

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 93/74/EEC

of 13 September 1993

on feedingstuffs intended for particular nutritional purposes

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

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

Having regard to the opinion of the European Parliament ⁽²⁾,

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

Whereas feedingstuffs intended for particular nutritional purposes are playing an increasing role in the diet of pet animals; whereas such products are also used in the rearing of productive livestock;

Whereas, in some Member States, feedingstuffs covered by this Directive are already marketed in such a way as to draw the attention of users to their particular composition;

Whereas a common definition should be laid down for the products concerned; whereas that definition must provide that products presented as intended to meet certain specific nutritional needs must have a specific composition and/or be manufactured using special methods; whereas it is essential to establish the principle that such feedingstuffs must be clearly distinguished, in their characteristics and purpose, from both ordinary feedingstuffs and medicated feedingstuffs;

Whereas the composition and preparation of feedingsuffs intended for particular nutritional purposes must be

specially designed to meet the particular nutritional needs of categories of pets or productive livestock whose process of assimilation, absorption or metabolism could briefly be impaired or is temporarily or irreversibly impaired;

Whereas, when rules are being laid down for the marketing of feedingstuffs intended for particular nutritional purposes, care should be taken to ensure that such feedingstuffs have a beneficial effect on the animals which ingest them; whereas feedingstuffs must therefore always be of merchantable quality; whereas they must neither present a hazard for animal or human health or for the environment nor be marketed in a manner liable to mislead;

Whereas this Directive applies without prejudice to other Community provisions on feedingstuffs, and particularly the rules applicable to compound feedingstuffs;

Whereas the user of feedingstuffs intended for particular nutritional purposes needs to be provided with accurate and meaningful information;

Whereas in order to distinguish between the feedingstuffs meeting the criteria laid down in this Directive and other feedingstuffs, a single qualifying expression, 'dietetic', must accompany the description of the feedingstuff;

Whereas, as in the case of ordinary feedingstuffs, at least the levels of analytical constituents having a direct effect on the quality of the feedingstuff should be declared; whereas provision should be made for the declaration of certain additional analytical constituents which give the feedingstuff its dietetic properties;

Whereas all producers of feedingstuffs intended for particular nutritional purposes must have the option of indicating on the label certain particulars useful to the user;

⁽¹⁾ OJ No C 231, 9. 9. 1992, p. 6.

⁽²⁾ OJ No C 21, 25. 1. 1993, p. 73.

⁽³⁾ OJ No C 73, 15. 3. 1993, p. 25.

Whereas it is not necessary for the supply of feedingstuffs intended for particular nutritional purposes to be subject to presentation of a veterinary prescription since these products contain no medicinal substances within the meaning of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products⁽¹⁾, but, to ensure the appropriate use of feedingstuffs with a very specific character, the user should be warned that it is desirable to seek a specialist's opinion before using them;

Whereas, however, for feedingstuffs designed to satisfy the nutritional requirements of animals with irreversibly impaired processes of assimilation, absorption or metabolism or which are in a pathological state requiring medical supervision, the possibility should be provided of laying down additional labelling rules which provide that a recommendation shall be given to the user to request the prior opinion of a veterinarian instead of the general recommendation to consult a specialist;

Whereas a positive list should also be drawn up at Community level of the intended uses of animal feedingstuffs for particular nutritional purposes, indicating their precise use, essential nutritional characteristics, compulsory or optional declarations and special labelling requirements; whereas, bearing in mind the importance of this list for the implementation of this Directive, such list should be adopted in good time;

Whereas the marketing of feedingstuffs intended for particular nutritional purposes which satisfy the requirements of this Directive must not be subject to any restriction on grounds of content, methods of manufacture, presentation or labelling;

Whereas, in cases where a product presents a hazard to animal or human health or the environment, provision should be made for any Member State to request that the Commission take the appropriate measures, on justified grounds;

Whereas, for cases where the Council empowers the Commission to apply the rules laid down in respect of feedingstuffs intended for particular nutritional purposes, a procedure should be provided for close cooperation between the Member States and the Commission in the Standing Committee on Feedingstuffs set up by Council Decision 70/372/EEC⁽²⁾;

