II

*(Acts whose publication is not obligatory)*

# COUNCIL

## COUNCIL DIRECTIVE

**of 29 November 1984**

**amending Directive 70/524/EEC concerning additives in feedingstuffs**

(84/587/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100 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 the application of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (4), as last amended by the 46th Commission Directive 84/547/EEC (5), has revealed a need to redefine certain fundamental concepts so as to take account of scientific and technical developments and satisfy the imperative need to ensure the best possible protection of animal health, human health and the environment;

Whereas experience has demonstrated, in particular, that the current rules on the use of additives in feedingstuffs have not afforded the required degree of safety; whereas it is therefore indispensable that additional measures be taken in connection with the production, marketing and distribution of additives and premixtures of additives;

Whereas, to facilitate the application of the Directive, the list of definitions should be extended and certain definitions amended; whereas the concept of an additive should be more clearly defined in such a way that authorizations granted for the use of additives of certain categories refer to the specific preparations, which in future will be named in the Annexes;

Whereas the interests of clarity call for a codification of the Annexes so that successive amendments made may be incorporated therein;

Whereas the prohibitions on the use of mixtures of additives of certain categories should be extended so as to prevent the unfavourable effects which may arise from certain associations;

Whereas, to ensure observance of the fundamental principles which must be obeyed if any new use of an additive is to be authorized, it is necessary — in the case of certain categories of additive — to require that a dossier be submitted officially by a Member State; whereas, to facilitate examination of the additives in question, dossiers must be drawn up in accordance with common guidelines to be determined by the Council;

Whereas, for the purpose of identifying additives used in feedingstuffs, it is important that, in the case of antibiotics, coccidiostats and other medicinal substances, as also in that of growth promoters, a monograph be introduced indicating the criteria for the identification and characterization of each authorized additive;

(1) OJ No C 197, 18. 8. 1977, p. 3.
(2) OJ No C 63, 13. 3. 1978, p. 53.
(3) OJ No C 84, 8. 4. 1978, p. 4.
(4) OJ No L 270, 14. 12. 1970, p. 1.
(5) OJ No L 297, 15. 11. 1984, p. 40.

Whereas it is, moreover, necessary to introduce precise rules on the labelling of additives and premixtures marketed within the Community;

Whereas it is appropriate that the production and use of antibiotics, coccidiostats and other medicinal substances, growth promoters and premixtures prepared from such additives for the purpose of incorporation in compound feedingstuffs be limited to those who have the competence and the appropriate installations and equipment for the manufacture of additives, premixtures or compound feedingstuffs and who are included on the list of manufacturers of a Member State; whereas these manufacturers and any intermediaries should, in addition, be required to maintain a register by means of which the competent authorities can effectively verify the identity and destination of the additives and premixtures produced;

Whereas antibiotics, coccidiostats and other medicinal substances could, however, be the subject of provisions to be adopted concerning the application of Directives 81/851/EEC and 81/852/EEC (1) and of rules to be adopted relating to the free movement of medicated feedingstuffs; whereas such new provisions could give rise to the amendment of the rules on these products;

Whereas additives authorized for use in human foodstuffs, other than those listed in the Annexes, are tolerated in animal feedingstuffs only where they are present purely due to the fact that they were contained in the edible part of the foodstuff used; whereas such additives must not fulfil any technological function in animal feedingstuffs or have any harmful effect on animal health,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

1. Articles 1 to 16b of Directive 70/524/EEC are hereby replaced by the following:

'*Article 1*

This Directive shall apply to additives in feedingstuffs.

*Article 2*

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

(a) *Additives:* substances, or preparations containing substances, other than premixtures referred to in (h) which, when incorporated in feedingstuffs, are likely to affect their characteristics or livestock production;

(b) *Feedingstuffs:* 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;

(c) *Daily ration:* the average total quantity of feedingstuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age category and yield, to satisfy all its needs;

(d) *Complete feedingstuffs:* mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration;

(e) *Supplementary feedingstuffs:* mixtures of feedingstuffs which have a high content of certain substances and which, by reason of their composition, are sufficient for a daily ration only if they are used in combination with other feedingstuffs;

(f) *Straight feedingstuffs:* the various vegetable or animal products in their natural state, fresh or preserved, and products derived from the industrial processing thereof, as well as the various organic or inorganic substances, whether or not containing additives, intended as such for oral animal feeding;

(g) *Compound feedingstuffs:* mixtures of products of vegetable or animal origin in their natural state, fresh or preserved, or products derived from the industrial processing thereof, or organic or inorganic substances, whether or not containing additives, for oral animal feeding in the form of complete feedingstuffs or supplementary feedingstuffs;

(h) *Premixtures:* mixtures of additives or mixtures of one or more additives with substances used as carriers, intended for the manufacture of feedingstuffs;

(i) *Animals:* animals belonging to species normally nourished and kept or consumed by man;

(j) *Pet animals:* animals belonging to species normally nourished and kept, but not consumed, by man, except animals bred for fur.

