

COMMON POSITION (EC) No 2/2006**adopted by the Council on 8 December 2005****with a view to adopting Regulation (EC) No .../2006 of the European Parliament and of the Council of ... on the addition of vitamins and minerals and of certain other substances to foods**

(2006/C 80 E/02)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Community provisions, relevant national rules may apply without prejudice to the provisions of the Treaty.

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 European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽²⁾,

Whereas:

(1) There is a wide range of nutrients and other ingredients that might be used in food manufacturing, including, but not limited to, vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre, various plants and herbal extracts. Their addition to foods is regulated in Member States by differing national rules that impede the free movement of these products, 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 harmonising national provisions relating to the addition of vitamins and minerals and of certain other substances to foods.

(2) This Regulation aims to regulate the addition of vitamins and minerals to foods and the use of certain other substances or ingredients containing substances other than vitamins or minerals that are added to foods or used in the manufacture of foods under conditions that result in the ingestion of amounts greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers. In the absence of specific Community rules regarding prohibition or restriction of use of substances or ingredients containing substances other than vitamins or minerals under this Regulation or under other specific

(3) Some Member States require the mandatory addition of some vitamins and minerals to certain ordinary foods, for reasons dictated by public health considerations. These reasons may be pertinent at national or even regional level, but would not currently justify harmonisation of the mandatory addition of nutrients across the Community. However, if and when this became appropriate, such provisions could be adopted at Community level. Meanwhile, it would be useful for information on such national measures to be compiled.

(4) Vitamins and minerals may be added to foods voluntarily by food manufacturers or must be added as nutritional substances as provided for by specific Community legislation. They may also be added for technological purposes as additives, colourings, flavourings or other such uses including authorised oenological practices and processes provided for by relevant Community legislation. This Regulation should apply without prejudice to the specific Community rules concerning the addition to or use of vitamins and minerals to specific products or groups of products or their addition for purposes other than those covered by this Regulation.

(5) Given that detailed rules on food supplements containing vitamins and minerals have been adopted by 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 ⁽³⁾, provisions of this Regulation regarding vitamins and minerals should not apply to food supplements.

(6) Vitamins and minerals are added to foods by manufacturers for a number of purposes including to restore their content where this has been reduced during manufacturing, storage or handling procedures or to provide a similar nutritional value to foods for which they are intended as alternatives.

⁽¹⁾ OJ C 112, 30.4.2004, p. 44.

⁽²⁾ Opinion of the European Parliament of 26 May 2005, Council Common Position of 8 December 2005 and position of the European Parliament of (not yet published in the Official Journal).

⁽³⁾ OJ L 183, 12.7.2002, p. 51.

