



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a  
**EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE**

amending Council Directive 93/74/EEC on feedingstuffs intended for particular  
nutritional purposes and amending Directives 74/63/EEC, 79/373/EEC and  
82/471/EEC

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(presented by the Commission)

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Note : The modifications made to Directive 93/74/EEC are underlined

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## EXPLANATORY MEMORANDUM

1. On 13 September 1993 the Council adopted Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes<sup>1</sup>, the use of which has expanded considerably over the past few years.

Applying solely dietary principles (the use of medicines being excluded), those feedingstuffs were able to cover the specific needs of certain categories of animal in particular situations and thus prevent physiological imbalances at critical periods which could entail significant production losses (for example: to reduce the risk of calving fever in dairy cows, stress in pigs, or urinary concretions in ruminants).

In accordance with the provisions of Directive 94/39/EC the Commission adopted on 25 July 1994 the list of intended uses of feedingstuffs intended for particular nutritional purposes<sup>2</sup>.

That list contains the nutritional purposes both for productive livestock and for pets; feedingstuffs intended for particular nutritional purposes can also be used to help pets suffering from a chronic metabolic disorder such as renal insufficiency.

It now appears necessary to expand the scope of Directive 93/74/EEC to include a new generation of products called "nutritional supplements for animals".

Like feedingstuffs intended for particular nutritional purposes, nutritional supplements for animals are intended to meet the requirements of animals in certain physiological conditions or in particular environmental conditions.

However, because of their nature, concentration and method of administration they cannot be likened to complementary feedingstuffs or additive premixes.

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<sup>1</sup> OJ No L 237, 22.9.1993, p. 23.

<sup>2</sup> QJ No L 207, 10.8.1994, p. 20.

In fact, they are preparations likely to contain high levels of minerals, trace elements, vitamins, amino acids, etc., which are administered orally over an often very short period in the form of an individual dose in drinking water or via daily feed.

For example, nutritional supplements are very useful in coping with unforeseeable situations such as heat-stroke which affects pig and poultry farms in summer; in that case, the animals need the rapid administration of a multi-vitamin supplement over a short period to offset a reduction in, or even the ceasing of, feed intake.

Individual supplements to feedingstuffs may also be needed in the case of calving, weaning or large litters where the mother is not lactating sufficiently.

2. To prevent nutritional supplements from evading any form of regulation, it is proposed to extend the principles applying to feedingstuffs intended for particular nutritional purposes to this new generation of products.

This approach is justified for safety reasons: the administration of high doses of vitamins, trace elements or minerals may have an adverse effect on animal health or on public health if residues are left in animal products. Like feedingstuffs intended for particular nutritional purposes, nutritional supplements will be subject to a Community registration procedure intended to verify their effectiveness and safety vis-à-vis the purpose claimed for them. Authorisations will also be granted by the Commission after consulting the Standing Committee for Feedingstuffs.

Just as for feedingstuffs intended for particular nutritional purposes, the Commission will draw up the list of approved supplements, indicating for each its precise use, particular nutritional characteristics, obligatory and optional declarations and conditions of use.

The general rules applying to feedingstuffs intended for particular nutritional purposes with regard to controls, safeguard clauses, free circulation, etc., will also be extended to nutritional supplements.

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of  
amending Council Directive 93/74/EEC on feedingstuffs intended for particular  
nutritional purposes and amending Directives 74/63/EEC, 79/373/EEC and  
82/471/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission<sup>1</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>2</sup>,

Acting in accordance with the procedure laid down in Article 189b of the Treaty<sup>3</sup>

Whereas, since the adoption of Council Directive 93/74/EEC of 13 September 1993 on  
feedingstuffs intended for particular nutritional purposes<sup>4</sup> and Commission Directive  
94/39/EC of 25 July 1994 establishing a list of intended uses of animal feedingstuffs for  
particular nutritional purposes<sup>5</sup>, a new category of products called "nutritional  
supplements for animals" has appeared on the market;

