

COMMISSION DIRECTIVE 96/66/EC
of 14 October 1996
amending Council Directive 70/524/EEC concerning additives in feedingstuffs
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs⁽¹⁾, as last amended by Directive 96/51/EC⁽²⁾, and in particular Article 7 thereof,

Whereas Directive 70/524/EEC provides for regular amendment of the content of its Annexes to take account of advances in scientific and technical knowledge; whereas the Annexes have been consolidated by Commission Directive 91/248/EEC⁽³⁾;

Whereas new uses for additives belonging to the group Coccidiostats and other medicinal substances have been successfully tested in certain Member States; whereas the new uses should be authorized provisionally at national level pending their approval at Community level;

Whereas the Chernobyl accident caused radioactive caesium fallout which contaminated forage in certain regions of northern Europe; whereas, in order to protect human and animal health and introduce preventive measures to combat pollution by radioactive caesium nuclides, a new group of additives should be established, namely 'radionuclide binders'; whereas a new additive belonging to this group which allows absorption of caesium nuclides by animals to be substantially reduced has been successfully tested in certain Member States; whereas this new additive should be authorized provisionally at national level pending its approval at Community level;

Whereas the investigation of various additives currently listed in Annex II and therefore capable of authorization at national level has not yet been completed; whereas, therefore, the period of authorization of these substances should be extended for a specific period;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Feedingstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annexes to Directive 70/524/EEC are hereby amended as set out in the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions needed to comply with the Annex to this Directive by 31 March 1997 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, 14 October 1996.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ No L 270, 14. 12. 1970, p. 1.

⁽²⁾ OJ No L 235, 17. 9. 1996, p. 39.

⁽³⁾ OJ No L 124, 18. 5. 1991, p. 1.

ANNEX

1. Annex I:

1.1. In the English-language version, in part A 'Antibiotics', item E 716 'Salinomycin sodium', and in part D 'Coccidiostats and other medicinal substances' item E 766 'Salinomycin sodium', the text of column 'Chemical formula, description' is replaced each time by the following text:

$C_{12}H_{19}O_{11}Na$ (sodium salt of a polyether monocarboxylic acid produced by *Streptomyces albus*)

Elatophyllin content: less than 42 mg per kg of salinomycin sodium

17-*epi*-20-desoxy-salinomycin content: less than 40 g per kg of salinomycin sodium

2. In Annex II:

2.1. In part A 'Antibiotics':

2.1.1. under item 30 'Virginiamycin' the date '30. 11. 1996' in the column 'Period of authorization' is replaced by '30. 11. 1997' for the category of animal 'Sows';

2.1.2. under item 31 'Bacitracin zinc' the date '30. 11. 1996' in the column 'Period of authorization' is replaced each time by '30. 11. 1997' for the categories of animal 'Chickens for fattening' and 'Pigs';

2.1.3. under item 32 'Ardacin' the date '30. 11. 1996' in the column 'Period of authorization' is replaced by '30. 11. 1997' for the category of animal 'Chickens for fattening';

2.2. In part D 'Coccidiostats and other medicinal substances':

2.2.1. under item 25 'Halofuginone' the date '30. 11. 1996' in the column 'Period of authorization' is replaced by '12. 7. 1997' for the category of animal 'Chickens treated for laying';

2.2.2. (a) under item 26 'Salinomycin sodium' the date '30. 11. 1996' in the column 'Period of authorization' is replaced by '30. 11. 1997' for the category of animal 'Rabbits for fattening';

(b) item 26 'Salinomycin sodium' is completed as follows:

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content mg/kg of complete feedingsstuff		Maximum content	Other provisions	Period of authorization
					Minimum content	Maximum content			
			'Chickens treated for laying'	12 weeks	30	50		Indicate in the instructions for use: — "Dangerous for equines" — "This feedingsstuff contains an ionophore; simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated"	30. 11. 1997

(c) in the English-language version, item 26 'Salinomycin sodium', the text of column 'Chemical formula, description' is replaced each time by the following text:

