

COMMISSION REGULATION (EC) No 2316/98

of 26 October 1998

concerning authorisation of new additives and amending the conditions for authorisation of a number of additives already authorised 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 Commission Directive 98/19/EC⁽²⁾, and in particular Articles 9j and 3 thereof,

Whereas Directive 70/524/EEC provides that new additives or uses of additives may be authorised, taking account of advances in scientific and technical knowledge;

Whereas Council Directive 96/51/EC of 23 July 1996 amending Directive 70/524/EEC concerning additives in feedingstuffs⁽³⁾ lays down a new procedure for the authorisation of additives by Regulation, which will be fully applicable from 1 October 1999; whereas during the transitional period the Member States must be able to adopt legal provisions to prevent any confusion as to the legislation in force; whereas the Member States must ensure that all legislation not complying with this Regulation is repealed;

Whereas new additives belonging to Part 1 'Carotenoids and xanthophylls' of the group 'Colouring matters including pigments' have been successfully tested in certain Member States; whereas the new additives should be provisionally authorised;

Whereas, in order to distinguish a new additive belonging to Part 1 'Carotenoids and xanthophylls' of the group 'Colouring matters including pigments' from another additive belonging to the same group which has already been authorised, the name of the latter should be changed;

Whereas new additives belonging to the group 'Trace elements', and more specifically to the elements 'Copper-Cu', 'Manganese-Mn' and 'Zinc-Zn', have been widely tested in some Member States; whereas, on the basis of the studies carried out, it appears that these new additives can be authorised;

Whereas, to prevent any negative effects on dogs, the maximum permitted level in a complete feedingstuff of

the additive Ethoxyquin, belonging to the group 'Anti-oxidants', should be reduced;

Whereas a new use for an additive belonging to Part 1 'Carotenoids and xanthophylls' of the group 'Colouring matters including pigments' which has already been authorised has been successfully tested in some Member States; whereas the new use should be provisionally authorised;

Whereas a new use for the additive 3-phytase belonging to the group 'Enzymes' which has already been authorised has been successfully tested in some Member States; whereas the new use should be provisionally authorised;

Whereas, in the interests of transparency, the Annexes to this Regulation include, where appropriate, other additives belonging to the same group or other authorised uses of the additive; whereas it is appropriate to extend by a specific period the deadline for authorisation of additives, which are already authorised at national level but study of which has not been completed, belonging to the same groups of additives as the substances newly authorised by this Regulation;

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

HAS ADOPTED THIS REGULATION:

Article 1

1. Beta-carotene, belonging to Part 1 'Carotenoids and xanthophylls' of the group 'Colouring matters including pigments', may be authorised in accordance with Directive 70/524/EEC as additive E 160a in feedingstuffs under the conditions laid down in Annex I to this Regulation.

2. Astaxanthin-rich *Phaffia rhodozyma* (ATCC 74219), belonging to Part 1 'Carotenoids and xanthophylls' of the group 'Colouring matters including pigments', may be authorised in accordance with Directive 70/524/EEC as additive 12 in feedingstuffs under the conditions laid down in Annex I to this Regulation.

⁽¹⁾ OJ L 270, 14. 12. 1970, p. 1.

⁽²⁾ OJ L 96, 28. 3. 1998, p. 39.

⁽³⁾ OJ L 235, 17. 9. 1996, p. 39.

3. The substance 'cupric chelate of amino acids hydrate', belonging to the group 'Trace elements', element E4 'Copper-Cu', shall be authorised in accordance with Directive 70/524/EEC as an additive in feedingstuffs under the conditions laid down in Annex II to this Regulation.

4. The substance 'manganese chelate of amino hydrate', belonging to the group 'Trace elements', element E5 'Manganese-Mn', shall be authorised in accordance with Directive 70/524/EEC as an additive in feedingstuffs under the conditions laid down in Annex II to this Regulation.

5. The substance 'zinc chelate of amino acids hydrate', belonging to the group 'Trace elements', element E6 'Zinc-Zn', shall be authorised in accordance with Directive 70/524/EEC as an additive in feedingstuffs under the conditions laid down in Annex II to this Regulation.

Article 2

1. The conditions for authorisation of the additive E 324 Ethoxyquin, belonging to the group 'Antioxidants', shall be replaced in accordance with Directive 70/

524/EEC by the conditions laid down in Annex III to this Regulation.

