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***I
REPORT

on the 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 foods
(COM(2003)0671 – C5-0538/2003 – 2003/0262(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Karin Scheele

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the 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 foods (COM(2003)0671 – C6-0538/2003 – 2003/0262(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2003)0671)[1],

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0538/2003),

– having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,

– having regard to Rules 51 and 35 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on the Internal Market and Consumer Protection (A6-0124/2005),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission	Amendments by Parliament
	Amendment 1 Recital 10
(10) Some nutrient deficiencies, although not very frequent, can be demonstrated to exist today 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	***deleted***

[1] Not yet published in OJ.

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. Taking into account the above it is considered that in Community rules the definition on fortification should include but also be extended beyond what is provided in the relevant Codex Alimentarius General Principles.

Justification

The Commission states that some nutrient deficiencies are very rarely recorded without, however, giving details of these observations. Nevertheless, such nutrient deficiencies are used by the Commission to propose and justify opportunities for voluntarily adding vitamins and minerals to all foods. The Community should aim for a market situation in which producers add vitamins and minerals to foods on nutritional or health grounds and not for marketing reasons.

Furthermore, fortified foodstuffs containing certain nutrients for a specific, closely defined population group (with a deficiency or with a higher requirement, for instance pregnant women) can already be marketed as foodstuffs for particular nutritional requirements or as foodstuffs for medicinal purposes under existing Community rules.

Amendment 2
Recital 12

(12) The chemical substances used as sources of vitamins and minerals ***to*** be added to food ***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 for Food (opinion expressed on 12 May 1999), on the basis of the above criteria of safety and bioavailability, and can be used in the manufacture of foods intended for infants and young children, in other foods for	(12) The chemical substances used as sources of vitamins and minerals ***which may*** be added to food ***must*** 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 for Food (opinion expressed on 12 May 1999), on the basis of the above criteria of safety and bioavailability, and can be used in the manufacture of foods intended for ***all sections of the population, including*** infants

particular nutritional uses or in food supplements should appear in this positive list.	and young children, in other foods for particular nutritional uses or in food supplements should appear in this positive list.

Justification

Different groups of the population have different needs for either supplementary intake of vitamins, minerals or other substances. Voluntary fortification with these nutrients may not counteract particular nutritional needs of vulnerable groups, such as children, pregnant women or elderly.

Amendment 3
Recital 16

(16) For that reason these 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 according to the purpose of the addition and the contribution of the food to the overall diet.	(16) For that reason these 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 ***(e.g. the addition of iodine only to salt)***, priority should be given according to the purpose of the addition and the contribution of the food to the overall diet.

Justification

To ensure that the harmonisation of the addition of iodine to food in Europe is consistent with the worldwide system of universal salt iodisation for preventing iodine deficiency-related diseases.

Amendment 4
Recital 20 a (new)

	(20a) Articles 28 and 30 of the EC Treaty provide an exception to the rule of free movement of goods within the Community which national authorities can invoke provided that certain conditions are

satisfied.

In exercising their discretion relating to the protection of public health under the EC Treaty, national authorities must comply with the principle of proportionality. It is for the national authorities to show that their rules are necessary to give effective protection based on a detailed assessment of the risk. They have to ensure that the alleged real risk to public health appears to be sufficiently established on the basis of the latest scientific data available.

Justification

The addition of vitamins and minerals to foods may only be prohibited if a serious danger to public health through the enrichment with vitamins and minerals can be scientifically substantiated. This reflects the recent case law of the European Court of Justice. (Judgement of 5 February 2004, Case 24/00, Commission/France). These recitals serve to clarify the scope of Article 13 of the proposed Regulation.

Amendment 5
Recital 20 b (new)

(20b) The recommended daily allowances (RDA) in Directive 90/496/EEC do not cover all the vitamins and minerals listed in Annex I and II and are also out of date.

Amendment 6
Article 1, paragraph 2

2. The provisions of this Regulation ***regarding vitamins and minerals*** shall not apply to food supplements covered by Directive 2002/46/EC.	2. The provisions of this Regulation shall not apply to food supplements covered by Directive 2002/46/EC.

Justification

Food supplements are already regulated under Directive 2002/46/EC. This Directive foresees a report of the European Commission to the European Parliament and Council on the advisability of establishing specific rules for categories of nutrients or substances with a nutritional or physiological effect other than vitamins and minerals by 12 July 2007 at the latest. It therefore seems inappropriate to regulate certain kinds of ingredients in one category of foodstuffs, namely food supplements, under two different legal acts.

Amendment 7
Article 1, paragraph 3, point (d a) (new)

(da) to specific provisions laid down in Community legislation concerning drinking water.

Justification

Drinking water is a food and should be subject to the provisions of this regulation.

Amendment 8
Article 2, point (1)

(1) “restoration” means the addition to a food of vitamins and minerals which are lost during the course of good manufacturing practice, or during normal storage and handling procedures, in amounts which will result in the presence in the food of the levels of the vitamins and minerals present in the edible portion of the food before processing, storage or handling;

Does not affect English version

Justification

Does not affect English version.

Amendment 9
Article 2, point (4 a) (new)

(4a) "Certain other substances" means biologically active substances obtained either by extraction or synthesis which have a proven physiological effect and can be used as ingredients of fortified foods and which are not regulated by Regulation (EEC) No 258/97 of the European Parliament and of the Council on novel foods and novel food ingredients.

Justification

Vitamins and minerals allowed for fortification are listed and defined in Annexes I and II. At the minimum, therefore, a definition of 'certain other substances' is also required in this regulation. This amendment is intended to replace Amendment 6 in the draft report, and replaces the words 'nutritional and physiological' with 'physiological', thereby ensuring that such substances as caffeine are also covered.

Amendment 10
Article 2, point (4 b) (new)

(4b) "Recommended daily intake" means an amount to be fixed by the food business operator, as defined in Regulation (EC) No 178/2002, taking into account the maximum amounts set in Article 7(1) and the recommended daily allowances (RDA) for nutrients laid down in Directive 90/496/EEC.

Justification

In order to avoid misuse of vitamins and minerals or other substances, and to give consumers proper scientifically-based guidance it is first of all essential to specify the recommended daily intake or recommended daily allowance of specific nutrients or other substances.

Article 5 of Directive 2002/46 on food supplements already requires maximum levels of food supplements to be set on the basis of the daily portion of consumption as recommended by the manufacturer. These are to be based on upper safe levels, as laid down in Article 5(1)(a) of Directive 2002/46, and should have been set under the procedure laid down in Article 13(2) of the directive, but this has still not been done. The food supplements directive was to have been implemented by 31 July 2003. The Commission is therefore late in establishing upper safe levels, maximum amounts and minimum amounts of vitamins and minerals for the purposes of the food supplements directive. Any further delay in effective implementation of the provisions of the food supplements legislation and the rules for fortifying foodstuffs with vitamins and minerals would be unacceptable from the point of view of consumer protection and public health.

Upper safe levels should also be established for other substances in the interests of public health and legal certainty.

