this amendment that aims to obtain a workable definition depicting current practices. It considers however that some drafting changes are necessary to achieve this aim.
- Amendment 9 proposes some principles for the adoption of purity criteria for vitamin preparations and mineral substances listed in Annex II. The Commission can accept the aim to be more concrete on this point. It notes however that a relevant text is included in the Commission Directive on substances that may be added for specific nutritional purposes in foods for particular nutritional uses that was adopted on 15 February 2001 (to be published). For reasons of coherence of Community rules the same text should appear in this Directive.
- Amendment 12 to Article 5(1) proposes to take into account requirements of children and adults when setting maximum levels for vitamins and minerals. The principle can be extended to take into account "sensitivities of different consumer groups" and not only children and adults. Further the point should be inserted in a more appropriate place in the Article than the one suggested. Therefore amendment 12 can be accepted with the necessary drafting changes.
- Amendment 20 aims to allow for derogation to the prohibition of Article 7. It can be accepted in principle with editorial changes to clarify that this derogation would apply in certain circumstances concerning the diet of specific population groups where this has been established by generally accepted scientific data.

The Commission cannot accept amendments 3, 8, 10, 13, 14, 15, 16, 18, 21, 22, 23, 24, 25, 26, 31, 32, 36, 39, 43, 47, 48 and 49 for the following reasons:

- A number of amendments propose modifications to well-established procedures and working rules for the subsequent management of the Directive. They aim to condition or to

put a time frame on Commission action (amendments 3, 24), or to put down certain rules for the work of the Scientific Committee for Food (amendments 10, 25). Such modifications are not appropriate in the context of this Directive and cannot be accepted. Amendment 13 proposes that the Comitology procedure shall be subject to the principle of transparency. Although the Commission subscribes to that principle it believes that this is one to be applied generally to procedures dealing with products across the board and that reference to this principle in a sectoral directive is not appropriate.

- Amendment 8 proposes to add a new paragraph to Article 3 that includes part of the text added to recital 6 with amendment 37. The Commission accepted that amendment and the principle therein, but does not consider that the same text needs to be included in an article.
- Amendment 47 infringes upon the right of initiative of the Commission and cannot be accepted for institutional reasons.
- Partly for the same institutional reasons the identical amendments 31, 36 and 48 for a new article cannot be accepted. In addition the basic idea of these 3 amendments is included in a new recital 6a proposed by amendments 30, 38 and 42 and accepted by the Commission. It is not necessary to have an article with the same text.
- Amendment 14 refers to the name of the product. In terms of labelling there is a very significant difference between the "name of the product" and the "labelling". The name of the product must be set in EU legislation otherwise Member States can do that at the national level. This would create great confusion for consumers. For this reason amendment 14 cannot be accepted. However the Commission takes note of the request of the Parliament that the name of the product should include the words "food supplement".
- The text proposed by amendment 15 and is not expressing a different principle than the one expressed by the text of the proposal. It is rather a drafting amendment that does not achieve greater clarity on this point.
- Amendment 16 proposes the deletion of a statement to the effect that food supplements should not be used as a substitute for a diversified diet. The Commission considers that such a statement is important for consumers both for information and education and cannot accept its deletion.
- Amendment 18 although well intended would be potentially contradictory to Article 1(2)(a) that excludes foods for particular nutritional uses from the scope of this Directive.
- Amendment 21 proposes the addition of two sentences to Article 9. The principle expressed in the first sentence, that excess doses should be avoided, is already covered in article 6. The second sentence deals with the issue of tolerance limits for declared quantities of certain nutrients that have stability problems. This is a highly technical issue that needs to be considered by appropriate experts and if necessary be dealt with through technical implementing measures.
- Amendment 22 proposes to adopt principles of Good Manufacturing Practices by legally binding measures. This is not the practice in the area of foodstuffs and would set a precedent. There are horizontal rules on hygiene and control that apply to all foods and will apply to food supplements also. There are purity criteria for many of the substances that are listed in Annex II and it is intend to adopt them also for the rest. These binding horizontal rules seem to be enough.

- Amendment 23 would make it obligatory for Member States to require manufactures to notify to the authorities food supplements when marketed. The proposal of the Commission allows Member States to waive such requirement if they can otherwise monitor these products in their territory. The Commission thinks that this is an issue that should be left to the discretion of Member States.
- Amendments 32, 39 and 49 cannot be accepted because they are directly linked to amendments 31, 36 and 48 which are not acceptable as explained above. However this should not be taken as a judgement on their content of substances. Substances included therein are to be evaluated for their safety by the Scientific Committee for Food before prior to their eventual inclusion in Annex II. In the absence of these substances from Annex II the inclusion of the 5 additional minerals to Annex I proposed by amendment 26 is meaningless.
- It is not clear what are the testing procedures set out in this directive that other ingredients should be subjected as suggested by amendment 43. The Commission is not convinced that this amendment will improve its proposal.

The amendments to the initial Commission proposal have been highlighted using *strikethrough* for deleted text and *bold* and *underlined* for new or amended text.

## 2000/0080(COD)

## Amended 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

## (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<sup>1</sup>,

Having regard to the Opinion of the Economic and Social Committee<sup>2</sup>,

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.

