

## FIFTEENTH COMMISSION DIRECTIVE

of 21 June 1976

amending the Annexes to the Council Directive of 23 November 1970 concerning additives in feedingstuffs

(76/603/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Council Directive of 23 November 1970 concerning additives in feedingstuffs <sup>(1)</sup>, as last amended by the Fourteenth Commission Directive of 8 June 1976 <sup>(2)</sup>, and in particular Article 6 thereof,

Whereas this Directive provides for the contents of the Annexes to be regularly amended to take account of developments in scientific and technical knowledge;

Whereas in a previous amendment of the Directive an error occurred regarding the conditions of use of oleandomycin for poultry; whereas this should be corrected;

Whereas the provisions of the Annexes relating to anti-oxidants, emulsifiers and stabilizers need to be adapted to the Community provisions adopted in this regard in the field of foodstuffs;

Whereas the use of the coccidiostats decoquinate and monensin sodium for chickens and robenidine for chickens and turkeys, included hitherto in Annex II have been widely tested in the Community; whereas it should therefore be authorized, subject to certain conditions, at Community level;

Whereas most of the preservatives covered by Community provisions in the field of foodstuffs are also

used in the Community for preserving animal feedingstuffs; whereas they should therefore be included in the Annexes;

Whereas the use of certain additives belonging to the groups of antibiotics, coccidiostats and other medicinal substances, emulsifiers, stabilizers, thickeners and gelling agents, colouring matters, growth promoters and manufacturing aids, already included in Annex II, requires further examination; whereas their period of authorization should therefore be extended;

Whereas livestock production conditions for young animals in certain Member States require the use of antibiotics in Annex I at higher levels than those laid down therein; whereas this use should be authorized at national level under restricted conditions which cannot involve risks for animal or human health;

Whereas the use of the antibiotic avoparcin for chickens and swine has been successfully tested in certain Member States; whereas it should be authorized, subject to certain conditions, at least at national level, pending its admission at Community level;

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

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

The Annexes to the Council Directive of 23 November 1970 concerning additives in feedingstuffs are hereby amended as set out in the following Articles.

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

<sup>(2)</sup> OJ No L 160, 22. 6. 1976, p. 11.

content', relating to 'turkeys' and 'other poultry excluding ducks, geese, laying hens, pigeons' shall be replaced by the figures '2' and '10' respectively.

### 1. Part A 'Antibiotics'.

## 2. Part B 'Anti-oxidants'.

The existing provisions shall be replaced by the following text:

EEC No	Additives	Chemical formula description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions
					ppm of complete feedingstuffs		

### B. Anti-oxidants

E 300	L-Ascorbic acid	All species of animals	All feedingstuffs
E 301	Sodium L-ascorbate		
E 302	Calcium L-ascorbate		
E 303	5,6-diacetyl-L-ascorbic acid		
E 304	6-palmityl-ascorbic acid		
E 306	Tocopherol-rich extracts of natural origin		
E 307	Synthetic alpha-toco- pherol		
E 308	Synthetic gamma-toco- pherol		
E 309	Synthetic delta-toco- pherol		
E 311	Octyl gallate		
E 312	Dodecyl gallate		
E 320	Butylated hydroxyani- sole (BHA)	150: alone or together	
E 321	Butylated hydroxytolu- ene (BHT)		
E 324	Ethoxyquin		

3. Part D 'Coccidiostats and other medicinal substances'.  
The following items shall be added:

EEC No	Additives	Chemical formula description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions
					ppm of complete feedingstuffs		
E 756	Deco- quinate	ethyl 6-decyloxy- 7-ethoxy-4- hydroxyquinoline- 3-carboxylate	Chickens for fattening		20	40	Use prohibited at least three days before slaughter
E 757	Monen- sin- sodium	Ester complex of sodium butyrate C <sub>36</sub> H <sub>61</sub> O <sub>11</sub> Na	Chickens for fattening		100	125	Use prohibited at least three days before slaughter
E 758	Robeni- dine	1,3 bis (p-chloro- benzylidenea- mino) guanadine hydrochloride	Chickens for fattening, turkeys		30	36	Use prohibited at least five days before slaughter

