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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

(OJ L 332, 30.12.1995, p. 15)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Council Directive 98/92/EC of 14 December 1998	L 346	49	22.12.1998
►**M2**	Council Directive 1999/20/EC of 22 March 1999	L 80	20	25.3.1999
►**M3**	Council Directive 1999/29/EC of 22 April 1999	L 115	32	4.5.1999
►**M4**	Council Regulation (EC) No 806/2003 of 14 April 2003	L 122	1	16.5.2003

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European 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]),

1. Whereas Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ([4]), lays down the minimum conditions to be met by manufacturers of certain additives, premixtures and compound feedingstuffs containing such additives;

2. Whereas these rules restrict the manufacture or use of certain categories of additives, premixtures and compound feedingstuffs containing such additives and premixtures to those manufacturers who are included on a national list;

3. Whereas individuals holding goods covered by this Directive for the sole purposes of their trade promotion or their transport are not regarded as being intermediaries as defined in this Directive;

4. Whereas with the operation of the internal market in mind, some optional provisions which still allow the Member States to derogate from the Community provisions applying to the sector in question should be abolished and the criteria for approving or registering manufacturers or intermediaries should be specified so as to avoid distortions of competition caused by the Member-States' different ways of applying and interpreting pre-existing approval conditions and to forestall any potentially adverse effects on animals, humans or the environment, given the risks inherent in using certain additives;

5. Whereas, to forestall certain particularly undesirable substances occurring in feedingstuffs, Council Directive 74/63/EEC of 17 December 1973 on undesirable substances and products in animal nutrition ([5]), aims to limit their presence in raw materials to an acceptable level; whereas these rules also restrict the use of those raw materials to those persons who have the necessary qualifications, facilities and equipment for the dilution operations which ensure that the maximum levels laid down in the Directive as regards the various types of compound feedingstuffs are complied with;

6. Whereas establishments producing certain substances listed in Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ([6]), should also be subject to approval, as should intermediaries;

([1]) OJ No C 348, 28. 12. 1983, p. 18.
([2]) OJ No C 91, 28. 3. 1994, p. 296.
([3]) OJ No C 148, 30. 5. 1994, p. 21.
([4]) OJ No L 270, 14. 12. 1970, p. 1. Directive as last amended by Commission Directive 95/37/EC (OJ No L 172 an 22. 7. 1995, p. 21).
([5]) OJ No L 38, 11. 2. 1974, p. 31. Directive as last amended by Commission Directive 94/16/EC (OJ No L 104, 23. 4. 1994, p. 32).
([6]) OJ No L 213, 21. 7. 1982, p. 8. Directive as last amended by Commission Directive 95/33/EC (OJ No L 167, 18. 7. 1995, p. 17).

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7. Whereas, with a view to ensuring the quality of the product and preventing the occurrence of residues of certain additives in animal products or of high levels of certain undesirable substances which might result from defective manufacture, all manufacturers of additives, premixtures, compound feedingstuffs and certain products covered by Directive 82/471/EEC, and intermediaries should be approved or registered on the basis of standard, specific criteria;

8. Whereas the level of requirements for the exercise of activities laid down in this Directive must be in proportion to the risks involved in the manufacture or use by establishments of additives and premixtures listed in Directive 70/524/EEC, products covered by Directive 82/471/EEC or raw materials containing undesirable substances or products listed in Directive 74/63/EEC;

9. Whereas establishments which intend to manufacture or use products deemed sensitive under the Directive must receive prior approval on the basis of very strict conditions that should safeguard animals, humans and the environment, whereas, however, in exceptional cases Member States may decide not to approve a specific category of establishment, provided such measures do not hinder the free movement of agricultural products in the territory of the Member States; whereas, conversely, for establishments using less sensitive products, mere registration based on an undertaking by the establishment to comply with a number of conditions will suffice; whereas this distinction must also apply to intermediaries which wrap, package, store or put into circulation additives, premixtures of additives or products covered by Directive 82/471/EEC;

10. Whereas, on grounds of equal treatment, the fundamental principles of these new rules must apply both to establishments which put products into circulation and to manufacturers/stock farmers who manufacture feedingstuffs solely for the requirements of their own farms, without any distinction; whereas, nonetheless, some relief should be allowed the latter on account of the particular circumstances in which they exercise their activity;

11. Whereas provision should be made for amending or withdrawing approval if an establishment changes or ceases its activities or if it no longer fulfils one of the essential conditions applicable to its activity; whereas the same rules should apply, *mutatis mutandis*, to registration;

