COUNCIL DIRECTIVE

of 21 December 1976

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

(77/94/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas the 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 establishment and functioning of the common market;

Whereas the approximation of these laws is therefore necessary;

Whereas this approximation pre-supposes, in an initial stage, the preparation 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, in a subsequent stage, the Council will have to adopt the definitions and determine the particular characteristics applicable to certain groups of these products;

Whereas the word 'dietetic' (or 'dietary') does not have the same accepted meaning in all the Member States; whereas the latter must be able to take into account the customs existing when this Directive is implemented;

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 might be necessary, therefore, to provide for derogations to the general or specific provisions applicable to foodstuffs in order to arrive at the specific nutritional objective;

Whereas the determination of the sampling procedures and methods of analysis for verifying the additives and the composition and manufacturing specifications of the various groups of foodstuffs intended for particular nutritional uses is an implementing measure of a technical nature; whereas its adoption should be entrusted to the Commission in order to simplify and expedite the procedure;

Whereas in all the cases for which the Council confers powers on the Comission for implementing rules laid down in the fields of foodstuffs intended for human consumption, provisions should be made for a procedure for establishing close cooperation between the Member States and the Commission within the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns foodstuffs for particular nutritional uses.

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.

(1) OJ No C 139, 28. 10. 1969, p. 39.
(2) OJ No C 10, 27. 1. 1970, p. 27.

(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 a controlled consumption of certain substances in foodstuffs, or

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

3. The Council, in accordance with the procedure laid down in Article 100 of the Treaty, shall, by means of Directives, adopt the specific provisions applicable to certain groups of products defined in this Article (specific Directives).

Article 2

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 may be characterized as 'dietetic' or 'dietary'.

However, Member States may restrict the use of these adjectives to the products defined in Article 1 (2) (b) (i) or (b) (i) and (ii).

3. In trade in foodstuffs for normal consumption and in advertisements for them, Member States shall prohibit:

(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.

4. However, in accordance with the specific Directives or, in their absence, in accordance with national provisions, 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

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 and provided that these changes are permitted under the specific Directive or, in their absence, under national provisions.

Article 4

1. The label or method of labelling, the presentation and 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.

The specific Directives or, in their absence, national provisions may provide for derogations from the first subparagraph in exceptional and clearly defined cases.

2. The specific Directives or, in their absence, national provisions shall lay down the conditions under which any 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.

3. 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 5

1. The provisions concerning the labelling of foodstuffs in general or of certain specified foodstuffs for normal consumption shall apply to the products referred to in Article 1.

2. The following particulars shall also appear on the labels of the products referred to in Article 1:

(a) the particular nutritional characteristics accompanying the description; however, in the case of the products referred to in Article 1 (2) (b) (iii), this reference may be replaced by a reference to the purpose for which they are intended;