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| COUNCIL COMMON POSITION | AMENDMENTS BY PARLIAMENT |
|---|---|

(Amendment 8)

*Annex VII (3.6.2)*

| | |
|---|---|
| 3.6.2. There shall be at least one doorway through which wheelchair users can pass. In the case of vehicles of Class I at least one wheelchair access door shall be a service door. The wheelchair access door shall bear a boarding aid complying with the provisions of paragraph 3.11.2, *3.11.3 or 3.11.4* of this Annex. | 3.6.2. There shall be at least one doorway through which wheelchair users can pass. In the case of vehicles of Class I at least one wheelchair access door shall be a service door. The wheelchair access door shall bear a boarding aid complying with the provisions of paragraph 3.11.2 **(a kneeling system)** of this Annex; **this shall be in combination with the provisions of paragraph 3.11.3 (a lift) or 3.11.4 (a ramp) unless local infrastructure design already guarantees level access to secure boarding of all persons with reduced mobility including wheelchair users in the area of operation.** |

## 13. Food supplements ***I

**A5-0025/2001**

**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 was amended as follows:

| TEXT PROPOSED BY THE COMMISSION [1] | AMENDMENTS BY PARLIAMENT |
|---|---|

(Amendment 37)

*Recital 6*

| | |
|---|---|
| (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. | (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, 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 should be subject to national provisions. Specific rules concerning other nutrients or other substances used as ingredients in food supplements should be laid down as soon as adequate and appropriate scientific data is available. Products which contain both vitamins and/or minerals and other ingredients should be subject to this Directive only in respect of their vitamin and mineral content.** |

[1] OJ C 311 E, 31.10.2000, p. 207.

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| TEXT PROPOSED BY THE COMMISSION | AMENDMENTS BY PARLIAMENT |
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| | (Amendments 30, 38 and 42) |
| | *Recital 6a (new)* |
| | **(6a) There is a wide range of nutrients and other ingredients contained in food supplements currently marketed in the Member States which have not yet been evaluated according to the procedure referred to in Article 13(2) and which are therefore not yet included in Annex II. The Commission should submit these substances to the Scientific Committee for Food (SCF) as soon as the appropriate documents are submitted by the interested parties. The Commission should ensure that evaluations are completed on these substances as a matter of urgency.** |
| | (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 nutrients that could potentially arise should be avoided. Therefore it is appropriate to establish a positive list of those vitamins and minerals. |
| | (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. |
| | (Amendment 4) |
| | *Recital 14* |
| (14) General labelling provisions and definitions are contained *in Council Directive 79/112/EEC of 18 December 1978* on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs *for sale to the ultimate consumer* [1], as last amended by Directive 97/4/EC of the European Parliament and of the Council [2], 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 **European Parliament and Council Directive 2000/13/EC of 20 March 2000** on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs **[1]**, and do not need to be repeated. This Directive **should** therefore be confined to the necessary additional provisions. |

[1] *OJ L 33, 8.2.1979, p. 1.*
[2] *OJ L 109, 6.5.2000, p. 29.*

**[1] OJ L 43, 14.2.1997, p. 21.**

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| TEXT PROPOSED BY THE COMMISSION | AMENDMENTS BY PARLIAMENT |
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(Amendment 43)

*Recital 16a (new)*

| | |
|---|---|
| | **(16a) Some Member States do not have regulations concerning food supplements. Member States may allow more products on their markets than those that comply with this Directive. Producers wishing to market products that do not comply with this Directive in another Member State should submit their ingredients to the testing procedures set out in this Directive.** |

(Amendments 33 and 44)

*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 **or other substances with a nutritional or physiological function,** alone or in combination**,** marketed in dose form, whose purpose is to supplement the intake of those nutrients in the normal diet; |

(Amendments 34 and 46)

*Article 2(b)(iia) (new)*

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

(Amendment 7)

*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, **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**. |

(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. |

| TEXT PROPOSED BY THE COMMISSION | AMENDMENTS BY PARLIAMENT |
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| | **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 and/or minerals and other ingredients shall be subject to this Directive only in respect of their vitamin and mineral content.** |
| | (Amendment 9) |
| | *Article 4(2)* |
| 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). | 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). **They must as a minimum be based on general principles of hygiene and good manufacturing practice.** |
| | (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 shall afford the parties concerned the opportunity to provide further data prior to the adoption of the final opinion of the Scientific Committee for Food.** |
| | (Amendment 47) |
| | *Article 4(3a) (new)* |
| | **3a. The European Parliament and the Council shall decide as soon as the necessary scientific data is available, and without prejudice to the competence of the Commission, on the inclusion of other ingredients with a nutritional or physiological function within the scope of this Directive with a view to further pursuing the goals of this Directive.** |
| | (Amendments 31, 36 and 48) |
| | *Article 4(3b) (new)* |
| | **(3b) The Commission shall ensure that nutrients and ingredients contained in food supplements marketed in the Community prior to the date of adoption of this Directive and listed in Part B of Annex II, but not covered by this Directive, undergo scientific evaluation as soon as the necessary documents are submitted to the Commission by the parties concerned. Those ingredients that are approved in accordance with the procedure in Article 13(2) shall then be transferred from Part B to Part A of Annex II.** |