4. Part E 'Emulsifiers' shall be deleted and replaced by the following text:

EEC No	Additives	Chemical formula description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions
					ppm of complete feedingstuffs		

E. Emulsifiers, stabilizers, thickeners and gelling agents

E 322	Lecithins	All species of animals					All feedingstuffs
E 400	Alginic acid						
E 401	Sodium alginate						
E 402	Potassium alginate						
E 403	Ammonium alginate	All species of animals with the exception of aquarium fish					
E 404	Calcium alginate						
E 405	Propylene glycol algi- nate (1,2-propanediol alginate)						
E 406	Agar						
E 407	Carrageenan (carrageen)	All species of animals					
E 408	Furcelleran, furcellaran						

EEC No	Additives	Chemical formula description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions
					ppm of complete feedingstuffs		
E 410	Locust bean gum (carob gum)	All species of animals	All feedingstuffs				
E 411	Tamarind seed flour						
E 412	Guar gum (guar flour)						
E 413	Tragacanth						
E 414	Acacia (arabic gum)						
E 420	Sorbitol						
E 421	Mannitol						
E 422	Glycerol						
E 440	Pectins						
E 460	Microcrystalline cellulose						
E 461	Methylcellulose						
E 462	Ethylcellulose						
E 463	Hydroxypropylcellulose						
E 464	Hydroxypropylmethyl-cellulose						
E 465	Methylethylcellulose						
E 466	Carboxymethylcellulose (sodium salt of carboxy-methyl-cellulose)						
E 470	Sodium, potassium and calcium salts of edible fatty acids alone or in mixtures, derived either from edible fats or distilled edible fatty acids						
E 471	Mono- and di-glycerides of fatty acids						
E 472	Mono and di-glycerides of food fatty acids esterfied with the following acids:  a) acetic b) lactic c) citric d) tartaric e) mono-acetyltartaric and di-acetyltartaric						

EEC No	Additives	Chemical formula description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions
					ppm of complete feedingstuffs		
E 473	Sucroesters (esters of saccharose and edible fatty acids)		All species of animals				All feedingstuffs
E 474	Sucroglycerides (mixture of esters of saccharose and mono- and diglycerides of edible fatty acids)						
E 475	Polyglycerol esters of non polymerized edible fatty acids						
E 477	Mono-esters of propyleneglycol (1,2-propanediol) and edible fatty acids, alone or in mixture with diesters						
E 480	Stearoyl-2-lactylic acid						
E 481	Sodium stearoyl-2-lactylate						
E 482	Calcium stearoyl-2-lactylate						
E 483	Stearyl tartrate						

5. Part G ‘Stabilizers’ shall be deleted and replaced by the following text:

EEC No	Additives	Chemical formula description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions
					ppm of complete feedingstuffs		

## G. Preservatives

E 200	Sorbic acid	All species of animals	All feedingstuffs
E 201	Sodium sorbate		
E 202	Potassium sorbate		
E 203	Calcium sorbate		
E 236	Formic acid		
E 237	Sodium formate		
E 238	Calcium formate		
E 260	Acetic acid		
E 261	Potassium acetate		
E 262	Sodium diacetate		

EEC No	Additives	Chemical formula description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions	
					ppm of complete feedingstuffs			
E 263	Calcium acetate	}	All species of animals				}	All feedingstuffs
E 270	Lactic acid							
E 325	Sodium lactate							
E 326	Potassium lactate							
E 327	Calcium lactate							
E 280	Propionic acid							
E 281	Sodium propionate							
E 282	Calcium proprionate							
E 283	Potassium proprionate							
E 330	Citric acid							
E 331	Sodium citrates							
E 332	Potassium citrates							
E 333	Calcium citrates							
E 334	Tartaric acid							
E 335	Sodium tartrates							
E 336	Potassium tartrates							
E 337	Sodium-potassium tartrate							
E 338	Orthophosphoric acid							

