


Procedure file

Basic information	
<p>COD - Ordinary legislative procedure (ex-codecision procedure) Directive</p> <p>1994/0076(COD)</p>	Procedure completed
<p>Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)</p> <p>Repealed by 2008/0003(COD)</p> <p>Subject</p> <p>3.10.10 Foodstuffs, foodstuffs legislation</p>	

Key players			
European Parliament	Former committee responsible		
	ENVI Environment, Public Health and Consumer Protection	EDN SANDBÆK Ulla Margrethe	27/07/1994
Council of the European Union	Council configuration	Meeting	Date
	Energy	2176	11/05/1999
	General Affairs	2070	23/02/1998
	Agriculture and Fisheries	2025	22/07/1997
	Competitiveness (Internal Market, Industry, Research and Space)	1993	13/03/1997
	Competitiveness (Internal Market, Industry, Research and Space)	1929	28/05/1996
	Industry	1913	28/03/1996

Key events			
27/03/1994	Legislative proposal published	COM(1994)0097	Summary
18/04/1994	Committee referral announced in Parliament, 1st reading		
26/07/1995	Vote in committee, 1st reading		
25/07/1995	Committee report tabled for plenary, 1st reading	A4-0192/1995	
10/10/1995	Debate in Parliament		
11/10/1995	Decision by Parliament, 1st reading	T4-0451/1995	Summary
28/11/1995	Modified legislative proposal published	COM(1995)0588	Summary
28/03/1996	Debate in Council	1913	
21/07/1997	Council position published	07775/1/1997	Summary
18/09/1997	Committee referral announced in Parliament, 2nd reading		
27/11/1997	Vote in committee, 2nd reading		Summary

26/11/1997	Committee recommendation tabled for plenary, 2nd reading	A4-0379/1997	
17/12/1997	Debate in Parliament		Summary
18/12/1997	Decision by Parliament, 2nd reading	T4-0627/1997	Summary
23/02/1998	Parliament's amendments rejected by Council		
18/03/1999	Formal meeting of Conciliation Committee		Summary
18/03/1999	Final decision by Conciliation Committee		
12/04/1999	Joint text approved by Conciliation Committee co-chairs	3607/1999	
18/04/1999	Report tabled for plenary, 3rd reading	A4-0225/1999	
04/05/1999	Debate in Parliament		
05/05/1999	Decision by Parliament, 3rd reading	T4-0402/1999	Summary
11/05/1999	Decision by Council, 3rd reading		
07/06/1999	Final act signed		
07/06/1999	End of procedure in Parliament		
08/07/1999	Final act published in Official Journal		

Technical information

Procedure reference	1994/0076(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Repealed by 2008/0003(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	CODE/4/09809

Documentation gateway

Legislative proposal		COM(1994)0097 OJ C 108 16.04.1994, p. 0017	28/03/1994	EC	Summary
Economic and Social Committee: opinion, report		CES0847/1994 OJ C 388 31.12.1994, p. 0001	01/06/1994	ESC	Summary
Committee opinion	ECON	PE212.315/DEF	31/05/1995	EP	
Committee draft report		PE211.178	13/06/1995	EP	
Committee report tabled for plenary, 1st reading/single reading		A4-0192/1995 OJ C 269 16.10.1995, p. 0010	26/07/1995	EP	
Text adopted by Parliament, 1st reading/single reading		T4-0451/1995 OJ C 287 30.10.1995, p. 0076-0104	11/10/1995	EP	Summary