(1) OJ No L 317, 6. 11. 1981, pp. 1 and 16.

*Article 3*

1. Member States shall provide that, as regards feedingstuffs, only those additives listed in Annex I which comply with this Directive may be marketed and that they may be incorporated in feedingstuffs only subject to the requirements set out in that Annex. These additives may not be used in any other way for the purposes of animal feeding.

2. Member States shall, in particular, ensure that additives may be incorporated in straight feedingstuffs only as long as their use is expressly provided for in Annex I or Annex II.

*Article 4*

1. By way of derogation from Article 3 (1), Member States may authorize the marketing and use, within their own territory, of :

(a) additives listed in Annex II, provided that they comply with the provisions laid down for them by this Directive ;

(b) additives belonging to groups other than those listed in Annex I or Annex II, provided that tests have shown that the conditions set out in Article 7 (2) (A) are satisfied. This derogation shall not apply to substances having a hormonal or anti-hormonal effect.

2. Member States shall forward :

— before 3 January 1985 the list of groups and additives authorized under paragraph 1 (b) to the other Member States and to the Commission,

— before 3 December 1985 the documents justifying these authorizations with reference to the conditions set out in Article 7 (2) (A).

*Article 5*

Before 3 December 1988 the national authorizations granted pursuant to Article 4 (1) (b) shall be decided on in accordance with the procedure laid down in Article 23.

*Article 6*

1. The maximum and minimum contents listed in Annex I and Annex II shall refer to complete feedingstuffs with a moisture content of 12 % in so far as no special provisions are set forth in the said Annexes.

If the substance permitted as an additive also exists in the natural state in certain ingredients of the feedingstuff, the amount of additive to be incorporated is calculated so that the total of the elements added and the elements present naturally does not exceed the maximum content provided for in Annexes I and II.

2. The mixing of additives named in this Directive shall be permitted in premixtures and feedingstuffs only where, in relation to the effects desired, there is physical and chemical compatibility between the components of the mixture.

3. Unless the mixture concerned is set out in Annex I or Annex II, Member States shall require that :

(a) antibiotics and growth promoters may not be mixed together, either with substances from their own group or with substances from the other group ;

(b) coccidiostats may not be mixed with antibiotics and growth promoters where coccidiostats also act, for the same category of animal, as an antibiotic or as a growth promoter ;

(c) coccidiostats and other medicial substances may not be mixed together if their effects are similar.

4. Member States may, for experimental or scientific purposes, provide for derogations from the provisions of Article 3 or of paragraphs 2 or 3 of this Article on condition that there is adequate official supervision.

*Article 7*

1. Amendments to be made to Annexes on account of the growth of scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 23.

A codified version of the Annexes shall be adopted at regular intervals in accordance with the same procedure, the aim being to incorporate the successive amendments made pursuant to this paragraph.

2. When amendments are made to Annex I or Annex II, the following principles shall be applied :

A. An additive shall be included in Annex I only if :

(a) it has a favourable effect on the characteristics of those feedingstuffs or on livestock production when incorporated in such feedingstuffs ;

(b) at the level permitted in feedingstuffs, it does not adversely affect human or animal health or the environment, nor harm the consumer by altering the characteristics of livestock products ;

(c) its presence in feedingstuffs can be controlled ;

(d) at the level permitted in feedingstuffs, treatment or prevention of animal disease is excluded ; this condition does not apply to substances of the kind listed in Annex I (D) ;

(e) for serious reasons concerning human or animal health its use must not be restricted to medical or veterinary purposes.

B. An additive shall be deleted from Annex I if any of the conditions listed under A is no longer satisfied. However, such an additive may be inserted in Annex II for a specified period, if as a minimum the conditions of subparagraph A (b) and (e) are always satisfied.

C. A new additive or a new usage attributed to an additive may be inserted in Annex II only if the conditions stipulated under subparagraph A (b), (c) and (e) are satisfied and it can be assumed, taking into account available results, that the other conditions stipulated under subparagraph A are also satisfied.

The length of time for which a new additive or new use is authorized must not exceed five years, from its being entered in that Annex.

*Article 8*

1. When an additive belonging to the groups of "antibiotics", "coccidiostats" and "other medicinal substances" or "growth promoters" is added to Annex I or Annex II, a monograph indicating the identification process or the criteria for the identification and characterization of the additive, particularly its composition and degree of purity and its physico-chemical and biological properties, shall be drawn up by means of a Directive, taking account of scientific and technical knowledge, in accordance with the procedure laid down in Article 23.

2. By 31 December 1988 at the latest, monographs shall also be drawn up for such additives belonging to the groups referred to in paragraph 1 as are added to Annex I or Annex II before the date on which this Directive is adopted.

3. In accordance with paragraph 1, monographs may also be drawn up for additives belonging to groups other than those referred to in that paragraph.

4. The amendments to be made thereafter to the monographs as a result of developments in scientific or technical knowledge shall be adopted in accordance with the procedure laid down in Article 23.

