

DIRECTIVES

DIRECTIVE 2009/39/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 6 May 2009

on foodstuffs intended for particular nutritional uses

(recast)

(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⁾. Since further amendments are to be made, it should be recast in the interests of clarity.

(2) Differences 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 functioning of the internal market.

(3) The approximation of national laws presupposes 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.

(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.

(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.

(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.

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

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

⁽¹⁾ OJ C 211, 19.8.2008, p. 44.

⁽²⁾ Opinion of the European Parliament of 23 September 2008 (not yet published in the Official Journal) and Council Decision of 30 March 2009.

⁽³⁾ OJ L 186, 30.6.1989, p. 27.

⁽⁴⁾ See Annex II, Part A.

- (9) 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 at a later stage, after consultation of the European Food Safety Authority.
- (10) 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.
- (11) The drawing-up of specific Directives implementing the basic principles of Community rules and amendments thereto are implementing measures of a technical nature. Their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.
- (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 ⁽¹⁾.
- (13) In particular, the Commission should be empowered to adopt certain specific Directives, a list of substances with specific nutritional purposes and of 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, provisions rendering it possible to indicate on foodstuffs for normal consumption that they are suitable for a particular nutritional use, special provisions for foods for persons suffering from carbohydrate metabolism disorders (diabetes), rules for the use of terms concerning the reduction or absence of sodium or salt content or the absence of gluten, which may be used to describe the products, as well as conditions under which reference may be made in labelling, presentation and advertising to a diet or to a category of persons. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (14) When, on imperative grounds of urgency, the normal time limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption and amendment of a list of substances with specific nutritional purposes and of 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, as well as for adoption of amendments to this Directive or to specific Directives when it is established that a foodstuff intended for a particular nutritional use endangers human health although it complies with the relevant specific Directive.
- (15) The new elements introduced into this Directive only concern the committee procedures. They therefore do not need to be transposed by the Member States.
- (16) This Directive should be without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and application of the Directives set out in Annex II, Part B,
- HAVE ADOPTED THIS DIRECTIVE:
- Article 1*
1. This Directive concerns foodstuffs for particular nutritional uses.
2. Foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs 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 shall 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 covered by points (a) and (b) of Article 1(3) may be characterised as 'dietetic' or 'dietary'.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

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 those 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.

However, in accordance with provisions to be adopted by the Commission, 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 that suitability.

The measures referred to in the second subparagraph, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3).

Article 3

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

2. The products referred to in Article 1 shall 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.

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, by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3).

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

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, 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. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3).

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

3. The Commission shall adopt a list of substances with specific nutritional purposes such as vitamins, mineral salts, amino acids and of 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.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3).

On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 15(4).

Article 5

The Commission shall adopt 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.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3).

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 that report, the Commission shall either:

- (a) proceed with the preparation of the special provisions concerned; or
- (b) present, in accordance with the procedure laid down in Article 95 of the Treaty, any appropriate proposals for amendments to this Directive.

The measures referred to in point (a), designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3).

Article 7

The Commission may adopt 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.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3).

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 to such products for the prevention, treatment or cure of human disease or imply such properties.

Derogations from the first subparagraph may be provided for in exceptional and clearly defined cases. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3). 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.

Article 9

1. Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs⁽¹⁾ 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 covered by point (c) of Article 1(3), that 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, those particulars may be replaced either by the words 'energy value less than 50 kilojoules (12 kilocalories) per 100 grams' or by the words 'energy value less than 50 kilojoules (12 kilocalories) per 100 millilitres'.

⁽¹⁾ OJ L 109, 6.5.2000, p. 29.

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

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.

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) when a product as referred to above 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) where 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) where 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) and (3) together with the information provided for in point (a) of Article 9(3). 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 paragraph 2 may be adopted in accordance with the regulatory procedure referred to in Article 15(2).

4. Every three years, and for the first time before 8 July 2002, the Commission shall send the European Parliament and the Council a report on the implementation of this Article.

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.

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, 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 the national measure must be dispensed with or modified, it shall adopt the appropriate measures in accordance with the regulatory procedure referred to in Article 15(2).

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 a particular nutritional use 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.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 15(4).

The Member State which has adopted safeguard measures may in that event retain them until the amendments have been adopted.

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⁽¹⁾.

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. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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 and application of the Directives set out in Annex II, Part B.

References made 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 20th day following its publication in the *Official Journal of the European Union*.

Article 18

This Directive is addressed to the Member States.

Done at Strasbourg, 6 May 2009.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
J. KOHOUT

⁽¹⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

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 ⁽¹⁾, 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 a specific Directive is adopted will not be affected by it.

ANNEX II

PART A

**Repealed Directive with list of 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)

point 15 of Annex III only

PART B

**Time limits for transposition into national law and application
(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 ⁽¹⁾	16 May 1991 ⁽¹⁾
96/84/EC	30 September 1997	—	—
1999/41/EC	8 July 2000	8 July 2000 ⁽²⁾	8 January 2001 ⁽²⁾

⁽¹⁾ In accordance with Article 15 of Directive 89/398/EEC:

‘1. Member States shall amend their laws, regulations and administrative provisions in such a 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.’

⁽²⁾ In accordance with Article 2 of Directive 1999/41/EC:

‘Member States shall bring into force the laws, regulations and administrative provisions necessary for them to comply with this Directive not later than 8 July 2000. They shall forthwith inform the Commission thereof.

These measures shall be applied in such a way as to:

- permit trade in products complying with this Directive by 8 July 2000,
- prohibit trade in products not complying with this Directive by 8 January 2001.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.’

ANNEX III

CORRELATION TABLE

Directive 89/398/EEC	This Directive
Article 1(1)	Article 1(1)
Article 1(2) point (a)	Article 1(2)
Article 1(2) point (b)	Article 1(3)
Article 1(2) point (b)(i), (ii) and (iii)	Article 1(3) points (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 2(2), fourth subparagraph
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(1) and (2)	Article 15(1) and (2)
Article 13(3)	—
—	Article 15(3) and (4)
Articles 14 and 15	—
—	Articles 16 and 17
Article 16	Article 18
Annex I	Annex I
Annex II	—
—	Annexes II and III