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***I
REPORT

on the proposal for a European Parliament and Council directive on the approximation of the laws of the Member States relating to food supplements (COM(2000) 222 – C5-0234/2000 – 2000/0080(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Emilia Franziska Müller

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)

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PROCEDURAL PAGE

By letter of 10 May 2000 the Commission submitted to Parliament, pursuant to Article 251(2) and Article 95 of the EC Treaty, the proposal for a European Parliament and Council directive on the approximation of the laws of the Member States relating to food supplements (COM(2000) 222 - 2000/0080 (COD)).

At the sitting of 19 May 2000 the President of Parliament announced that she had referred this proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Industry, External Trade, Research and Energy and the Committee on Legal Affairs and the Internal Market for their opinions (C5-0234/2000).

The Committee on the Environment, Public Health and Consumer Policy appointed Emilia Franziska Müller rapporteur at its meeting of 23 May 2000.

The committee considered the Commission proposal and draft report at its meetings of 17 October 2000, 21 November 2000 and 24 January 2001.

At the latter meeting it adopted the draft legislative resolution by 21 votes to 1, with 27 abstention.

The following were present for the vote: Caroline F. Jackson, chairman; Guido Sacconi, Alexander de Roo and Ria G.H.C. Oomen-Ruijten, vice-chairmen; Emilia Franziska Müller, rapporteur; Per-Arne Arvidsson, Maria del Pilar Ayuso González, Hans Blokland, David Robert Bowe, John Bowis, Hiltrud Breyer, Martin Callanan, Massimo Carraro (for Carlos Lage), Gerard Collins (for Jim Fitzsimons pursuant to Rule 153(2)), Dorette Corbey, Chris Davies, Avril Doyle, Cristina García-Orcoyen Tormo, Robert Goodwill, Cristina Gutiérrez Cortines, Heidi Anneli Hautala (for Marie Anne Isler Béguin), Anneli Hulthén, Eija-Riitta Anneli Korhola, Bernd Lange, Marie-Noëlle Lienemann, Peter Liese, Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Patricia McKenna, Jorge Moreira Da Silva, Rosemarie Müller, Riitta Myller, Giuseppe Nisticò, Karl Erik Olsson, Doris Pack (for Christa Klaß pursuant to Rule 153(2)) , Marit Paulsen, Frédérique Ries, Dagmar Roth-Behrendt, Ulla Margrethe Sandbæk (for Jean Saint-Josse), Karin Scheele, Ursula Schleicher (for Marielle de Sarnez), Inger Schörling, María Sornosa Martínez, Gabriele Stauner (for Karl-Heinz Florenz pursuant to Rule 153(2)), Catherine Stihler, Antonios Trakatellis, Phillip Whitehead, Joachim Wuermeling (for Marialiese Flemming pursuant to Rule 153(2)).

The opinion of the Committee on Industry, External Trade, Research and Energy is attached; the Committee on Legal Affairs and the Internal Market decided on 21 June 2000 not to deliver an opinion.

The report was tabled on 25 January 2001.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

LEGISLATIVE PROPOSAL

Proposal for a European Parliament and Council directive on the approximation of the laws of the Member States relating to food supplements
(COM(2000) 222 – C5-0234/2000 – 2000/0080(COD))

The proposal is amended as follows:

Text proposed by the Commission [1]	Amendments by Parliament
(Amendment 1) Recital 6	
There is a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to, vitamins, minerals, amino acids, ***essential*** fatty acids, fibre and various plant and herbal extracts. However, as a first stage, this Directive should only cover food supplements containing vitamins and minerals.	There is a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to, vitamins, minerals, amino acids, fatty acids, fibre and various plant and herbal extracts. However, as a first stage, this Directive should only cover food supplements containing vitamins and minerals. ***Food supplements containing substances other than those covered by this Directive shall be subject to national provisions. Products which contain both vitamins or minerals and other ingredients shall be subject to this Directive only in respect of their vitamin and mineral content.***

Justification:

The addition of the word 'essential' means in dietary terms substances where it is scientifically accepted that deficiency diseases occur in healthy people without an adequate intake of these nutrients. Scientific developments may show that substances which are not at present characterised as being essential are considered to be so in future. Certain population groups may also benefit from taking a particular nutrient although this is not the case for the whole population. The main reason for including a nutrient in Annexes I and II must therefore be that the substance is safe and that the user can benefit from it. To require that the substance is essential is too severe and restricts consumer choice.

It should be made clear that food supplements which are not covered fully by the Directive are subject to national provisions. However, vitamins and minerals in food supplements should be covered by the Directive even when these supplements also contain other ingredients.

[1] OJ C311, 31.10.2000, p. 207.

(Amendment 2)
Recital 7

(7) Only vitamins and minerals normally found in and consumed as part of the diet ***and considered essential nutrients*** should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Controversy as to the identity of those essential nutrients that could potentially arise should be avoided. Therefore it is appropriate to establish a positive list of those vitamins and minerals.	(7) Only vitamins and minerals normally found in and consumed as part of the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Controversy as to the identity of those essential nutrients that could potentially arise should be avoided. Therefore it is appropriate to establish a positive list of those vitamins and minerals.

