Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2000/0080(COD)
Food supplements: approximation of the laws of the Member States Subject 3.10.10 Foodstuffs, foodstuffs legislation 4.60.02 Consumer information, advertising, labelling 4.60.04.04 Food safety	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy	PPE-DE MÜLLER Emilia Franziska	23/05/2000
	Former committee responsible		
	ENVI Environment, Public Health, Consumer Policy	PPE-DE MÜLLER Emilia Franziska	23/05/2000
	Former committee for opinion		
	JURI Legal Affairs and Internal Market	The committee decided not to give an opinion.	
	ITRE Industry, External Trade, Research, Energy	ELDR THORS Astrid	06/06/2000

Council of the European Union	Council configuration	Meeting	Date
	Development	2429	30/05/2002
	Employment, Social Policy, Health and Consumer Affairs	2392	03/12/2001
	Competitiveness (Internal Market, Industry, Research and Space)	2371	27/09/2001
	Competitiveness (Internal Market, Industry, Research and Space)	2351	30/05/2001

European Commission	Commission DG	Commissioner
	Health and Food Safety	

Key events

08/05/2000	Legislative proposal published	COM(2000)0222	Summary
19/05/2000	Committee referral announced in Parliament, 1st reading		

24/01/2001	Vote in committee, 1st reading		Summary
24/01/2001	Committee report tabled for plenary, 1st reading	A5-0025/2001	
13/02/2001	Debate in Parliament		
14/02/2001	Decision by Parliament, 1st reading	T5-0079/2001	Summary
19/03/2001	Modified legislative proposal published	COM(2001)0159	Summary
30/05/2001	Debate in Council	2351	Summary
03/12/2001	Council position published	12394/2/2001	Summary
13/12/2001	Committee referral announced in Parliament, 2nd reading		
20/02/2002	Vote in committee, 2nd reading		Summary
20/02/2002	Committee recommendation tabled for plenary, 2nd reading	A5-0044/2002	
12/03/2002	Debate in Parliament		
13/03/2002	Decision by Parliament, 2nd reading	T5-0103/2002	Summary
30/05/2002	Act approved by Council, 2nd reading		
10/06/2002	Final act signed		
10/06/2002	End of procedure in Parliament		
12/07/2002	Final act published in Official Journal		

Technical information

Procedure reference	2000/0080(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/14422

Documentation gateway

Legislative proposal		COM(2000)0222 OJ C 311 31.10.2000, p. 0207 E	08/05/2000	EC	Summary
Economic and Social Committee: opinion, report		CES1212/2000 OJ C 014 16.01.2001, p. 0042	19/10/2000	ESC	
Committee report tabled for plenary, 1st reading/single reading		A5-0025/2001	24/01/2001	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0079/2001 OJ C 276 01.10.2001, p. 0052-0126	14/02/2001	EP	Summary
Modified legislative proposal		COM(2001)0159 OJ C 180 26.06.2001, p. 0248 E	19/03/2001	EC	Summary

Council position		12394/2/2001 OJ C 090 16.04.2002, p. 0001 E	03/12/2001	CSL	Summary
Commission communication on Council's position		SEC(2001)1975	07/12/2001	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0044/2002	20/02/2002	EP	
Text adopted by Parliament, 2nd reading		T5-0103/2002 OJ C 047 27.02.2003, p. 0088-0237 E	13/03/2002	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2002)0177	08/04/2002	EC	Summary
Follow-up document		COM(2008)0824	05/12/2008	EC	Summary
Follow-up document		SEC(2008)2976	05/12/2008	EC	
Follow-up document		SEC(2008)2977	05/12/2008	EC	