- (7) An adequate and varied diet can, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities such as those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is being achieved neither for all vitamins and minerals nor by all groups of the population across the Community. Foods to which vitamins and minerals have been added appear to make an appreciable contribution to the intake of these nutrients and as such may be considered to make a positive contribution to overall intakes.
- (8) Some nutrient deficiencies, although not very frequent, can be demonstrated to exist at present in the Community. Changes in the socio-economic situation prevailing in the Community and the life styles of different groups of the population have led to different nutritional requirements and to changing dietary habits. This in turn has led to changes in the energy and nutrient requirements of various groups of the population and to intakes of certain vitamins and minerals for these groups that would be below those recommended in different Member States. In addition, progress in scientific knowledge indicates that intakes of some nutrients for maintaining optimal health and well-being could be higher than those currently recommended.
- (9) Only vitamins and minerals normally found in and consumed as part of the diet and considered essential nutrients should be allowed to be added to foods although this does not mean that their addition thereto is necessary. Controversy as to the identity of these essential nutrients that could potentially arise should be avoided. It is therefore appropriate to establish a positive list of these vitamins and minerals.
- (10) The chemical substances used as sources of vitamins and minerals which may be added to foods should be safe and also be bio-available i.e. available to be used by the body. For this reason a positive list of these substances should also be established. Such substances that have been approved by the Scientific Committee on Food in an opinion expressed on 12 May 1999, on the basis of the above criteria of safety and bio-availability, and can be used in the manufacture of foods intended for infants and young children, other foods for particular nutritional uses or food supplements should appear in this positive list. Although sodium chloride (common salt) does not appear among the substances in this list, it may continue to be used as an ingredient in the preparation of food.
- (11) In order to keep up with scientific and technological developments, it is important to revise the above 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.
- (12) Foods to which vitamins and minerals are added are, in most cases, promoted by manufacturers and may be perceived by consumers as products having a nutritional, physiological or other health advantage over similar or other products without such nutrients added. This may induce consumer choices that may be otherwise undesirable. To counter this potential undesirable effect, it is considered appropriate to impose some restrictions on the products to which vitamins and minerals can be added, in addition to those that would result naturally from technological considerations or become necessary for safety reasons when maximum limits of vitamins and minerals in such products are set. The content in the product of certain substances, such as alcohol, would, in this context, be an appropriate criterion for not allowing vitamins and minerals to be added to it. Any derogation from banning the addition of vitamins and minerals to alcoholic beverages should be limited to protecting traditional wine recipes, with the relevant products being notified to the Commission. No claims about any nutritional or health benefits of the additions should be made. Moreover, in order to avoid any confusion for the consumer as to the natural nutritional value of fresh foods, the addition of vitamins and minerals thereto should not be allowed.
- (13) This Regulation is not intended to cover the use of vitamins and minerals in trace quantities as authenticity markers used with the objective of combating fraud.
- (14) Excessive intakes of vitamins and minerals may result in adverse effects and it is therefore necessary to set maximum safe levels for them when they are added to foods, as the case may be. These levels must ensure that the normal use of the products, under the instructions for use provided by the manufacturer and in the context of a diversified diet, will be safe for the consumer. Therefore those levels should be total maximum safe levels for the vitamins and minerals present in the food naturally and/or added to the food for whatever purpose, including for technological uses.

- (15) For that reason, those maximum levels and any other conditions restricting their addition to foods, where necessary, should be adopted taking into account their upper safe levels established by scientific risk assessment based on generally acceptable scientific data and their potential intake from other foods. Due account should also be taken of the population reference intakes of vitamins and minerals. Where it is necessary, for certain vitamins and minerals, to establish restrictions regarding the foods to which they can be added, priority should be given to the purposes of restoring their content where this has been reduced during manufacturing, storage or handling procedures and of providing a similar nutritional value to foods for which those foods are intended as alternatives.
- (16) Vitamins and minerals added to foods should result in a minimum amount being present in the food. Otherwise the presence of too small and insignificant amounts in these fortified foods would not offer any benefit to consumers and would be misleading. The same principle underlies the requirement that these nutrients should be present in a significant amount in the food in order to be allowed to be declared in nutrition labelling. Therefore it would be appropriate that the minimum amounts of vitamins and minerals in foods to which vitamins and minerals have been added should be the same as those significant amounts that should be present for those nutrients to be declared in nutrition labelling unless otherwise provided for by appropriate derogations.
- (17) The adoption of maximum levels and any conditions of use based on the application of the principles and criteria stipulated in this Regulation and the adoption of minimum levels 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.
- (18) 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⁾. This Regulation should therefore be confined to the necessary additional provisions. Those additional provisions should also apply without prejudice to Regulation (EC) No/2006 of the European Parliament and of the Council of on nutrition and health claims made on foods⁽²⁾.
- (19) Given the nutritional importance of products to which vitamins and minerals have been added and their potential impact on dietary habits and overall nutrient intakes, the consumer should be able to evaluate the global nutritional quality of those products. Therefore, by derogation from Article 2 of Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs⁽³⁾, nutrition labelling should be compulsory.
- (20) A normal and varied diet contains many ingredients, which in turn contain many substances. The intake of these substances or ingredients resulting from their normal and traditional use in current diets would not cause concern and does not need to be regulated. Some substances other than vitamins and minerals or ingredients containing them are added to foods as extracts or concentrates and may result in intakes that are significantly higher than those that could be ingested through eating an adequate and varied diet. The safety of such practices is in some cases seriously contested and the benefits are unclear; therefore they should be regulated. It is appropriate, in such cases, that food operators, responsible for the safety of the foods they place on the market, assume the burden of proof in relation to their safety.
- (21) Given the particular nature of foods to which vitamins and minerals are added, means additional to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.
- (22) Since the objective of this Regulation, namely to ensure the effective functioning of the internal market as regards the addition of vitamins and minerals and certain other substances to foods whilst providing a high level of consumer protection, cannot be sufficiently achieved by the Member States, and can therefore be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

