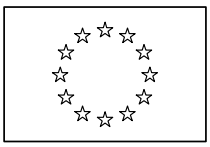

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 22.4.2004
COM(2004) 290 final

2004/0090 (COD)

C6-0035/04

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on foodstuffs intended for particular nutritional uses

(Codified version)

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. In the context of a people's Europe, the Commission attaches great importance to simplifying and clarifying Community law so as to make it clearer and more accessible to the ordinary citizen, thus giving them new opportunities and the chance to make use of the specific rights it gives him.

   This aim cannot be achieved so long as numerous provisions that have been amended several times, often quite substantially, remain scattered, so that they must be sought partly in the original instrument and partly in later amending ones. Considerable research work, comparing many different instruments, is thus needed to identify the current rules.

   For this reason a codification of rules that have frequently been amended is also essential if Community law is to be clear and transparent.

2. On 1 April 1987 the Commission therefore decided[1] to instruct its staff that all legislative measures should be codified after no more than ten amendments, stressing that this was a minimum requirement and that departments should endeavour to codify at even shorter intervals the texts for which they are responsible, to ensure that the Community rules were clear and readily understandable.

3. The Conclusions of the Presidency of the Edinburgh European Council (December 1992) confirmed this[2], stressing the importance of codification as it offers certainty as to the law applicable to a given matter at a given time.

   Codification must be undertaken in full compliance with the normal Community legislative procedure.

   Given that no changes of substance may be made to the instruments affected by codification, the European Parliament, the Council and the Commission have agreed, by an interinstitutional agreement dated 20 December 1994, that an accelerated procedure may be used for the fast track adoption of codification instruments.

4. The purpose of this proposal is to undertake a codification Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses[3]. The new Directive will supersede the various acts incorporated in it[4]; this proposal fully preserves the content of the acts being codified and hence does no more than bring them together with only such formal amendments as are required by the codification exercise itself.

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1 COM(87) 868 PV.

2 See Annex 3 to Part A of such Conclusions.

3 Carried out pursuant to the Communication from the Commission to the European Parliament and the Council – Codification of the Acquis communautaire, COM(2001) 645 final.

4 See Annex II, Part A of this proposal.

5. The codification proposal was drawn up on the basis of a preliminary consolidation, in all official languages, of Directive 89/398/EEC and the instruments amending it, carried out by the Office for Official Publications of the European Communities, by means of a data-processing system. Where the Articles have been given new numbers, the correlation between the old and the new numbers is shown in a table contained in Annex III to the codified Directive.

↓ 89/398/EEC (adapted)

2004/0090 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on foodstuffs intended for particular nutritional uses

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article ⌦ 95 ⌫ thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[2],

Whereas:

↓

(1) Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses[3] has been substantially amended several times[4]. In the interests of clarity and rationality the said Directive should be codified.

↓ 89/398/EEC Recital 2 (adapted)

(2) ⌦ D ⌫ifferences between national laws relating to foodstuffs for particular nutritional uses impede their free movement, may create unequal conditions of competition, and thus ⌦ have ⌫ a direct impact on the establishment and functioning of the common market.

1 OJ C

2 OJ C

3 OJ L 186, 30.6.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

4 See Annex II, Part A.

↓ 89/398/EEC Recital 3 (adapted)

(3) The approximation of national laws presuppose ⌦ s ⌫ the drawing-up of a common definition, the determination of measures enabling the consumer to be protected against fraud concerning the nature of these products and the adoption of rules to be complied with in labelling the products in question.

↓ 89/398/EEC Recital 4

(4) The products covered by this Directive are foodstuffs, the composition and preparation of which must be specially designed to meet the particular nutritional requirements of the persons for whom they are mainly intended. It may be necessary, therefore, to provide for derogations from the general or specific provisions applicable to foodstuffs in order to achieve the specific nutritional objective.

↓ 89/398/EEC Recital 5

(5) Although foodstuffs intended for particular nutritional uses which are the subject of specific provisions can be efficiently monitored on the basis of the general rules for monitoring all types of foodstuffs, this is not always the case for those foodstuffs in respect of which no such specific provisions exist.

↓ 89/398/EEC Recital 6

(6) For the latter the usual means available to the monitoring bodies might not in certain cases enable them to check whether a foodstuff actually has the particular nutritional properties attributed to it. It is necessary therefore to provide that, where necessary, the person responsible for placing that foodstuff on the market should assist the monitoring body in carrying out its activities.