Whereas effective inspection of feedingstuffs intended for particular nutritional purposes must be ensured; whereas in certain circumstances the usual means at the disposal of the inspection services may be insufficient to allow

verification that a feedingstuff actually possesses the particular nutritional properties attributed to it; whereas it should therefore be provided that, where necessary, the person responsible for marketing the product should assist the inspection service in its duties,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns feedingstuffs intended for particular nutritional purposes.
2. Member States shall prescribe that feedingstuffs intended for particular nutritional purposes may be marketed only if they:
 - fulfil the conditions referred to in Article 3,
 - are labelled in accordance with the provisions laid down in Article 5,
 - their intended uses are included in the list drawn up pursuant to Article 6 and they fulfil the other provisions laid down in that list.

Article 2

For the purposes of this Directive, the following definitions shall apply:

- (a) 'feedingstuffs' shall mean products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding;
- (b) 'compound feedingstuffs' shall mean mixtures of products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the industrial processing thereof, or of organic or inorganic substances, whether or not containing additives, for oral animal feeding in the form of complete feedingstuffs or complementary feedingstuffs;
- (c) 'feedingstuffs intended for particular nutritional purposes' shall mean compound feedingstuffs which, by virtue of their particular composition or method of manufacture, can be clearly distinguished from both ordinary feedingstuffs and the products defined in Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community⁽³⁾, and are presented as intended to meet specific nutritional requirements;

⁽¹⁾ OJ No 22, 9. 2. 1965, p. 369/65.

⁽²⁾ OJ No L 170, 3. 8. 1970, p. 1.

⁽³⁾ OJ No L 92, 7. 4. 1990, p. 42.

(d) 'particular nutritional purpose' shall mean the purpose of satisfying the specific nutritional needs of certain pets or productive livestock whose process of assimilation, absorption or metabolism could be temporarily impaired or is temporarily or irreversibly impaired and are therefore able to derive benefit from ingestion of feedingstuffs appropriate to their condition.

Article 3

The Member States shall require that the nature of composition of the feedingstuffs referred to in Article 1 (1) shall be such that the products are appropriate for their intended particular nutritional purpose.

Article 4

This Directive shall apply, subject to the specific provisions laid down therein, without prejudice to the Community provisions on:

- (a) compound feedingstuffs;
- (b) additives used in feedingstuffs;
- (c) undesirable substances and products in animal nutrition;
- (d) certain products used in animal nutrition.

Article 5

In addition to the labelling provisions in Article 5 of Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs⁽¹⁾ the Member States shall require that:

1. the following additional indications appear in the space provided for the purpose on the packaging, on the container or on the label of the feedingstuffs referred to in Article 1 (1):
 - (a) the qualifying expression 'dietetic' together with the description of the feedingstuff;
 - (b) the precise use, i.e. the particular nutritional purpose;
 - (c) the indication of the essential nutritional characteristics of the feedingstuffs;
 - (d) the declarations prescribed in column 4 in the Annex concerning the particular nutritional purpose;
 - (e) the recommended length of time for use of the feedingstuff.

The indications referred to in points (a) to (e) must comply with the content of the list of intended uses in the Annex and the general provisions to be laid down in accordance with Article 6 (b);

2. indications other than those referred to in paragraph 1 may be supplied in the space provided for the purpose, in so far as they are covered by Article 6 (a);

3. without prejudice to Article 5e of Directive 79/373/EEC, the labelling of feedingstuffs as referred to in Article 1 (1) may make reference to a specific pathological condition in so far as that condition corresponds to the nutritional purpose laid down in the list of uses drawn up in accordance with Article 6 (a);
4. the label or the directions for use of the feedingstuffs referred to in Article 1 (1) must bear the indication 'It is recommended that a specialist's opinion be sought before use.'

It may, however, be provided in the list of intended uses in the Annex that this declaration shall be replaced for specific dietetic feedingstuffs with a recommendation to request the prior opinion of a veterinarian;

5. the provisions of Article 5c (5) of Directive 79/373/EEC shall also apply to the feedingstuffs referred to in Article 1 (1) and intended for animals other than pets;
6. the labelling of the feedingstuffs referred to in Article 1 (1) may also highlight the presence or the low level of one or more analytical constituents which are essential for the description of the feedingstuff. In such cases, the minimum or maximum level of the analytical constituents expressed as percentage weight of the feedingstuff must be clearly indicated in the list of declared analytical constituents;
7. the qualifying expression 'dietetic' shall be reserved solely for feedingstuffs as referred to in Article 1 (1).