Justification:

The addition of the word 'essential' means in dietary terms substances where it is scientifically accepted that deficiency diseases occur in healthy people without an adequate intake of these nutrients. Scientific developments may show that substances which are not at present characterised as being essential are considered to be in future. Certain population groups may also benefit from taking a particular nutrient although this is not the case for the whole population. The main reason for including a nutrient in Annexes I and II must therefore be that the substance is safe and that the user can benefit from it. To require that a substance is essential is too severe and restricts consumer choice.

The second part of the amendment refers to the Dutch text of the Commission proposal and does not apply to the English text.

(Amendment 3)
Recital 9

(9) In order to keep up with scientific and technological developments it is important to revise the lists promptly, when necessary. Such revisions would be implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.	(9) In order to keep up with scientific and technological developments it is important to revise the lists promptly, when necessary. Such revisions would be implementing measures of a technical nature and their adoption ***– in this case on the manufacturer's request to the Commission – after consultation of the relevant committees -*** should be entrusted to the Commission in order to simplify and expedite the procedure .

Justification:

To increase the transparency of the decision-making process manufacturers should be able to submit a request to the Commission for a substance to be added to the lists in the annexes. The Commission will then amend these lists in accordance with the procedure in Article 13, after consultation of the Scientific Committee for Food and the Consumer Committee. This amendment is consistent with the amendments to Article 4(3) and Article 14.

(Amendment 4)
Recital 14

(14) General labelling provisions and definitions are contained ***in Council Directive 79/112 of 18 december on the approximation of the laws of Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer, as last amended by Directive 97/4/EC of the European Parliament and of the Council*** and do not need to be repeated. This Directive ***can*** therefore be confined to the necessary additional provisions.	(14) General labelling provisions and definitions are contained ***in Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of Member States relating to the labelling, presentation and advertising of foodstuffs*** and do not need to be repeated. This directive ***should*** therefore be confined to the necessary additional provisions.

Justification:

The amended directive was published on March 20th and did repeal the original to which reference is made in the Commission proposal.

(Amendment 5)
Article 2 (a)

(a) "food supplements" means foodstuffs that are concentrated sources of nutrients as specified in (b) alone or in combination, marketed in dose form, whose purpose is to supplement the intake of those nutrients in the normal diet;	(a) "food supplements" means foodstuffs that are concentrated sources of nutrients as specified in (b) alone or in combination ***also with other substances,*** marketed in dose form, whose purpose is to supplement the intake of those nutrients in the normal diet;

Justification:

This amendment is suggested as to clarify that the scope of the directive is as well vitamins and minerals in combination with other products not mentioned in the annexes.

(Amendment 6)
Article 2(b) (iia) (new)

(iia) other ingredients with a nutritional function which, in accordance with Article 4(3a); are included in Annex I;

Justification:

There are other ingredients such as amino acids, fatty acids and herbal extracts which can also contribute to good health. These ingredients are already available on the market and should therefore be brought within the scope of this Directive as quickly as possible in accordance with Article 4(4) (new).

(Amendment 7)
Article 2(c)

"dose form" means forms such as capsules, tablets, pills and other similar forms, sachets of powder, ampoules of liquids and drop dispensing bottles.	"dose form" means forms such as capsules, ***pastilles,*** tablets, pills and other similar forms, sachets of powder, ampoules of liquids and drop dispensing bottles***, liquid and powder preparations administered with a measuring spoon or beaker and other similar forms of measured quantity***.

Justification:

It should be made clear that flexible implementation of appropriate forms refers to all suitable forms and not only specific set forms.

(Amendment 8)
Article 3

Member States shall ensure that the food supplements containing the nutrients listed in Article 2(b) may be marketed within the Community only if they comply with the rules laid down in this Directive.	***1.*** Member States shall ensure that the food supplements containing the nutrients listed in Article 2(b) may be marketed within the Community only if they comply with the rules laid down in this Directive. ***2. Food supplements listed in paragraph 1, and which do not comply with the***

	Directive, and which may contain substances other than those covered by this Directive shall be subject to national provisions. Products which contain both vitamins or minerals and other ingredients shall be subject to this Directive only in respect of their vitamin and mineral content.

Justification:

The Directive restricts the minerals and vitamins that may be used for the manufacture of food supplements. This may exclude many food supplements which have existed on the marketplace safely for many years. i.e. (those containing other substances such as essential fatty acids and amino acids).

(Amendment 9)
Article 4(2)

The criteria of purity for the substances, referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 13(2).	The criteria of purity for the substances, referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 13(2). ***The criteria of purity must as a minimum be based on the general principles of hygiene and good manufacturing practice.***

Justification:

To improve consumer protection the text of the Directive should specify minimum quality and purity requirements. Details should be laid down using the procedure specified by the Commission, with due regard for the greatest possible transparency. The relevant provisions of food legislation and the standards established under the Codex Alimentarius or the European pharmacopoeia should be taken into account.

(Amendment 10)
Article 4(3)

3. ***Modifications to the*** lists referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 13 (2).	3. ***A specific procedure for the evaluation of the safety of substances*** referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 13 (2). ***This procedure shall be subject to the principle of transparency and introduce the***

opportunity for the parties concerned to provide further data prior to the adoption of the final SCF opinion.