↓ 89/398/EEC Recital 8 (adapted)

(7) ⌦ Specific provisions applicable to certain groups of foodstuffs should be laid down by means of specific Directives. ⌫

↓ 96/84/EC Recital 4 (adapted)

(8) A procedure ⌦ should ⌫ be laid down which allows the foodstuffs resulting from technological innovations to be placed on the market on a temporary basis in order that proper benefit may be derived from the fruits of industry research pending the amendment of the specific Directive concerned.

↓ 96/84/EC Recital 5 (adapted)

(9) However, on the grounds of consumer health protection, marketing authorisation may be granted only after consultation of the ⌦ European Food Safety Authority ⌫ .

↓ 1999/41/EC Recital 5 (adapted)

(10) ⌦ Since it ⌫ is not clear whether an adequate basis exists for specific provisions to be adopted for the group of foods intended for persons suffering from carbohydrate metabolism disorders (diabetes) ⌦ , the Commission should be allowed to adopt or propose the relevant provisions in a later stage, after consultation of the European Food Safety Authority ⌫ .

↓ 1999/41/EC Recital 7

(11) It is still possible to harmonise, at Community level, rules applicable to other groups of foodstuffs for particular nutritional uses, in the interests of consumer protection and the free movement of such foodstuffs.

↓

(12) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[5].

(13) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex II, Part B,

↓ 89/398/EEC

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns foodstuffs for particular nutritional uses.

↓ 89/398/EEC (adapted)

2. Foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs

[5] OJ L 184, 17.7.1999, p. 23.

for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.

⌦ 3. ⌫ A particular nutritional use must fulfil the particular nutritional requirements:

⌦ (a) ⌫ of certain categories of persons whose digestive processes or metabolism are disturbed; or

⌦ (b) ⌫ of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or

⌦ (c) ⌫ of infants or young children in good health.

Article 2

1. The products referred to in Article ⌦ 1(3)(a) and (b) ⌫ may be characterised as 'dietetic' or 'dietary'.

↓ 89/398/EEC

2. In the labelling, presentation and advertising of foodstuffs for normal consumption the following shall be prohibited:

(a) the use of the adjectives 'dietetic' or 'dietary' either alone or in conjunction with other words, to designate these foodstuffs;

(b) all other markings or any presentation likely to give the impression that one of the products referred to in Article 1 is involved.

↓ 89/398/EEC (adapted)

However, in accordance with provisions to be adopted according to the procedure ⌦ referred to ⌫ in Article ⌦ 15(2)⌫ , it shall be possible for foodstuffs for normal consumption which are suitable for a particular nutritional use to indicate such suitability.

⌦ Such ⌫ provisions may lay down the arrangements for indicating this suitability.

↓ 89/398/EEC

Article 3

1. The nature or composition of the products referred to in Article 1 must be such that the products are appropriate for the particular nutritional use intended.

2. The products referred to in Article 1 must also comply with any mandatory provisions applicable to foodstuffs for normal consumption, save as regards changes made to them to ensure their conformity with the definitions given in Article 1.

↓ 89/398/EEC (adapted)

Article 4

1. The specific provisions applicable to the groups of ⌦ foodstuffs ⌫ for particular nutritional uses appearing in Annex I shall be laid down by means of specific Directives.

Such specific Directives may cover in particular:

(a) essential requirements as to the nature or composition of the products;

(b) provisions regarding the quality of raw materials;

(c) hygiene requirements;

(d) permitted changes within the meaning of Article 3(2);

(e) a list of additives;

(f) provisions regarding labelling, presentation and advertising;

(g) sampling procedures and methods of analysis necessary for checking compliance with the requirements of the specific Directives.

Such specific Directives shall be adopted:

– in the case of point (e), in accordance with the procedure laid down in Article ⌦ 95 of the Treaty ⌫ ,

– in the case of the other points, in accordance with the procedure ⌦ referred to ⌫ in Article ⌦ 15(2) of this Directive ⌫ .