Amendment 11
Article 3, paragraph 2, introductory part

2. Vitamins and minerals may be added to foods only for the purpose of:	2. Vitamins and minerals ***in a form that is bio-available to the human body*** may be added to foods only for the purpose of:

Justification

It must be possible for all vitamins and minerals added to foods to be absorbed by the body otherwise consumers are being misled and in extreme cases there may be negative side-effects

on health (such as diarrhoea or reduced absorption of other nutrients).

Amendment 12
Article 3, paragraph 2 a (new)

2a. The addition of vitamins and minerals to foods shall not be used to mislead or deceive the consumer as to the nutritional merit of the food, whether by means of labelling, presentation, advertising or the additive itself.

Justification

The paragraph concerning misleading in Article 8, paragraph 2 is so important that it should be moved from Article 8 to Article 3, where conditions for the addition of vitamins and minerals are listed.

Amendment 13
Article 3, paragraph 3

3. Implementing rules for the addition of vitamins and minerals to foods for the ***purpose*** of restoration ***and*** nutritional equivalence of substitute foods may be adopted, as necessary, in accordance with the procedure referred to in Article 16(2).	3. Implementing rules for the addition of vitamins and minerals to foods for the ***purposes*** of restoration ***or ensuring the*** nutritional equivalence of substitute foods may be adopted, as necessary, in accordance with the procedure referred to in Article 16(2) ***after obtaining the opinion of the Authority. Prior to setting such rules, the Commission shall carry out consultation with interested parties, in particular food business operators and consumer groups.***

Justification

The opinion of the EFSA and consultations with interested parties are needed to fulfil the objectives of the Regulation.

Amendment 14
Article 4, introductory part

By way of derogation from Article 3 paragraph 1 and until (***seven*** years from the entry into force of this Regulation), Member States may allow in their territory the use of vitamins and minerals not listed	By way of derogation from Article 3 paragraph 1 and until (***three*** years from the entry into force of this Regulation), 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:	in Annex I, or in forms not listed in Annex II, provided that:

Justification

Seven years is too long a period for transitional provisions.

Amendment 15
Article 4, point (b), subparagraph 1

b) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food, 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 (***three years*** from the entry into force of this Regulation).	b) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food, 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 (***18 months*** from the entry into force of this Regulation).

Amendment 16
Article 4, paragraph 1 a (new)

	Member States shall inform the Commission about the use of vitamins and minerals allowed in their territory although they are not listed in Annex I, or in forms not listed in Annex II. The Commission shall make this information available to the public.

Justification

In order to ensure legal security and predictability to market operators, it is necessary to have a transparent system, which provides the operators with an overview of the substances that may or may not be added to food in each of the Member States of the EU.

Amendment 17
Article 4, paragraph 2

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	***During the transition period, other*** Member States may, ***on the basis of public safety grounds and*** in compliance with the rules of the Treaty, continue to apply existing

included in the list in Annex I or in the forms not listed in Annex II are added.	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. ***Member States shall keep the Commission informed about any such national restriction or ban and the Commission shall make such information available to the public.***

Amendment 18
Article 5, paragraph 1, point (b)

b) beverages containing more than 1.2% by volume of alcohol**.**	b) ***foods and*** beverages containing more than 1.2% by volume of alcohol***, except, and by way of derogation from Article 3(2),*** ***- to traditional products, in quantities not exceeding 0.5% weight/volume,*** ***- as authenticity indicators, in quantities not exceeding 600 parts per billion per individual substance,*** ***and provided no nutrition or health claim is made.***

Justification

The UK has long established tonic wine production, which involves the addition of certain mineral substances to (red) wine according to 19th century recipes. Today minerals characterise the product but are not added to fortify or enrich it and no claims are made. The proposed amendment would allow the continued production and marketing of tonic wine, but subject to quantitative limits on the addition of minerals and underlining that no related nutrition and health claims may be made.

It is necessary to retain the potential use of vitamins and minerals, in very small quantities, as authenticity markers in spirit drinks. The spirits industry (gin, vodka, etc.) uses a range of substances as chemical markers in branded products to enable the authenticity of products to be verified. Such markers are a valuable tool in the fight against counterfeit spirit drinks, which can present health risks to consumers from uncontrolled ingredients, including methanol, and cost the legitimate producers substantial amounts each year.

Nowadays, foods may also contain alcohol. One insidious example is the addition of alcohol to ice-cream, which, moreover, is marketed to children.

Amendment 19
Article 5, paragraph 2

Additional foods or categories of foods to which vitamins and minerals may not be added may be determined in accordance with the procedure laid down in Article 16(2) and in the light of scientific evidence.	Additional foods or categories of foods to which ***particular*** vitamins and minerals may not be added may be determined in accordance with the procedure laid down in Article 16(2) and in the light of scientific evidence ***if a danger to public health exists***.

Justification

A ban can be instituted only if there are grounds for fearing that there will be a danger to public health if the allowed daily intake is exceeded.

Amendment 20
Article 6, paragraph 1

1. The purity criteria for substances listed in Annex II shall be adopted in accordance with the procedure referred to in Article 16(2), except where they apply pursuant to paragraph 2.	1. The purity criteria for substances listed in Annex II shall be adopted ***no later than ... **** in accordance with the procedure referred to in Article 16(2), except where they apply pursuant to paragraph 2. **** Date of entry into force of this Regulation***

Justification

In the interests of legal certainty and effective consumer protection, the purity criteria should be established before the Regulation enters into force.

Amendment 21
Article 7, paragraph 1, subparagraph 1

1. When a vitamin or a mineral is added to foods for the purposes specified in Article 3(2), the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed amounts that shall be set. For concentrated and dehydrated products the maximum amounts that shall be set shall be those present in the foods when prepared for consumption according to the manufacturers instructions.	1. When a vitamin or a mineral is added to foods for the purposes specified in Article 3(2), the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed amounts that shall be set ***no later than ... **** . For concentrated and dehydrated products the maximum amounts that shall be set shall be those present in the foods when prepared for consumption according to the manufacturers instructions. **** Date of entry into force of this Regulation***

Justification

In the interests of legal certainty and effective consumer protection, the maximum and minimum amounts should be established before the Regulation enters into force.

Amendment 22
Article 7, paragraph 2, point (b)

b) intakes of vitamins and minerals from other dietary sources	b) intakes of vitamins and minerals from other dietary sources***, including food supplements***

Justification

Food supplements are becoming increasingly fashionable and are taken regularly or repeatedly by many consumers. Many food supplements contain substantial amounts of vitamins and minerals and it is important to emphasise that the intake of vitamins and minerals through food supplements must also be borne in mind.

Amendment 23
Article 7, paragraph 2, point (b a) (new)

	(ba) the contribution of individual products to the overall diet of the population in general or of sub-groups of the population;

Amendment 24
Article 7, paragraph 4, point (c)

(c) the nutrient profile of the product established as foreseen by Regulation (EC) No ../2003 on nutrition and health claims made on foods.	***deleted***

Justification

Not necessary in this Regulation since this regulation is based on safety and does not deal with the aspect of communication to the consumer.

