EUROPEAN PARLIAMENT

1999 **** 2004

Session document

FINAL **A5-0044/2002**

21 February 2002

***II RECOMMENDATION FOR SECOND READING

on the Council common position for adopting a European Parliament and Council directive on the approximation of the laws of the Member States relating to food supplements

 $(1239\overline{4}/2/2001 - \overline{C5}-0640/2001 - 2000/0080(COD))$

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Emilia Franziska Müller

RR\462199EN.doc PE 312.624

EN EN

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.

CONTENTS

	Page
PROCEDURAL PAGE	4
DRAFT LEGISLATIVE RESOLUTION	5
EXPLANATORY STATEMENT	7

PROCEDURAL PAGE

At the sitting of 14 February 2001 Parliament adopted its position at first reading 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 - 2000/0080 (COD)).

At the sitting of 13 December 2001 the President of Parliament announced that the common position had been received and referred to the Committee on the Environment, Public Health and Consumer Policy (12394/2/2001 - C5-0640/2001).

The committee had appointed Emilia Franziska Müller rapporteur at its meeting of 23 May 2000.

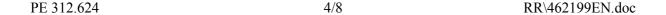
It considered the common position and draft recommendation for second reading at its meetings of 22 January and 20 February 2002.

At the latter meeting it adopted the draft legislative resolution by 36 votes to 18, with 3 abstentions.

The following were present for the vote: Caroline F. Jackson, chairman; Alexander de Roo, Mauro Nobilia and Anneli Hulthén, vice-chairmen; Emilia Franziska Müller, rapporteur; Nuala Ahern (for Hiltrud Breyer pursuant to Rule 153(2)), Per-Arne Arvidsson, María del Pilar Ayuso González, Jean-Louis Bernié, Hans Blokland, David Robert Bowe, John Bowis, Philip Bushill-Matthews (for Raffaele Costa), Martin Callanan, Dorette Corbey, Chris Davies, Avril Dovle, Anne Ferreira, Jim Fitzsimons, Karl-Heinz Florenz, Pernille Frahm, Laura González Álvarez, Robert Goodwill, Françoise Grossetête, Jutta D. Haug (for Béatrice Patrie), Marie Anne Isler Béguin, Christa Klaß, Eija-Riitta Anneli Korhola, Hans Kronberger, Bernd Lange, Giorgio Lisi (for Marialiese Flemming), Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Patricia McKenna, Jorge Moreira da Silva, Rosemarie Müller, Riitta Myller, Giuseppe Nisticò, Ria G.H.C. Oomen-Ruijten, Neil Parish (for Cristina Gutiérrez Cortines), Marit Paulsen, Frédérique Ries, María Rodríguez Ramos (for María Sornosa Martínez), Dagmar Roth-Behrendt, Encarnación Redondo Jiménez (for Cristina García-Orcoyen Tormo), Guido Sacconi, Giacomo Santini (for Horst Schnellhardt), Karin Scheele, Ursula Schleicher for Caroline F. Jackson), Inger Schörling, Jonas Sjöstedt, Catherine Stihler, Astrid Thors, Antonios Trakatellis, Elena Valenciano Martínez-Orozco, Kathleen Van Brempt, Phillip Whitehead and Stavros Xarchakos (for Peter Liese).

The recommendation for second reading was tabled on 21 February 2002.

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





DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the Council common position for adopting a European Parliament and Council directive on the approximation of the laws of the Member States relating to food supplements (12394/2/2001 – C5-0640/2001 – 2000/0080(COD))

(Codecision procedure: second reading)

The European Parliament,

- having regard to the Council common position (12394/2/2001 C5-0640/2001),
- having regard to its position at first reading¹ on the Commission proposal² and amended proposal³ to Parliament and the Council (COM(2000) 222 and COM(2001) 159),
- having regard to Article 251(2) of the EC Treaty,
- having regard to Rule 80 of its Rules of Procedure,
- having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Consumer Policy (A5-0044/2002),
- 1. Amends the common position as follows;
- 2. Instructs its President to forward its position to the Council and Commission.

_

¹ Texts adopted, 14.2.2001.

² OJ C 311, 31.10.2000, p. 207.

³ OJ C 180, 26.6.2001, p. 248.

Amendment 1 Article 4, paragraph 6, point (b)

- (b) the Scientific Committee for Food 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 supplements, 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 after the date of entry into force of this Directive.
- (b) the Scientific Committee for Food 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 supplements, 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....*
- * 36 months after the date of entry into force of this Directive.

Justification

This extension takes account of the needs of small manufacturers who may find it prohibitively expensive to carry out safety testing over a short period on a large number of products. Without this adjustment, the generosity of the seven-year grace period is more apparent than real.

Amendment 2 Article 9, paragraph 2 a (new)

2a. In order to ensure quality and safety, food supplements shall be produced in accordance with good manufacturing practice, to be decided upon in accordance with the procedure referred to in Article 13(2).

Justification

Reintroduces Amendment 22 from first reading.

PE 312.624 6/8 RR\462199EN.doc



EXPLANATORY STATEMENT

1. Background

1.1. Aim of the directive

The directive essentially has two aims: firstly to harmonise national legal provisions on food supplements, in order to reduce or eliminate the considerable problems facing the free movement of food supplements, and secondly to establish an appropriate level of consumer protection in the use of food supplements in the Member States of the European Union.

Achievement of both these aims requires the following in particular:

- an appropriate definition of food supplements
- a scientific assessment of all ingredients and their minimum and maximum doses
- clear criteria and/or requirements as regards consumer information
- appropriate quality standards
- an adequate monitoring system.

1.1. Parliament's opinion at first reading

The European Parliament welcomed the Commission proposal on food supplements in principle, but considered that amendments were needed in three areas in particular:

- comprehensive inclusion of all relevant minerals and their chemical compounds, which may provide evidence of their inoffensiveness
- ♦ an extension of the definition to include substances with a nutritional or physiological effect, whilst adhering to the principle of scientific assessment of all authorised substances
- improved labelling provisions aimed at more effective consumer information
- ensuring adequate purity and stability requirements
- compulsory notification procedure.

1.2. The Commission's amended proposal

In its amended proposal of 19 March 2001 the Commission incorporated a number of Parliament's amendments, in particular as regards labelling, definitions and, to some extent, the criteria for quality control.

2. Common position

The common position incorporated most points in the amended proposal and hence a number of Parliament's amendments. In addition, account was taken of Parliament's position regarding omitted substances and their chemical compounds, and an inspection mechanism over a period of five years was proposed.

However, the Council did not meet Parliament's demands for a general obligation of good manufacturing practice and a compulsory notification procedure.

With regard to the criteria for the establishment of maximum doses of vitamins and minerals in food supplements (Article 5) the Council made an amendment without which all those concerned considered a common position could not have been reached.

3. Assessment of the common position

Your rapporteur proposes that the Council's common position be assessed on the basis of the following considerations:

- (a) the common position takes into account Parliament's main requests and constitutes, overall, a *balanced* legal framework for food supplements. *Appropriate* account is taken of the directive's main aims regarding the free movement of food supplements and consumer protection.
- (b) the directive needs to be adopted soon in the interests of providing an *adequate*European legal framework in view of the intensive public debates on food supplements.

 All the groups concerned would benefit from a clear and transparent legal basis.
- (c) the Commission is obliged to submit a report to the European Parliament and the Council on implementation of the directive and any additional proposals. This is to ensure that any amendments needed may be incorporated in the text of the directive within a reasonable period of time.

All in all, it would seem appropriate to approve the common position.