Justification:

This amendment seeks to improve procedures for updating the Positive List in order to encourage product development and to promote consumer choice.

(Amendment 11)
Article 4(3)a (new)

3a. The Commission shall submit a proposal to the Council and the European Parliament for the inclusion of other ingredients with a nutritional function within the scope of this Directive, as soon as the necessary scientific data is available.

Justification:

As soon as the scientific information exists the scope of the Directive should be extended by the inclusion of other ingredients in the annexes.

(Amendment 12)
Article 5(1)(ca) (new)

(ca) the requirement for children and adults respectively.

Justification:

The acceptable daily intake for children may be considerably lower than for adults as ADI depends on body weight.

(Amendment 13)
Article 5(3)

3. The maximum and minimum amounts of vitamins and minerals referred to paragraphs 1 and 2 shall be adopted in accordance with	3. The maximum and minimum amounts of vitamins and minerals referred to paragraphs 1 and 2 shall be adopted in accordance with

the procedure referred to in Article 13 (2).	the procedure referred to in Article 13 (2). ***This procedure shall be subject to the principle of transparency.***

Justification:

Self explanatory

(Amendment 14)
Article 6(1)

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

Justification:

It is not suitable to include the word 'supplement' and the name of the category of the nutrient in the name under which the product is sold as this would lead to unnecessary legal problems with the name under which the product is sold. The word 'food supplement', which is undoubtedly appropriate, and the name of the category of the nutrient should form part of the labelling. The consumer still has the information, and indeed better information, as it will allow more flexible implementation as regards labelling.

The proposed amendments to this paragraph are based on the principle that a substance should be defined as being a 'food supplement' rather than as not being a pharmaceutical product. The inclusion of the term 'food supplement' is in itself sufficiently clear as to prevent confusion in the minds of consumers.

(Amendment 15)
Article 6(3)(b)

(b) a ***warning as to the possible health risks, as the case may be, in exceeding*** the recommended portion for daily consumption;	(b) a ***statement that*** the recommended portion for daily consumption ***should not be exceeded. If there are health risks should the amount be exceeded this must be explained on the package leaflet. If there is no leaflet the statement must appear on the product***;

Justification:

A warning with regard to exceeding the recommended portion for daily consumption must be given as the decision on upper levels adopted in the directive also means that when the daily portion is exceeded the safety margin is breached. The consumer must be made aware of the potential risks

(Amendment 16)
Article 6(3)(c)

a statement to the effect that food supplements should not be used as a substitute for a diversified diet.	***Deleted***

Justification:

In the case of a number of vitamins and minerals it will be difficult or unlikely for a desirable level of nutrient intake to be achieved through diet in view of normal eating habits. If it is assumed that the intake of some nutrients in quantities higher than the recommended levels can have health benefits (see point 3 of the Commission's explanatory memorandum) the food supplements would in this case not only make up nutrient deficiencies in the diet but would also supply an additional amount which could not be achieved even if recommended intakes were adhered to or could be achieved only through a specific, possibly unbalanced, diet.

As it is extremely difficult to differentiate between vitamins and minerals as regards their nutritional usefulness, it is desirable to delete the whole reference.

Any exaggerated recommendation is prevented by the prohibition set out in Article 7.

(Amendment 17)
Article 6(3)(ca) (new)

	ca) a statement to the effect that the products should be stored out of the reach of children.

Justification:

Amendment is self-explanatory.

(Amendment 18)
Article 6(3)(cb) (new)

	cb) may be taken by pregnant women or children under the age of one only after consultation of a doctor or health visitor.

Justification:

Amendment is self-explanatory.

(Amendment 19)
Article 6(4)

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

Justification:

As food supplements are generally considered to be foodstuffs, there seems little reason for a special statement that they are not medicinal products. Such a statement would deviate from the usual principles of foodstuffs labelling, namely the principle of stating the characteristics of a product. References to characteristics which are lacking are not the norm and are by their nature incomplete. A statement should in general provide information to the consumer and such a reference might, rather, tend to cause confusion.

(Amendment 20)
Article 7

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

Justification:

According to newer scientific evidence there might be special situations, when persons do not even according to an adequate and diversified diet get enough of nutrients. The classic example quoted is that of Folic Acid for pregnant women. Therefore it is justified to allow this labelling, when there is scientific proof of it.

(Amendment 21)

Article 9(1)

The declared values mentioned in Article 8(1) and (2) shall be average values based on the manufacturer's analysis of the product. The rules for implementing this paragraph with regard in particular to the differences between the declared values and those established in the course of official checks shall be decided upon in accordance with the procedure referred to in Article 13(2).	The declared values mentioned in Article 8(1) and (2) shall be average values based on the manufacturer's analysis of the product. The rules for implementing this paragraph with regard in particular to the differences between the declared values and those established in the course of official checks shall be decided upon in accordance with the procedure referred to in Article 13(2). ***Excess doses which could harm the consumer must be avoided. For substances where there are no stability problems, the specified weighed portion is adequate within a 10% tolerance limit.***

Justification:

Even when excess doses could be useful to ensure adequate quantities of the active ingredients, these should not exceed an appropriate quantity. The rules referred to in Article 9(1) for implementing this paragraph are not relevant for substances for which there are no problems of stability.

