

## 31970L0524

### **Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs**

*Official Journal L 270 , 14/12/1970 P. 0001 - 0017*

*Danish special edition: Series I Chapter 1970(III) P. 0743*

*English special edition: Series I Chapter 1970(III) P. 0840*

*Greek special edition: Chapter 03 Volume 6 P. 0060*

*Spanish special edition: Chapter 03 Volume 4 P. 0082*

*Portuguese special edition Chapter 03 Volume 4 P. 0082*

*Finnish special edition: Chapter 3 Volume 3 P. 0118*

*Swedish special edition: Chapter 3 Volume 3 P. 0118*

COUNCIL DIRECTIVE of 23 November 1970 concerning additives in feeding-stuffs (70/524/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;

Having regard to the Opinion of the European Parliament (1);

Having regard to the Opinion of the Economic and Social Committee;

Whereas livestock production occupies a very important place in the agriculture of the European Economic Community ; whereas satisfactory results depend to a large extent on the use of appropriate good-quality feeding-stuffs;

Whereas the existence of rules concerning feeding-stuffs is essential to an increase in agricultural productivity;

Whereas animal feeding increasingly involves the use of additives;

Whereas the provisions laid down in the Member States by law, regulation or administrative action concerning additives in feeding-stuffs, insofar as they exist, differ as regards their basic principles ; whereas it follows that they directly affect the establishment and functioning of the common market and should therefore be harmonised;

Whereas, as a general rule, "additives" means substances which improve both the feeding-stuffs in which they are incorporated and livestock production ; whereas, for this reason, antibiotics should also be regarded as additives since, when used in small quantities, they have a physiological nutritional effect, although when used in large quantities they have a medicinal effect;

Whereas these substances must not be used in feeding-stuffs for the prime purpose of diagnosing, treating or preventing disease ; whereas they should, however be authorised for the sole purpose of improving feeding-stuffs by preventing nutritional deficiencies;

Whereas, furthermore, certain purely medicinal substances such as coccidiostats should, during a first stage, be regarded in relation to feeding-stuffs as additives, since most Member States have been using them for collective prophylaxis, principally in poultry-farming ; whereas, however, they will be examined further if a directive on medicinal feeding-stuffs is drawn up;

Whereas the basic principle underlying rules in this field must be that only those additives which are named in this Directive may be contained in feeding-stuffs and only subject to the requirements set out herein, and that such additives may not, subject to the exceptions provided for, be used in any other way for the purposes of animal feeding;

Whereas it is necessary, at the time when additives are authorised, to make sure that they

have a favourable effect on the characteristics of the feeding-stuffs to which they are added or on livestock production ; whereas they must not endanger animal or human health nor harm the consumer of livestock products ; whereas, subject to the exceptions provided for, it is advisable to examine whether such additives may now be used for the treatment or prevention of disease or whether there are still serious reasons for restricting their use to medical or veterinary purposes; (1)OJ No C 135, 14.12.1968, p. 20.

Whereas, because of the special situation of certain Member States, and in particular because of their different systems of animal feeding, it is necessary in certain cases to allow derogations from the above-mentioned principles to an extent acceptable for animal and human health;

Whereas Member States should also retain the power to suspend the use of certain additives or to lower their maximum levels if animal or human health is being endangered ; whereas Member States should not, however, be able to have recourse to that power in order to hinder the free movement of the various products;

Whereas provision should be made for feeding-stuffs containing additives to be specially labelled so that the user may know the nature of the additive and be protected against fraud ; whereas this provision refers particularly to supplementary feeding-stuffs containing concentrates of certain additives;

Whereas Community rules should not apply to feeding-stuffs intended for export to third countries, as the latter generally apply different rules;

Whereas, in order to ensure that the requirements laid down in respect of additives are satisfied during marketing, Member States must make provision for appropriate control arrangements;

Whereas feeding-stuffs satisfying these requirements must be subject only to the marketing restrictions provided for in this Directive;

Whereas, in order to facilitate implementation of this Directive, a procedure should be applied which establishes close co-operation between Member States and the Commission within the Standing Committee for Feeding-stuffs;

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

This Directive shall apply to additives in feeding-stuffs.

#### Article 2

For the purpose of this Directive the following definitions shall apply: (a) Additives : substances which, when incorporated in feeding-stuffs, are likely to affect their characteristics or livestock production;

(b) Feeding-stuffs : 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 feeding-stuffs, 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 feeding-stuffs : mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration;

(e) Supplementary feeding-stuffs : mixtures of feeding-stuffs 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 feeding-stuffs;

(f) Premixtures : additive concentrates intended for the industrial manufacture of compound animal feeding-stuffs.

