

## II

*(Acts whose publication is not obligatory)*

## COUNCIL

## SECOND COUNCIL DIRECTIVE

of 28 April 1975

amending Directive No 70/524/EEC concerning additives in feedingstuffs

(75/296/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 <sup>(1)</sup>;

Having regard to the Opinion of the Economic and Social Committee <sup>(2)</sup>;

Whereas, in the course of implementing Council Directive No 70/524/EEC <sup>(3)</sup> of 23 November 1970 concerning additives in feedingstuffs, as last amended by Eleventh Commission Directive No 75/267/EEC <sup>(4)</sup>, as far as the Annexes are concerned, the need has become apparent to define the term 'animals';

Whereas, in so far as this term also covers pets, it will be necessary to examine later whether a special Directive should be adopted for feedingstuffs for these animals;

Whereas, taking into account amendments made to the Annexes by the Commission, it is necessary to make certain amendments of a technical nature to the enacting terms of Directive No 70/524/EEC;

Whereas it is also necessary to transfer into the Annexes of that Directive all the technical provisions concerning the substances or groups of substances hitherto shown only in the enacting terms;

Whereas experience gained in connection with Annex II, which lists all the additives that may be permitted by Member States on a national scale until the end of 1975, has shown that the Annex should in future constitute an intermediate stage in determining the inclusion of additives in, and their exclusion from, the list of those permitted in the Community (Annex I); whereas it is therefore necessary to fix special conditions governing the inclusion of substances in Annex II;

Whereas in accordance with Council Directive No 73/103/EEC <sup>(5)</sup> of 28 April 1973 amending the Directive of 23 November 1970 concerning additives in feedingstuffs, the adaptation of the Annexes to the development of scientific and technical knowledge, and hence the admission and deletion of the additives, have been subjected to the procedure of the

<sup>(1)</sup> OJ No C 5, 8. 1. 1975, p. 57.

<sup>(2)</sup> OJ No C 16, 23. 1. 1975, p. 19.

<sup>(3)</sup> OJ No L 270, 14. 12. 1970, p. 1.

<sup>(4)</sup> OJ No L 118, 8. 5. 1975, p. 45.

<sup>(5)</sup> OJ No L 124, 10. 5. 1973, p. 17.

Standing Committee for Feedingstuffs; whereas the fixing of the criteria for the characterization of the additives concerned should therefore be authorized under the same procedure;

Whereas the experience gathered during the marketing of feedingstuffs containing additives shows the need to improve the marking of these feedingstuffs,

HAS ADOPTED THIS DIRECTIVE:

#### *Article 1*

Directive No 70/524/EEC shall be amended in accordance with the following Articles.

#### *Article 2*

Article 2 shall be supplemented by the following subparagraph:

'(g) *Animals*: animals belonging to species normally nourished and kept or consumed by man.'

#### *Article 3*

Article 3 (7) shall be deleted.

#### *Article 4*

Article 4 (1) shall be amended as follows:

1. in subparagraph (a) the word 'five' shall be replaced by the word 'eight' and the words 'in Annex I' shall be replaced by the words 'in Annex I or II';
2. in subparagraph (b), the words 'during a period of five years following notification of this Directive' shall be deleted;
3. subparagraphs (c), (d), (e) and (f) shall be deleted.

#### *Article 5*

Article 6 shall be replaced by the following:

#### *'Article 6*

1. Amendments to be made to the Annexes on account of the growth of scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 16 (a).

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

A. A substance 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 endanger animal or human health 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. A substance shall be deleted from Annex I if any of the conditions listed under A is no longer satisfied. However, such a substance may be inserted in Annex II for a specified period, if as a minimum the conditions of subparagraph A (b) and (e) are satisfied.

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

3. The criteria for the characterization of the additives referred to in this Directive, particularly the criteria of both composition and purity and the physico-chemical and biological properties, may be fixed, taking account of scientific and technical knowledge, in accordance with the procedure laid down in Article 16 (a).'

#### *Article 6*

Article 9 (1) shall be amended as follows:

1. in the first sentence, the words 'growth promoters' (Annex I (J)) shall be inserted after the words 'Vitamins D (Annex I (H) No 1)';

2. in subparagraph (b), the words, 'growth promoters' shall be inserted after the words 'Vitamins D';
3. in subparagraph (c), the following indent shall be inserted:  
'— for growth promoters, 1 000 ppm.'

*Article 7*

Article 10 shall be amended as follows:

1. in paragraph 1 (a), the words 'and growth promoters' shall be added after the word 'antibiotics';
2. in paragraph 1, the text of subparagraph (g) shall be replaced by the following:  
'(g) non-protein nitrogen compounds: nature and level and conditions of use as laid down in the Annexes';
3. paragraph 1 shall be supplemented by the following subparagraph:  
'(h) preservatives: nature';

4. the following paragraph shall be added:

'2a. The Member States shall prescribe that the nature of the additives permitted under Article 4 (1) (a) and (b) must be specified on the package or label. They may prescribe that the content must also be specified.'

*Article 8*

In Article 11 (1), second subparagraph, the words 'of Annex I or II' shall replace the words 'of Annex I'.

*Article 9*

Annex II shall be amended as follows:

1. a new column headed 'Period of authorization' shall be added. The date of 30 June 1976 shall be entered in this column for each of the additives listed in the aforesaid Annex prior to 1 May 1975;
2. a new part D (a) headed 'Trace elements', comprising the following headings, shall be added:

No	Additives	Chemical formula, description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorization
					ppm of complete feedingstuff			
1	Molybdenum	Mo				2.5		—
2	Selenium	Se				0.5		—

3. the following heading shall be added to Part E:

No	Additives	Chemical formula, description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorization
					ppm of complete feedingstuff			
9	Saccharin	C <sub>7</sub> H <sub>5</sub> O <sub>3</sub> NS						—

*Article 10*

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply:

- (a) by 1 July 1975 at the latest, with Article 4 (1) and (2), Article 5, Article 6 and Article 9;
- (b) by 1 July 1976 at the latest, with the other provisions.

*Article 11*

This Directive is addressed to the Member States.

Done at Brussels, 28 April 1975.

*For the Council*

*The President*

M. A. CLINTON

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