Amendment 25
Article 7, paragraph 5

5. The addition of a vitamin or a mineral to	5. The addition of a vitamin or a mineral to

food for the purpose of fortification shall result in the presence of this vitamin or mineral in the food in at least a significant amount ***as this is defined in the Annex of Directive 90/496/EEC***. The minimum amounts, including any lower amounts, by derogation to the significant amounts mentioned above, for specific foods or categories of foods shall be adopted in accordance with the procedure referred to in Article 16(2).	food for the purpose of fortification shall result in the presence of this vitamin or mineral in the food in at least a significant amount, ***i.e. 15% of the Nutrient Reference Value (NRV) per 100g (solids) or 7.5% of NRV per 100ml (liquids) or 5% of NRV per 100kcal (12% of NRV 1MJ) or 15% of NRV per serving***. The minimum amounts, including any lower amounts, by derogation to the significant amounts mentioned above, for specific foods or categories of foods shall be adopted in accordance with the procedure referred to in Article 16(2).

Justification

The reference levels should be aligned to the Codex Alimentarius guidelines, so that different levels should apply to solid products as opposed to liquid products because the portion size for liquids (beverages) is usually larger than for solids.

Amendment 26
Article 7 a (new)

	Article 7a
	Recommended daily allowances
	The Commission shall establish without delay - no later than the entry into force of this Regulation - recommended daily allowances for all the vitamins and minerals listed in Annexes I and II, taking into account the latest scientific knowledge and international recommendations.

Amendment 27
Article 8, paragraph 1

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 16(2)***.	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.

Justification

There is no justification for this derogation. Such foodstuffs are not voluntarily fortified products but dietetic products or products whose fortification is mandatory, for example iodised cooking salt in Austria and Germany.

Amendment 28
Article 8, paragraph 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 the food that may result from the addition of these nutrients.	***deleted***

Justification

As a result of amendment 12 to Article 3, paragraph 2 a (new).

Amendment 29
Article 8, paragraph 3

3. 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 …/2003 on nutrition and health claims made on foods.	***deleted***

Justification

The reference made in Article 8(3) to the nutrition and health claims proposal is not proportionate as it could severely limit the consumer's right to be informed about the presence of vitamins and minerals in specific food products. Moreover, Article 8(5) takes care of other relevant legislation in this respect.

Amendment 30
Article 8, paragraph 4

4. Nutrition labelling of products to which vitamins and minerals have been added and covered by this Regulation shall be compulsory. The information to be	4. Nutrition labelling of products to which vitamins and minerals have been added and covered by this Regulation shall be compulsory. The information to be

provided shall consist of that specified in Article 4, paragraph 1, Group 2 of that Directive and of the total amounts present of the vitamins and minerals added to the food.	provided shall consist of that specified in Article 4, paragraph 1, Group 2 of that Directive and of the total amounts present of the vitamins and minerals added to the food. ***In addition the following information must be provided:*** ***(a) information on vitamins and minerals should be given per serving size (amount per serving) in absolute numbers and as a percentage of the recommended daily allowance (RDA); in addition, information should be expressed per 100g or per 100ml;*** ***(b) the manufacturer's recommended daily intake of the product - where appropriate and in a way in which the serving size can easily be derived;*** ***(c) a warning not to exceed the stated recommended daily allowance;***

Justification

This amendment will make sure that consumers only receive relevant information to protect themselves from overdosing on vitamins and minerals. The proposal on recommended daily intake and the warning statement is also in line with Directive 2002/46/EC on food supplements.

Amendment 31
Article 9, paragraph 2

2. Where there are no Community provisions, Member States may make provisions for the mandatory addition of vitamins and minerals to specified foods or categories of foods, in accordance with the procedure laid down in Article 14.	2. Where there are no Community provisions, Member States may make provisions for the mandatory addition of vitamins and minerals to specified foods or categories of foods, in accordance with the procedure laid down in Article 14.
Within six months from the entry into force of this Regulation, Member States shall inform the Commission of existing relevant national provisions.	Within six months from the entry into force of this Regulation, Member States shall inform the Commission of existing relevant national provisions. ***The Commission shall make this information public.***

Justification

The public availability of this information is in the interests of transparency, in accordance with the general principles set in Regulation 178/2002/EC.

Amendment 32
Article 9 a (new)

Article 9a

Within 18 months of the entry into force of this Regulation, the Member States shall notify the Commission of the substances or ingredients which are used in their territory to enrich foodstuffs and the substances other than vitamins or minerals that these may contain. The Commission shall forward this information to the Authority and shall publish the reports received.

Justification

It is important that adequate information should be available on the addition of certain other substances.

Amendment 33
Article 10 a (new)

Article 10a

Restricted and prohibited substances or substances under Community scrutiny

1. If the Commission or a Member State considers that the addition of a substance other than vitamins or minerals or an ingredient containing a substance other than vitamins or minerals may lead to the intake of amounts of that substance exceeding average intake levels derived from official statistics on nutritional status, it must notify the Commission without delay.

2. The Commission shall take a decision, in each case following a mandatory evaluation of the available information by

the Authority, in accordance with the procedure referred to in Article 16(2) and shall include the substance in Annex III.

If a substance or ingredient proves to be harmful to health, it shall

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

(b) or 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 and subject to the maximum levels specified therein. For this purpose, maximum levels need to be established for these substances by the Authority.

Where, following in each case an evaluation of available information by the Authority, the possibility of harmful effects on health resulting from such use is identified but scientific uncertainty persists, the substance shall be placed in Annex III, Part C, in accordance with the procedure referred to in Article 16(2).

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. Where there are no Community provisions, Member States may make provision for such prohibitions or restrictions, in accordance with the procedure referred to in Article 14.

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.

5. Within four years from the date on which a substance has been listed in Annex III, Part C, a decision shall be

	taken, in accordance with the procedure referred to in Article 16(2) and taking into account the opinion of the Authority on any files submitted for evaluation as mentioned in paragraph 4, 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.

Justification

This amendment clarifies what constitutes an excessive amount by saying that account should be taken of official statistics on nutritional status (food profile, food intake data, etc.). In the medium-term Europe-wide nutritional data should be available as a reference.

A uniform and transparent procedure should also be established for the other substances that will have to be evaluated.

As for vitamins and minerals (see Article7), maximum levels for other substances should be established where an EFSA evaluation has identified safety concerns and where this is scientifically feasible. Maximum levels can only be established for those substances where an EFSA evaluation has identified safety concerns (Annex III B). In cases where substances are under scrutiny (Annex III C) no final EFSA evaluation is available and therefore no maximum levels can be set.

Amendment 34
Article 10

Article 10	***deleted***
Restricted and prohibited substances	
1. Where a substance, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods at 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 where, following in each case an assessment of available information by the Authority, a harmful effect on health resulting from such use has been identified, the substance and/or the ingredient containing the substance, where necessary, shall, in accordance with the procedure referred to in Article	

16(2):

a) either be placed in Annex III, Part A and its addition to foods or its use in the manufacture of foods shall be prohibited;

b) or 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.

2. 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. Where there are no Community provisions, Member States may make provision for such prohibitions or restrictions, in accordance with the procedure laid down in Article 14.

Justification

See amendment introducing new Article 10a.