⁽¹⁾ OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

⁽²⁾ Common position (EC) No 3/2006 (page ... of this Official Journal).

⁽³⁾ OJ L 276, 6.10.1990, p. 40. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

(23) The measures necessary for the implementation of this Regulation 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 ⁽¹⁾,

No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽²⁾.

HAVE ADOPTED THIS REGULATION:

CHAPTER II

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to the addition of vitamins and minerals and of certain other substances to foods, with the purpose of ensuring the effective functioning of the internal market, whilst providing a high level of consumer protection.
2. The provisions of this Regulation regarding vitamins and minerals shall not apply to food supplements covered by Directive 2002/46/EC.
3. This Regulation shall apply without prejudice to specific provisions laid down in Community legislation concerning:
 - (a) foods for particular nutritional uses and, in the absence of specific provisions, compositional requirements of such products rendered necessary by the particular nutritional requirements of the persons for whom they are intended;
 - (b) novel foods and novel food ingredients;
 - (c) genetically modified food;
 - (d) food additives and flavourings;
 - (e) authorised oenological practices and processes.

Article 2

Definitions

For the purposes of this Regulation, 'Authority' means the European Food Safety Authority established by Regulation (EC)

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

ADDITION OF VITAMINS AND MINERALS

Article 3

Requirements for the addition of vitamins and minerals

1. Only vitamins and/or minerals listed in Annex I, in the forms listed in Annex II, may be added to foods, subject to the rules laid down in this Regulation.
2. Vitamins and minerals may be added to foods, whether or not they are usually contained therein, in order to take into account:
 - (a) a deficiency of one or more vitamins and/or minerals in the population or specific population groups that can be demonstrated by clinical or sub-clinical evidence of deficiency or indicated by estimated low levels of intake of nutrients; or
 - (b) the potential to improve the nutritional status of the population or specific population groups and/or correct possible deficiencies in dietary intakes of vitamins or minerals due to changes in dietary habits; or
 - (c) evolving generally acceptable scientific knowledge on the role of vitamins and minerals in nutrition and consequent effects on health.

3. Modifications to the lists referred to in paragraph 1 of this Article shall be adopted in accordance with the procedure referred to in Article 14(2), taking account of the opinion of the Authority.

⁽²⁾ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

Article 4

Restrictions on the addition of vitamins and minerals

Vitamins and minerals may not be added to:

- (a) unprocessed foodstuffs, including, but not limited to, fruit, vegetables, meat, poultry and fish;
- (b) beverages containing more than 1,2 % by volume of alcohol, except and by way of derogation from Article 3(2), to products:
 - (i) referred to in Article 44(6) and (13) of Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine ⁽¹⁾;
 - (ii) which were marketed prior to the adoption of this Regulation; and
 - (iii) which have been notified to the Commission by a Member State in accordance with Article 11,

and provided that no nutrition or health claim is made.

Additional foods or categories of foods to which vitamins and minerals may not be added may be determined in accordance with the procedure referred to in Article 14(2) in the light of scientific evidence and taking into account their nutritional value.

Article 5

Purity criteria

1. The purity criteria for vitamin formulations and mineral substances listed in Annex II shall be adopted in accordance with the procedure referred to in Article 14(2), except where they apply pursuant to paragraph 2 of this Article.
2. Purity criteria for vitamin formulations and mineral 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 Regulation, shall apply.
3. For those vitamin formulations and mineral 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.