#### Article 3

1. The Member States shall provide that, as regards feeding-stuffs, only those additives which are listed in Annex I may be incorporated in feeding-stuffs and only subject to the requirements set out therein. These additives may not be used in any other way for the purposes of animal feeding.

2. The maximum and minimum contents listed in Annex I refer to complete feeding-stuffs.

3. The mixing of additives named in this Directive shall be permitted in feeding-stuffs only where, in relation to the effects desired, there is physical and chemical compatibility between

the components of the mixture.

4. An antibiotic (Annex I (A) and Annex II (A)) may be mixed with only one single other antibiotic, unless the mixture to be produced is already provided for in those Annexes. The components may not belong to the same chemical group. The maximum authorised level of each component shall be that fixed by this Directive, reduced to a level proportional to its percentage in the mixture.

5. Coccidiostats and other medicinal substances (Annex I (D) and Annex II (B)) may not be mixed together unless the mixture is already provided for in those Annexes.

6. Member States may, for experimental or scientific purposes, provide for derogations from the provisions of paragraph 1, 3, 4 or 5 on condition that there is adequate official supervision.

7. By way of derogation from paragraph 1, Member States may, during a period of five years following notification of this Directive, increase, for their own territory, the maximum authorised antibiotic level (Annex I (A)), except in the case of substances E 709, E 711 and E 712, as follows: A. Oleandomycin, up to 25 ppm of the complete feeding-stuff: (a) for poultry, excluding ducks and geese, from the time of hatching until the end of the fourth week;

(b) for swine, from birth until the end of the eighth week;

B. All other antibiotics, up to 50 ppm of the complete feeding-stuff: (a) for poultry, excluding ducks and geese, from the time of hatching until the end of the fourth week;

(b) for calves, lambs and kids, from birth until the end of the sixteenth week;

(c) for swine, from birth until the end of the eighth week;

(d) for animals bred for their fur.

#### Article 4

1. By way of derogation from Article 3 (1), Member States may authorise the use of the following within their territory: (a) during a period of five years following notification of this Directive, substances belonging to groups other than those listed in Annex I, provided that tests show that the conditions set out in Article 6 (2) (A) are satisfied. This derogation shall not apply to substances having a hormonal or anti-hormonal effect;

(b) during a period of five years following notification of this Directive, substances listed in Annex II, provided that tests show that the conditions set out in Article 6 (2) (A) are satisfied;

(c) urea for adult ruminants, provided that tests show that the conditions set out in Article 6 (2) (A) are satisfied;

(d) molybdenum, up to 2.5 ppm of the complete feeding-stuff;

(e) selenium, up to 0.5 ppm of the complete feeding-stuff;

(f) saccharin.

2. Member States shall inform the other Member States and the Commission within two months of all measures taken under paragraph 1 and shall furnish the documents which they consider justify their authorisation.

#### Article 5

Within a reasonable period following authorisation of an additive by a Member State under Article 4 (1) (a), the Commission shall consider whether, in view of the provisions of Article 6, the additive may be included in Annex I or whether authorisation should be revoked. The Commission shall make the appropriate proposals to the Council, which shall act as prescribed in Article 6.

#### Article 6

1. The Council shall, acting on a proposal from the Commission and in the light of scientific and technical knowledge: - fix criteria of purity for the additives with which this Directive is concerned,

- adopt any amendments to be made to Annex I.

2. When amending Annex I, the Council shall apply the following principles: A. A substance shall be included in Annex I only if: (a) it has a favourable effect on the characteristics of those feeding-stuffs or on livestock production when incorporated in such feeding-stuffs;

(b) at the level permitted in feeding-stuffs it does not endanger animal or human health nor harm the consumer by altering the characteristics of livestock products;

- (c) its nature and level in feeding-stuffs can be controlled;
- (d) at the level permitted in feeding-stuffs, 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. A substance shall be deleted from Annex I if any of the conditions listed under A is no longer satisfied.

#### Article 7

1. Where the use in feeding-stuffs of one of the additives listed in Annex I or the maximum level fixed for such additive might endanger animal or human health, a Member State may, for a maximum period of four months, suspend the authorisation to use that additive or may reduce the fixed maximum level. It shall forthwith inform the Commission, which shall consult the Member States within the Standing Committee for Feeding-stuffs set up by the Council Decision of 20 July 1970 (1).

2. The Council, acting unanimously on a proposal from the Commission shall decide without delay whether Annex I should be amended and, if so, adopt by directive the necessary amendments. The Council, acting by a qualified majority on a proposal from the Commission, may also, if necessary, extend for a maximum period of one year the period set in paragraph 1.