Amendment 35
Article 11

Article 11	***deleted***
Substances under Community scrutiny	
1. Where a substance, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods at 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 where, following in each case an assessment of available information by the Authority, the possibility of harmful effects on health resulting from such use is identified but scientific uncertainty persists, the substance shall be placed in Annex III,	

Part C, in accordance with the procedure referred to in Article 16(2).

2. 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.

3. 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 16(2) and taking into account the opinion of the Authority on any files submitted for evaluation as mentioned in paragraph 2, 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.

Justification

See amendment introducing new Article 10a.

Amendment 36
Article 11 a (new)

Article 11a

Labelling, presentation and advertising

The labelling, presentation and advertising of foods to which certain other substances have been added shall not include any mention stating or implying that a balanced and preventive diet of conventional foods is unnecessary.

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

3. The labelling of products to which

certain other substances have been added may bear a statement indicating such addition under the conditions laid down in Regulation (EC) No …/2003 on nutrition and health claims made on foods.

4. Nutrition labelling of products to which certain other substances have been added and covered by this Regulation shall be compulsory. The information to be provided shall consist of that specified in Article 4, paragraph 1, Group 2 of that Directive and of the total amounts present of the substances added to the food. In addition the following information must be provided:

(a) information on certain other substances should be given per serving size (amount per serving) in absolute numbers and as a percentage of the recommended daily allowance (RDA); in addition, information should be expressed per 100g or per 100ml;

(b) the manufacturer's recommended daily intake of the product - where appropriate and in a way in which the serving size can be easily derived.

(c) a warning not to exceed the stated recommended daily allowance.

5. This Article shall apply without prejudice to Directive 2000/13/EC, Regulation (EC) No ../2003 on nutrition and health claims made on foods, and 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 16(2).

Justification

It must be absolutely clear to consumers what substances have been added to foods and how the amounts added relate to the recommended intake per 100g/ml or the recommended daily allowance. Where a recommended daily intake has been established, it should therefore be indicated.

Amendment 37
Article 11 b (new)

Article 11b

Recommended daily allowances and upper safe levels

Recommended daily allowances and upper safe levels shall be set for the certain other substances listed in Annex III B and C. Article 7 of this Regulation shall be applied by analogy.

Justification

Upper safe levels should also be set for certain other substances in the same way as for vitamins and minerals.

Amendment 38
Article 12, paragraph 2, points (f a) (new) and (f b) (new)

(fa) A list of vitamins, minerals and certain other substances whose addition is mandatory under national provisions pursuant to Article 9.

(fb) A list of substances whose addition is prohibited or restricted at national level pursuant to Article 4.

Justification

The amendments proposed are in the same spirit as the proposals in Articles 4 and 9; the aim is to institute a transparent system.

Amendment 39
Article 13

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***.

1. Without prejudice to ***paragraph 2***, Member States may not restrict or forbid trade in foods which comply with this Regulation and Community acts adopted for its implementation.

2. This Regulation shall not affect the right

	of Member States to keep or introduce, in accordance with the Treaty, in particular Articles 28 and 30 thereof, more stringent rules concerning the addition of certain other substances which they deem necessary in order to protect public health and which do not conflict with this Regulation.
	3. Within six months of the entry into force of this Regulation, the Member States shall notify the Commission of relevant existing national provisions.

Justification

This amendment is intended to replace the rapporteur's Amendment 28. In the case of 'certain other substances', Member States should be given the power to keep or introduce national provisions. The third paragraph of Amendment 28 is omitted, as it is covered by Amendment 22 to Article 10 a (new), paragraph 3.

Amendment 40
Article 14, paragraph 3

3. The Commission shall consult the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002***, if it considers such consultation to be useful or if a Member State so requests*** and shall give an opinion on the envisaged measures.	3. The Commission shall consult the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002 and shall give an opinion on the envisaged measures.

Justification

The Standing Committee on the Food Chain and Animal Health should also be consulted.

Amendment 41
Article 16, paragraph 1

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002, hereafter referred to as the "Committee".	1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002, hereafter referred to as the "Committee"***, which shall take into account the opinion of the Authority***.

Justification

The Committee should, when delivering an opinion in the framework of commitology, take its decisions on the basis of scientific evidence and take into account the opinion delivered by EFSA.

Amendment 42
Article 17

To facilitate efficient monitoring of foods to which vitamins and minerals have been added, and of foods containing substances listed in Annex III, Part B and Part 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 forwarding it a model of the label used for the product.	***For the exclusive purpose of facilitating*** efficient monitoring of foods to which vitamins and minerals have been added, and of foods containing substances listed in Annex III, Part B and Part 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 forwarding it a model of the label used for the product. ***Member States shall forward this information to the Commission and the Authority.*** ***The Commission shall make this information available to the public.***

Justification

Mandatory monitoring means that all manufacturers are treated equally and at the same time enhances consumer protection. Publication ensures transparency as to what is on the market and facilitates monitoring.

Amendment 43
Annex I, section 2, entry 13

Fluoride	***deleted***

Justification

There is no call for the addition of fluoride to food.

Amendment 44
Annex II, add new entry under "Mineral substances"

	Calcium sulphate

Justification

Reference to Directive 2004/5/EC of 20 January 2004 which authorised the use of calcium sulphate in dietetic foods.

Amendment 45
Annex II, add new entry under "Mineral substances"

potassium phosphate

sodium phosphate

Justification

Potassium phosphate and sodium phosphate are permitted under EC legislation on miscellaneous additives.

Amendment 46
Annex II, add a new entry under 'Mineral substances'

Pyridoxine dipalmitate

Justification

To remedy an omission in so far as these substances are already authorised.

EXPLANATORY STATEMENT

At international level the 1987 Codex Alimentarius established the general principle that the addition of nutrients to foods should be allowed for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific sub-groups of the population.

Today there are wide differences between national regulations on the voluntary addition of vitamins, minerals and certain other substances to food.

Some countries have rules making the addition of nutrients compulsory, whereas others have no rules whatsoever.

There are countries that impose severe restrictions on the voluntary addition of vitamins and minerals and certain other substances whereas in other countries the fortification rules are framed in very broad terms.

These significant differences in national provisions obviously create barriers to trade in fortified products on the internal market.

It is therefore sensible to work towards harmonisation of Community provisions for the addition of vitamins and minerals and certain other substances, provided that harmonisation brings about a high level of consumer protection. In this context, it is important to ensure that the relevant products do not present any risk to public health and that the nutritional principle that a balanced and varied diet provides the necessary and adequate amount of nutrients is not undermined.

The proposal will undoubtedly make it easier to trade fortified foodstuffs on the internal market; however, it fails to take sufficient account of public health considerations and the need for a high level of consumer protection.

1. Legal basis

In order to emphasise the consumer protection aspect to greater degree, the legal basis for the Regulation should be supplemented by a reference to Article 153 of the Treaty, particularly as Article 1(1) of the Commission proposal refers specifically to the objective of a high level of consumer protection.

2. Nutrient profile

Fortified foodstuffs are marketed by food business operators as products that are beneficial and therefore 'good' or 'better' for the consumer. This means that many consumers might increase their intake of these foods to quantities that exceed current intake levels. It is therefore important that vitamins and minerals should only be added to foodstuffs which meet a particular nutritional profile, so as to avoid negative effects.