Provisions likely to have an effect on public health shall be adopted after consultation of the ⌦ European Food Safety Authority. ⌫

↓ 96/84/EC Art. 1 (adapted)

⌦ 2. ⌫ To enable foodstuffs intended for particular nutritional uses and resulting from scientific and technological progress to be placed on the market rapidly, the Commission may, after consulting the ⌦ European Food Safety Authority ⌫ and in accordance with the procedure ⌦ referred to ⌫ in Article ⌦ 15(2)⌫, authorise for a two-year period the placing on the market of foodstuffs which do not comply with the rules as to composition laid down by the specific directives ⌦ for groups of foodstuffs for particular nutritional uses ⌫ referred to in Annex I.

If necessary, the Commission may add in the authorisation decision labelling rules relating to the change in composition.

↓ 89/398/EEC (adapted)

⌦ 3. ⌫ A list of substances with specific nutritional purposes such as vitamins, mineral salts, amino acids and other substances intended to be added to foodstuffs intended for particular nutritional uses, together with the purity criteria applicable to them, and, where appropriate, the conditions under which they should be used, shall be adopted in accordance with the procedure ⌦ referred to ⌫ in Article ⌦ 15(2) ⌫.

↓ 1999/41/EC Art. 1 pt. 1 (adapted)

Article 5

Rules for the use of terms concerning the reduction or absence of sodium or salt (sodium chloride, table salt) content ⌦ or ⌫ the absence of gluten, which may be used to describe the products referred to in Article 1, shall be adopted in accordance with the procedure ⌦ referred to ⌫ in Article ⌦ 15(2) ⌫ .

Article 6

Before 8 July 2002, the Commission shall, after consulting the ⌦ European Food Safety Authority ⌫ , present to the European Parliament and to the Council a report on the desirability of special provisions for foods for persons suffering from carbohydrate metabolism disorders (diabetes).

In the light of the conclusions of this report, the Commission shall either, in accordance with the procedure ⌦ referred to ⌫ in Article ⌦ 15(2) ⌫ , proceed with the preparation of the special provisions concerned or shall present, in accordance with the procedure laid down in Article 95 of the Treaty, any appropriate proposals for amendments to this Directive.

↓ 89/398/EEC Art. 5 (adapted)

Article 7

Conditions under which reference may be made in labelling, presentation and advertising to a diet or to a category of persons for which a product referred to in Article 1 is intended may be adopted in accordance with the procedure ⌦ referred to ⌫ in Article ⌦ 15(2) ⌫ .

↓ 89/398/EEC Art. 6 (adapted)

Article 8

1. The labelling and the labelling methods used, the presentation and the advertising of the products referred to in Article 1 ⌦ shall ⌫ not attribute properties for the prevention, treatment or cure of human disease to such products or imply such properties.

   Derogations from the first subparagraph may be provided for in accordance with the procedure ⌦ referred to ⌫ in Article ⌦ 15(2) ⌫ in exceptional and clearly defined cases. Derogations may be continued until that procedure has been completed.

2. Paragraph 1 shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy.

↓ 89/398/EEC Art. 7 (adapted)

Article 9

1. ⌦ Directive 2000/13/EC of the European Parliament and of the Council ⌫[6] , shall apply to the products referred to in Article 1 ⌦ of this Directive ⌫ , under the conditions set out ⌦ in paragraphs 2, 3 and 4 of this Article ⌫ .

2. The designation under which a product is sold shall be accompanied by an indication of its particular nutritional characteristics. However, in the case of the products referred to in Article ⌦ 1(3)(c) ⌫ , this reference shall be replaced by a reference to the purpose for which they are intended.

3. The labelling of products for which no specific Directive has been adopted in accordance with Article 4 shall also include:

   (a) the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product its particular nutritional characteristics;

   (b) the available energy value expressed in kilojoules and kilocalories and the carbohydrate, protein and fat content per 100 grams or 100 millilitres of the product as marketed and, where appropriate, per specified quantity of the product as proposed for consumption.

   If, however, the energy value is less than 50 kilojoules (12 kilocalories) per 100 grams or 100 millilitres of the product as marketed, these particulars may be replaced either by the words ‘energy value less than 50 kilojoules (12 kilocalories)

[6] ⌦ OJ L 109, 6.5.2000, p. 29 ⌫.

per 100 grams' or by the words 'energy value less than 50 kilojoules (12 kilocalories) per 100 millilitres'.