(Amendment 22)
Article 9 (2a) (new)

	2a. Food supplements have to be produced according to good manufacturing practice to be decided upon in accordance with the procedure referred to in Article 13(2).

Justification:

See amendment 9.

(Amendment 23)
Article 10

To facilitate efficient monitoring of food supplements, when a product is placed on the market the manufacturer or, where a product is manufactured in a third country, the importer, shall notify the competent authority of each Member State where the product is being marketed by forwarding it	To facilitate efficient monitoring of food supplements, when a product is placed on the market the manufacturer or, where a product is manufactured in a third country, the importer, shall notify the competent authority of each Member State where the product is being marketed by forwarding it

a model of the label used for the product. ***Member States may not impose this requirement, if they can demonstrate to the Commission that notification is not necessary in order to monitor those products efficiently in their territory.***	a model of the label used for the product.

Justification:

Because of the special characteristics of food supplements the establishment of a notification procedure seems appropriate. This is particularly relevant with regard to questions concerning health claims, which are not dealt with in detail and which operate differently in the various Member States of the European Union. The option for Member States to refrain from making a notification could involve the risk of market distortions and make European harmonisation more difficult. The possibility of not using the notification procedure should therefore be deleted.

(Amendment 24)
Article 12(2)

2. The Commission shall examine ***as soon as possible*** the grounds adduced by the Member State concerned and shall consult the Member States within the Standing Committee for Foodstuffs, and shall then deliver its opinion without delay and take appropriate measures.	2. The Commission shall examine ***within three months*** the grounds adduced by the Member State concerned and shall consult the Member States within the Standing Committee for Foodstuffs, and shall then deliver its opinion without delay and take appropriate measures ***within one month of that consultation***.

Justification:

It is appropriate to increase users' rights by guaranteeing that disputes will be resolved within specific deadlines.

(Amendment 25)
Article 14

14. Provisions that may have an effect upon public health shall be adopted after consultation with the Scientific Committee for Food.	14. Provisions that may have an effect upon public health shall be adopted after consultation with the Scientific Committee for Food. ***The Committee shall be required to determine and publish guidelines for the criteria, the procedure, and the timetable it***

shall adopt in assessing substances. It shall be open and transparent in its communications with applicants.

Justification:

The amendment seeks to ensure that applicants seeking approval for products to be placed on the positive list are treated openly, fairly, equally and without unnecessary delay.

(Amendment 26)
ANNEX I

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

1. Vitamins	**1. Vitamins**
Vitamin A (µg RE)	Vitamin A (µg RE ***or IU***)
Vitamin D (µg)	Vitamin D (µg ***or IU***)
Vitamin B6 (***µg***)	Vitamin B6 (***mg***)
2. Minerals	**2. Minerals**
Calcium (mg)	Calcium (mg)
Magnesium (mg)	Magnesium (mg)
Iron (mg)	Iron (mg)
Copper (µg)	Copper (µg ***or mg***)
Iodine (µg)	Iodine (µg)
Zinc (mg)	Zinc (mg)
Manganese (mg)	Manganese (mg)
Sodium (mg)	Sodium (mg)
Potassium (mg)	Potassium (mg)
Selenium (µg)	Selenium (µg)
Chromium (µg)	Chromium (µg)
Molybdenum (µg)	Molybdenum (µg)
Fluoride (mg)	Fluoride (mg)
Chloride (mg)	Chloride (mg)
Phosphorus (mg)	Phosphorus (mg)
	Boron (µg or mg)
	Nickel (µg or mg)
	Silicon (µg or mg)
	Vanadium (µg or mg)
	Tin (µg or mg)

Justification:

Those minerals should be included where evidence can be provided of their usefulness in food supplements, which is clearly the case for boron, nickel, silicon, vanadium and tin. The range of minerals in food supplements should therefore in principle be extended to include these substances. In relation to the setting of maximum and minimum doses, the competent scientific committee should re-examine the justification for these minerals in food supplements and determine the units of measurement.

(Amendment 27)
ANNEX II

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

1. Vitamins	**1. Vitamins**
VITAMIN A	VITAMIN A
- retinol	- retinol
- retinyl acetate	- retinyl acetate
- retinyl palmitate	- retinyl palmitate
- beta-carotene	- beta-carotene
	- carotenoids
	- cholecalciferol-cholesterol
VITAMIN D	VITAMIN D
- cholecalciferol	- cholecalciferol
- ergocalciferol	- ergocalciferol
	- cholecalciferol-cholesterin
VITAMIN B1	VITAMIN B1
- thiamin hydrochloride	- thiamin hydrochloride
- thiamin mononitrate	- thiamin mononitrate
	- thiamine monophosphate
VITAMIN C	VITAMIN C
- L-ascorbic acid	- L-ascorbic acid
- sodium-L-ascorbate	- sodium-L-ascorbate
- calcium-L-ascorbate	- calcium-L-ascorbate
- potassium-L-ascorbate	- potassium-L-ascorbate
- L-ascorbyl 6-palmitate	- L-ascorbyl 6-palmitate
	- magnesium ascorbate
2. Minerals	**2. Minerals**
calcium carbonate	***boron amino acid chelate***
calcium chloride	***sodium borate***
calcium salts of citric acid	calcium carbonate
calcium gluconate	calcium chloride
calcium glycerophosphate	calcium salts of citric acid
calcium lactate	calcium gluconate