12. Whereas Member States may be entitled to levy fees for granting approval; whereas the levels of such fees should subsequently be harmonized in order to obviate distortion of competition; whereas such harmonization will fall within the general framework of future Community rules on fees or charges to be levied in the animal feed sector;

13. Whereas it is necessary to give the Commission the task of adopting detailed rules for the application of this Directive, including the conditions for approval and registration of establishments in third countries;

14. Whereas, should the Council confer on the Commission responsibility for implementing the rules laid down on the conditions and arrangements for approving and registering the establishments in question, provision should be made for close cooperation between the Member States and the Commission within the Standing Committee for Feedingstuffs established by Decision 70/372/EEC ([1]);

15. Whereas to ensure greater transparency the conditions and arrangements relating to the approval and registration of establishments in the animal feed sector should be brought together in a single text; whereas this entails adapting existing legislation;

([1]) OJ No L 170, 3. 8. 1970, p. 1.

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16. Whereas the requirement for manufacturers to be approved or registered will make it possible for Member States to check on manufacturers and intervene, if necessary, where substances are being used illegally, in particular where prohibited substances such as hormones or beta-agonists are in use; whereas Member States have a duty to check beforehand that establishments requiring approval actually meet the minimum conditions which the Directive lays down for exercise of the relevant activity; whereas national supervisory authorities must also ensure subsequently, by means of appropriate checks, that approved or registered establishments and intermediaries are indeed complying with the conditions imposed upon them; whereas these provisions must apply without prejudice to Community rules governing the organization of official checks on animal feed;

17. 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,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

1. This Directive lays down the conditions and arrangements applicable to certain categories of establishments and intermediaries in the animal feedsector to allow them to exercise the activities described in Articles 2 and 7 and Articles 3 and 8 respectively.

2. This Directive shall apply without prejudice to the Community provisions concerning the organization of official checks on animal feed.

3. For the purposes of this Directive:

(a) ‘putting into circulation’ means holding products for the purposes of sale, including offering for sale, or for the purposes of any other form of transfer, whether or not free of charge, to third parties, and the sale and other forms of transfer themselves;

(b) ‘establishment’ means any unit producing or manufacturing additives, premixtures prepared from additives, 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 for the exclusive requirements of his holding, compound feedingstuffs, who holds additives, premixtures prepared from additives, 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.

4. The definitions laid down in Community legislation on animal feed shall apply where necessary.

CHAPTER II

APPROVAL OF ESTABLISHMENTS AND INTERMEDIARIES

Article 2

Approval of establishments

1. An establishment wishing to exercise one or more of the activities referred to in paragraph 2 must receive approval for each of its activities. A Member State may decide not to approve establishments referred to in paragraph 2 (f).

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2. To be approved by the competent authorities an establishment:

(a) manufacturing additives or products covered by Directive 82/471/EEC and referred to in Chapter I.1 (a) of the Annex to this Directive with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter I.1 (b) of the said Annex 1;

(b) manufacturing premixtures prepared from additives referred to in Chapter I.2 (a) of the Annex, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter I.2 (b) of the said Annex;

(c) manufacturing compound feedingstuffs containing premixtures prepared from additives referred to in Chapter I.3 (a) of the Annex, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter I.3 (b) of the Annex;

(d) manufacturing compound feedingstuffs, with a view to putting them into circulation, from raw materials referred to in Article 3a (2) of Directive 74/63/EEC which contain high levels of undesirable substances or products, must meet the minimum conditions laid down in Chapter I.4 of the Annex to this Directive;

(e) producing, for the exclusive requirements of its holding, compound feedingstuffs containing premixtures which include additives referred to in Chapter I.3 (a) of the Annex must meet the minimum conditions laid down in Chapter I.3 (b) of the Annex, with the exception of the requirements set out in point 7;

(f) producing, for the exclusive requirements of its holding, compound feedingstuffs which contain raw materials referred to in Article 3a (2) of Directive 74/63/EEC containing high levels of undesirable substances or products, must meet the minimum conditions laid down in Chapter 1.4 of the Annex to this Directive, with the exception of the requirements set out in point 7.

3. Approval shall be:

— withdrawn if an establishment ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time,

— amended if the establishment has demonstrated its ability to engage in activities which are additional to those for which it was first approved or which replace them.

Article 3

Approval of intermediaries

1. Where additives, products covered by Directive 82/471/EEC or premixtures of additives 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 8 (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 or products covered by Directive 82/471/EEC.

2. Approval shall be:

— withdrawn if an intermediary ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time;

— amended if the intermediary has demonstrated its ability to engage in activities which are additional to those for which it was first approved or which replace them.