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| TEXT PROPOSED BY THE COMMISSION | AMENDMENTS BY PARLIAMENT |
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| | (Amendment 12)<br>*Article 5(1)(ca) (new)* |
| | **(ca) the requirements of children and adults respectively.** |
| | (Amendment 13)<br>*Article 5(3)* |
| 3. The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1 and 2 shall be adopted in accordance with the procedure referred to in Article 13 (2). | 3. The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1 and 2 shall be adopted in accordance with the procedure referred to in Article 13 (2). **This procedure shall be subject to the principle of transparency.** |
| | (Amendment 14)<br>*Article 6(1)* |
| 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. | 1. The **labelling of** products covered by this Directive shall include the **words** '**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. |
| | (Amendment 15)<br>*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**; |
| | (Amendment 16)<br>*Article 6(3)(c)* |
| *(c) a statement to the effect that food supplements should not be used as a substitute for a diversified diet.* | **Deleted** |
| | (Amendment 17)<br>*Article 6(3)(ca) (new)* |
| | **(ca) a statement to the effect that the products should be stored out of the reach of children;** |
| | (Amendment 18)<br>*Article 6(3)(cb) (new)* |
| | **(cb) a statement that the product may be taken by pregnant women or children under the age of one only after the agreement of a doctor or health visitor.** |

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| TEXT PROPOSED BY THE COMMISSION | AMENDMENTS BY PARLIAMENT |
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(Amendment 19)

*Article 6(4)*

| | |
|---|---|
| *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** |

(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.** |

(Amendment 21)

*Article 9(1), second paragraph*

| | |
|---|---|
| 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 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 shall be adequate within a 10 % tolerance limit.** |

(Amendment 22)

*Article 9(2a) (new)*

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

(Amendment 23)

*Article 10, second paragraph*

| | |
|---|---|
| *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.* | **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**. |

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| TEXT PROPOSED BY THE COMMISSION | AMENDMENTS BY PARLIAMENT |
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| | (Amendment 25)<br>*Article 14, second paragraph (new)* |
| | **The Committee shall lay down and publish guidelines concerning the criteria, the procedure, and the timetable it shall adopt in assessing substances. It shall be open and transparent in its communications with applicants.** |
| | (Amendment 26)<br>*ANNEX I* |
| 1. Vitamins | 1. Vitamins |
| Vitamin A (µg RE) | Vitamin A (µg RE **or IU**) |
| Vitamin D (µg) | Vitamin D (µg **or IU**) |
| Vitamin E (mg α-TE) | Vitamin E (mg α-TE) |
| Vitamin K (µg) | Vitamin K (µg) |
| Vitamin B1 (mg) | Vitamin B1 (mg) |
| Vitamin B2 (mg) | Vitamin B2 (mg) |
| Niacin (mg NE) | Niacin (mg NE) |
| Pantothenic acid (mg) | Pantothenic acid (mg) |
| Vitamin B6 (*µg*) | Vitamin B6 (**mg**) |
| Folic acid (µg) | Folic acid (µg) |
| Vitamin B12 (µg) | Vitamin B12 (µg) |
| Biotin (µg) | Biotin (µg) |
| Vitamin C (mg) | Vitamin C (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)** |

| TEXT PROPOSED BY THE COMMISSION | AMENDMENTS BY PARLIAMENT |
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| | (Amendments 39, 49 and 32/rev.)<br>*ANNEX II, Part B (new)* |
| | **B. Vitamin and Mineral substances marketed in the EU which should undergo scientific evaluation** |
| | **1. Vitamins** |
| | **VITAMIN A** |
| | **— carotenoids** |
| | **VITAMIN D** |
| | **— cholecalciferol-cholesterin** |
| | **VITAMIN B1** |
| | **— thiamine monophosphate** |
| | **VITAMIN C** |
| | **— magnesium ascorbate** |
| | **2. Minerals** |
| | **boron amino acid chelate** |
| | **sodium borate** |
| | **calcium phosphate** |
| | **dicalcium phosphate** |
| | **calcium pidolate** |
| | **calcium amino acid chelate dolomite** |
| | **chromium amino acid chelate** |
| | **chromium picolinate** |
| | **chromium polynicotinate** |
| | **magnesium pidolate** |
| | **magnesium amino acid chelate** |
| | **iron oxide** |
| | **iron amino acid chelate** |
| | **copper amino acid chelate** |
| | **copper oxide** |
| | **tin chloride** |
| | **nickel sulphate** |
| | **nickel sulphide** |
| | **stannous chloride** |
| | **zinc stearate** |
| | **zinc yeast** |
| | **zinc amino acid chelate** |
| | **manganese pidolate** |
| | **potassium orotate** |
| | **potassium iodide** |
| | **potassium iodate** |
| | **potassium sulphate** |
| | **potassium amino acid chelate** |

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| | **potassium aspartate** |
| | **magnesium orotate** |
| | **molybdenum amino acid chelate** |
| | **sodium caseinate** |
| | **selenium yeast** |
| | **selenomethionine** |
| | **chromium chelate** |
| | **chromium (III) oxide** |
| | **chromium (III) nitrate** |
| | **boron chelate** |
| | **sodium metasilicate** |
| | **sodium molybdate** |
| | **silicon dioxide** |
| | **sodium metavanadate** |
| | **colloidal silica** |
| | **orthosilicic acid** |
| | **selenium lacto-bacillus** |
| | **vanadium amino acid chelate** |
| | **vanadyl sulphate** |
| | **zinc amino acid chelate** |
| | **zinc picolinate** |

**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 C 311 E, 31.10.2000, p. 207.