⁽¹⁾ OJ L 179, 14.7.1999, p. 1. Regulation as last amended by Commission Regulation (EC) No 1795/2003 (OJ L 262, 14.10.2003, p. 13).

Article 6

Conditions for the addition of vitamins and minerals

1. When a vitamin or a mineral is added to foods, the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed maximum amounts that shall be set in accordance with the procedure referred to in Article 14(2). For concentrated and dehydrated products, the maximum amounts set shall be those present in the foods when prepared for consumption according to the manufacturer's instructions.
2. Any conditions restricting or prohibiting the addition of a specific vitamin or mineral to a food or a category of foods shall be adopted in accordance with the procedure referred to in Article 14(2).
3. The maximum amounts referred to in paragraph 1 and the conditions referred to in paragraph 2 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, taking into account, as appropriate, the varying degrees of sensitivity of different groups of consumers;
 - (b) intakes of vitamins and minerals from other dietary sources.
4. When the maximum amounts referred to in paragraph 1 and the conditions referred to in paragraph 2 are set, due account shall also be taken of reference intakes of vitamins and minerals for the population.
5. When the maximum amounts referred to in paragraph 1 and the conditions referred to in paragraph 2 are set for vitamins and minerals whose reference intakes for the population are close to the upper safe levels, the following shall also be taken into account, as necessary:
 - (a) the contribution of individual products to the overall diet of the population in general or of subgroups of the population;
 - (b) the nutrient profile of the product established as provided for by Regulation (EC) No .../2006 ^(*).

^(*) Regulation on nutrition and health claims from recital 18.

6. The addition of a vitamin or a mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount where this is defined according to the Annex to Directive 90/496/EEC. The minimum amounts, including any lower amounts, by derogation from the significant amounts mentioned above, for specific foods or categories of foods shall be adopted in accordance with the procedure referred to in Article 14(2).

CHAPTER III

ADDITION OF CERTAIN OTHER SUBSTANCES

Article 8

Article 7

Labelling, presentation and advertising

1. The labelling, presentation and advertising of foods to which vitamins and minerals have been added shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients. Where appropriate a derogation concerning a specific nutrient may be adopted in accordance with the procedure referred to in Article 14(2).

2. The labelling, presentation and advertising of foods to which vitamins and minerals have been added shall not mislead or deceive the consumer as to the nutritional merit of a food that may result from the addition of these nutrients.

3. Nutrition labelling of products to which vitamins and minerals have been added and which are covered by this Regulation shall be compulsory. The information to be provided shall consist of that specified in Article 4(1), Group 2 of Directive 90/496/EEC and of the total amounts present of the vitamins and minerals when added to the food.

4. The labelling of products to which vitamins and minerals have been added may bear a statement indicating such addition under the conditions laid down in Regulation (EC) No .../2006 (*).

5. This Article shall apply without prejudice to other provisions of food law applicable to specified categories of foods.

6. Rules for implementing this Article may be specified in accordance with the procedure referred to in Article 14(2).

(*) Regulation on nutrition and health claims from recital 18.

Substances prohibited, restricted or under Community scrutiny

1. The procedure provided for in this Article shall be followed where a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

2. On its own initiative or on the basis of information provided by Member States, the Commission may take a decision, following in each case an assessment of available information by the Authority and in accordance with the procedure referred to in Article 14(2), to include, if necessary, the substance or ingredient in Annex III. In particular:

(a) if a harmful effect on health has been identified, the substance and/or the ingredient containing the substance shall:

(i) be placed in Annex III, part A, and its addition to foods or its use in the manufacture of foods shall be prohibited; or

(ii) be placed in Annex III, part B, and its addition to foods or its use in the manufacture of foods shall only be allowed under the conditions specified therein;

(b) if the possibility of harmful effects on health is identified but scientific uncertainty persists, the substance shall be placed in Annex III, part C.