Diet-related chronic illnesses are on the increase among Europe's population. Such illnesses include cardiovascular diseases, diabetes, obesity, dental caries and so on. A diet that is high

in calories, fat, salt and sugar and low in fibre encourages the development of these illnesses. Consequently, products which are particular high in calories, fat, sugar and/or salt and/or low in fibre and/or have a bad fat profile, in relation to the product group concerned, do not become healthier simply because vitamins and minerals have voluntarily been added to them.

Fortified products should not conflict with current dietary recommendations and national nutrition policies.

3. Annex III

Vitamins and minerals in foods are scientifically assessed and closely investigated. Consequently, the Commission could also draw up positive lists in Annex I and Annex II of the Regulation.

Although there is no point in a positive list of 'certain other substances', the Regulation should nonetheless define what 'certain other substances' means.

Moreover, as in the case of vitamins and minerals, maximum or minimum levels should also be set for these other substances. The labelling provisions should also apply to these other substances in the same way as to vitamins and minerals.

The provisions concerning the procedure for evaluating substances have been redrafted in a clearer and more consistent way in the new Article 10a.

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS ON THE PROPOSED LEGAL BASIS

Mr Karl-Heinz Florenz
Chairman
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Legal basis of the 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 foods (COM(2003)0671 – C5-0538/2003 – 2003/0262(COD))[2]

Dear Mr Chairman,

By letter of 16 February 2005 you asked the Committee on Legal Affairs pursuant to Rule 35(2) to consider whether the legal basis of the above Commission proposal was valid and appropriate.

The committee considered the above question at its meeting of 31 March 2005.

The initiative is based on Article 95 of the EC Treaty. However, Mrs Karin Scheele, rapporteur for the committee responsible, has proposed adding a reference to Article 153 of the EC Treaty.

According to settled case-law, in the context of the organisation of the powers of the Community the choice of the legal basis for a measure must be based on objective factors which are amenable to judicial review. Those factors include in particular the aim and the content of the measure[3].

The proposal's aim is to harmonise the diverging national rules on adding vitamins, minerals and other substances to foodstuffs so as to safeguard a high level of consumer protection and the free movement of goods throughout the Community.

First of all it should be remembered that the effect of the proposed addition will not be to change the procedure for adopting the act, since codecision and consultation of the Economic and Social Committee are required in both cases.

Second, it may be considered that Article 153(3)(a) has only a declaratory effect, and that an act seeking to harmonise the national provisions on consumer protection should be based exclusively on Article 95 of the EC Treaty.

Consequently, the reference to Article 153 must be considered as a reference to paragraph 3(b), namely to 'measures which support, supplement and monitor the policy pursued by the

[2] Not yet published in OJ.
[3] See in particular the judgment of 23 February 1999 in Case C-42/97, [1999] ECR I-869, point 36.

Member States'.

I would draw your attention to the fact that the scope of Article 153(3)(b) might constitute a limitation of the objectives announced in Article 1 of the proposed regulation, 'ensuring the effective functioning of the internal market' by eliminating distortion of competition caused by divergences between current national legislations.

As to the second purpose of the act, consumer protection cannot be identified as the main or predominant component, given that the same purpose is provided by Article 95(3), which consequently constitutes an adequate legal basis.

At its meeting of 31 March 2005 the Committee on Legal Affairs accordingly decided unanimously[4] to recommend that you maintain the legal basis proposed by the Commission, namely Article 95 of the EC Treaty, without adding a reference to Article 153 of the EC Treaty.

Yours sincerely,

Giuseppe Gargani

[4] The following were present for the vote: Andrzej Jan Szejna (acting chairman), Manuel Medina Ortega (draftsman, and for Nicola Zingaretti), Alexander Nuno Alvaro (for Antonio Di Pietro), Maria Berger, Marek Aleksander Czarnecki, Bert Doorn, Piia-Noora Kauppi, Kurt Lechner (for Antonio López-Istúriz White), Klaus-Heiner Lehne, Antonio Masip Hidalgo, Hans-Peter Mayer, Aloyzas Sakalas, József Szájer (for Tadeusz Zwiefka) and Jaroslav Zvěřina.

21.4.2005

OPINION OF THE COMMITTEE ON THE INTERNAL MARKET AND CONSUMER PROTECTION

for the Committee on the Environment, Public Health and Food Safety

on the 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 foods
(COM(2003)0671 – C5-0538/2003 – 2003/0262(COD))

Draftsman: Alexander Stubb

SHORT JUSTIFICATION

Draftsperson's Position

The draftsman welcomes the Commission's proposal and supports those measures which address market anomalies, particularly those identified in recent judgements of the European Court of Justice (C-192/01, C-95/01 and C-24/00).

The draftsman is particularly grateful for the work done by Piia-Noora Kauppi, as draftswoman for the Committee on the Internal Market and Consumer Protection during the fifth parliament.

The draftsman believes that the guiding principle for a European consumer protection policy should be that consumers are free to make decisions regarding their consumption and that of their families. The primary role for legislation should be to ensure that accurate relevant information is available and to allow consumers to gain redress if they suffer loss as a result of inaccurate information.

Proportionality and necessity

As with other regulations, the draftsman believes that these proposals should be subjected to tests of necessity and proportionality and therefore:

- welcomes the fact that the Commission decided not to refer to nutrient profiles as a criterion on the basis of which the addition of vitamins and minerals should be allowed. However, the Commission proposes to take account of nutrient profiles when setting maximum levels of vitamins and minerals added to food. The draftsman opposes this criterion;

- endorses the principle of minimum and maximum levels in order to ensure that the consumption of fortified food in the context of a diversified diet would not result in any risk for consumer. However, restrictions should only be set where there are safety concerns. Any potential restrictions placed on the addition of nutrients to foods should be limited to vitamins and minerals for which the Scientific Committee for Food identifies specific safety concerns;

- agrees that nutrition labelling should become mandatory for all foods to which vitamins and minerals are added on a voluntary basis and that the proposed regulation on nutrition and health claims should apply to fortified food;

- encourages the Commission to agree with competent authorities and interested parties on common nomination of substances to be used in labelling (e.g. B2-vitamine or riboflavin), in order to facilitate the functioning of the internal market and to protect consumers;

- requests the Commission to set out rules to facilitate efficient and harmonised monitoring in all Member States.

Proposed measure and legal basis. Subsidiarity.

In its White Paper on Food Safety the Commission proposed a directive as a measure to regulate fortified food. This was also supported in the Parliament's resolution of June 2001. The draftsperson is of the opinion that a change of measure from a directive to a regulation based on Art. 95 of the EC Treaty is justified by the fact that at this stage the Commission proposes to harmonise only the addition of nutrients on a voluntary basis. It does not therefore intend to harmonise existing national rules on compulsory addition of nutrients to foods. The proposed regulation complies with Art. 5 of the EC Treaty.

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[5]	Amendments by Parliament
Amendment 1 Title	
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on the addition of vitamins and minerals ***and of certain other substances*** to foods	on the addition of vitamins and minerals to foods

[5] Not yet published in OJ.