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1 OJ No

2 OJ No

3 OJ No

4 OJ No L 237, 22.9.1993, p. 23.

5 OJ No L 207, 10.8.1994, p. 20.

Whereas while nutritional supplements are similarly intended to satisfy the particular nutritional requirements of animals, they cannot be considered feedingstuffs for particular nutritional purposes within the meaning of Directive 93/74/EEC because of their composition, method of administration and, in certain cases, their specific purpose; whereas the scope of Directive 93/74/EEC should therefore be extended to include this new category of products and provisions similar to those laid down for the authorisation and marketing of feedingstuffs intended for particular nutritional purposes should be introduced for the new category;

Whereas it will also be necessary to amend Directive 94/39/EC to take account of the extension of the scope of Directive 93/74/EEC to include nutritional supplements for animals;

Whereas nutritional supplements for animals cannot be deemed to be compound feedingstuffs; whereas they are not therefore subject to the general provisions of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs<sup>6</sup>; whereas labelling and packaging rules applicable to those products must therefore be laid down;

Whereas any authorisation of a new type of feedingstuff intended for a particular nutritional purpose implies the need for prior verification of the composition, method of administration and intended use of the product so as to ensure that it actually meets the nutritional requirements of the categories of animals for which it is intended; whereas to aid that verification Member States and the Commission should possess a dossier containing all the scientific and technical information demonstrating the beneficial effect of the product on the category of animal concerned; whereas the Commission will, if necessary, have to lay down guidelines for the presentation of the dossiers;

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<sup>6</sup> OJ No L 86, 6.4.1979, p. 30.

Whereas the other provisions of Community legislation apply where necessary to animal feedingstuffs for particular nutritional purposes and to nutritional supplements for animals, in particular with regard to the use of additives; whereas, however, those provisions will have to be inserted into Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs<sup>7</sup>, to take account of the special requirements of the animals receiving the products in question; whereas establishments manufacturing the nutritional supplements for animals should also be subject to the provisions governing the approval of manufacturers of premixes in Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC<sup>8</sup>;

Whereas, in view of the large number of amendments to be made to Directive 93/74/EEC, for the sake of clarity and rationality the current text of that Directive should be replaced by a new text,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 93/74/EEC is hereby amended as follows:

1. The title of the Directive is replaced by the following:

"Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes and nutritional supplements for animals."

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<sup>7</sup> OJ No L 270, 14.12.1970, p. 1.

<sup>8</sup> OJ No L 332, 30.12.1995, p. 15.

2. Articles 1 to 13 are replaced by the following:

"Article 1

1. This Directive concerns feedingstuffs intended for particular nutritional purposes and nutritional supplements for animals.

2. Member States shall prescribe that:

(a) feedingstuffs intended for particular nutritional purposes may be marketed only if:

- they fulfil the conditions referred to in Article 3,
- they are labelled in accordance with the provisions laid down in Article 6, and
- their intended uses are included in the list in Part B of the Annex to Directive 94/39/EC and they fulfil the other provisions laid down in that list.

(b) nutritional supplements for animals may only marketed if:

- they fulfil the conditions referred to in Article 3.
- they are labelled in accordance with the provisions laid down in Article 7, and
- their intended uses are included in the list drawn up pursuant to Article 8 and they fulfil the other provisions laid down in that list.



## Article 2

1. 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<sup>9</sup>, and are presented as intended to meet specific nutritional requirements;

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<sup>9</sup> OJ No L 92, 7.4.1990, p. 42.

(d) 'nutritional supplements for animals' shall mean preparations made up by the mixture of additives or by the mixture of additives and products authorised by Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition<sup>10</sup>, whether or not containing basic materials for feedingstuffs, which are intended to be administered orally so as to meet the temporary and specific nutritional needs of animals in special breeding or living conditions or to achieve specific nutritional purposes, and which, because of their nature, concentration or method of administration cannot be considered as complementary feedingstuffs;

(e) '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.