Additional information

European Commission	EUR-Lex

Final act

Directive 2002/46
OJ L 183 12.07.2002, p. 0051-0057 Summary

Food supplements: approximation of the laws of the Member States

PURPOSE : to present a Directive on the approximation of the laws of the Member States relating to food supplements. CONTENT : a wide range of products, known under the term food supplements, diet integrators or others, have been marketed in Community Member States for a number of years. The national rules applicable to them may differ substantially. This has led to obstacles to intracommunity trade that the application of the principle of mutual recognition did not succeed in overcoming. For a number of years now, there have been many comments received from Member States and other interested parties which emphasised the need to adopt Community rules on these products marketed as foodstuffs. The products in question are usually concentrated sources of nutrients and other ingredients, alone or in combination and marketed in dose form. These ingredients include, among others, vitamins, minerals, amino acids, essential fatty acids, fibre, various plant and herbal extracts. The task of covering products containing all these ingredients would be enormous and very complicated. It has therefore been decided for practical reasons to deal at this stage in detail with products containing vitamins and minerals. The measures may be amended in the future to cover in detail products containing other nutrients and/or ingredients. Furthermore, there is an important range of vitamins and mineral supplements on the market. They vary from single nutrient products of variable nutrient levels to multi-nutrient products also of variable nutrient levels for individual nutrients. Prevalence of one or the other product is determined by consumer preferences and differs from one Member State to another. Thus, the choice must be made exempt of any risks health by ensuring that products appropriate and correct information about these products through labelling. Ensuring that food is safe and providing adequate and clear information on the label have been two fundamental principles of Community food law. Another very important element regarding the safety of these products is the maximum levels of minerals they contain. These levels should therefore be stipulated in order to ensure their safety. Upper safe intake levels for some nutrients (e.g. vitamins A, D, B6 and folic acid, iron, selenium, zinc) may be close to amounts that are recommended as population reference intakes (PRI). Therefore, for these few nutrients the PRIs should be taken into account when setting maximum levels in food supplements. On the other hand, the setting of a minimum level of vitamins and minerals in these products is desirable in order to guarantee that food supplements contain a significant amount that would justify the intended purpose of the product. Once the principles for setting maximum and minimum limits have been agreed the adoption of specific limits or each nutrient, based on the opinion of the Scientific Committee for Food (SCF), is a technical matter and should be delegated to the Commission. It should be noted that excess intake of some vitamins and minerals may cause undesirable or adverse effects. Hence, the need to ensure the safety of these products which includes labelling the products with clear instructions about the use of the product, in particular the quantity to be consumed. Asit is, food supplements are excluded from the scope of Directive 90/496/EEC on nutrition labelling. Therefore, the specific relevant rules must be stipulated. These products contain hardly any significant amounts of energy, protein, carbohydrate or fat and, therefore their declaration in the nutritional labelling would be irrelevant. Their nature and intended use, however, as sources of vitamins and minerals would justify that labelling for these nutrients should be compulsory.?

Food supplements: approximation of the laws of the Member States

The committee adopted the report by Emilia Franziska MÜLLER (EPP-ED, D) broadly approving the proposal under the codecision procedure (1st reading), subject to a number of amendments. It sought to include extra vitamins and minerals and their chemical compounds in the list of

substances which could be used in the manufacture of food supplements, arguing that there was clear evidence of their usefulness. The other amendments concerned provisions on labelling to ensure consumers were properly informed, adequate purity and quality requirements, and binding notification procedures. Lastly, the committee wanted to ensure that disputes were resolved within specific deadlines and that the Scientific Committee for Food was required to publish guidelines for the criteria, procedure and timetable it adopted when assessing substances so that applicants seeking approval for products were treated openly and fairly and without unnecessary delay.?

Food supplements: approximation of the laws of the Member States

The European Parliament adopted the report by Mr Emilia Franziska MÜLLER (EPP/ED, D), however, the text was subject to numerous amendments. The amendments call for: - ingredients such as amino acids, fatty acids and herbal extracts, which can also contribute to good health and are already available on the market, to be brought within the scope of the Directive; - the labelling of products covered by this Directive to always include the words 'food supplement' and the name of the category of the nutrients characterising the product and/or the ingredients characterising the product; - warnings to be carried against exceeding the recommended amount for daily consumption; if there are health risks this must be explained on then package leaflet or appear on the product itself; - products to carry warnings stating that they may be taken by pregnant women or children under the age of one only with the agreement of a doctor or health visitor; - excessive doses which could harm the user must be avoided; - certain minerals to be included in Annex I of the directive, such as boron, nickel and tin, when evidence can be provided of their usefulness in food supplements. Lastly, the Parliament calls for certain vitamin and mineral substances marketed in the EU to undergo scientific evaluation.?

Food supplements: approximation of the laws of the Member States

The amended proposal accepts, in total or in part, 16 of the 38 amendments proposed by the European Parliament at first reading. The Commission can accept the amendments which aim to: - specify that the ingredients of food supplements may be some substances that nutritional function (e.g. vitamins, minerals, amino acids, fatty acids) or physiological one (e.g. fibre and various plant and herbal extracts); - propose to include on the label a statement to the effect that food supplements should be stored out of reach of children; - proposes to delete Article 6(4) that would result in the vast majority of food supplements bearing in mind the statement "This is not a medicinal product". The Commission can in principle accept the amendments which aim in particular to: - underline that specific rules on vitamins and minerals laid down in the future directive should be applicable to food supplements containing vitamins, minerals and other ingredients. Otherwise it would be very easy to avoid applying these rules by adding just a small quantity of another ingredient to a food supplement containing vitamins or minerals. On the other hand, in the absence of specific Community rules concerning other ingredients relevant national rules may continue to apply, without prejudice to the provisions of the Treaty; - state in a recital that that priority should be given to the evaluation by the Scientific Committee for Food of Substances that are not included in Annex II of the proposal but which are used in the manufacture of products currently marketed in some Member States; - propose some principles for the adoption of purity criteria for vitamin preparations and mineral substances listed in Annex II; - take into account requirements of children and adults when setting maximum levels for vitamins and minerals. ?