2. Additive E161g Canthaxanthin, belonging to Part 1 'Carotenoids and xanthophylls' of the group 'Colouring matters including pigments' for the category of 'Pet and ornamental birds', may be authorised in accordance with Directive 70/524/EEC under the conditions laid down in Annex I to this Regulation.

3. Additive 3-phytase (EC 3.1.3.8), belonging to the group 'Enzymes', may be authorised in accordance with Directive 70/524/EEC under the conditions laid down in Annex IV to this Regulation.

4. Additive 11, Astaxanthin-rich *Phaffia rhodozyma*, belonging to Part 1 'Carotenoids and xanthophylls' of the group 'Colouring matters including pigments' for the category of animal 'Salmon, trout', may be authorised in accordance with Directive 70/524/EEC under the conditions laid down in Annex I to this Regulation.

Article 3

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

It shall apply from 15 December 1998.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 26 October 1998.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX I

No	EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content mg/kg of complete feedingstuff		Maximum content	Other provisions	Duration of authorisation
						Minimum content	Maximum content			
		Colouring matters including pigments 1. Carotenoids and xanthophylls								
	E 160a	Beta-carotene	$C_{40}H_{56}$	Canaries	—	—	—	—	—	30. 9. 1999
	E 160c	Capsanthin	$C_{40}H_{56}O_3$	Poultry	—	—	80 (alone or with the other caro- tenoids and xantho- phylls)	—	—	Without a time limit
	E 160e	Beta-apo-8'-carotenal	$C_{30}H_{40}O$	Poultry	—	—	80 (alone or with the other caro- tenoids and xantho- phylls)	—	—	Without a time limit
	E 160f	Ethyl ester of beta-apo- 8'-carotenoic acid	$C_{32}H_{44}O_2$	Poultry	—	—	80 (alone or with the other caro- tenoids and xantho- phylls)	—	—	Without a time limit

No	EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content mg/kg of complete feedingstuff		Maximum content	Other provisions	Duration of authorisation
						Minimum content	Maximum content			
	E 161b	Lutein	$C_{40}H_{56}O_2$	Poultry	—	—	80 (alone or with the other caro- tenoids and xantho- phylls)	—	—	Without a time limit
	E 161c	Cryptoxanthin	$C_{40}H_{56}O$	Poultry	—	—	80 (alone or with the other caro- tenoids and xantho- phylls)	—	—	Without a time limit
	E 161g	Canthaxanthin	$C_{40}H_{52}O_2$	Poultry	—	—	80 (alone or with the other caro- tenoids and xantho- phylls)	—	—	Without a time limit
				Salmon, trout	—	—	80	Use permitted from the age of six months onwards The mixture of cantha- xanthin with astaxanthin is allowed provided that the total concentration of the mixture does not exceed 100 mg/kg in the complete feedingstuff	—	Without a time limit

No	EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content mg/kg of complete feedingstuff		Maximum content	Other provisions	Duration of authorisation
						Minimum content	Maximum content			
				Dogs, cats and ornamental fish	—	—	—	—	Without a time limit	
				Pet and orna- mental birds	—	—	—	—	30. 9. 1999	
	E 161h	Zeaxanthin	$C_{40}H_{56}O_2$	Poultry	—	—	80 (alone or with the other caro- tenoids and xantho- phylls)	—	Without a time limit	
	E 161i	Citranaxanthin	$C_{33}H_{44}O$	Laying hens	—	—	80 (alone or with the other caro- tenoids and xantho- phylls)	—	Without a time limit	
	E 161j	Astaxanthin	$C_{40}H_{52}O_4$	Salmon, trout	—	—	100	Use only permitted from the age of six months onwards The mixture of astaxan- thin with canthaxanthin is allowed provided that the total concentration of the mixture does not exceed 100 mg/kg in the complete feedingstuff	Without a time limit	