*Article 9*

1. For the purposes of checking whether the additives comply with the principles defined in Article 7 (2), Member States shall ensure that a dossier complying with paragraph 2 below is officially forwarded to the Member States and to the Commission.

2. The Council, acting on a proposal from the Commission, shall adopt, by means of a Directive, the guidelines for preparing the dossiers referred to in paragraph 1, so that these guidelines can be applied by 3 December 1986.

The amendments to be made thereafter to the guidelines as a result of developments in scientific or technical knowledge shall be adopted in accordance with the procedure laid down in Article 23.

3. At the reasoned request of the applicant, Member States and the Commission shall ensure that any information which, if disseminated, could affect industrial or commercial property rights is kept confidential.

Industrial and commercial secrecy shall not apply to :

— the denomination and composition of the additive,

— the physico-chemical and biological characteristics of the additive,

— the interpretation of the pharmacological, toxicological and ecotoxicological data,

— the analytical methods for monitoring the additive in the feedingstuffs.

*Article 10*

Member States shall require that additives and premixtures may be marketed only in closed packages or closed containers. Member States shall require that packages or containers must be closed in such a way that the fastener is damaged on opening and cannot be re-used.

*Article 11*

1. Where a Member State, as a result of new information or of a reassessment of existing information made since the provisions in question were adopted, has detailed grounds for establishing that the use of one of the additives listed in Annex I or its use in conditions which may be specified constitutes a danger to animal or human health or the environment although it complies with the provisions of this Directive, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving reasons for its decision.

2. The Commission shall, as soon as possible, examine the grounds cited by the Member State concerned and consult the Member States within the Standing Committee for Feedingstuffs ; it shall then deliver its opinion without delay and take the appropriate measures.

3. Should the Commission consider that amendments to the Directive are necessary in order to mitigate the difficulties mentioned in paragraph 1 and to ensure the protection of human or animal health or the environment, it shall initiate the procedure laid down in Article 24 with a view to adopting these amendments; the Member State which has adopted safeguard measures may in that event retain them until the amendments enter into force.

*Article 12*

1. Member States shall require that supplementary feedingstuffs, diluted as specified, may not contain levels of the additives named in this Directive which exceed those fixed for complete feedingstuffs.

2. Member States may require that the levels of antibiotics, coccidiostats and other medicinal substances, growth promoters, D vitamins and antioxidants in supplementary feedingstuffs may exceed the maximum levels fixed for complete feedingstuffs in the case of:

(a) supplementary feedingstuffs which a Member State has authorized to be made available to all users, provided that their level of antibiotics, D vitamins or growth promoters does not exceed five times the fixed maximum level;

(b) supplementary feedingstuffs which are intended for certain species of animal and which a Member State is permitted to authorize to be made available within its territory to all users because of special feeding systems, provided that their level does not exceed:

— for antibiotics and growth promoters, 1 000 mg/kg and, provided that the use of these substances is permitted, 2 000 mg/kg in the case of cattle for fattening;

— for antioxidants, coccidiostats and other medicinal substances, five times the fixed maximum level;

— for D vitamins, 200 000 IU/kg.

Member States shall prescribe that if, in the manufacture of supplementary feedingstuffs, recourse is had to the possibility referred to in (a), the possibility referred to in (b) may not be made use of at the same time.

3. Where paragraph 2 is invoked, Member States shall require that the feedingstuff has one or more compositional characteristics (as regards, for example, proteins or minerals) which in practice ensure that the level of additives fixed for complete feedingstuffs is not exceeded and that the feedingstuff is not used for other species of animal.

*Article 13*

1. Member States shall require that antibiotics, coccidiostats and other medicinal substances and the growth promoters listed in Annex I or Annex II, premixtures prepared from these additives with a view to being incorporated in compound feedingstuffs and compound feedingstuffs containing these premixtures may only be put on the market under the conditions referred to in Annex III and, in particular, only if they have been produced by manufacturers found by at least one Member State to have fulfilled the minimum conditions laid down in Annex III.

Moreover, in the case of additives, premixtures or compound feedingstuffs referred to in the first subparagraph produced in third countries with a view to being marketed in the Community, Member States shall stipulate that manufacturers have a representative established within the Community who fulfils the conditions laid down for him in Annex III.

They shall require that the name of the representative established within the Community appears opposite the name of the manufacturer on the list referred to in paragraph 3.

2. Member States shall require that the additives referred to in paragraph 1 may be delivered at the final stage of marketing:

— only to manufacturers of premixtures, and

— in the form of premixtures, only to manufacturers of compound feedingstuffs

who fulfil the minimum conditions set out in Annex III.

3. Each Member State shall publish annually and, at the latest by 30 November each year, the list of manufacturers of additives, premixtures and compound feedingstuffs who have, to the satisfaction of the Member State concerned, complied with the requirements listed in Annex III.

It shall forward such list to the other Member States and to the Commission before 31 December each year.

Any amendments made to these lists after 30 November shall be forwarded separately to the other Member States and to the Commission.