Qualifying expressions other than 'dietetic' shall be prohibited in the labelling and presentation of these feedingstuffs;

8. Notwithstanding the provisions of Article 5c (3) of Directive 79/373/EEC, the declaration of ingredients may be made in the form of categories grouping several ingredients, even where the declaration of certain ingredients by their specific name is required to justify the nutritional characteristics of the feedingstuff.

Article 6

Pursuant to the procedure laid down in Article 9:

- (a) a list of intended uses shall be established in accordance with the Annex not later than 30 June 1994. That list shall contain:
 - the indications referred to in Article 5 (1) (b), (c), (d) and (e), and
 - where appropriate, the indications referred to in Article 5 (2) and Article 5 (4), second subparagraph;

⁽¹⁾ OJ No L 86, 6. 4. 1979, p. 30.

- (b) general provisions regarding the application of the indications referred to in (a), including applicable tolerances, may be established;
- (c) the measures adopted in accordance with (a) and (b) may be modified, following developments in scientific and technical knowledge.

Article 7

The Member States shall ensure that feedingstuffs as referred to in Article 1 (1) are not, for reasons concerning the provisions of this Directive, subject to marketing restrictions other than those provided for in this Directive.

Article 8

1. Where a Member State establishes that the use of a feedingstuff as referred to in Article 1 (1) or its use in the prescribed conditions presents a hazard for animal or human health or for the environment, it shall immediately inform the Commission, giving the reasons for its decision.

2. The Commission shall initiate as soon as possible the procedure laid down in Article 9 with a view to adopting any appropriate measures.

Article 9

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

2. 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 for 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 as provided in that Article. The chairman shall not vote.

3. 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, present 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 three months from the date of referral to the Council, the Council has not acted, the proposed

measures shall be adopted by the Commission unless the Council has decided against those measures by a simple majority.

Article 10

To allow effective official inspection of feedingstuffs as referred to in Article 1 (1), the following specific provisions shall apply:

1. Member States shall make all necessary arrangements for official inspection during manufacture or marketing, at least by sampling, in order to ensure compliance with the requirements of this Directive;
2. where appropriate, the competent authority shall be empowered to require the person responsible for placing the product on the market to produce data and information establishing the feedingstuff's conformity with this Directive.

If such data have been published in readily accessible form, a reference to the publication shall suffice.

Article 11

The following Directives are hereby amended as specified:

1. the following shall be added to Article 1 (2) of Council Directive 74/63/EEC of 17 December 1973 on the fixing of maximum permitted levels for undesirable substances and products in feedingstuffs⁽¹⁾:

'(f) feedingstuffs for particular nutritional purposes';

2. in Directive 79/373/EEC:

(a) the following shall be added to Article 1 (2):

'(h) feedingstuffs for particular nutritional purposes';

(b) the first indent of the second subparagraph of Article 5e shall be replaced by the following:

'— may not be designed to indicate the presence or content of analytical constituents other than those the declaration of which is provided for in Article 5 of this Directive or Article 5 (2) of Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes⁽²⁾;

(¹) OJ No L 237, 22. 9. 1993, p. 23';

3. the following shall be added to Article 1 (2) of Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition⁽²⁾:

'(f) feedingstuffs for particular nutritional purposes';

(¹) OJ No L 38, 11. 2. 1974, p. 31.

(²) OJ No L 213, 21. 7. 1982, p. 8.

Article 12

The Member States shall bring into force the laws, regulations and administrative provisions necessary for them to comply with this Directive no later than 30 June 1995. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall include references to this Directive or shall accompany them with such references on their official publication. The Member States shall lay down the manner in which such references shall be made.

Article 13

This Directive is addressed to the Member States.

Done at Brussels, 13 September 1993.

For the Council

The President

Ph. MAYSTADT

ANNEX

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time for use	Other provisions
1	2	3	4	5	6