COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

amending Council Directive 95/69/EC
laying down the conditions and arrangements for approving
and registering certain establishments and intermediaries
operating in the animal feed sector

(presented by the Commission)

Explanatory Memorandum

Directive ../.../EC[1] amending Directive 93/74/EEC on feedingstuffs intended for particular nutritional purposes[2] extends the scope of Directive 93/74/EEC to cover a new generation of products called "nutritional supplements for animals".

Nutritional supplements are similar in composition to premixtures of additives.

Therefore, with regard to manufacturing conditions, establishments manufacturing nutritional supplements for animals and their intermediaries should be subject to the same rules as those laid down in Directive 95/69/EC[3] for approving establishments manufacturing premixtures.

It is also necessary to provide for the registration of users of nutritional supplements for animals, i.e. livestock farmers, to ensure that they possess the necessary facilities for making appropriate use of the products in question on the farm.

The scope of this proposal is restricted to laying down the rules which Member States must follow when approving or registering establishments and intermediaries manufacturing nutritional supplements for animals;

It is necessary to adopt these measures at Community level in order better to achieve the objectives of guaranteeing the quality and safety of feedingstuffs.

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1 OJ No L

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

3 OJ No L 332, 30.12.1995, p. 15.

European Parliament and Council Directive
amending Council Directive 95/69/EC
laying down the conditions and arrangements for approving
and registering certain establishments and intermediaries
operating in the animal feed sector

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[1],

Having regard to the opinion of the Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article 189b of the Treaty[3],

Whereas Council Directive 95/69/EC of 22 December 1995 lays down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amends Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC[4],

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4 OJ No L 332, 30.12.1995, p. 15.

Whereas European Parliament and Council Directive ../../EC[5] extends the scope of Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes[6] to cover nutritional supplements for animals; whereas nutritional supplements for animals are similar in composition to premixtures of additives; whereas establishments manufacturing nutritional supplements for animals and their intermediaries should therefore be subject to the rules laid down in Directive 95/69/EC for approving establishments manufacturing premixtures of additives and for intermediaries involved at an intermediate stage between production and use by livestock farmers in order to guarantee that these products are safe to use and to prevent harmful effects on human or animal health or the environment; whereas users of nutritional supplements for animals should also be registered to ensure that they possess the necessary facilities for making appropriate use of the products in question;

Whereas Council Directive 96/51/EC of 23 July 1996 has amended Council Directive 70/524/EEC concerning additives in feedingstuffs[7] to take account of the amendments indicated in Article 17 of Directive 95/69/EC; whereas that Article is now superfluous and should be deleted;

Whereas the scope of this Directive is restricted to laying down the rules which Member States must follow when approving or registering establishments and intermediaries manufacturing nutritional supplements for animals;

Whereas it is necessary to adopt these measures at Community level in order better to achieve the objectives of guaranteeing the quality and safety of feedingstuffs,

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

7 OJ No L 235, 17.9.1996, p. 39.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 95/69/EC is hereby amended as follows:

1. Article 1(3)(b) and (c) are replaced by the following:

"(b) 'establishment' means any unit producing or manufacturing additives, premixtures prepared from additives, nutritional supplements for animals, compound feedingstuffs or products covered by Directive 82/471/EEC and referred to in Chapter I.1(a) of the Annex to this Directive;

(c) 'intermediary' means any person other than the manufacturer or the person producing compound feedingstuffs for the exclusive requirements of his holding who holds additives, premixtures prepared from additives or nutritional supplements for animals, or one of the products covered by Directive 82/471/EEC and referred to in Chapter I.1(a) of the Annex to this Directive at an intermediate stage between production and use."

2. In Article 2:

(i) The following is added to paragraph 2:

"(g) manufacturing nutritional supplements for animals as referred to in Directive ../.../EC, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter I.2 (b) of the Annex."

(ii) The following paragraph is added:

"4. Approved establishments engaged in the corresponding activities referred to in paragraph 2(b) shall automatically be deemed to meet the conditions referred to in paragraph 2(g)."

3. Article 3(1) is replaced by the following:

"Article 3

Approval of intermediaries

1. Where additives, products covered by Directive 82/471/EEC, premixtures of additives or nutritional supplements for animals referred to in Chapters I.1(a) and I.2(a) of the Annex respectively are put into circulation, intermediaries must be approved.

The provisions laid down in point 7 of Chapter I.1(b) or Chapter I.2(b) of the Annex shall apply, as appropriate, to intermediaries which wrap, package, store or put into circulation additives, premixtures of additives, nutritional supplements for animals or products covered by Directive 82/471/EEC. "

4. Article 6(2) is replaced by the following:

"2. Before 31 December each year, Member States shall send the Commission the list referred to in paragraph 1.