Justification

The Commission has not yet specified which other substances or categories of substances would be covered by these provisions. Proposals to extend the scope of this legislation to cover other substances should be subject to open and transparent consideration in the course of normal legislative procedures, rather than being decided behind closed doors under commitology. Parliament should not be willing to give the Commission a blank cheque.

Further amendments on this point will follow to ensure coherence in the text.

Amendment 2
Recital 1 a (new)

	(1a) It may subsequently prove necessary to consider the addition to food of certain other substances and, if there are genuine safety concerns, to adopt further legislation.

Justification

This recognises why "other substances" have not been defined within this draft Regulation and provides for the possibility that an amending Regulation could be needed in the light of subsequent scientific evidence.

Amendment 3
Recital 3

(3) This Regulation restricts itself ***in*** regulating the addition of vitamins and minerals to foods ***and the use of certain other substances*** or ingredients containing ***them*** that are added to foods or used in the manufacture of foods at 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.	(3) This Regulation restricts itself ***to*** regulating the addition of vitamins and minerals to foods ***and the addition of*** ingredients containing ***vitamins and minerals*** that are added to foods or used in the manufacture of foods at 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.

Justification

The reference to "other substances" is deleted for consistency.

Amendment 4
Recital 11 a (new)

(11a) For the protection of consumers, a positive list of certain other bioactive substances which may be used in foodstuffs should be established after consultation with the European Food Safety Authority.

Justification

Vitamins and minerals allowed for fortification are on a positive list. Consumers need the same level of protection for bioactive substances, which are being added to give specific properties to foodstuffs. Extracts with hormonal effects (mainly phytohormones) or bioactive substances like caffeine, or quinine should be carefully checked before any addition to food is authorised. Therefore a positive list, indicating the restrictions of use and maximum contents, needs to be established for such extracted or synthesised substances.

Amendment 5
Recital 12

(12) The chemical substances used as sources of vitamins and minerals ***to*** be added to food ***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 for Food (opinion expressed on 12 May 1999), on the basis of the above criteria of safety and bioavailability, and can be used in the manufacture of foods intended for infants and young children, in other foods for particular nutritional uses or in food supplements should appear in this positive list.	(12) The chemical substances used as sources of vitamins and minerals ***which may*** be added to food ***must*** 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 for Food (opinion expressed on 12 May 1999), on the basis of the above criteria of safety and bioavailability, and can be used in the manufacture of foods intended for ***all sections of the population, including*** infants and young children, in other foods for particular nutritional uses or in food supplements should appear in this positive list.

Justification

Different groups of the population have different needs for either supplementary intake of vitamins, minerals or other substances. Voluntary fortification with these nutrients may not counteract particular nutritional needs of vulnerable groups, such as children, pregnant women or elderly.

Amendment 6
Recital 21

(21) 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 food products they place in the market, assume the burden of proof of the safety of them.	***deleted***

Justification

Following the deletion of "other substances" in other amendments, the reasoning outlined in this recital is no longer required and should be deleted.

Amendment 7
Article 1, paragraph 1

1. This Regulation is intended to harmonise 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	1. This Regulation is intended to harmonise the provisions laid down by law, regulation or administrative action in Member States which relate to the addition of vitamins and minerals to foods, with the purpose of ensuring the effective functioning of the

effective functioning of the internal market whilst providing a high level of consumer protection.	internal market whilst providing a high level of consumer protection.

Justification

Following the deletion of "other substances" in other amendments, the reasoning outlined in this recital is no longer required and should be deleted.

Amendment 8
Article 3, paragraph 3

3. Implementing rules for the addition of vitamins and minerals to foods for the ***purpose*** of restoration ***and*** nutritional equivalence of substitute foods may be adopted, as necessary, in accordance with the procedure referred to in Article 16(2).	3. Implementing rules for the addition of vitamins and minerals to foods for the ***purposes*** of restoration ***or ensuring the*** nutritional equivalence of substitute foods may be adopted, as necessary, in accordance with the procedure referred to in Article 16(2). ***Prior to adopting such rules, and respecting the various systems and practices of the Member States, the Commission shall consult interested parties, in particular food business operators and consumer groups.***

Justification

Such consultation is necessary in order to ensure that the aims of the Regulation are not jeopardised.

Amendment 9
Article 4, paragraph 1 a (new)

	Member States shall inform the Commission of ***i) any vitamins and minerals, other than those listed in Annex I, and*** ***ii) any vitamin formulation or mineral substance other than those listed in Annex II*** ***that may be added to foods in their territory. The Commission shall make this information available to interested parties.***

Justification

In order to ensure legal security and predictability to market operators, it is necessary to

have a transparent system, which provides operators with an overview of the substances that may or may not be added to food in each of the Member States of the EU.

Amendment 10
Article 4, paragraph 2

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.	***During the transitional period, other*** Member States may, ***on grounds of public safety and*** 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. ***Member States shall keep the Commission informed about any such national restriction or ban and the Commission shall make such information available to interested parties.***

Justification

In order to ensure legal security and predictability to market operators, it is necessary to have a transparent system, which provides operators with an overview of the substances that may or may not be added to food in each of the Member States of the EU.

Amendment 11
Article 5, point (a a) (new)

	(aa) food marketed as organic, except where the vitamin or mineral is added for the purpose of restoration;

Justification

Council Regulation (EEC) No 2092/91 lays down the framework for organic production of farm products and thus information about agricultural products and foodstuffs. Articles 6 and 7 lay down conditions relating to organic products, and pursuant to Article 5(4), certain ingredients which do not fulfil these requirements may be contained in organic products provided that the product does not contain more than 5% of them. On the other hand, no position has been adopted on whether or not organic foodstuffs may be fortified. This should therefore be clarified, preferably as an addition to Directive 2092/91, but also here.

Amendment 12
Article 5, paragraph 2

Additional foods or categories of foods to which vitamins and minerals may not be	Additional foods or categories of foods to which ***certain*** vitamins and minerals may

added may be determined in accordance with the procedure laid down in Article 16(2) and in the light of scientific evidence.	not be added ***shall be based on public safety and*** may be determined in accordance with the procedure laid down in Article 16(2) and in the light of scientific evidence.

Amendment 13
Article 7, paragraph 1, subparagraph 2

The maximum amounts of vitamins and minerals referred to in the first subparagraph ***and 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 16(2).	The maximum amounts of vitamins and minerals referred to in the first subparagraph shall be adopted in accordance with the procedure referred to in Article 16(2) ***within 6 months of the entry into force of this Regulation.***

Justification

Maximum and minimum amounts mentioned in art. 7 should be defined rapidly in order to ensure that the Regulation can be effectively implemented and obstacles to trade can be removed to guarantee a level playing field. Commission should propose these measures within 6 months after the entry into force of this Regulation. This would also be coherent with Art. 19 of the Regulation which provides that the Regulation "shall apply from [first day of 6th month following the publication]".

Amendment 14
Article 7, paragraph 1, subparagraph 2 a (new)

	Any conditions that restrict the addition of a specific vitamin or mineral to a food or a category of foods or that restrict the maximum level of such additions shall be adopted in accordance with the procedure referred to in Article 16(2) and the maximum level shall be fixed at such a level as is necessary to prevent people from consuming dangerously high quantities of that vitamin or mineral.

