COUNCIL DIRECTIVE

of 3 May 1989

on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses

(89/398/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Council Directive 77/94/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (4), as last amended by Directive 85/7/EEC (5), has been amended on a number of occasions; whereas, on the occasion of new amendments, the said Directive should, for reasons of clarity, be redrafted;

Whereas the adoption of Directive 77/94/EEC was justified by the fact that the differences between national laws relating to foodstuffs for particular nutritional uses impeded their free movement, may have created unequal conditions of competion, and thus had a direct impact on the establishment and functioning of the common market;

Whereas the approximation of national laws presupposed, in an initial stage, 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;

Whereas 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; whereas it may be necessary, therefore, to provide for derogations to the general or specific provisions applicable to foodstuffs in order to achieve the specific nutritional objective;

Whereas, 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;

Whereas 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; whereas 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;

Whereas the current state of development of Community rules on additives means that it is not possible, in the framework of this Directive, to adopt provisions on the use of additives in foodstuffs intended for particular nutritional uses if they do not belong to one of the groups mentioned in Annex I; whereas this question should therefore be re-examined in due course;

Whereas the drawing-up of specific Directives implementing the basic principles of Community rules and amendments thereto are implementing measures of a technical nature; whereas their adoption should be entrusted to the Commission in order to simplify and expedite the procedure;

Whereas in all cases where the Council empowers the Commission to implement rules relating to foodstuffs intended for human consumption, provision should be made for a procedure establishing close cooperation between the Member States and the Commission within the Standing Committee for Foodstuffs, set up by Decision 69/414/EEC (6);

Whereas this Directive does not affect the time limits within which the Member States must comply with Directive 77/94/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns foodstuffs for particular nutritional uses.

(1) OJ No C 124, 23. 5. 1986, p. 7, and OJ No C 161, 19. 6. 1987, p. 12.
(2) OJ No C 99, 13. 4. 1987, p. 54, and OJ No C 120, 16. 5. 1989.
(3) OJ No C 328, 22. 12. 1986, p. 9.
(4) OJ No L 26, 31. 1. 1977, p. 55.
(5) OJ No L 2, 3. 1. 1985, p. 22.
(6) OJ No L 291, 19. 11. 1969, p. 9.

2. (a) 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.

(b) A particular nutritional use must fulfil the particular nutritional requirements:

(i) of certain categories of persons whose digestive processes or metabolism are disturbed; or

(ii) 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

(iii) of infants or young children in good health.

Article 2

1. The products referred to in Article 1 (2) (b) (i) and (ii) may be characterized as 'dietetic' or 'dietary'.

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.

3. However, in accordance with provisions to be adopted according to the procedure provided for in Article 13, it shall be possible for foodstuffs for normal consumption which are suitable for a particular nutritional use to indicate such suitability.

The aforesaid provisions may lay down the arrangements for indicating this suitability.

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.

Article 4

1. The specific provisions applicable to the groups of foods 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), by the Council acting in accordance with the procedure laid down in Article 100a,

— in the case of the other points, in accordance with the procedure laid down in Article 13.

Provisions likely to have an effect on public health shall be adopted after consultation of the Scientific Committee for Food, set up by Decision 74/234/EEC [1].

2. 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 laid down in Article 13.

Article 5

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 laid down in Article 13.

[1] OJ No L 136, 20. 5. 1974, p. 1.

Article 6

1. The labelling and the labelling methods used, the presentation and the advertising of the products referred to in Article 1 must 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 laid down in Article 13 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.

Article 7

1. Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [1], as last amended by Directive 89/395/EEC [2], shall apply to the products referred to in Article 1, under the conditions set out below.

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 (2) (b) (iii), 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 must 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) 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.

Article 8

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, however, permit derogations from these provisions for purposes of the retail trade provided that the product is accompanied by the particulars provided for in Article 7 at the time when it is put on sale.

Article 9

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:

1. 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.

2. 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.

3. 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) together with the information provided for in Article 7 (3) (a). If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

4. Member States shall communicate to the Commission the identity of the competent authorities within the meaning of this Article and any other useful information on them.

   The Commission shall publish this information in the *Official Journal of the European Communities*.

   Detailed rules for implementing this paragraph may be adopted in accordance with the procedure laid down in Article 13.

5. Four years after notification of this Directive, the Commission shall send the Council a report on the implementation of this Article, if necessary, together with appropriate proposals.

[1] OJ No L 33, 8. 2. 1979, p. 1.
[2] See page 17 of this Official Journal.

Article 10

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 11

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) 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 Standing Committee for Foodstuffs, 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 initiate the procedure laid down in Article 13 for the adoption of appropriate measures.

Article 12

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 Standing Committee for Foodstuffs, 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 initiate the procedure laid down in Article 13 with a view to adopting those amendments. The Member State which has adopted safeguard measures may in that event retain them until the amendments have been adopted.

Article 13

Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee for Foodstuffs, hereinafter referred to as 'the Committee', either on his own initiative or at the request of the representative of a Member State.

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date on which the matter was referred to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 14

Directive 77/94/EEC is hereby repealed.

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

Article 15

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.

Article 16

This Directive is addressed to the Member States.

Done at Brussels, 3 May 1989.

For the Council

The President

P. SOLBES

ANNEX I

Groups of foods for particular nutritional uses for which specific provisions will be laid down by specific Directives (1)

1. Infant formulae
2. Follow-up milk and other follow-up foods
3. Baby foods
4. Low-energy and energy-reduced foods intended for weight control
5. Dietary foods for special medical purposes
6. Low-sodium foods, including low-sodium or sodium-free dietary salts
7. Gluten-free foods
8. Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen
9. Foods for persons suffering from carbohydrate-metabolism disorders (diabetes)

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

ANNEX II

CORRELATION TABLE

Directive 77/94/EEC	This Directive
Article 1 (1)	Article 1 (1)
Article 1 (2)	Article 2 (2)
Article 1 (3)	—
Article 2 (1)	Article 3 (1)
Article 2 (2) first subparagraph	Article 2 (1)
Article 2 (2) second subparagraph	—
Article 2 (3)	Article 2 (2)
Article 2 (4)	Article 2 (3)
Article 3	Article 3 (2)
—	Article 4
Article 4 (1)	Article 6 (1)
Article 4 (2)	Article 5
Article 4 (3)	Article 6 (2)
Article 5 (1)	Article 7 (1)
Article 5 (2) point (a)	Article 7 (2)
Article 5 (2) points (b) and (c)	Article 7 (3) points (a) and (b)
Article 5 (2) point (d)	—
Article 5 (2) point (e)	Article 7 (4)
Article 5 (3)	—
Article 6	Article 8
—	Article 9
Article 7 (1)	Article 10 (1)
—	Article 10 (2)
Article 7 (2)	—
Article 8	—
—	Article 11
—	Article 12
Article 9	Article 13
Article 10	—
Article 11	—
—	Article 14
Article 12	Article 15
Article 13	Article 16
—	Annex I