calcium salts of orthophosphoric acid calcium hydroxide calcium oxide	calcium glycerophosphate calcium lactate calcium salts of orthophosphoric acid calcium hydroxide calcium oxide ***calcium phosphate*** ***dicalcium phosphate*** ***calcium pidolate*** ***calcium amino acid chelate dolomite*** ***dicalcium phosphate*** ***chromium amino acid chelate*** ***chromium picolinate*** ***chromium polynicotinate***
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	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 ***magnesium pidolate*** ***magnesium amino acid chelate***
ferrous carbonate ferrous citrate ferric ammonium citrate ferrous gluconate ferrous fumarate ferric sodium diphosphate ferrous lactate ferrous sulphate ferric diphosphate (ferric pyrophosphate) ferric saccharate elemental iron (carbonyl+electrolytic+hydrogen reduced)	ferrous carbonate ferrous citrate ferric ammonium citrate ferrous gluconate ferrous fumarate ferric sodium diphosphate ferrous lactate ferrous sulphate ferric diphosphate (ferric pyrophosphate) ferric saccharate elemental iron (carbonyl+electrolytic+hydrogen reduced) ***iron oxide*** ***iron amino acid chelate***
cupric carbonate cupric citrate cupric gluconate	cupric carbonate cupric citrate cupric gluconate ***copper amino acid chelate*** ***copper oxide***

cupric sulphate copper lysine complex	cupric sulphate copper lysine complex ***tin chloride*** ***nickel sulphate*** ***nickel sulphide*** ***stannous chloride*** ***iron amino acid chelate***
sodium iodide sodium iodate potassium iodide potassium iodate	sodium iodide sodium iodate potassium iodide potassium iodate
zinc acetate zinc chloride zinc citrate zinc gluconate zinc lactate zinc oxide zinc carbonate zinc sulphate	zinc acetate zinc chloride zinc citrate zinc gluconate zinc lactate zinc oxide zinc carbonate zinc sulphate ***zinc stearate*** ***zinc yeast*** ***zinc amino acid chelate***
manganese carbonate manganese chloride manganese citrate manganese gluconate manganese glycerophosphate manganese sulphate	manganese carbonate manganese chloride manganese citrate manganese gluconate manganese glycerophosphate manganese sulphate ***manganese pidolate***
sodium bicarbonate sodium carbonate sodium chloride sodium citrate sodium gluconate sodium lactate sodium hydroxide sodium salts of orthophosphoric acid	sodium bicarbonate sodium carbonate sodium chloride sodium citrate sodium gluconate sodium lactate sodium hydroxide sodium salts of orthophosphoric acid
potassium bicarbonate potassium carbonate potassium chloride potassium citrate potassium gluconate potassium glycerophosphate	potassium bicarbonate potassium carbonate potassium chloride potassium citrate potassium gluconate potassium glycerophosphate

potassium lactate	potassium lactate
potassium hydroxide	potassium hydroxide
potassium salts of orthophosphoric acid	potassium salts of orthophosphoric acid
	potassium orotate
	potassium iodide
	potassium iodate
	potassium sulphate
	potassium amino acid chelate
	potassium aspartate
	magnesium amino acid chelate
	magnesium orotate
	molybdenum amino acid chelate
sodium selenate	sodium selenate
sodium hydrogen selenite	sodium hydrogen selenite
sodium selenite	sodium selenite
	sodium borate
	sodium caseinate
	selenium yeast
	selenomethionine
	chromium chelate
chromium (III) chloride	chromium (III) chloride
	chromium (III) oxide
chromium (III) sulphate	chromium (III) sulphate
	chromium (III) nitrate
	chromium amino acid chelate
ammonium molybdate (molybdenum (VI))	ammonium molybdate (molybdenum (VI))
potassium molybdate (molybdenum (VI))	potassium molybdate (molybdenum (VI))
potassium fluoride	potassium fluoride
sodium fluoride	sodium fluoride
	sodium molybdate
	molybdenum amino acid chelate
	sodium borate
	boron chelate
	sodium metasilicate
	sodium molybdate
	nickel sulphate
	silicon dioxide
	sodium metavanadate
	colloidal silica
	tin chloride
	orthosilicic acid
	selenium lacto-bacillus
	vanadium amino acid chelate
	vanadyl sulphate

zinc amino acid chelate
zinc picolinate

Justification:

The additions arise from the comments on the previous amendment. It should be possible to use all appropriate chemical compounds of vitamins and minerals in food supplements.

DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the proposal for a European Parliament and Council directive on the approximation of the laws of the Member States relating to food supplements (COM(2000) 222 – C5-0234/2000 – 2000/0080(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2000) 222[1]),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0234/2000),

– having regard to Rule 67 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinion of the Committee on Industry, External Trade, Research and Energy (A5-0025/2001),

1. Approves the Commission proposal as amended;

2. Asks to be consulted again should the Commission intend to amend its proposal substantially or replace it with another text;

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

[1] OJ C311, 31.10.2000, p. 207.