### Article 3

Annex II shall be amended as follows:

#### 1. Part A 'Antibiotics'.

- 1.1 For item No 2 'Erythromycin' there shall be added the words 'chickens for fattening, swine' in the column headed 'species of animal' and the figures '5' and '20' respectively in the columns headed 'Minimum content' and 'Maximum content' relating to these species.
- 1.2 For items No 2 'Erythromycin', No 6 'Tylosin', No 17 'Lincomycin', No 18 'Bacitracin-methylene-disalicylate' and for the use of additive No 15 'Zinc-bacitracin' for ducks, the date '30 June 1976' in the column headed 'Period of authorization' shall be replaced by the date '31 December 1977'.
- 1.3 For item No 3 'Hygromycin B' the date '30 June 1976' in the column headed 'Period of authorization' shall be replaced by the date '31 December 1976'.
- 1.4 There shall be added to item No 15 'Zinc-bacitracin' the following:

No	Additives	Chemical formula description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorization
					ppm of complete feedingstuffs			
15.			Poultry with the exception of ducks and geese	Until the end of the fourth week	> 20	50		31 December 1977
			Swine	Until the end of the 10th week	> 20	50		
			Calves, lambs and kids	Until the end of the 16th week	> 20	50		
			Animals bred for fur		> 20	50		

## 1.5 The following items 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 feedingstuffs			
19.	Oleandomycin	C <sub>35</sub> H <sub>61</sub> O <sub>12</sub> N (base) Macrolide	Poultry with the exception of ducks and geese	Until the end of the fourth week	> 10	25		31 December 1977
			Swine	Until the end of the 10th week	> 10	25		
20.	Spiramycin	I. C <sub>46</sub> H <sub>78</sub> O <sub>16</sub> N <sub>2</sub> II. C <sub>47</sub> H <sub>80</sub> O <sub>16</sub> N <sub>2</sub> III. C <sub>48</sub> H <sub>82</sub> O <sub>16</sub> N <sub>2</sub> (base) Macrolide	Poultry with the exception of ducks and geese	Until the end of the fourth week	> 20	50		
			Swine	Until the end of the 10th week	> 20	50		
			Calves, lambs and kids	Until the end of the 16th week	> 20	50		
			Animals bred for fur		> 20	50		
21.	Virginiamycin	I. C <sub>28</sub> H <sub>35</sub> N <sub>3</sub> O <sub>7</sub> II. C <sub>48</sub> H <sub>40</sub> N <sub>7</sub> O <sub>10</sub>	Poultry with the exception of ducks and geese	Until the end of the fourth week	> 20	50		

No	Additives	Chemical formula description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorization
					ppm of complete feedingstuffs			
21.	Virginia-mycin ( <i>cont'd</i> )		Swine	Until the end of the 10th week	> 20	50		31 December 1977
			Calves	Until the end of the 16th week	> 20	50		
22.	Avo-parcin		Chickens for fattening		7.5	15		
			Swine	Until the end of the 10th week	10	40		
				More than 10 weeks	5	20		

## 2. Part B 'Coccidiostats and other medicinal substances'.

2.1 The date '30 June 1976' in the column headed 'Period of authorization' shall be replaced by the date '31 December 1977' for the following items:

- No 2 'Dimetridazole'
- No 4 'Furazolidone'
- No 6 'Nicarbazin'
- No 7 'Nitrofurazone'
- No 8 'Sulphaquinoxaline'
- No 9 'Sulphaquinoxaline + pyrimethamine'
- No 10 'Sulphaquinoxaline + diaveridine'
- No 11 'Sulphadimethoxine + diaveridine'
- No 12 'Ronidazol'
- No 13 'Bifuran (nitrofurazone + furazolidone)'
- No 19 '3,5-dinitrosalicylic acid (5-nitrofurfurylidene) hydrazide'
- No 20 'Amprolium + sulphaquinoxaline + ethopabate'
- No 21 'Amprolium + sulphaquinoxaline + ethopabate + pyrimethamine'