<sup>&</sup>lt;sup>1</sup> OJ C

<sup>&</sup>lt;sup>2</sup> OJ C

- (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.
- (7) However as <u>As</u> a first stage, this Directive should only cover food supplements containing vitamins and minerals. <u>Food supplements containing vitamins or</u> <u>minerals among their ingredients should be in conformity with the specific rules</u> <u>on vitamins and minerals laid down in this Directive.</u>
- (8) Specific rules concerning other nutrients or other substances with nutritional or physiological function 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 the adoption of such specific Community rules and without prejudice to the provisions of the Treaty, national rules concerning nutrients or other substances with nutritional or physiological function as ingredients of food supplements, for which no Community specific rules have been adopted, may be applicable.
- (79) 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.
- (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 for Food and consequently are not included in the positive lists. These should be submitted to the Scientific Committee for Food for urgent evaluation, as soon as appropriate files are presented by the interested parties.
- (811) 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.
- (912) 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.
- (1013) 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<u>14</u>) 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.

- (1215) 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.
- (1316) 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<u>17</u>) General labelling provisions and definitions are contained in Council Directive 79/112/EEC of 18 December 1978 Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs<sup>3</sup> for sale to the ultimate consumer, as last amended by Directive 97/4/EC of the European Parliament and of the Council<sup>4</sup>, and do not need to be repeated. This Directive can should therefore be confined to the necessary additional provisions.
- (4518) Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs<sup>5</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.
- (1619) 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.
- (1720) 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>6</sup>, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

## HAVE ADOPTED THIS DIRECTIVE:

<sup>&</sup>lt;sup>3</sup> OJ L 109, 6.5.2000, p. 29 OJ L 33, 8.2.1979, p. 1.

<sup>&</sup>lt;sup>4</sup> OJ L 43, 14.2.1997, p. 21.

<sup>&</sup>lt;sup>5</sup> OJ L 276, 6.10.1990, p. 40.

<sup>&</sup>lt;sup>6</sup> OJ L 184, 17.7.1999, p. 23.

- 1. This Directive concerns food supplements marketed in pre-packaged form as foodstuffs and presented as such.
- 2. This Directive does not apply to:
  - (a) foods for particular nutritional uses covered by Council Directive 89/398/EEC<sup>7</sup>;
  - (b) medicinal products covered by Council Directive  $65/65/EEC^8$ .

## Article 2

- 1. For the purposes of this Directive:
  - (a) "food supplements" means foodstuffs that are concentrated sources of nutrients as specified in (b) or other substances with a nutritional or physiological function, 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, <u>pastilles</u>, tablets, pills and other similar forms, sachets of powder, ampoules of liquids<u>a</u> and drop dispensing bottles <u>and other similar forms of liquids and powders designed to be</u> <u>taken in measured small unit quantities</u>.

#### 2. <u>Specific rules on other substances with a nutritional or physiological function</u> <u>shall be laid down at a later stage.</u>

## Article 3

Member States shall ensure that the food supplements containing the nutrients listed in Article  $2(\underline{1})(b)$  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.

<sup>&</sup>lt;sup>7</sup> OJ L 186, 30.6.1989, p. 27.

<sup>&</sup>lt;sup>8</sup> OJ L 22, 9.2.1965, p. 369.

- The criteria of purity criteria for the substances, referred to in paragraph 1 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. <u>Purity criteria for substances listed in Annex II, specified by Community</u> <u>legislation for their use in the manufacture of foodstuffs for purposes other than</u> <u>those covered by this Directive, shall apply</u>.
- 4. For those substances listed in Annex II for which purity criteria are not specified by Community legislation, and until the adoption of such specifications, generally acceptable purity criteria recommended by international bodies shall apply. National rules setting stricter purity criteria may be maintained.
- 35. Modifications to the lists referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 13(2).

- 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 <u>that take into</u> <u>account, as appropriate, the varying degrees of sensitivity of different groups of the population;</u>
  - (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 <del>79/112/EEC</del> <u>2000/13/EC</u>, 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-:
  - (d) <u>a statement to the effect that the products should be stored out of the</u> reach of children.
- 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.

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 <u>in general</u>. This shall not prevent the provision therein of information about the need for <u>supplementation of the diet of specific population groups where this has been established</u> by generally accepted scientific data.

## Article 8

- 1. The amount of the nutrient(s) listed in Article 2(1)(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.

- 1. The Commission shall be assisted by the Standing Committee for Foodstuffs instituted by Decision  $69/414/\text{EEC}^9$ .
- 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.

OJ L 291, 19.11.1969, p. 9.

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.

Done at Brussels, [...]

For the European Parliament The President [...] For the Council The President [...]

#### ANNEX I

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

## 1. Vitamins

Vitamin A ( $\mu$ g RE) Vitamin D ( $\mu$ g) Vitamin E (mg  $\alpha$ -TE) Vitamin K ( $\mu$ g) Vitamin B1(mg) Vitamin B2(mg) Niacin (mg NE) Pantothenic acid (mg) Vitamin B6 ( $\mu$ g) Folic acid( $\mu$ g) Vitamin B12 ( $\mu$ g) Biotin ( $\mu$ g) 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) Fluoride (mg) Chloride (mg) Phosphorus (mg)

## <u>ANNEX II</u>

# 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

- phylloquinone (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 calcium hydroxide calcium oxide

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 sulphate

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 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 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 salts of orthophosphoric acid

sodium selenate sodium hydrogen selenite sodium selenite chromium (III) chloride chromium (III) sulphate

ammonium molybdate (molybdenum (VI)) potassium molybdate (molybdenum (VI))

potassium fluoride sodium fluoride