

COMMISSION DIRECTIVE 97/72/EC
of 15 December 1997
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 97/6/EC⁽²⁾, and in particular Article 7 thereof,

Whereas Directive 70/524/EEC stipulates that the contents of its Annexes are to be kept up to date with advances in scientific and technical knowledge; whereas the Annexes were consolidated by Commission Directive 91/248/EEC⁽³⁾;

Whereas for an additive belonging to the group 'Antibiotics', the details in the column 'Chemical formula, description' should be supplemented;

Whereas a new use of an additive belonging to the group 'Coccidiostats and other medicinal substances' and a new use of one belonging to the group 'Binders, anti-caking agents and coagulants' have been widely tested in certain Member States; whereas in the light of the experience gained and research carried out these new uses may be authorized throughout the Community;

Whereas the provisions of the Annexes on one additive of the group 'Emulsifiers, stabilizers, thickeners and gelling agents' require adjustment to the Community provisions adopted on this matter as regards foodstuffs;

Whereas for two additives of the group 'Emulsifiers, stabilizers, thickeners and gelling agents' and for one of the group 'Preservatives' the entry in the 'Other provisions' column should be altered;

Whereas a new use of an additive of the group 'Antibiotics' and of one of the group 'Coccidiostats and other medicinal substances' have been successfully tested in certain Member States; whereas provisional national authorization of these new uses should be permitted pending possible general Community authorization;

Whereas the minimum authorized content of an additive of the 'Micro-organisms' group should be altered;

Whereas research into various additives in Annex II, use of which can accordingly be authorized nationally, has not yet been completed; whereas for each of these this option should therefore be extended by a set period;

Whereas Directive 97/6/EC prohibited use of the glycopeptide antibiotic avoparcin with effect from 1 April 1997 on the grounds that it could not be ruled out that its use in animal feed was liable to induce resistance to glycopeptides used in human medicine;

Whereas another glycopeptide, ardacin, was given provisional authorization by Commission Directive 94/77/EC of 20 December 1994 amending Council Directive 70/524/EEC concerning additives in feedingstuffs⁽⁴⁾; whereas although this additive is not at present marketed, as a precautionary measure and in line with the Scientific Committee's recommendations, in the absence of results from the research still to be carried out on avoparcin, its authorization should not be prolonged;

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, immediately informing the Commission thereof, the laws, regulations and administrative provisions needed to comply with the Annex to this Directive by 31 March 1998.

These provisions shall contain a reference to this Directive or be accompanied by such a reference on official publication. Details of the reference shall be set by the Member State.

⁽¹⁾ OJ L 270, 14. 12. 1970, p. 1.

⁽²⁾ OJ L 35, 5. 2. 1997, p. 11.

⁽³⁾ OJ L 124, 18. 5. 1991, p. 1.

⁽⁴⁾ OJ L 350, 31. 12. 1994, p. 113.

2. Member States shall send the Commission the text of primary provisions of national law adopted on the matters regulated 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, 15 December 1997.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX

1. In Annex I:

1.1. In part A 'Antibiotics', under item E 717 'Avilamycin', the entry in the column 'Chemical formula, description' is replaced by the following:

'C₅₇H₆₂Cl₂O_{31.32} (mixture of oligosaccharides of the orthosomycin group produced by *Streptomyces viridochromogenes*, NRRL 2860)

Factor composition:

Avilamycin A: not less than 60 %

Avilamycin B: not more than 18 %

Avilamycins A + B: not less than 70 %

Other single avilamycins: not more than 6 %.

1.2. In part D 'Coccidiostats and other medicinal substances', item E 764 'Halofuginone' is supplemented as follows:

| EC Number | Additive | Chemical formula (description) | Species or category of animal | Maximum age | Minimum content | | Maximum content | Other provisions |
|-----------|----------|-----------------------------------|----------------------------------|----------------|------------------------------------|---|-----------------|------------------|
| | | | | | mg/kg of complete feedingsstuff | | | |
| | | | 'Chickens reared for laying | 16 weeks | 2 | 3 | | — |

1.3. In Part E 'Emulsifiers, stabilizers, thickeners and gelling agents':

1.3.1. Item E 408 'Furcelleran' is deleted.

1.3.2. For items E 418 'Gellan gum' and E 499 'Cassia gum' the entry in the 'Other provisions' column is replaced by 'Feedingsstuffs with a moisture content exceeding 20 %'.

1.4. In Part G 'Preservatives', for item E 250 'Sodium nitrite' the entry in the 'Other provisions' column is replaced by 'Feedingsstuffs with a moisture content exceeding 20 %'.