Modified legislative proposal		COM(1995)0588 OJ C 035 08.02.1996, p. 0017	29/11/1995	EC	Summary
Council position		07775/1/1997 OJ C 297 29.09.1997, p. 0001	22/07/1997	CSL	Summary
Commission communication on Council's position		SEC(1997)1473	03/09/1997	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A4-0379/1997 OJ C 388 22.12.1997, p. 0003	27/11/1997	EP	
Text adopted by Parliament, 2nd reading		T4-0627/1997 OJ C 014 19.01.1998, p. 0101-0123	18/12/1997	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(1998)0069	11/02/1998	EC	Summary
Committee draft report		PE229.841	12/04/1999	EP	
Joint text approved by Conciliation Committee co-chairs		3607/1999	13/04/1999	CSL/EP	
Report tabled for plenary by Parliament delegation to Conciliation Committee, 3rd reading		A4-0225/1999 OJ C 279 01.10.1999, p. 0010	19/04/1999	EP	
Text adopted by Parliament, 3rd reading		T4-0402/1999 OJ C 279 01.10.1999, p. 0163-0196	05/05/1999	EP	Summary
Follow-up document		COM(2008)0393	27/06/2008	EC	Summary

Additional information

European Commission

[EUR-Lex](#)

Final act

[Directive 1999/41](#)
[OJ L 172 08.07.1999, p. 0038](#) Summary

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

This proposal aimed to amend Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, with a view to removing from its annex various products for which the directive provided for the subsequent adoption of specific directives. In addition to infant formulae and follow-on formulae, which were already covered by the specific Directive 91/321/EEC, products that no longer had any need to be on the list were removed: - low-sodium foods, including low-sodium or sodium-free dietary salts; - gluten-free foods; - foods intended to meet the expenditure of intense muscular effort (sport); - foods for diabetics; The following foods remained on the list: - cereal-based foods and other baby foods; - foods for weight control diets; - foods for special medical purposes. ?

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

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Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

In adopting the report by Mrs Ulla SANDBAEK (EDN), the European Parliament approved the proposal for a directive with the following amendments: - the addition to Annex I to Directive 89/398/EEC of new groups of foodstuffs for particular nutritional uses for which specific provisions would be laid down in specific directives, namely foods for diabetics and gluten-free foods; - the Commission's obligation to submit by 1 June 1996 a directive amending Directive 91/321/EEC which would set out the rules governing the use of foodstuffs from organic farming in the manufacture of foods for babies and infants, the methods of processing which preserve the quality of products and do not introduce

harmful substances and the rigorous controls to ensure that there are no residues; - the Commission shall, within 12 months of the adoption of the directive, lay down special provisions on labelling for gluten-free foods, low-sodium foods and foods intended for diabetics. ?

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

The Commission's amended proposal took over the European Parliament's amendments concerning: - the introduction of a new recital referring to a "modus vivendi" between the EP, the Council and the Commission; - the inclusion of foodstuffs for diabetics in the groups of foods listed in Annex I for which specific provisions would be laid down by specific directives; - the definition of the conditions for use of the terms low-sodium foods, low-sodium, sodium-free and gluten-free where permitted by scientific data; - the reminder in the recitals that it was still possible to harmonise other rules applicable to other groups of foodstuffs for particular nutritional uses. However, the Commission did not take over the amendments concerning: - the inclusion of low-sodium and gluten-free foods in the groups of foods listed in Annex I for which specific directives should be adopted; - the level of pesticides and residues in infant formulae and follow-on formulae; - the inclusion of a paragraph indicating that the new groups of foodstuffs intended for particular nutritional uses could be added to Annex I; - the creation of a new Annex Ia to include authorised claims relating to foodstuffs intended for particular nutritional uses. ?

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

The Council's common position differs substantially from the Commission's proposal but takes into consideration, on several points, suggestions made and concerns expressed by Parliament. Thus, the Council adopted the amendment stipulating that the aims of harmonizing national provisions on foodstuffs intended for particular nutritional uses were to protect the consumer on the one hand, and on the other, to respect free movement of goods. The common position replaces the category of foods for diabetics with 'sports' foods in the list of foods for weight control which will be provided for in specific directives. Moreover, as requested by Parliament, it indicates that the adoption of a specific directive on diabetic foods will be subject to the conclusions of a Commission report, to be presented to the Council and Parliament, on whether there should be special provisions for this group of products. The common position does not include the category of gluten-free foods. However, the Council takes some of Parliament's wishes into consideration by laying down specific provisions on labelling for gluten-free foodstuffs and low-sodium foods. Finally, as regards foodstuffs intended for young children, the Council accepted, in principle, the substance of the amendments relating to the use of no harmful substances. ?