EXPLANATORY STATEMENT

I. Introduction

Being healthy and remaining healthy are among the wishes most frequently expressed by European citizens. Lifestyles and eating habits have a lasting impact on health which explains the great interest in the products known as ‘food supplements’, ‘diet integrators’, etc. The most important ingredients in these products are vitamins and minerals.

It is now generally recognised that the lifestyles and eating habits of some of the population can give rise, inter alia, to inadequate intakes of essential nutrients including certain vitamins and minerals. It is not enough just to draw attention to the need for a varied and balanced diet. The possibility of taking a food supplement is in principle a sensible option so as to avoid possible deficiencies or to stay healthy.

However, when assessing the situation the possibility of abuse must be taken into account. The presentation of various products in the past and the claims made for them are unacceptable from the point of view of consumer protection. In specific cases widespread media campaigns are involved. Furthermore, food supplements offered for sale electronically or via the Internet require some regulation at European level.

It is absolutely clear that food supplements must pose no health risks of any kind. A rigorous approach to determining their safety and meaningful information for consumers are therefore fundamental principles when assessing such preparations.

The Commission’s initiative is therefore basically to be welcomed.

II. Background to the Commission proposal and general assessment.

The Commission’s justification for its proposal is based primarily on the differing national legal provisions on food supplements. The differences between the Member States relate to areas such as product composition, dosage, criteria relating to purity, statements relating to products, labelling or the required approval procedure. In drawing up a framework directive the Commission is trying to establish a European basis for food supplements. Aspects such as labelling provisions are covered in some detail while maximum and minimum doses of ingredients, for example, are to be assessed first by the competent scientific committees. Only the fundamental criteria are to be settled in the Directive.

The approach chosen by the Commission is basically sensible and follows the guidelines of the European Treaties. Even if internal market considerations are the real factor underlying the proposal, the approach is in line with health considerations with regard to this group of products.

The increasing globalisation in the field of food supplements requires international assessments to be taken into account. For several years the Codex Alimentarius, in the context of the Codex Committee for nutrition and dietary foodstuffs, has been working towards a directive on vitamin and mineral supplements and thus for a provision acceptable throughout the world. On several key points, such as maximum doses, agreement, however, seems a long

way off. Taking Codex recommendations into account in a European provision on food supplements thus seems possible to only a very limited extent.

However, it is certainly useful to take account of provisions both in the Member States and in countries outside Europe when developing a European legal framework. In that process it becomes clear that a decision of principle is first needed with regard to definition of the status of the products. Food supplements fall between foodstuffs and medicinal products. The Commission's approach in its proposal of concentrating on vitamins and minerals is to be welcomed. The content is much more complex for other ingredients, such as plant ingredients, where a therapeutic purpose is often the central aspect for the consumer and demands that such products are classified as medicinal products. However, classification of these substances in the medicinal products sector requires appropriate special provisions. The fact that the Commission is working on clarification with regard to traditional and in particular herbal medicinal products is therefore to be welcomed. These proposals should be forwarded to the Council and Parliament as quickly as possible in order to facilitate a comprehensive discussion.

As already mentioned, this directive was developed initially to eliminate obstacles to trade in the internal market. However the proposal for a directive is also contained in the White Paper on Food Safety and is thus part of the measures to improve consumer protection. The proposal is closely linked to the proposals, also announced in the White Paper on Food Safety, on fortified foods and health claims. There are widely differing views in relation to health claims in particular and a rapid European agreement should still be sought. This proposal on food supplements will not initially completely harmonise the situation with regard to food supplements in Europe. Differing national practices, for example on product claims, are still possible in the Member States.

The Commission proposal provides for considerable involvement by the relevant Commission scientific committees in areas such as minimum and maximum doses or criteria of purity. This approach can also be accepted for reasons of practicality and the ability to adapt rapidly. However scientists must be chosen in a more transparent manner than in the past. Representatives of the European Parliament should be involved in the choice.

III. Practical assessment of the proposal for a directive

Even though the Commission proposal is to be welcomed in principle, amendments are needed in the following areas:
- comprehensive inclusion of relevant minerals and their chemical compounds;
- provisions on labelling which take into account the principles of effective communication with the consumer;
- safeguards for adequate requirements with regard to purity and quality;
- binding notification procedure.

1. Comprehensive inclusion of relevant minerals and their chemical compounds

It is appropriate for the Directive to concentrate on minerals and vitamins. However, all vitamins and minerals should be included where evidence can be provided for their efficacy. In relation to the proposed setting of maximum and minimum doses for all vitamins and

minerals, the competent scientific committee should re-examine the justification for these minerals and their chemical compounds in food supplements.

2. Provisions on labelling which take into account the principles of effective communication with the consumer

The labelling provisions must require the provision of information which guides the consumer to make appropriate use of the product and gives significant assistance in assessing its composition. Additional information should not be the subject of binding provisions as it restricts effective communication with the consumer.

3. Safeguards for adequate requirements with regard to purity and quality

The proposal for a directive does not specify adequately the necessary purity and quality requirements. Minimum standards should already be laid down in the Directive. Details can then be established by the Commission with the involvement of the relevant scientific committees. These detailed provisions should, however, be drawn up with as much transparency as possible.