Food supplements: approximation of the laws of the Member States

The Presidency concluded that its compromise proposals for a common position on the Directive relating to food supplements did not meet with a sufficient degree of agreement. The Council will therefore revert to this issue at one of its next sessions. ?

Food supplements: approximation of the laws of the Member States

In general, the Council has followed the Commission's amended proposal. It has accepted - either in whole or in substance - the sixteen amendments adopted at first reading by the European Parliament as set out by the Commission in its amended proposal. The other European Parliament amendments which were not incorporated into the Commission's amended proposal have also been omitted by the Council. However, the idea expressed in 3 amendments according to which some vitamins and substances currently marketed but not covered in the Annex should undergo scientific evaluation, has been taken into account to some extent. The main innovations introduced by the Council relate to: 1) the setting of quantities of food supplments: Article 5 ensure a balanced approach guaranteeing both the safety of such supplements and due regard for reference intakes of the population; 2) authorisation of the placing on the market of existing food supplements not listed in Annex I or II: Article 4(6) and (7), in conjunction with Article 15 on the text's entry into force, aims to allay the concern of participants in this market by laying down clear procedures and time limits for all current supplements not listed in Annexes I or II to the text, thereby reassuring both industry and the consumer; 3) the revision of the Directive: Article 4(8) establishes an amendment procedure after a period of 5 years, which will enable the Commission usefully to take stock of the implementation of the Directive, particularly with regard to its scope, and to propose amendments if necessary. Furthermore, the Council has considered that the obligation to provide information when a product is placed on the market is ultimately the responsibility of the Member States. Lastly, it has introduced a clause providing for the possibility of the participation of the Standing Committee on Foodstuffs in order to specify the procedures for implementing Articles 7 and 8 on labelling, presentation and advertising of food supplements. The Council considers that the common position responds to a large extent to the basic wishes expressed by the European Parliament, while at the same time taking sufficient account of the concern expressed by Member States, inter alia with regard to public health and/or Community harmonisation. The Council considers that the common position achieves a good balance between the prerequisites for the proper functioning of the single market and consumer protection/information.?

Food supplements: approximation of the laws of the Member States

The Commission is of the opinion that the common position is a carefully balanced compromise, in particular on the issue of the criteria to be

used for setting maximum levels for vitamins and minerals in these products. It is in line with the basic principles of food law, namely that food should be safe and properly labelled so that consumers can make an informed choice from a wide range of safe products. The Commission included in the modified proposal those amendments adopted in first reading by the European Parliament that were acceptable. Those amendments remain in the common position in a way that should be satisfactory to the EP. There are three main differences between the modified proposal and the common position: 1) in the common position, the issue of setting maximum limits for vitamins and minerals in food supplements is resolved by providing the scientific risk assessment and intakes from other sources will be primarily factors to be taken into account for the safety of these products, and that in the overall exercise the reference intakes for the population will be given due consideration. While this differs from the Commission proposal, supported by the Parliament, that the reference intakes be taken into account only in the case of some nutrients, the Commission can accept the common position because it strengthens the process of establishing safe maximum levels for vitamins and minerals in food supplements; 2) Article 4.8 of the common position requires the Commission to submit to the European Parliament and the Council, within 5 years from the entry into force of the Directive, a report on the advisability of establishing specific rules on other nutrients or substances with a nutritional or physiological effect, accompanied by any proposals for appropriate legal measures. The Commission can accept the request to submit a report on the subject within a specified time limit while maintaining the right of initiative to propose appropriate measures; 3) Article 4.6 of the common position is new. It foresees a transnational period during which vitamins and minerals and certain of their forms that are not listed in the Annexes but are currently in food supplements marketed in some Member States, may continue to be used until their evaluation by the Scientific Committee for Food and eventual insertion in the Annexes. It was introduced to give effect to an amendment of the European Parliament that was not acceptable in its original form. The Commission supports this new position.?

Food supplements: approximation of the laws of the Member States

The committee adopted the draft recommendation for 2nd reading (codecision procedure) by Emilia Franziska MÜLLER (EPP-ED, D) broadly approving the Council's common position subject to some minor changes. One key amendment adopted sought to lengthen the period for the submission of safety dossiers to 36 months (rather than 18 months as stated in the proposal) after the directive's entry into force. MEPs felt the extra time was crucial to give small companies longer to comply with the directive. It should be pointed out that a considerable minority of MEPs from different political groups took the view that the common position should be rejected. They argued that, given the different cultures in the Member States and the fact that an absence of legislation had so far caused no problems, there was no need for a directive in this area. ?