3. Community provisions applicable to specified foods may provide for restrictions or prohibitions on the use of certain substances in addition to those laid down in this Regulation.

4. Food business operators, or any other interested parties may, at any time, submit for evaluation to the Authority a file containing the scientific data demonstrating the safety of a substance listed in Annex III, part C, under the conditions of its use in a food or in a category of foods and explaining the purpose of that use. The Authority shall inform without delay the Member States and the Commission of the submission and shall make the file available to them.

5. Within four years from the date a substance has been listed in Annex III, part C, a decision shall be taken, in accordance with the procedure referred to in Article 14(2) and taking into account the opinion of the Authority on any files submitted for evaluation as mentioned in paragraph 4 of this Article, to generally allow the use of a substance listed in Annex III, part C, or to list it in Annex III, part A or B, as appropriate.

6. The Commission shall establish, in accordance with the procedure referred to in Article 14(2), implementing rules for the application of this Article, including rules concerning the submission referred to in paragraph 4 of this Article.

- (f) the substances for which dossiers have been submitted as provided for in Article 17(1)(b);
 - (g) information about the substances referred to in Annex III and the reasons for their inclusion therein.
3. The Register shall be made available to the public.

Article 10

Free movement of goods

Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, Member States may not restrict or forbid trade in foods which comply with this Regulation and Community acts adopted for its implementation by the application of non-harmonised national provisions governing the addition of vitamins and minerals to foods.

Article 11

National provisions

1. By ... (*), Member States shall inform the Commission of existing national provisions on the mandatory addition of vitamins and minerals and of products covered by the derogation provided for in Article 4(b).

2. If a Member State, in the absence of Community provisions, considers it necessary to adopt new legislation:

- (a) on the mandatory addition of vitamins and minerals to specified foods or categories of foods; or
- (b) on the prohibition or restriction on the use of certain other substances in the manufacture of specified foods,

it shall notify the Commission in accordance with the procedure laid down in Article 12.

Article 12

Notification procedure

1. If a Member State considers it necessary to adopt new legislation, it shall notify the Commission and the other Member States of the envisaged measures and give the reasons justifying them.

2. The Commission shall consult the Committee referred to in Article 14, if it considers such consultation to be useful or if a Member State so requests, and shall give an opinion on the envisaged measures.

(*) Six months from the entry into force of this Regulation.

CHAPTER IV

GENERAL AND FINAL PROVISIONS

Article 9

Community Register

1. The Commission shall establish and maintain a Community Register on the addition of vitamins and minerals and of certain other substances to foods, hereinafter referred to as 'the Register'.

2. The Register shall include the following:

- (a) the vitamins and minerals which may be added to foods as listed in Annex I;
- (b) the vitamin formulations and mineral substances which may be added to foods as listed in Annex II;
- (c) the maximum and minimum amounts of vitamins and minerals which may be added to foods and any associated conditions set in accordance with Article 6;
- (d) the information regarding national provisions on the mandatory addition of vitamins and minerals referred to in Article 11;
- (e) any restrictions on the addition of vitamins and minerals as set out in Article 4;

3. The Member State concerned may take the envisaged measures only six months after the notification referred to in paragraph 1, and provided that the Commission's opinion is not negative.

If the Commission's opinion is negative, it shall determine, in accordance with the procedure referred to in Article 14(2) and before the expiry of the period referred to in the first subparagraph of this paragraph, whether the envisaged measures may be implemented. The Commission may require certain amendments to be made to the envisaged measures.

Article 13

Safeguard measures

1. Where a Member State has serious grounds for considering that a product endangers human health despite complying with this Regulation, 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. In accordance with the procedure referred to in Article 14(2), a decision shall be taken, where appropriate after obtaining an opinion from the Authority.

The Commission may initiate this procedure on its own initiative.

3. The Member State referred to in paragraph 1 may maintain the suspension or restriction until the decision referred to in paragraph 2 has been notified to it.

Article 14

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58(1) of Regulation (EC) No 178/2002, 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.