4. Compulsory notification procedure

Lastly, there is a need for a minimum level of official checks on food supplements. Notification should take place in all Member States. All notified products should be made public by the national authorities via the internet so that all interested parties are able to make an assessment and this would also facilitate monitoring.

20 November 2000

OPINION OF THE COMMITTEE ON INDUSTRY, EXTERNAL TRADE, RESEARCH AND ENERGY

for the Committee on the Environment, Public Health and Consumer Policy

on the proposal for a directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements
(COM(2000) 222 – C5-0234/2000 – 2000/0080(COD))

Draftsman: Astrid Thors

PROCEDURE

The Committee on Industry, External Trade, Research and Energy appointed Astrid Thors draftsman at its meeting of 6 June 2000.

It considered the draft opinion at its meetings of 13 September and 6 November 2000.

At the last meeting it adopted the amendments below by unanimously.

The following were present for the vote: Carlos Westendorp y Cabeza, chairman; Renato Brunetta, Nuala Ahern , Peter Michael Mombaur, vice-chairmen; Astrid Thors, draftsman; Maria del Pilar Ayuso González (for Concepció Ferrer), Ward Beysen (for Willy C.E.H. De Clercq), Massimo Carraro, Giles Bryan Chichester, Harlem Désir, Francesco Fiori (for Guido Bodrato), Colette Flesch, Christos Folias, Jacqueline Foster (for Godelieve Quisthoudt-Rowohl), Pat the Cope Gallagher, Neena Gill (for Mechtild Rothe), Norbert Glante, Alfred Gomolka (for Werner Langen), Michel Hansenne, Malcolm Harbour, Philippe A.R. Herzog, Hans Karlsson, Wolfgang Kreissl-Dörfler (for Glyn Ford pursuant to Rule 153(2), Bernd Lange (for Reino Kalervo Paasilinna), Rolf Linkohr, Caroline Lucas, Erika Mann, Véronique Mathieu (for Yves Butel pursuant to Rule 153(2), Marjo Tuulevi Matikainen-Kallström, Eryl Margaret McNally, Emilio Menéndez del Valle (for Elena Valenciano Martínez-Orozco pursuant to Rule 153(2), Elizabeth Montfort, Angelika Niebler, Giuseppe Nisticò (for Umberto Scapagnini), Hervé Novelli (for Anders Wijkman), Samuli Pohjamo (for Nicholas Clegg), John Purvis, Daniela Raschhofer, Imelda Mary Read, Christian Foldberg Rovsing, Paul Rübig, Konrad K. Schwaiger, Esko Olavi Seppänen, Astrid Thors, Claude Turmes (for Yves Piétrasanta), Jaime Valdivielso de Cué, W.G. van Velzen, Alejo Vidal-Quadras Roca, Dominique Vlasto, Teresa Zabell Lucas, François Zimeray, Myrsini Zorba

SHORT JUSTIFICATION

1. Background and justification for the directive

In the Green Paper on Food Law the Commission raised the issue of food supplements, as well as in a working paper in 1997 , the latter reaching many comments from the member states. After this consultation it has been decided to divide some related issues into three parts

This directive thus forms a part of a packet of three directives on additivies and health related issues concerning food. The other two directives that are under consideration is the question on addition of nutrients to food and finally health claims. The question of if and how claims could be made that a food has good effects for your health, has long been discussed as the European legislation has variations and allegations are made that the European food industry is disadvantaged visavi that of other continents. On the other hand experts are divided on how to proof the claims concerning the effects of food stuff.

The starting point for this directive as well as for other foodrelated questions is a high standard of protection of consumers , which should be reached through use of scientific expertise and clear labelling. This is a good starting point, and should of course be primarily visavi other justifications such as the functioning of the internal market.

It is clear that the internal market in food supplements is not working. This is partially proven by the number of infringement proceedings raised by the Commission.

According to information from the Commission the following number of infringement proceedings have been raised by the Commission services by the end of September 2000:

Cases concerning food supplements
Austria: 4 cases (2 cases before the ECJ, 2 at a preliminary stage)
Finland: 1 case (formal notice)
France: 8 cases (3 cases before the ECJ, 5 others waiting for the Court's decision).
Germany: 11 cases (3 before the ECJ, 8 at a preliminary stage)
Greece: 3 cases (reasoned opinion)

This also highlights the need for a harmonisation of the rules in the EU. According to the Commission the different rules have lead to obstacles to intracommunity trade that the application of the principle of mutual recognition has not succeeded in overcoming. There clearly is need for regulation at the European level, as the aims could not be reached without Community rules

2. The consumption of food supplements in some European countries

The consumption of food supplements varies grately in the Member States, as can be seen from Table 1. Reasons for the different levels of consumption might be sought in the different legal approaches to food supplements as well as in difference of traditions.