Food supplements: approximation of the laws of the Member States

The European Parliament adopted the recommendation by Mrs Emilia MÜLLER (EPP-ED, D) subject to one amendment. (Please refer to the text dated 20/02/02).?

Food supplements: approximation of the laws of the Member States

The European Parliament adopted one amendment in second reading. That amendment proposes to increase the maximum time period allowed for the submission to the Commission of dossiers for scientific evaluation, in the context of Article 4.6.b, from 18 to 36 months. It has been argued that this would facilitate the task of preparing these dossiers by the companies concerned, in particular small and medium enterprises. The Commission can accept this amendment.?

Food supplements: approximation of the laws of the Member States

PURPOSE : to bring closer the laws of the Member States on food supplements. COMMUNITY MEASURE : Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements. CONTENT : this Directive, as amended by the European Parliament, is aimed at maintaining both a high level of public health protection and the free circulation of products concerned by ensuring that food supplements are safe and bear adequate and appropriate labelling. The Directive provides in particular : - the setting of maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account: upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups; intake of vitamins and minerals from other dietary sources. When the maximum levels are set, due account should also be taken of reference intakes of vitamins and minerals for the population. To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily portion of consumption as recommended by the manufacturer shall be set, as appropriate. - the presentation by the Commission, in the five years following that of its adoption, of a report on the possibility to establish specific rules concerning other nutriments or substances which have a nutritional or physiological effect, accompanied by any proposals for amendment to this Directive which the Commission deems necessary; - a transition period, during which the continued use of vitamins and minerals not specified in the Annexes shall be authorised. ENTRY INTO FORCE : 12/07/2002. IMPLEMENTATION : Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 July 2003. They shall forthwith inform the Commission thereof. Those laws, regulations and administrative provisions shall be applied in such a way as to permit trade in products complying with this Directive, from 1 August 2003 at the latest; and to prohibit trade in products which do not comply with the Directive, from 1 August 2005 at the latest.?

Food supplements: approximation of the laws of the Member States

The Commission has presented its report on the use of substances other than vitamins and minerals in food supplements.

Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements partially harmonises the rules applicable to the placing of food supplements on the market. The scope of the Directive covers all food supplements, with certain requirements ? in particular those concerning labelling information ? applying to all food supplements, regardless of their composition.

However, only the rules applicable to the use of vitamins and minerals in the manufacture of food supplements are laid down in the Directive. The use of substances other than vitamins or minerals in the manufacture of food supplements therefore continues to be subject to the rules in force in national legislation.

These principles are mentioned in Recital 8 of the Directive, which states that specific rules concerning nutrients, other than vitamins and minerals, or other substances with a nutritional or physiological effect used as ingredients of food supplements should be laid down at a later stage.

It is also stated that, in any event, such rules cannot be laid down until adequate and appropriate scientific data become available. In view of this, the Directive lays down that the Commission shall submit to the European Parliament and the Council a report on the advisability of establishing specific rules, including, where appropriate, positive lists, on categories of nutrients or of substances with a nutritional or physiological effect other than vitamins and minerals.

Considering all the issues described and analysed in this report, the Commission concludes that laying down specific rules applicable to substances other than vitamins and minerals for use in food supplements is not justified. Moreover, the Commission doubts the feasibility of such a measure, which, in any case, is not necessary in the short term.

Feasibility: unlike vitamins and minerals, the use of which is fairly similar throughout the Member States, the other substances correspond to very varied consumption habits. Moreover, given the available scientific information, which is essentially limited to substances that may be added for specific nutritional purposes to foods for particular nutritional uses, the Commission believes that a proposal for harmonisation in this area could only be limited to some substances, thus restricting its usefulness.

Taking account, also, of the scientific and methodological difficulties which would have to be overcome, the Commission believes that the prospect of extending Directive 2002/46/EC to substances other than vitamins and minerals could only be envisaged in the light of the experience gained when the rules on the use of vitamins and minerals were being laid down.

Necessity: according to the Commission, the conditions of use of the substances in question in foodstuffs, including food supplements, or their prohibition, can undergo harmonisation over time in the framework of the procedures provided for in those instruments. Furthermore, the legislation on novel foods is another factor likely to contribute to such harmonisation, within the limits of its specific scope.

Lastly, the Commission would point out that, in general terms, despite certain limitations, mutual recognition is a useful instrument for facilitating the free movement of the products concerned.

To conclude, the Commission believes that the existing Community legal instruments already constitute a sufficient legislative framework for regulating this area. However, since substances other than vitamins or minerals, including substances derived from plants, are now being added to ordinary foodstuffs and not only to food supplements, the Commission does not rule out the possibility, at a later state, of carrying out a supplementary analysis to this report, examining the conditions for the addition of these substances to foodstuffs in general.