4. The particular labelling requirements for those products for which a specific Directive has been adopted shall be laid down in that Directive.

↓ 89/398/EEC Art. 8 (adapted)

Article 10

1. The products referred to in Article 1 shall only be allowed on the retail market in pre-packaged form, and the packaging shall completely cover the products.

2. Member States may permit derogations from ⌦ paragraph 1 ⌫ for purposes of the retail trade provided that the product is accompanied by the particulars provided for in Article ⌦ 9 ⌫ at the time when it is put on sale.

↓ 89/398/EEC Art. 9 (adapted)

Article 11

⌦ 1. ⌫ To permit efficient official monitoring of foodstuffs intended for a particular nutritional use which do not belong to one of the groups listed in Annex I the following specific provisions shall apply:

⌦ (a)⌫ ⌦ w ⌫hen a product is placed on the market for the first time the manufacturer or, where a product is manufactured in a third State, the importer, shall notify the competent authority of the Member State where the product is being marketed by forwarding it a model of the label used for the product ⌦ ; ⌫

⌦ (b) ⌫ ⌦ w ⌫here the same product is subsequently placed on the market in another Member State the manufacturer or, where appropriate, the importer, shall provide the competent authority of that Member State with the same information, together with an indication of the recipient of the first notification ⌦ ; ⌫

⌦ (c) ⌫ ⌦ w ⌫here necessary, the competent authority shall be empowered to require the manufacturer or, where appropriate, the importer, to produce the scientific work and the data establishing the product's compliance with Article 1(2) together with the information provided for in Article ⌦ 9 ⌫(3)(a). If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

⌦ 2. ⌫ Member States shall communicate to the Commission the identity of the competent authorities within the meaning of ⌦ paragraph 1 ⌫ and any other useful information on them.

The Commission shall publish this information in the *Official Journal of the European* ⌦ *Union* ⌫ .

⌦ 3. ⌫ Detailed rules for implementing paragraphs ⌦ 1 and 2 ⌫ may be adopted in accordance with the procedure ⌦ referred to ⌫ in Article ⌦ 15(2) ⌫.

↓ 1999/41/EC Art. 1 pt. 2 (adapted)

⌦ 4. ⌫ Before 8 July ⌦ 2005 ⌫ and every three years thereafter, the Commission shall send the European Parliament and the Council a report on the implementation of this Article.

↓ 89/398/EEC Art. 10

Article 12

1. Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and where appropriate, with Directives adopted in implementation of this Directive.

2. Paragraph 1 shall not affect national provisions which are applicable in the absence of Directives adopted in implementation of this Directive.

↓ 89/398/EEC Art. 11 (adapted)

Article 13

1. Where a Member State has detailed grounds for establishing that a foodstuff intended for a particular nutritional use which does not belong to one of the groups listed in Annex I does not comply with Article 1(2) ⌦ and (3) ⌫ or endangers human health, albeit freely circulating in one or more Member States, that Member State may temporarily suspend or restrict trade in that product within its territory. It shall immediately inform the Commission and the other Member States thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the grounds adduced by the Member State concerned, consult the Member States within the Committee ⌦ referred to in Article 15(1) ⌫ , and shall then deliver its opinion without delay and take appropriate measures.

3. If the Commission considers that the national measure must be dispensed with or modified, it shall ⌦ adopt the appropriate measures in accordance with ⌫ the procedure ⌦ referred to ⌫ in Article ⌦ 15(2) ⌫ .

↓ 89/398/EEC Art. 12 (adapted)

Article 14

1. Where a Member State, as a result of new information or of a reassessment of existing information made since one of the specific Directives was adopted, has detailed grounds for establishing that a foodstuff intended for particular nutritional uses endangers human health although it complies with the relevant specific Directive, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

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 Committee ⌦ referred to in Article 15(1) ⌫ , and shall then deliver its opinion without delay and take appropriate measures.

3. If the Commission considers that amendments to this Directive or to the specific Directives are necessary in order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall ⌦ adopt those amendments in accordance with ⌫ the procedure ⌦ referred to ⌫ in Article ⌦ 15(2) ⌫ . The Member State which has adopted safeguard measures may in that event retain them until the amendments have been adopted.

↓ 1882/2003 Art. 3 and Annex III, pt. 15 (adapted)

Article 15

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 ⌦ of the European Parliament and of the Council ⌫ [7], hereinafter referred to as "the Committee".