Article 15

Monitoring

To facilitate efficient monitoring of foods to which vitamins and minerals have been added, and of foods containing substances listed in Annex III, parts B and C, Member States may require the manufacturer or the person placing such foods on the market in their territory to notify the competent authority of that placing on the market by providing a model of the label used for the product. In such cases, information on the withdrawal of the product from the market may also be required.

Article 16

Evaluation

By ... (*), the Commission shall submit to the European Parliament and the Council a report on the effects of implementing this Regulation, in particular concerning the evolution of the market in foods to which vitamins and minerals have been added, their consumption, nutrient intakes for the population and changes in dietary habits, the addition of certain other substances, accompanied by any proposals for amendment to this Regulation which the Commission deems necessary. In this context Member States shall provide the necessary relevant information to the Commission by ... (**). Rules for implementing this Article shall be specified in accordance with the procedure referred to in Article 14(2).

Article 17

Transitional measures

1. By way of derogation from Article 3(1) and until ... (***), 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 for addition to foods marketed in the Community on ... (****); and

(*) The first day of the sixth months following the date of entry into force of this Regulation + six years.

(**) The first day of the sixth months following the date of entry into force of this Regulation + five years.

(***) Seven years from the date of entry into force of this Regulation.

(****) The date of entry into force of this Regulation.

(b) the 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, 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 ... (*).

2. Until ... (**), Member States may, in compliance with the rules of the Treaty, continue to apply existing national restrictions or bans on trade in foods to which vitamins and minerals not included in the list in Annex I or in the forms not listed in Annex II are added.

3. Member States may, in compliance with the rules of the Treaty, continue to apply existing national provisions on maximum and minimum amounts of vitamins and minerals

listed in Annex I added to foods and on the conditions applicable to this addition until the adoption of corresponding Community measures in accordance with Article 6 or under other specific Community provisions.

Article 18

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from ... (**).

Foods placed on the market or labelled prior to ... (***) which do not comply with this Regulation may be marketed until ... (****).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at...,

For the European Parliament
The President

For the Council
The President

(*) Three years from the date of entry into force of this Regulation.

(**) Seven years from the date of entry into force of this Regulation.

(***) The first day of the sixth months following the date of entry into force of this Regulation.

(****) The last day of the 29th month following the date of entry into force of this Regulation.

ANNEX I

VITAMINS AND MINERALS WHICH MAY BE ADDED TO FOODS

1. Vitamins

Vitamin A
Vitamin D
Vitamin E
Vitamin K
Vitamin B1
Vitamin B2
Niacin
Pantothenic acid
Vitamin B6
Folic acid
Vitamin B12
Biotin
Vitamin C

2. Minerals

Calcium
Magnesium
Iron
Copper
Iodine
Zinc
Manganese
Sodium
Potassium
Selenium
Chromium
Molybdenum
Fluoride
Chloride
Phosphorus

ANNEX II

VITAMIN FORMULATIONS AND MINERAL SUBSTANCES WHICH MAY BE ADDED TO FOODS

1. **Vitamin formulations**

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

pyridoxine dipalmitate

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. **Mineral substances**

calcium carbonate

calcium chloride

calcium salts of citric acid

calcium gluconate

calcium glycerophosphate

calcium lactate

calcium salts of orthophosphoric acid

calcium hydroxide

calcium oxide

calcium sulphate

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

ANNEX III

SUBSTANCES WHOSE USE IN FOODS IS PROHIBITED, RESTRICTED OR UNDER COMMUNITY SCRUTINY

Part A — Prohibited substances

Part B — Restricted substances

Part C — Substances under Community scrutiny

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. The Commission forwarded to Council on 14 November 2003 a proposal for a Regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foodstuffs. The proposal is based on Article 95 of the Treaty.
2. The European Parliament has adopted its opinion at first reading on 26 May 2005 ⁽¹⁾.

The European Economic and Social Committee gave its opinion on 31 March 2004 ⁽²⁾.