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

The Commission considers that its own original proposal would have best responded to the decisions taken by the European Council in December 1992. The common position adopted did not fully attain the original goal of simplifying the relevant legislation. Furthermore, the unequal treatment of two contentious groups of products, namely food for diabetics and 'sports' foods, was neither scientifically sound nor politically balanced. Consequently, the Commission was not able to support the common position. ?

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

The Committee adopted amendments to the common position of the Council on a directive covering a number of special directives relating to food intended for particular nutritional uses. The rapporteur is Mrs Ulla SANDBAEK (I-EDN, Dk). Thus the committee has rejected the Council's wish that a special directive be adopted governing foods intended to take account of intense muscular effort, especially by sportsmen. Members pointed out that it was difficult to define what constituted a "sportsman". Moreover, nutritional requirements might differ considerably from one sport to another, eg pole vaulting as opposed to swimming. Special foods for sportsmen were of no significant advantage and could cost up to three times as much as the equivalent ordinary food. Otherwise, the committee accepted the common position (co-decision, second reading) on a proposal for a directive amending framework directive 89/398/EEC on food for particular nutritional uses. In accordance with the wishes of the 1992 European Council in Edinburgh for the simplification of food legislation, the aim is to whittle down the number of specific food directives required over and above the framework directive. As a result, the common position provides for a limited number of specific directives: for infant formulae and follow-on formulae, baby foods, foods for weight reduction and dietary foods for special medical purposes. In addition, the adoption of a special directive on foods for diabetics - as requested by Parliament at first reading - will depend upon the conclusions of a Commission report that is being prepared. Furthermore, the Council has taken account of Parliament's request for a special directive on gluten-free foods by laying down special provisions on labelling for such foods. ?

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

Commissioner Brittan said that the Commission did not agree with the solution adopted in the Council's common position according to which sports food should be covered by a specific directive. He also stated that he could not accept Amendment No 3 on the obligation to add the term "pesticide-free", among others, to baby food as this subject should be regulated elsewhere.

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

In adopting the recommendation for the second reading by Mrs Ulla SANDBAEK (I-EDN, DK) Parliament approved subject to amendments the Council's common position amending a 1989 directive on foodstuffs intended for particular nutritional uses. The rapporteur's amendments seek to delete the reference to specific provision for foods for those engaged in sporting activity. ?

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

The Commission rejects Parliament's amendment aiming to introduce a requirement that baby foods and cereal-based foods be free of pesticides. The Commission considers that this matter should be dealt with in a specific directive to be adopted by the Commission as stipulated in Article 4 of Directive 89/398/EEC. ?

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

Food for babies, infants and young children should be as free as possible from pesticide residues: this has been the firm stance of Parliament throughout protracted discussions with the Council and Commission on a Commission proposal streamlining existing Community legislation on food for special nutritional purposes. These talks ended successfully when the joint Parliament/Council Conciliation Committee adopted the proposal without debate. At its second reading of the proposal on 18 December 1997 Parliament adopted a single amendment to the Council's common position. This amendment insisted that specific provisions be drawn up to ensure that processed cereal-based baby foods be free of pesticides. As a result of parliamentary pressure throughout the talks, the Commission has now secured the agreement of the Member States to two Commission directives which stipulate that pesticide residues not only in cereal-based baby foods but also in infant formulae must not exceed 0.01 mg/kg (which, in practice, is said to be the minimum detectable level). As a result, Parliament was able to withdraw its second-reading amendment.?

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

The Decision on the joint text, approved by the Conciliation Committee, for a European Parliament and Council Directive on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses was approved by the Parliament (Rapporteur : Ms. Ulla SANDBAEK (EDN, DK)).?