Justification

Conditions restrictions and maximum levels should be defined on a nutrient-by-nutrient basis and with reference to the maximum quantity at which the nutrient can be consumed before there is significant risk of serious damage to the consumer's health.

Amendment 15
Article 7, paragraph 2, point (a)

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 consumer groups;	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 consumer groups; ***and***

Amendment 16
Article 7, paragraph 4, point (a)

a) the requirements for addition of certain vitamins or minerals to foods for the purpose of restoration and/or for the purpose of nutritional equivalence of substitute foods;	a) the requirements for addition of certain vitamins or minerals to foods for the purpose of restoration and/or for the purpose of nutritional equivalence of substitute foods; ***and***

Amendment 17
Article 7, paragraph 4, point (c)

c) the nutrient profile of the product established as foreseen by Regulation (EC) No. .../2003 on nutrition and health claims made on foods.	***deleted***

Justification

.
Maximum permitted levels should relate to the highest quantity that can be safely consumed. This level does not change as a result of the nutritional profile and therefore nutritional profiling should not be taken into account when setting the level. The desirability of nutritional profiling being considered as part of other draft legislation and this report should not seek to prejudge a question that is still being considered by the Parliament and the Council.

Amendment 18
Article 7, paragraph 5

5. The addition of a vitamin or a mineral to food for the purpose of fortification shall result in the presence of this vitamin or mineral in the food in at least a significant amount as this is defined in the Annex of Directive 90/496/EEC. The minimum amounts, including any lower amounts, by derogation to the significant amounts mentioned above, for specific foods or categories of foods shall be adopted in accordance with the procedure referred to in Article 16(2).	5. The addition of a vitamin or a mineral to food for the purpose of fortification shall result in the presence of this vitamin or mineral in the food in at least a significant amount as this is defined in the Annex of Directive 90/496/EEC. ***For drinks 7.5% of the RDA per serving, regardless of it being a single or multi-serving pack, should be set as a significant amount.*** The minimum amounts, including any lower amounts, by derogation to the significant amounts mentioned above, for specific foods or categories of foods shall be adopted in accordance with the procedure referred to in Article 16(2).

Justification

As drinks have a higher consumption pattern than foods this is a more appropriate level and is directly related to the amount consumed. In addition it removes the current consumer confusion where single serving packs have a different formulation to products in larger multi-serving packs.

Amendment 19
Article 8, paragraph 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 the food that may result from the addition of these nutrients.	***deleted***

Justification

The amendment questions the need for Article 8.2 on misleading claims as current EU legislation, in particular Directive 2000/13, already provide similar provisions to ensure the protection of consumers.

Amendment 20
Article 8, paragraph 3

3. 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.../2003 on nutrition and health claims made on foods.	***deleted***

Justification

As it stands, and in relation to the Nutrition and Health Claims proposal, those products to which vitamins or minerals have been added would not be allowed to make any health claim on the grounds that this would be misleading to the consumer, regardless of whether or not the addition of that vitamin or mineral is beneficial.

Amendment 21
Article 8, paragraph 4

4. Nutrition labelling of products to which vitamins and minerals have been added and covered by this Regulation shall be compulsory. ***The information to be provided shall consist of that specified in Article 4, paragraph 1, Group 2 of that Directive and of the total amounts present of the vitamins and minerals added to the food.***	4. Nutrition labelling of products to which vitamins and minerals have been added and covered by this Regulation shall be compulsory ***and shall comply with Directive 90/496/EEC on nutrition labelling***.

Justification

The Nutrition Labelling Directive is the appropriate tool to set the detailed requirements with respect to nutrition labelling. Moreover, this Directive will soon be subject to a revision and it is not certain that the existing approach (Group1 and Group 2) will remain. In this context, leaving the specific labelling rules to be decided in the framework of such revision will provide more legal certainty and coherence.

Amendment 22
Article 8, paragraph 6

6. Rules for implementing this Article may be specified in accordance with the procedure referred to in Article 16(2).	***deleted***

Justification

The amendment questions why article 8.6 requires implementing measures since the measures proposed in the article are already clear and can be applied directly by manufacturers.

Amendment 23
Article 9, paragraph 2, subparagraph 1

Where there are no Community provisions, Member States may make provisions for the mandatory addition of vitamins and minerals to specified foods or categories of foods, in accordance with the procedure laid down in Article 14.	Where there are no Community provisions, Member States may***, on grounds of public safety,*** make provisions for the mandatory addition of vitamins and minerals to specified foods or categories of foods, in accordance with the procedure laid down in Article 14.

Justification

Important in order to point out that compulsory addition of vitamins and minerals is permissible only for safety reasons. Important to make all stakeholders aware of this.

Amendment 24
Article 9, paragraph 2, subparagraph 2

Within six months from the entry into force of this Regulation, Member States shall inform the Commission of existing relevant national provisions.	Within six months from the entry into force of this Regulation, Member States shall inform the Commission of existing relevant national provisions. ***The Commission shall make this information available to interested parties.***

Amendment 25
Article 10

Article 10	***deleted***
Restricted and prohibited substances	
1. Where a substance, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods at 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 where, following in each case an assessment of	

available information by the Authority, a harmful effect on health resulting from such use has been identified, the substance and/or the ingredient containing the substance, where necessary, shall, in accordance with the procedure referred to in Article 16(2):

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

(b) or 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.

2. 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. Where there are no Community provisions, Member States may make provision for such prohibitions or restrictions, in accordance with the procedure laid down in Article 14.

Justification

The Commission has not yet specified which other substances or categories of substances would be covered by these provisions. Proposals to extend the scope of this legislation to cover other substances should be subject to open and transparent consideration in the course of normal legislative procedures, rather than being decided behind closed doors under commitology. Parliament should not be willing to give the Commission a blank cheque.

The Scientific Committee for Food found insufficient scientific evidence to suggest such substances be restricted or prohibited. Furthermore, there is concern that EFSA may not be sufficiently resourced to deal with the complexity and scope of these 'certain other substances'.

Further amendments on this point will follow to ensure coherence in the text.

Amendment 26
Article 11

Article 11 ***deleted***

Substances under Community scrutiny

1. Where a substance, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods at 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 where, following in each case an assessment of available information by the Authority, the possibility of harmful effects on health resulting from such use is identified but scientific uncertainty persists, the substance shall be placed in Annex III, Part C, in accordance with the procedure referred to in Article 16(2).

2. 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.

3. 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 16(2) and taking into account the opinion of the Authority on any files submitted for evaluation as mentioned in paragraph 2, 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.

Justification

The Commission has not yet specified which other substances or categories of substances would be covered by these provisions. Proposals to extend the scope of this legislation to cover other substances should be subject to open and transparent consideration in the course of normal legislative procedures, rather than being decided behind closed doors under commitology. Parliament should not be willing to give the Commission a blank cheque.

The Scientific Committee for Food found insufficient scientific evidence to suggest such

substances be restricted or prohibited. Furthermore, there is concern that EFSA may not be sufficiently resourced to deal with the complexity and scope of these 'certain other substances'.