Before 31 December each year, Member States shall send the other Member States a list of the establishments referred to in Article 2(2)(a), (b) and (g) and of the intermediaries approved in accordance with Article 3(1).

Upon request, Member States shall send the other Member States all or part of the list of establishments referred to in Article 2(2)(c) to (f)."

5. The following is added to Article 7(2):

"(e) using, for the exclusive requirements of its holding, nutritional supplements for animals referred to in Chapter I.2(a) of the Annex must meet the minimum conditions laid down in Chapter II(c) of the Annex."

6. Article 14 is replaced by the following:

"Article 14

Fees

The Council, acting by a qualified majority on a proposal from the Commission, shall:

- before 1 April 1998, adopt the amounts of the fees to be charged for the approval of establishments as referred to in Article 2(2)(a) to (f) and their intermediaries and

- before 1 October 1999, adopt the amounts of the fees to be charged for the approval of establishments as referred to in Article 2(2)(g) and their intermediaries."

7. The first subparagraph of Article 15(a) is replaced by the following:

"(a) - before 1 April 1998, practical arrangements for the approval pursuant to Article 2(2)(a) to (f) and registration pursuant to Article 7(2)(a) to (d) of establishments located in a non-member country and putting additives, premixtures, products covered by Directive 82/471/EEC as referred to in Chapter I.1(a) of the Annex to this Directive or feedingstuffs into circulation within the Community, and,

- before 1 October 1999, practical arrangements for the approval pursuant to Article 2(2)(g) of establishments located in a non-member country and putting nutritional supplements for animals into circulation within the Community.

so that safeguards are provided equivalent to those supplied by establishments located in the Community.

8. Article 16 is replaced by the following:

"Article 16

Standing Committee for Feedingstuffs

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."

9. Article 17 is deleted.

10. Articles 18, 19, 20, 21, 22 and 23 become Articles 17, 18, 19, 20, 21 and 22 respectively.

11. The Annex to the Directive is amended as follows:

11.1. Chapters I.2(a) and I.2(b) of the Annex to the Directive are replaced by the following:

"**CHAPTER I.2.(a)**

- Additives referred to in Article 2(2)(b) and Article 3(1)	
- Antibiotics:	all additives in the group
- Coccidiostats and other medicinal substances:	all additives in the group
- Growth promoters:	all additives in the group
- Vitamins, provitamins and chemically well-defined substances having a similar effect:	A and D
- Trace elements:	Cu and Se
- Nutritional supplements for animals:	all nutritional supplements for animals referred to in Directive 93/74/EC as amended by Directive ../.../EC.

CHAPTER I.2.(b)

Minimum conditions which must be fulfilled by establishments referred to in Article 2(2)(b) and (g) and intermediaries referred to in Article 3(1) [premixtures of additives and nutritional supplements for animals referred to in Chapter I.2(a)]

1. Facilities and equipment

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of the premixtures or nutritional supplements for animals concerned. The layout, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination and any adverse effects generally on the quality of the products. Facilities and equipment to be used for operations which are essential for the quality of the products must undergo appropriate and regular checks in accordance with the written procedures established in advance by the manufacturer.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

2. Personnel

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the premixtures or nutritional supplements for animals concerned. An organisational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of the premixtures or nutritional supplements for animals concerned.

3. Production

A qualified person responsible for production must be designated.

The manufacturer must ensure that the different stages in production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process, such as incorporation of the additive in the premixture or mixing of the different components of the nutritional supplement for animals, chronological order of production, meters and weighing apparatus, mixer and returns, in such a way as to obtain the desired quality of the premixtures or nutritional supplements for animals concerned in accordance with Directive 70/524/EEC or Directive .../.../EC.

Technical or organisational measures must be taken to avoid cross-contamination and errors.

4. Quality control

A qualified person responsible for quality control must be designated.

The manufacturer must have access to a quality control laboratory having adequate staff and equipment to guarantee and check that the premixtures or nutritional supplements for animals concerned comply with the specifications defined by the manufacturer and which will guarantee and check, in particular, the nature, content, homogeneity and stability of the additives in the premixture or the components of the nutritional supplement for animals, and as low a level of cross-contamination as possible. The use of an outside laboratory is permitted.

A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications - and destination in the event of non-compliance - for carrier substances, additives, premixtures and the components and the nutritional supplement for animals itself ('products').

Samples of each batch of premixture or nutritional supplement for animals put into circulation must be taken in sufficient quantity by a procedure established in advance by the manufacturer and be retained in order to ensure traceability. These samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities at least until the guarantee date of the premixture or nutritional supplement for animals.