3. On 8 December 2005, the Council adopted its Common Position in accordance with Article 251 of the Treaty.

II. OBJECTIVE

The objective of the proposed Regulation is to harmonise the rules concerning the addition of vitamins and minerals to foodstuffs. This is with a view to facilitating the free circulation of these products within the Community as the existing relevant national rules on such addition vary widely and often result in obstacles to intra-community trade.

Such harmonisation will also ensure a high level of consumer protection across the Community and guarantee that products concerned do not present any risk for public health.

The proposed Regulation:

- lists the vitamins and the minerals which may be added to food (Annex I) and the forms in which they may be added (Annex II),
- provides for certain restrictions regarding the foods to which vitamins and minerals may be added, sets criteria for the establishment of maximum levels and provides for the setting of minimum levels of vitamins and minerals to be found in the final product,
- sets out the rules on labelling, presentation and advertising of the products concerned,
- provides the basis for scrutinising and, where necessary, prohibiting the addition to foods of certain substances other than vitamins and minerals.
- permits national measures on the mandatory addition of vitamins and minerals to foods provided the opinion of the Commission on these measures is not negative.

III. ANALYSIS OF THE COMMON POSITION

1. General remarks

The Council's common position conforms to the objectives of the Commission proposal while introducing a limited number of modifications. These include:

- removing the definitions in Article 2 on the purposes of the addition of vitamins and minerals to food in favour of explaining the circumstances in which vitamins and minerals may be added to food in Article 3 (Requirements),

⁽¹⁾ Doc. 9200/05.

⁽²⁾ OJ C 112, 30.4.2004, p. 44.

- a more precise description of derogations applicable to Article 4 (outlining the cases where the addition of vitamins and minerals may not take place) in relation to alcoholic beverages,
- streamlining the provisions applicable to substances other than vitamins and minerals (merging Articles 10 and 11 of the original proposal),
- clarifying the procedures for notification of existing and new national provisions (new Article 11 and deletion of Article 9 of the original text).

The Commission has accepted the common position agreed by the Council.

2. European Parliament amendments

In its Plenary vote on 26 May 2005, the European Parliament adopted 46 *amendments* to the proposal (*Amendment 8* is linguistic and does not affect the English version).

The Council:

(a) *introduced* in the common position 20 *amendments* in full, in part or in principle, as follows:

recitals

Amendment 1 (to recital 10) and *Amendment 2* (on recital 12): have been taken up in part, with the deletion of the last sentence of recital 8 and a modification in recital 10.

Amendment 4 (to recital 20a): taken up in principle and in part in recital 2 (second sentence) and in Article 11(2).

Amendment 5 (to recital 20b): taken in principle via a rewording of Article 6(6).

Articles

Amendment 13 (to Article 3(3)): taken up in part, as regards the opinion of the Authority, while the original reference to implementing rules has been deleted (given that there is no longer a reference to restoration, nutritional equivalence and substitute foods in Articles 2 and 3).

Amendment 16 (to Article 4(1) (new)): maintained in substance in Article 17(1)(b) and Article 9(2)(d).

Amendment 17 (to Article 4(2)): introduced in part in Article 17(2).

Amendments 49/rev and 54/rev (to Article 5(1)(b)): fully taken up in Article 4.

Amendment 25 (to Article 7(5)): taken up in part (as regards the suggested deletion) in Article 6(6). In this context, the Council also notes that the Commission has the intention to revise and update the reference values included in the Annex to Directive 90/496/EEC on nutrition labelling of foodstuffs.

Amendment 31 (to Article 9(2)(2)): the purpose of the Amendment is taken up in Article 9(2)(d) (see also Article 11).

Amendment 34 (to Article 10), *Amendment 55* (on Article 10a (new)) and *Amendment 35* (to Article 11): have been taken up in Article 8. The suggested new Article 10a(3) can be found in Article 11(2)(b).

Amendment 38 (to Article 12(2)(fa) and (fb) (new)): the intent of the amendment was partly taken into consideration in Article 9(2)(d)).