#### Article 8

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

#### Article 9

1. The Member States shall require that the levels of antibiotics (Annex I (A)), antioxidants (Annex I (B)), coccidiostats and other medicinal substances (Annex I (D)), vitamins D (Annex I (H) No 1) and of trace elements (Annex I (I)) in supplementary feeding-stuffs and premixtures may exceed the maximum levels fixed for complete feeding-stuffs only in the case of: (a) materials which are delivered to manufacturers of compound feeding-stuffs or to their suppliers;

(b) supplementary feeding-stuffs which a Member State has authorised to be made available to all users on condition that their level of antibiotics, vitamins D or trace elements does not exceed five times the fixed maximum level;

(c) supplementary feeding-stuffs which are intended for certain species of animal and which a Member State is permitted to authorise to be made available within its territory to all users because of special feeding systems, on condition that their level does not exceed: - for antibiotics, 1000 ppm;

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

- for vitamins D, 200 000 IU/kg.

This provision shall not apply in the case of authorisation granted under subparagraph (b).

2. Authorisation under paragraph 1 (b) or (c) may be granted only if the feeding-stuff contains compositional characteristics (as regards, for example, proteins or minerals) which in practice ensure that the level of additives fixed for complete feeding-stuffs is not exceeded and that the feeding-stuff is not used for species of animal other than those for which it was intended. Authorisation of such feeding-stuffs shall be determined by prior consultation between the Member States and the Commission within the Standing Committee for Feeding-stuffs.

#### Article 10

1. The Member States shall require that feeding-stuffs containing any of the substances listed below may be placed on the market only if the substance is specified on the packaging, either directly or by means of a label giving the following details: (a) antibiotics : nature, level and expiry date of the guarantee of that level;

(b) substances having antioxidant effects : nature;

(c) coccidiostats and other medicinal substances (Annex I (D)) : nature, level and conditions

of use as specified in the Annex;

(d) colouring matter, including pigments, listed in Annex I (F) No 2 : nature;

(e) Vitamins A, D and E : nature, level and expiry date of the guarantee of that level;

(f) copper : level expressed as Cu, if it exceeds 50 ppm;

(g) additives authorised under Article 4 (1) (a) : nature and level.

These substances shall be referred to by the customary terminology.

2. In the case of goods in bulk the details mentioned in paragraph 1 may be given on a document attached to the goods.

3. The presence of trace elements and of vitamins other than vitamins A, D and E, of provitamins and (1)OJ No L 170, 3.8.1970, p. 1.

other similar active substances may be indicated if the amounts of these substances present can be determined by official methods of analysis. In such cases the following details shall be given: (a) for trace elements : nature and level;

(b) for other substances : nature, level and expiry date of the guarantee of that level.

4. Any reference to additives other than in the form provided for in this Directive shall be prohibited.

#### Article 11

1. The Member States shall require that supplementary feeding-stuffs which contain additives in excess of the maximum levels fixed for complete feeding-stuffs may be placed on the market only if the packaging: (a) bears the words "supplementary feeding-stuffs" and indicates the nature of the feeding-stuff;

(b) gives directions for use and the following additional instruction:

"This feeding-stuff may be used only for... (species and age category of the animal)... up to a quantity of... grammes per kilogramme of daily ration."

These details must be in accordance with the provisions of Annex I. This provision shall not apply to materials delivered to manufacturers of compound feeding-stuffs or to their suppliers.

2. The declaration referred to in paragraph 1 (b) shall be so formulated that, when it is correctly followed, the proportion of additives does not exceed the maximum level fixed for complete feeding-stuffs.

#### Article 12

Where feeding-stuffs are marketed in other Member States the details referred to in Articles 10 and 11 shall be given in at least one of the official languages of the country of destination.

#### Article 13

The Member States shall ensure that feeding-stuffs which conform to the provisions of this Directive shall be subject, as regards the presence or absence of additives and as regards marking, to no marketing restrictions other than these provided for in this Directive.

#### Article 14

The Member States shall ensure that livestock products are not subject to any marketing restriction as a result of the application of this Directive.

#### Article 15

The Member States shall take all necessary measures to ensure that feeding-stuffs put on the market are officially controlled, at least by check sampling, to verify whether the conditions laid down in this Directive are satisfied.

#### Article 16

This Directive shall not apply to feeding-stuffs which are shown, at least by an appropriate indication, to be for export to third countries.

#### Article 17

Member States shall, within two years following notification thereof, bring into force the laws, regulations, or administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

#### Article 18

This Directive is addressed to the Member States.

Done at Brussels, 23 November 1970.

For the Council

The President

W. SCHEEL

ANNEX I

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ANNEX II

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