2. Where reference is made to this ⌦ paragraph ⌫ , Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

   The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

[7] OJ L 31, 1.2.2002, p. 1.

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Article 16

Directive 89/398/EEC, as amended by the acts listed in Annex II, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex II, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex III.

Article 17

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

↓ 89/398/EEC Art. 16

Article 18

This Directive is addressed to the Member States.

Done at Brussels, […]

For the European Parliament	*For the Council*
The President	*The President*
[...]	*[...]*

↓ 1999/41/EC Art. 1 pt. 3 (adapted)

ANNEX I

⌦ A. ⌫ Groups of foodstuffs for particular nutritional uses for which specific provisions will be laid down by specific Directives[1]:

1. infant formulae and follow-on formulae

2. processed, cereal-based foods and baby foods for infants and young children

3. food intended for use in energy-restricted diets for weight reduction

4. dietary foods for special medical purposes

5. foods intended to meet the expenditure of intense muscular effort, especially for sportsmen.

⌦ B. ⌫ Groups of foodstuffs for particular nutritional uses for which specific provisions will be laid down by a specific Directive[2], dependent on the outcome of the procedure described in Article ⌦ 6 ⌫ :

Foods for persons suffering from carbohydrate metabolism disorders (diabetes).

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[1] It is understood that products already on the market when Directive is adopted will not be affected by it.

[2] It is understood that products already on the market when Directive is adopted will not be affected by it.

↑

ANNEX II

Part A

Repealed Directive with its successive amendments
(referred to in Article 16)

Council Directive 89/398/EEC	(OJ L 186, 30.6.1989, p. 27)
Directive 96/84/EC of the European Parliament and of the Council	(OJ L 48, 19.2.1997, p. 20)
Directive 1999/41/EC of the European Parliament and of the Council	(OJ L 172, 8.7.1999, p. 38)
Regulation (EC) No 1882/2003 of the European Parliament and of the Council	(OJ L 284, 31.10.2003, p. 1)

Part B

List of time limits for transposition into national law
(referred to in Article 16)

Directive	Time-limits for transposition	Permission of trade in products complying with this Directive	Prohibition of trade in products not complying with this Directive
89/398/EEC		16 May 1990	16 May 1991[1]
96/84/EC	30 September 1997		
1999/41/EC	8 July 1999	8 July 2000	8 January 2001

[1] In accordance with Article 15 of Directive 89/398/EEC:
"1. Member states shall amend their laws, regulations and administrative provisions in such way as:
- to permit trade in products complying with this Directive not later than 16 May 1990,
- to prohibit trade in products not complying with this Directive with effect from 16 May 1991.
They shall forthwith inform the Commission thereof.
2. Paragraph 1 shall not affect those national provisions which in the absence of the Directives referred to in Article 4 apply to certain groups of foodstuffs intended for particular nutritional uses."

ANNEX III

CORRELATION TABLE

Directive 89/398/EEC	This Directive
Article 1(1)	Article 1(1)
Article 1(2)(a)	Article 1(2)
Article 1(2)(b)	Article 1(3)
Article 1(2)(b)(i), (ii) and (iii)	Article 1(3)(a), (b) and (c)
Article 2(1)	Article 2(1)
Article 2(2)	Article 2(2) first subparagraph
Article 2(3)	Article 2(2) second and third subparagraphs
Article 3	Article 3
Article 4(1)	Article 4(1)
Article 4(1a)	Article 4(2)
Article 4(2)	Article 4(3)
Article 4a	Article 5
Article 4b	Article 6
Article 5	Article 7
Article 6	Article 8
Article 7	Article 9
Article 8	Article 10
Article 9 introductory words	Article 11(1) introductory words
Article 9 points 1, 2 and 3	Article 11(1)(a), (b) and (c)
Article 9 point 4, first and second sentence	Article 11(2)
Article 9 point 4, third sentence	Article 11(3)
Article 9 point 5	Article 11(4)
Article 10	Article 12
Article 11	Article 13

Article 12	Article 14
Article 13	Article 15
Articles 14 and 15	–
–	Articles 16 and 17
Article 16	Article 18
Annex I	Annex I
Annex II	–
–	Annexes II and III