Table 1: Sales of vitamin and mineral preparations in some European states, 1999

	Euro millions
Austria	33.604
Czech Republic	32.776
Denmark	7.262
Finland	41.542
France	166.932
Germany	387.557
Ireland	18.932
Italy	154.936
Netherlands	95.294
Norway	5.920
Portugal	24.571
Spain	92.225
Sweden	34.278b
Switzerland	49.552
United Kingdom	470.444
T o t a l	**1 615.825**

Source: The Association of the European Self-Medication Industry (AESGP), Brussels, 2000
The was not statitistics available for your draftsman for all Member States.

3. Food supplements from a trade perspective

The importance of the food supplements in the context of transatlantic business activities and the differences in the approaches have become clear by the creation of issue group on dietary/food supplements within the so-called Transatlantic Business Dialogue (TABD). A reference to this category was made in the conclusions of the last TABD summit held in October 1999 in Berlin and there are currently considerable efforts to put together proposals for the development of a transatlantic regulatory environment. Results are expected to be presented at the next summit in November this year in Cincinnati and may provide then a longer-term perspective for developing a transatlantic market place.

It is interesting to note that it has been decided that the American FDA can not regulate food supplements. This has led to a situation where margarin is marketed in the USA as food supplements in some cases. The present proposal does not impose any undue restrictions or barriers to trade.

4. Evaluation of the proposal as a whole and suggested amendments

Your rapporteur for opinion welcomes the proposal of the Commission. There are however a few problematic points in the proposal.

A) The proposal might give the impression to contain an exhaustive list of “dose forms”

for food supplements (article 2). This is not the intention of the proposal. Also a clarification is needed that the vitamins and minerals contained in combination products should be subject to the requirements in the Directive

B) At this date the vitamins and minerals contained in the annex are those which the scientific evaluation consider essential. Through the committology procedure more vitamins or minerals can be added to the scope of the directive. To make it easier to include other food supplements without amending the directive, but only through the committology procedure, an amendment is suggested. Some ideas have been circulating that time limits should be set for the work of the scientific committees and the committology. This is something that can not be solved in this directive, but must be addressed in the general food safety context.

C) The proposal will not affect the selling of products including other ingredients than these listed in the Annexes. They will be sold under national regulations as long as community rules do not exist.

D) The proposal as it stands might give the impression that it risks infringing on trademark rights (article 6.1). An amendment is suggested.

E) Furthermore it sets additional labelling requirements for food supplements when they are presented in forms similar to pharmaceutical products (article 6.4). This requirement is unnecessary since food supplements by definition will be considered as foodstuffs after the adoption of this Directive. The question of labelling statements saying that a normal diet is sufficient is addressed in one amendment. In some situations a person might not get all food suppelements needed through the normal diet. A change is proposed.

AMENDMENTS

The Committee on Industry, External Trade, Research and Energy calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament
(Amendment 1) Recital 14	
(14) General labelling provisions and definitions are contained ***in Council Directive 79/112 of 18 december on the approximation of the laws of Member***	(14) General labelling provisions and definitions are contained ***in Directive 2000/13/EC of the European Parliament and of the Council on the approximation***

[1] OJ C311, 31.10.2000, p. 207.

States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer, as last amended by Directive 97/4/EC of the European Parliament and of the Council and do not need to be repeated. This Directive ***can*** therefore be confined to the necessary additional provisions.

of the laws of Member States relating to the labelling, presentation and advertising of foodstuffs and do not need to be repeated. This directive ***should*** therefore be confined to the necessary additional provisions.

Justification:

The amended directive was published on March 20th and did repeal the original to which reference is made in the Commission proposal

(Amendment 2)
Article 2 (a)

(b) "food supplements" means foodstuffs that are concentrated sources of nutrients as specified in (b) alone or in combination, marketed in dose form, whose purpose is to supplement the intake of those nutrients in the normal diet;	(b) "food supplements" means foodstuffs that are concentrated sources of nutrients as specified in (b) alone or in combination ***also with other substances,*** marketed in dose form, whose purpose is to supplement the intake of those nutrients in the normal diet;

Justification:

This amendment is suggested as to clarify that the scope of the directive is as well vitamins and minerals in combination with other products not mentioned in the annexes.

(Amendment 3)
Article 2 (b) (iia) new

	(ii)a other ingredients such as amino acids, fatty acids, and herb extracts which have been inserted in Annex I in accordance with the procedure referred to in Article 13(5);

Justification:

Amino acids, fatty acids, and herb extracts likewise promote good health. These ingredients

are already obtainable on the market and should consequently be made subject to the provisions of the Directive

(Amendment 4)
Article 2 (c)

(c) "dose form" means forms such as capsules, tablets, pills ***and other similar forms***, sachets of powder, ampoules of liquids and drop dispensing bottles.	(c) "dose form" means forms such as capsules, tablets, pills, sachets of powder, ampoules of liquids and drop dispensing bottles ***and other similar forms***.

Justification:

There has been a debate on the implications of this list explaining what is dose form. What does it mean if some form in which food supplements are usually used is not mentioned in this list. In order to make it really clear that the list is not exhaustiuve, this change is proposed.

(Amendment 5)
Article 7

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

Justification:

According to newer scientific evidence there might be special situations, when persons do not even according to an adequate and diversified diet get enough of nutrients. The classic example quoted is that of Folic Acid for pregnant women. Therefore it is justified to allow this labelling, when there is scientific proof of it.