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

PURPOSE : to amend Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses. COMMUNITY MEASURE : Directive 1999/41/EEC of the European Parliament and of the Council. CONTENT : Directive 89/398/EEC put in place common rules concerning labelling, the presentation and the advertising of foodstuffs. The Annex to this Directive lists nine groups of foodstuffs for particular nutritional uses for which specific provisions will be laid down by specific Directives to be adopted by the Commission following a Committee regulation procedure. Taking into account the experience gained since the adoption of this Directive and in light of the conclusions of the Edinburgh Summit (which had recommended a simplification of the legislation), the product categories necessitating particular measures amount to five, in the terms of the new Directive. It concerns the following categories : - infant formulae and follow-on formulae ; - processed cereal-based foods and baby foods for infants and young children; - food intended for the use in energy-restricted diets for weight reduction; - dietary foods for special medical purposes; - foods intended to meet the expenditure of intense muscular effort, especially for sportsmen. As for foods for persons suffering from carbohydrate-metabolism disorders (diabetes), a decision on whether to introduce specific measures will only be taken after a transition period of no more than three years starting from 07/06/1999. ENTRY INTO FORCE : 08/07/2000. DEADLINE SET FOR THE TRANSPOSITION : the measures shall be applied in such a way as to : permit trade in products complying with this Directive no later than 08/07/2000; and to prohibit trade in products not complying with this Directive by 08/01/2001.?

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

In accordance with Article 9(5) of Council Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (dietetic foods), the European Commission is required to send a report to the European Parliament and the Council on the implementation of Article 9 of the Directive.

In 1994, the Commission sent to the Council a report on this issue under the original provisions of Article 9(5) of the Directive. The report covered the notifications received from the entry into force of the Directive in 1989 up to 1994. In 1999, Directive 1999/41/EC amended the provisions of Article 9(5), requiring regular reports on the implementation of the Article to be sent to the European Parliament and the Council.

To enable the Commission to report on the implementation of this Article, the Member States were asked in 2002 and 2006 by the Commission services to provide information on: i) the number of food products that have been notified under Article 9 to their competent authority; ii) details of the particular nutritional uses of the notified products. The Member States were asked to indicate, when possible, if the notifications were related to the first time of placing a product on the market or if the products had been previously notified in another Member State.

This report integrates the information provided by Member States in 2002 and 2006 and covers reported notifications received by Member States up to the end of 2005. This time limit was requested by the Commission services. However, subsequently the preparation of the report was coupled with the preparation of the report on foods for people with carbohydrate-metabolism disorders (diabetes) and the reflection on the need for a global revision of Directive 89/398/EEC (including the implementation of Article 9). Such overall consideration of the issues took more time than expected but allowed for a more complete overview of the relevant sector.

The report recalls that the provisions of Article 9 aim at facilitating the official monitoring of the products placed on the market. But, as a general comment, the majority of the Member States consider that the notification system should be rationalised to ensure more harmonised implementation of the provisions of this article across the EU. Categories of products such as "gluten-free" and "lactose-free", which represent a substantial proportion of the notifications, will be regulated through specific rules for the use of such terms as provided for in Directive

89/398/EEC on dietetic foods (Article 4a) and Regulation 1924/2006 on nutrition and health claims made on foods (recital 22). Consequently, only the remaining products for which specific rules cannot be laid down because they are innovative products or because they are not part of a generally recognised category of food will be covered by the provisions of Article 9.

Inconsistencies may arise from different interpretations of the definition of "foodstuffs for particular nutritional uses" in Article 1 of Directive 89/398/EEC on dietetic foods, which has different elements and appears to be open to different interpretations by the authorities.

The provisions in Article 1 of Directive 89/398/EEC on dietetic foods indicate that, in addition to being aimed at certain categories of persons, dietetic foods have to be, owing to their special composition or manufacturing process, clearly distinguishable from foodstuffs for normal consumption. This report shows that this definition is not uniformly interpreted among the Member States and therefore agreement on the scope of application needs to be sought. This would also help to clarify the differences in the scope of application between different pieces of legislation such as Directive 2002/46/EC on food supplements and Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (fortified foods).

In the light of these considerations it becomes clear that revision of Article 9, together with revision of other relevant articles, as appropriate, would be required for more effective and harmonised implementation of the dietetic food legislation.