$C_{12}H_{19}O_{11}Na$ (sodium salt of a polyether monocarboxylic acid produced by *Streptomyces albus*)

Elatophyllin content: less than 42 mg per kg of salinomycin sodium

17-*epi*-20-desoxy-salinomycin content: less than 40 g per kg of salinomycin sodium;

2.2.3. under item 27 'Diclazuril', the date '30. 11. 1996' in the column 'Period of authorization' is replaced by '30. 11. 1997' for the category of animal 'Turkeys';

2.2.4. the following item is added:

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	Period of authorization
					mg/kg of complete feedingsstuff				
'28	Maduramicin ammonium	$C_{47}H_{83}O_{17}N$ (Ammonium salt of a polyether monocarboxylic acid produced by <i>Actinomadura yumaensis</i>)	Turkeys	16 weeks	5	5		Use prohibited at least 5 days before slaughter Indicate in the instructions for use: — "Dangerous for equines" — "This feedingsstuff contains an ionophore; simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated"	30. 11. 1997

3. In part F 'Colouring matters, including pigments', under item 11 'Astaxanthin-rich *Phaffia rhodozyma*' the date '30. 11. 1996' in the column 'Period of authorization' is replaced by '30. 11. 1997' for the category of animal 'Salmon, trout'.

4. In part L, 'Binders, anti-caking agents and coagulants':

4.1. under item 1 'Synthetic calcium aluminates' the date '30. 11. 1996' in the column 'Period of authorization' is replaced by '12. 7. 1997' for the category of animal 'Dairy cows, cattle for fattening, calves, lambs, kids';

4.2. under item 2 'Natrolite-phonolite' the date '30. 11. 1996' in the column 'Period of authorization' is replaced by '30. 11. 1997'.

5. In part N 'Enzymes', under item 1 '3-phytase (EC 3.1.3.8)', the date '30. 11. 1996' in the column 'Period of authorization' is replaced each time by '30. 11. 1997' for the categories of animal 'Pigs (all categories of animals)' and 'Chickens (all categories of animals)'.
6. In part O 'Micro-organisms':

6.1. under item 1 '*Bacillus cereus* var. *toyoi* (CNCM I-1012/NCIB 40112)' the date '30. 11. 1996' in the column 'Period of authorization' is replaced each time by '30. 11. 1997' for the categories of animal 'Piglets', 'Pigs' and 'Sows';

6.2. under item 2 '*Bacillus licheniformis* (DSM 5749)/*Bacillus subtilis* (DSM 5750) [in a 1/1 ratio]' the date '30. 11. 1996' in the column 'Period of authorization' is replaced by '30. 11. 1997' for the category of animal 'Piglets';

6.3. under item 3 '*Saccharomyces cerevisiae* (NCYC Sc 47)', the date '30. 11. 1996' in the column 'Period of authorization' is replaced by '30. 11. 1997' for the category of animal 'Cattle for fattening';

6.4. under item 4 '*Bacillus cereus* (ATCC 14893/CIP 5832)' the date '30. 11. 1996' in the column 'Period of authorization' is replaced each time by '30. 11. 1997' for the categories of animal 'Rabbits for fattening' and 'Breeding rabbits'.

7. The following group and item are added:

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content mg/kg of complete feedingstuff		Maximum content	Other provisions	Period of authorization
					Minimum content	Maximum content			
1.	P. Radionuclide binders Radioactive caesium binders (¹³⁷ Cs and ¹³⁴ Cs)								
1.1.	Ferric (III) ammonium hexacyanoferrate (II)	NH ₄ Fe(III)Fe(II)(CN) ₆	Ruminants (domestic and wild) Calves prior to the start of rumination Lambs prior to the start of rumination Kids prior to the start of rumination Pigs (domestic and wild)	— — — — —	50	500	Indicate in the instructions for use: "The quantity of Ferric (III) ammonium hexacyanoferrate (II) in the daily ration must be between 10 mg and 150 mg for 10 kg of body weight"	30.11.1997 30.11.1997 30.11.1997 30.11.1997 30.11.1997	