5. Storage

'Products' which meet the specifications - and those which do not - must be stored in suitable containers or in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorized by the manufacturer have access.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

The 'products' must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products and with medicinal substances. Premixtures and nutritional supplements for animals must be wrapped and labelled in accordance with Directive 70/524/EEC or Directive ../.../EC, as appropriate.

6. Documentation

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure the mastery of the critical points in the manufacturing process, and to establish and implement a quality control plan. The manufacturer must keep the results of the relevant controls. This set of documents must be kept in such a way as to make it possible to trace the manufacturing history of each batch of premixture or nutritional supplement for animals put into circulation and to establish responsibility if complaints arise.

6.2. **Register of premixtures and nutritional supplements for animals**

The manufacturer must record the following information in order to ensure traceability:

- the names and addresses of manufacturers of additives and products covered by Directive 82/471/EEC and referred to in Chapter I.1(a) or of intermediaries, the nature and quantity of the additives or products covered by Directive 82/471/EEC and referred to in Chapter I.1(a) used and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,

- the date of manufacture of the premixture or nutritional supplement for animals, the batch number where appropriate,

- the names and addresses of the intermediaries or manufacturers of compound feedingstuffs to whom the premixture is delivered or of the livestock farmers in the case of nutritional supplements for animals, the delivery date, the nature and quantity of the premixture or nutritional supplement for animals delivered, and the batch number where appropriate.

7. **Intermediaries referred to in Article 3 (1)**

Where the manufacturer delivers premixtures or nutritional supplements for animals to a person other than a manufacturer of compound feedingstuffs or a livestock farmer, that person and any subsequent intermediary by whom they are wrapped, packaged, stored or put into circulation shall be equally bound, as appropriate, by the obligations laid down in points 4, 5, 6.2 and 8 and, in the case of wrapping, by those laid down in point 3.

8. **Complaints and product recall**

The manufacturer or any intermediary putting a product into circulation under his own name must implement a system for registering and processing complaints.

Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

11.2. In Chapter II:

11.2.1. The following is inserted after Chapter II(b):

"**CHAPTER II(b)a**

Nutritional supplements for animals:

All the nutritional supplements for animals referred to in Directive 93/74/EEC as amended by Directive ../.../EC."

11.2.2. In Chapter II(c):

11.2.2.1. The introductory sentence and point 1 "Facilities and equipment" are replaced by the following:

"**CHAPTER II(c)**

Minimum conditions which must be fulfilled by establishments and intermediaries referred to in Article 7(2)(a) and (b) and Article 8(1), [additives for which a prescribed maximum level is set and which are not referred to in Chapter I.1(a)], premixtures of additives referred to in Chapter II(a), establishments referred to in Article 7(2)(c) and (d) [compound feedingstuffs containing premixtures of additives referred to in Chapter II(b) or additives referred to in Chapter II(a)] and establishments referred to in Article 7(2)(e) (users of nutritional supplements for animals).

1. **Facilities and equipment**

Facilities and technical equipment must be located, designed, constructed and maintained to suit the manufacture of the additives, premixtures of additives, compound feedingstuffs containing additives or premixtures of additives or nutritional supplements for animals concerned ('products concerned').

Establishments using nutritional supplements for animals must have the appropriate equipment for dosing and distributing the products; where a nutritional supplement for animals is distributed in drinking water, the establishment must have a separate water circuit for the purpose."

11.2.2.2. Point 5 is replaced by the following:

"5. **Storage**

Raw materials, additives, carrier substances, premixtures, nutritional supplements for animals and compound feedingstuffs must be stored in places designed, adapted and maintained in order to ensure good storage conditions.

The products must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products mentioned above and with medicinal substances or medicinal feedingstuffs. Products to be put into circulation must be wrapped, where appropriate, and labelled in accordance with the provisions of Directive 70/524/EEC or Directive 79/373/EEC, as appropriate."

11.2.2.3. The following is added to point 6:

"(d) for compound feedingstuffs containing nutritional supplements for animals:

- the names and addresses of the manufacturers of the nutritional supplements for animals or intermediaries, with the batch number where appropriate, and the nature and quantity of the nutritional supplement for animals used;

- the nature and quantity of the feedingstuffs manufactured, with the date of manufacture.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions needed to comply with this Directive by 1 October 1999 at the latest. They shall immediately inform the Commission thereof.

   The provisions adopted by the Member States shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by the Member States.

2. Member States shall forward to the Commission the text of the main provisions of domestic law which they adopt in the subject area governed by this Directive.

Article 3

This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

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