Amendment 39 (to Article 13): the concern underlying the Amendment was partly taken up in Article 11(2)(b) (as regards the introduction of new provisions).

Amendment 41 (to Article 16(1)): the principle is taken into account in Article 3(3), while the Council does not consider that the Authority should be involved automatically whenever the Committee procedure is invoked.

Amendment 44 (to Annex I) *Amendment 45* (to Annex II) and *Amendment 46* (to Annex II) are fully integrated in the Annexes (with a rewording for Amendment 45 and a change of placement for Amendment 46);

(b) *did not include 26 amendments* in the common position.

With respect to *Amendments 3, 6, 9, 10, 14, 15, 19, 20, 21, 23, 24, 26, 27, 29, 30, 32, 36, 37,40 and 43*, the Council followed the position expressed by the Commission.

As regards *Amendments 21, 26 and 30*, however, the Council notes the intention of the Commission to:

- consider, in the framework of its reflection on the revision of Directive 90/496/EEC on nutrition labelling of foodstuffs, the following elements in relation to vitamins and minerals:
 - revising/updating reference values included in the Annex to Directive 90/496/EEC and the levels that may be considered as significant amounts,
 - establishing tolerance levels for acceptable variation from the declared value of added vitamins and minerals on the nutrition label,
- reflect any modification to the compulsory elements of nutritional labelling that may be adapted in the future revision of nutrition labelling Directive, in Article 7(3) of the Regulation on the addition of vitamins and minerals and of certain other substances to foods,
- present as soon as possible and in any case within two years following the adoption of the Regulation a proposal for the establishment of maximum/ minimum amounts of vitamins and minerals and any conditions for their addition to food as referred to in Article 6(2).

As regards *Amendment 36*, introducing a new Article 11a on labelling, presentation and advertising of other substances, it should be noted that labelling rules can be considered by the Commission in the context of Article 8(6), on the adoption of implementing rules to apply Article 8.

In relation to *Amendments 11, 12, 22, 28,40 and 42*, accepted in part by the Commission but not included in the common position:

Amendment 11 (to Article 3(2), introductory part): it can be pointed out that the principle of the amendment, on the need for adding vitamins and minerals in a form that is bio-available to the human body, is already outlined in the first sentence of recital 11.

Amendment 12 (to Article 3a (new)): and *Amendment 28* (to Article 8(2)) the substance of these amendments is maintained in Article 7 (2) as it is the labelling (including ingredient listing), presentation and advertising which could mislead or deceive the consumer.

Amendment 22 (to Article 7(2)(b)): food supplements are considered implicitly covered by the paragraph in question according to which 'other dietary sources' should be taken into account while fixing the maximum amounts and the conditions for the addition of vitamins and minerals to food.

Amendment 40 (to Article 14(3)) can be found, in part and implicitly, in Article 12(3) second indent, given that the consultation of the Committee becomes obligatory whenever the Commission's opinion on the envisaged measure is negative.

Amendment 42 (to Article 17): the Council considers that, for the monitoring tasks carried out by competent authorities, the obligation to notify the Commission of any placing on the market of food products containing vitamins and minerals would not be compatible with the principles of subsidiarity and proportionality.

3. Other innovations introduced by the Council

Other innovations introduced in the common position include:

- the grouping of all the applicable transitional measures in a new Article 17, with the deletion of Article 4 of the original proposal,
- a revision of Articles 6 (on conditions on the addition of vitamins and minerals) and 7 (on labelling, presentation and advertising) following the deletion of the definitions in Article 2,
- a modification of Article 15 on monitoring, so that when a notification of placing on the market is required, information on the withdrawal of the product from the market can also be required,
- a reference to implementation rules for the application of Article 16,
- the deletion of sodium chloride from Annex II and with a corresponding modification of Recital 11 explaining this change.

IV. CONCLUSION

The Council considers that its common position, which incorporates the amendments mentioned in Sections III.2(a), takes good account of the opinion of the European Parliament in first reading and represents a balanced solution to ensure that the objectives of the Regulation will be achieved.