Further amendments on this point will follow to ensure coherence in the text.

Amendment 27
Article 12, paragraph 2, point (f)

f) Information about the substances referred to in Annex III and the reasons for their inclusion therein.	***deleted***

Justification

The Commission has not yet specified which other substances or categories of substances would be covered by these provisions. Proposals to extend the scope of this legislation to cover other substances should be subject to open and transparent consideration in the course of normal legislative procedures, rather than being decided behind closed doors under commitology. Parliament should not be willing to give the Commission a blank cheque.

The Scientific Committee for Food found insufficient scientific evidence to suggest such substances be restricted or prohibited. Furthermore, there is concern that EFSA may not be sufficiently resourced to deal with the complexity and scope of these 'certain other substances'.

Further amendments on this point will follow to ensure coherence in the text.

Amendment 28
Article 12, paragraph 2, point (f a) (new)

(fa) The list of substances whose addition is mandatory at national level.

Justification

Consistency with proposed amendment to Article 4, paragraph 1 a (new).

Amendment 29
Article 12, paragraph 2, point (f b) (new)

(fb) The list of substances whose addition is prohibited at national level.

Justification

Consistency with proposed amendment to Article 4, paragraph 1 a (new).

Amendment 30
Article 14, paragraph 2

2. 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. If***, for reasons of safety,*** 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 ***specific safety*** reasons justifying them.

Amendment 31
Article 17

To facilitate efficient monitoring of foods to which vitamins and minerals have been added, ***and of foods containing substances listed in Annex III, Part B and Part 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 forwarding it a model of the label used for the product.	***With the sole aim of facilitating the*** efficient monitoring of foods to which vitamins and minerals have been added, 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 forwarding ***to*** it a model of the label used for the product. ***Information obtained pursuant to this provision shall not be used for any other purpose.***

Justification

To avoid misuse of the provision notably a pre-market authorisation.

The deletion corresponds with the deletion of Chapter III in an earlier amendment.

Amendment 32
Article 19, paragraph 3

Foods placed on the market or labelled prior to [first day of ***sixth month*** following publication] which do not comply with this Regulation may be marketed until [last day of the ***seventeenth*** month following	Foods placed on the market or labelled prior to [first day of ***eighteenth month*** following publication] which do not comply with this Regulation may be marketed until [last day of the ***twenty-ninth*** month following publication]***, or until the end of the food's***

publication].	***shelf-life, whichever is later***.

Justification

This amendment is in support of harmonisation whilst limiting the burden on operators, notably the SMEs. It gives those relevant bodies time to work-out and finalise all the necessary requirements and ensure maximum safety of products marketed in the EU.

Amendment 33
Annex II, Mineral substances, (new item)

.	***calcium sulphate***

Amendment 34
Annex III

ANNEX III	***deleted***
Substances and whose use in foods is prohibited or subject to conditions	
Part A - Prohibited substances	
Part B – Restricted substances	
Part C - Substances under Community scrutiny	

Justification

Clarification with the deletion of Chapter III.

PROCEDURE

Title	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 foods
References	(COM(2003)0671 – C5-0538/2003 – 2003/0262(COD))
Committee responsible	ENVI
Committee asked for its opinion Date announced in plenary	IMCO 16.9.2004
Enhanced cooperation	NO
Drafts(wo)man Date appointed	Alexander Stubb 31.8.2004
Discussed in committee	28.9.2004 17.1.2005 2.2.2005 16.3.2005 18-19.4.2005
Date amendments adopted	19.4.2005
Result of final vote	for: 32 against: 3 abstentions: 0
Members present for the final vote	Mia De Vits, Bert Doorn, Janelly Fourtou, Evelyne Gebhardt, Małgorzata Handzlik, Malcolm Harbour, Christopher Heaton-Harris, Anna Hedh, Edit Herczog, Anneli Jäätteenmäki, Pierre Jonckheer, Alexander Lambsdorff, Kurt Lechner, Lasse Lehtinen, Arlene McCarthy, Toine Manders, Manuel Medina Ortega, Bill Newton Dunn, Béatrice Patrie, Zita Pleštinská, Heide Rühle, Leopold Józef Rutowicz, Andreas Schwab, Eva-Britt Svensson, József Szájer, Marianne Thyssen, Jacques Toubon, Barbara Weiler, Joachim Wuermeling
Substitutes present for the final vote	Charlotte Cederschiöld, Simon Coveney, Benoît Hamon, Joel Hasse Ferreira, Joseph Muscat, Alexander Stubb, Stefano Zappalà
Substitutes under Rule 178(2) present for the final vote	

PROCEDURE

Title	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 foods
References	COM(2003)0671 – C5-0538/2003 – 2003/0262(COD)
Legal basis	Articles 251(2) and 95 EC
Basis in Rules of Procedure	Rule 51
Date submitted to Parliament	16.9.2004
Committee responsible Date announced in plenary	ENVI 16.9.2004
Committee(s) asked for opinion(s) Date announced in plenary	IMCO 16.9.2004
Not delivering opinion(s) Date of decision	ITRE 18.10.2004
Enhanced cooperation Date announced in plenary	No
Rapporteur(s) Date appointed	Karin Scheele 27.9.2004
Previous rapporteur(s)	
Simplified procedure Date of decision	
Legal basis disputed Date of JURI opinion	ENVI 16.2.2005 JURI 31.3.2005
Financial endowment amended Date of BUDG opinion	
European Economic and Social Committee consulted Date of decision in plenary	
Committee of the Regions consulted Date of decision in plenary	
Discussed in committee	2.2.2005 25.4.2005 26.04.2005
Date adopted	26.04.2005
Result of final vote	for: 49 against: 5 abstentions: 0
Members present for the final vote	Georgs Andrejevs, Liam Aylward, Irena Belohorská, Johannes Blokland, John Bowis, Frederika Brepoels, Hiltrud Breyer, Dorette Corbey, Chris Davies, Avril Doyle, Mojca Drčar Murko, Anne Ferreira, Françoise Grossetête, Satu Hassi, Gyula Hegyi, Mary Honeyball, Marie Anne Isler Béguin, Caroline Jackson, Dan Jørgensen, Christa Klaß, Eija-Riitta Korhola, Holger Krahmer, Aldis Kušķis, Marie-Noëlle Lienemann, Peter Liese, Jules Maaten, Linda McAvan, Riitta Myller, Miroslav Ouzký, Dimitrios Papadimoulis, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Karin Scheele, Carl Schlyter, Richard Seeber, Kathy Sinnott, Jonas Sjöstedt, María Sornosa Martínez, Antonios Trakatellis, Thomas Ulmer, Anja Weisgerber, Åsa Westlund, Anders Wijkman

Substitutes present for the final vote	María del Pilar Ayuso González, Danutė Budreikaitė, Christofer Fjellner, Milan Gaľa, Genowefa Grabowska, Vasco Graça Moura, Miroslav Mikolášik, Pál Schmitt, Renate Sommer, Bart Staes, Phillip Whitehead
Substitutes under Rule 178(2) present for the final vote	
Date tabled – A6	28.4.2005 A6-0214/2005
Comments	...