2. The other definitions laid down in Community legislation in the animal feed sector shall apply wherever necessary.

### Article 3

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

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<sup>10</sup> OJ No L 213, 21.7.1982, p. 8.

#### 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;
- (e) basic materials for animal feedingstuffs;
- (f) the approval and registration of certain establishments and intermediaries operating in the animal feed sector.

#### Article 5

Member States shall prescribe that nutritional supplements for animals may be marketed only in sealed packages or containers. They shall also prescribe that the packages or containers be sealed in such a way that, when the package or container is opened, the seal is damaged and cannot be re-used.

#### Article 6

In addition to the labelling provisions in Article 5 of Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs, 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) indication of the essential nutritional characteristics of the feedingstuffs;
- (d) the declarations prescribed in column 4 and, where applicable, column 6 of the Annex to Directive 94/39/EC 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 to Directive 94/39/EC and the general provisions laid down in accordance with Article 8(3):

2. indications other than those referred to in point 1 may be supplied in the space provided for the purpose, insofar as they are covered by Article 8(1):

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 insofar as that condition corresponds to the nutritional purpose laid down in the list of intended uses drawn up in accordance with Article 8(1):

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 to Directive 94/39/EC 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 a percentage by 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 7

1. Member States shall prescribe that nutritional supplements for animals may be marketed only if the indications listed below, which shall be clearly visible, legible and indelible and for which the producer, packer, importer, seller or distributor established within the Community shall be held responsible, are set out in the package or container or on a label attached thereto:
  - (a) the description 'nutritional supplement for animals';
  - (b) the precise intended use, i.e. the particular nutritional purpose of the supplement and the species or category of animals for which the supplement is intended;
  - (c) the description of the main nutritional characteristics of the supplement;
  - (d) the declarations listed in column 4 and, where applicable, column 6 of the Annex;
  - (e) the duration of use of the supplement;
  - (f) directions for use permitting appropriate use of the supplement;
  - (g) the name or trade name and the address or registered office of the person responsible for the indications referred to in this paragraph;

- (h) the net weight as a unit of mass for solids and a unit of volume or mass for liquids;
- (i) the date of manufacture;
- (j) the expiry date or the final date for keeping the product starting from the date of manufacture;
- (k) the batch reference number;
- (l) the approval number allocated to the establishment in accordance with Article 5 of Council Directive 95/69/EC.

The indications in points (a) to (e) must satisfy the contents of the list of intended uses to be drawn up in accordance with the Annex and the general provisions to be laid down in accordance with Article 8(2):

2. Where other provisions of Community legislation require the indication of a minimum conservation date, a single date must be indicated, i.e. the first date to expire.
3. Indications other than those referred to in point 1 may be supplied in the space provided for the purpose, insofar as they are covered by Article 8(2).
4. The label or the directions for use of the nutritional supplements for animals 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 to be drawn up in accordance with the Annex that this declaration shall be replaced for nutritional supplements for specific animals with a recommendation to request the prior opinion of a veterinarian.

5. Information other than that laid down in this Article may be supplied by the person responsible for the labelling indications for the nutritional supplement for animals provided that such information:

- is not intended to declare the presence or the content of analytical constituents other than those the declaration of which is provided for in point 1(d);
- does not mislead the user, particularly by attributing to the supplement effects or properties which it does not possess or by suggesting that the nutritional supplement possesses special characteristics when all similar products possess those same characteristics;
- does not refer to properties for the prevention, treatment or cure of a disease; however, the information may make reference to a specific pathological condition where that condition corresponds to the nutritional purpose defined in the list of intended uses drawn up pursuant to Article 8(2);
- relates to objective or measurable aspects that can be justified;
- is quite separate from all the indications referred to in this Article.