2.2 The date '30 June 1976' in the column headed 'Period of authorization' shall be replaced by the date '31 December 1978' for the following items:

- No 14 'Methylbenzoquate'
- No 16 'Meticlorpindol + methylbenzoquate'

2.3 Items No 1 'Decoquinate', No 17 'Monensin-sodium' and No 18 'Robenidine' shall be deleted.



3. Part C 'Emulsifiers' shall be deleted and replaced by the following text:

No	Additives	Chemical formula description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorization
					ppm of complete feedingsuffs			

### C. Emulsifiers, stabilizers, thickeners and gelling agents

1.	Polyethylene glycol esters	All species of animals				All feeding-stuffs	
2.	Glycerine polyethylene-glycol ricinoleate						
3.	Polyglycerol alkylether (M.W. 650—700)	Calves	1 000	5 000	Milk feeds only	31 December 1977	
4.	1,2-Propyleneglycol						
5.	1,3-Butanediol	All species of animals				18 June 1979	
6.	Stearyl citrate						
7.	Maraya gum						
8.	Partial polyglycerol esters of polycondensed fatty acids of castor oil						
9.	Sorbitan monopalmitate						
10.	Sorbitan monostearate						
11.	Sorbitan tristearate						
12.	Polyoxyethylene (20) sorbitan monolaurate						
13.	Polyoxyethylene (20) sorbitan monopalmitate						
14.	Polyoxyethylene (20) sorbitan monostearate						
15.	Polyoxyethylene (20) sorbitan tristearate						
16.	Polyoxyethylene (20) sorbitan mono-oleate						
17.	Polyoxyethylene (8) stearate						
18.	Polyoxyethylene (40) stearate						
19.	Glyceric esters of fatty acids obtained from soya oil oxydized under heat						
20.	Ghatti gum						
21.	Xanthan gum						
22.	Extract of quillaia						

No	Additives	Chemical formula description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorization
					ppm of complete feedingstuffs			
23.	Lactylated fatty acid esters of glycerol and propylene glycol	All species of animals					All feeding-stuffs	18 June 1979
24.	Sorbitan monolaurate							
25.	Sorbitan mono-oleate							
26.	Dioctyl sodium sulphosuccinate							
27.	Ammonium phosphatides (synonym: emulsifier YN)							

4. Part D 'Stabilizers' shall be deleted and replaced by the following text:

No	Additives	Chemical formula description	Species of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorization
					ppm of complete feedingstuffs			

#### D. Preservatives

1.	Fumaric acid	All species of animals						
2.	Falsic acid							
3.	Hydrochloric acid							
4.	Sulphuric acid							
5.	Formaldehyde							
6.	Ethyl p-hydroxybenzoate (E 214)	Pets with the exception of cats					All feeding-stuffs	31 December 1977
7.	Sodium ethyl p-hydroxybenzoate (E 215)							
8.	Propyl p-hydroxybenzoate (E 216)							
9.	Sodium propyl p-hydroxybenzoate (E 217)							
10.	Methyl p-hydroxybenzoate (E 218)							
11.	Sodium-methyl p-hydroxybenzoate (E 219)	Pets						
12.	Sodium sulphite (E 221)							
13.	Sodium bisulphite (E 222)							
14.	Sodium metabisulphate (E 223)							
15.	Potassium metabisulphite (E 224)							
16.	Sodium nitrite (E 250)	Pets excepting birds and aquarium fish				200		



6. The following text 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 feedingstuffs			
H. Anti-oxidants								
1	Propylgallate		All species of animals			100: alone or with the other gallates	All feeding- stuffs	31 December 1977

#### Article 4

The Member States shall, not later than 31 December 1976, bring into force the laws, regulations or administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

#### Article 5

This Directive is addressed to the Member States.

Done at Brussels, 21 June 1976.

*For the Commission*

P. J. LARDINOIS

*Member of the Commission*