1.5. In Part L 'Binders, anti-caking agents and coagulants' item E 598 'Synthetic calcium aluminates' is supplemented as follows:

| EC Number | Additive | Chemical formula (description) | Species or category of animal | Maximum age | Minimum content | | Maximum content | Other provisions |
|-----------|----------|-----------------------------------|---|----------------|------------------------------------|-------|-----------------|--------------------|
| | | | | | mg/kg of complete feedingsstuff | | | |
| | | | 'Dairy cows, cattle for fattening, calves, lambs, kids | — | — | 8 000 | | All feedingsstuffs |

2. In Annex II:

2.1. In Part A 'Antibiotics':

2.1.1. Under item 30 'Virginamycin', for sows, the date '30.11.1997', in the 'Period of authorization' column is replaced by '3.6.1998'.

2.1.2. Under item 31 'Bacitracin zinc', for chickens for fattening and for pigs, the date '30.11.1997' in the 'Period of authorization' column is replaced by '30.11.1998'.

2.1.3. The following item is added:

| Number | 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 mg/kg of complete feedingstuff | Maximum content | | | |
| '33 | Avilamycin | $C_{57.62}H_{82.50}Cl_{1.2}O_{31.32}$ (mixture of oligosaccharides of the ortho- somyicin group produced by <i>Streptomyces</i> <i>viridochromogenes</i> , NRRL 2860) Factor composition: Avilamycin A: not less than 60 % Avilamycin B: not more than 18 % Avilamycin A + B: not less than 70 % Other single avilamycins: not more than 6 % | Turkeys | — | 5 | 10 | — | — | 30.11.1998' |

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

2.2.1. Under item 26 'Salinomycin sodium', for rabbits for fattening and chickens reared for laying, the date '30.11.1997' in the 'Period of authorization' column is replaced by '30.11.1998'.

2.2.2. Under item 27 'Diclazuril', for turkeys, the date '30.11.1997' in the 'Period of authorization' column is replaced by '30.11.1998'.

2.2.3. Item 27 'Diclazuril' is supplemented as follows:

| Number | 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 mg/kg of complete feedingstuff | Maximum content | | | |
| | | | 'Chickens reared for laying | 16 weeks | 1 | 1 | — | — | 30.11.1998' |

- 2.2.4. Under item 28 'Maduramycin ammonium', for turkeys the date '30.11.1997' in the 'Period of authorization' column is replaced by '30.11.1998'.
3. In Part F 'Colouring matters, including pigments', under item 11 '*Astaxanthin-reich Phaffia rhodozyma*', for salmon and trout, the date '30.11.1997' in the 'Period of authorization' column is replaced by '30.11.1998'.
4. In Part L 'Binders, anti-caking agents and coagulants', for item 2 'Natrolite-phonolite' the date '30.11.1997' in the 'Period of authorization' column is replaced by '30.11.1998'.
5. In Part N 'Enzymes', under item 1 '3-phytase (EC 3.1.3.8)', for pigs (all categories) and chickens (all categories) the date '30.11.1997' in the 'Period of authorization' column is replaced by '30.11.1998'.
6. In Part O 'Micro-organisms':
- 6.1. For item 1 '*Bacillus cereus var. toyoi* (CNCM I-1012/NCIB 40112)':
- 6.1.1. For sows the minimum CFU/kg of complete feedstuff specified is replaced by '0,5 × 10⁸'.
- 6.1.2. For piglets, pigs and sows the date '30.11.1997' in the 'Period of authorization' column is replaced by '30.11.1998'.
- 6.2. Under item 2 '*Bacillus liemiformis* (DSM 5749)/*Bacillus subtilis* (DSM 5750) (in a 1/1 ratio)', for piglets the date '30.11.1997' in the 'Period of authorization' column is replaced by '30.11.1998'.
- 6.3. Under item 3 '*Saccharomyces cerevisiae* (NCYC Sc 47)', for cattle for fattening the date '30.11.1997' in the 'Period of authorization' column is replaced by '30.11.1998'.
- 6.4. Under item 4 '*Bacillus cereus* (ATCC 14893/CIP 5832)', for rabbits for fattening and breeding rabbits the date '30.11.1997' in the 'Period of authorization' column is replaced by '30.11.1998'.
7. In Part P 'Radionuclide binders', under entry 1.1 'Ferric (III) ammonium hexacyanoferrate (II)', for 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 and pigs (domestic and wild) the date '30.11.1997' in the 'Period of authorization' column is replaced by '30.11.1998'.