## Article 8

Pursuant to the procedure laid down in Article 12 a list of intended uses concerning feedingstuffs intended for particular nutritional purposes and a list of intended uses for nutritional supplements for animals shall be drawn up in accordance with the models included in part A or part B of the Annex and with the following provisions:

1. For feedingstuffs having particular nutritional purposes, the list of intended uses established by Directive 94/39/EC shall apply. That list shall contain:
  - the indications referred to in Article 6(1)(b), (c), (d) and (e), and
  - where appropriate, the indications referred to in Article 6(2) and the second subparagraph of Article 6(4);
  
2. The list of intended uses for nutritional supplements for animals shall be adopted by no later than 30 June 1999. It shall contain:
  - the indications referred to in Article 7(1)(b), (c), (d) and (e), and
  - where applicable, the indications referred to in Article 7(2) and the second subparagraph of Article 7(4);
  
3. general provisions regarding the application of the indications referred to in points 1 and 2, including applicable tolerances, may be established;
  
4. the measures adopted in accordance with this Article may be modified, following developments in scientific and technical knowledge.

## Article 9

1. With a view to establishing the lists provided for in Article 8, Member States shall ensure that an application accompanied by a dossier is officially sent to the Member States and the Commission to justify the intended uses of the animal feedingstuffs intended for particular nutritional purposes and the nutritional supplements for animals.
2. The Commission, in accordance with the procedure laid down in Article 12, may adopt guidelines in accordance with which the dossiers referred to in paragraph 1 are to be established.

## Article 10

The Member States shall ensure that feedingstuffs and nutritional supplements for animals 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 11

1. Where a Member State establishes that the use of a feedingstuff or a nutritional supplement for animals 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 12 with a view to adopting any appropriate measures.

## Article 12

1. Where the procedure laid down in this Article is to be followed, the Commission shall be assisted in an advisory capacity by the Standing Committee for Feedingstuffs, set up by Council Decision 70/372/EEC, hereinafter referred to as "the Committee".
2. The Chairman 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 set according to the urgency of the matter, where necessary taking a vote.
3. The opinion shall be entered in the minutes; in addition, each Member State shall have the right to request that its position be entered in the minutes.
4. The Commission shall take the fullest account of all aspects of the opinion delivered by the Committee. It shall inform the Committee of the way in which it has taken account of its opinion.

### Article 13

To allow effective official inspection of feedingstuffs and nutritional supplements for animals 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 conformity of the feedingstuffs and the nutritional supplements for animals with this Directive.

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

3. The Annex to the Directive is replaced by the following:

"ANNEX

Part A

(model of the list of intended uses for feedingstuffs intended for particular nutritional purposes to be drawn up in accordance with Article 8)

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

ANNEX

Part B

(model of the list of intended uses for nutritional supplements for animals to be drawn up in accordance with Article 8)

Particular nutritional purpose	Essential nutritional characteristics	Animal species or category	Labelling declarations	Length of time of use	Other provisions
1	2	3	4	5	6

## Article 2

The following Directives are hereby amended as follows:

1. The following is 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<sup>11</sup>:

"(f) feedingstuffs for particular nutritional purposes and nutritional supplements for animals."

2. In Directive 79/373/EEC:

- (a) the following is added to Article 1(2):

"(h) feedingstuffs for particular nutritional purposes and nutritional supplements for animals."

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

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<sup>11</sup> OJ No L 38, 11.2.1974, p. 31.

"— 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 and nutritional supplements for animals<sup>12</sup>;"

3. the following is added to Article 1(2) of Council Directive 82/471/EEC:

"(f) feedingstuffs for particular nutritional purposes and nutritional supplements for animals."

### Article 3

1. 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 1999. 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.

2. Member States shall forward to the Commission the texts of the essential national provisions which they shall adopt in the field governed by this Directive.

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<sup>12</sup> OJ No L 237, 22.9.1993, p. 23.



Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament  
The President

For the Council  
The President

TABLE OF CONCORDANCE

Directive 93/74/EEC	Directive 93/74/EEC as amended
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