No	EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content mg/kg of complete feedingstuff		Maximum content	Other provisions	Duration of authorisation
						Minimum content	Maximum content			
11		Astaxanthin-rich <i>Phaffia rhodozyma</i> (CBS 116.94)	Concentrated biomass of the yeast <i>Phaffia rhodozyma</i> (CBS 116.94), killed, containing at least 2,5 g astaxanthin per kilogram additive	Ornamental fish Salmon, trout	—	—	—	—	Without a time limit 21. 4. 1999	
12		Astaxanthin-rich <i>Phaffia rhodozyma</i> (ATCC 74219)	Concentrated biomass of the yeast <i>Phaffia rhodozyma</i> (ATCC 74219), killed, containing at least 4,0 g astaxanthin per kilogram of additive and having a maximum ethoxyquin content of 2 000 mg/kg	Salmon, trout	—	—	100	100	The maximum content is expressed as astaxanthin Use only permitted from the age of six months onwards The mixture of the additive with canthaxanthin is allowed provided that the total concentration of astaxanthin and canthaxanthin does not exceed 100 mg/kg in the complete feedingstuff The maximum content is expressed as astaxanthin Use permitted only from the age of six months onwards The mixture of the additive with canthaxanthin is allowed provided that the total concentration of astaxanthin and canthaxanthin does not exceed 100 mg/kg in the complete feedingstuff Ethoxyquin content to be declared	30. 9. 1999

ANNEX II

EC No	Element	Additive	Chemical formula	Maximum content of the element in mg/kg of the complete feedingstuff	Other provisions	Duration of authorisation
E4	Copper-Cu	Cupric acetate, monohydrate	$\text{Cu}(\text{CH}_3\text{COO})_2 \cdot \text{H}_2\text{O}$	<p>Pigs for fattening: in Member States where the mean density of the porcine population is equal to or higher than 175 pigs per 100 ha of utilisable agricultural land: — up to 16 weeks: 175 (total) — from 17th week up to slaughter: 35 (total)</p> <p>in Member States where the mean density of the porcine population is lower than 175 pigs per 100 ha of utilisable agricultural land: — up to 16 weeks: 175 (total) — from 17th week up to 6 months: 100 (total) — over six months up to slaughter: 35 (total)</p> <p>Breeding pigs: 35 (total)</p> <p>Calves: — milk replacers: 30 (total) — other complete feedingsuffs: 50 (total)</p> <p>Ovines: 15 (total)</p> <p>Other species or categories of animals: 35 (total)</p>	—	Without limit
		Basic cupric carbonate, monohydrate	$\text{CuCO}_3 \cdot \text{Cu}(\text{OH})_2 \cdot \text{H}_2\text{O}$			Without limit
		Cupric chloride, dihydrate	$\text{CuCl}_2 \cdot 2\text{H}_2\text{O}$			Without limit
		Cupric methionate	$\text{Cu}(\text{C}_3\text{H}_7\text{NO}_2\text{S})_2$			Without limit
		Cupric oxide	CuO			Without limit
		Cupric sulphate, pentahydrate	$\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$			Without limit
						Without limit
						Without limit

EC No	Element	Additive	Chemical formula	Maximum content of the element in mg/kg of the complete feedingstuff	Other provisions	Duration of authorisation
		Cupric sulphate, monohydrate	$\text{CuSO}_4 \cdot \text{H}_2\text{O}$	<p>Pigs for fattening in Member States where the mean density of the porcine population is equal to or higher than 175 pigs per 100 ha of utilisable agricultural land:</p> <ul style="list-style-type: none"> — up to 16 weeks: 175 (total) — from 17th week up to slaughter: 35 (total) <p>in Member States where the mean density of the porcine population is lower than 175 pigs per 100 ha of utilisable agricultural land:</p> <ul style="list-style-type: none"> — up to 16 weeks: 175 (total) — from 17th week up to 6 months: 100 (total) — over six months up to slaughter: 35 (total) <p>Breeding pigs: 35 (total)</p> <p>Ovines: 15 (total)</p> <p>Other species or categories of animals with the exception of calves: 35 (total)</p>	<p>Denatured skimmed milk powder and compound feedingsuffs manufactured from denatured skimmed milk powder</p> <ul style="list-style-type: none"> — subject to the relevant provisions of Commission Regulations (EEC) No 368/77 and (EEC) No 443/77 — declaration of the amount of copper added, expressed as the element, on the label or package or container of denatured skimmed milk powder 	Without a time limit
		Cupric sulphate, pentahydrate	$\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$			

EC No	Element	Additive	Chemical formula	Maximum content of the element in mg/kg of the complete feedingstuff	Other provisions	Duration of authorisation
		Cupric chelate of amino acids hydrate	$\text{Cu (x)}_{1-3} \cdot n\text{H}_2\text{O}$ (x = anion of any amino acid derived from hydrolysed soya protein) Molecular weight not exceeding 1 500	Pigs for fattening: in Member States where the mean density of the porcine population is equal to or higher than 175 pigs per 100 ha of utilisable agricultural land: — up to 16 weeks: 175 (total) — from 17th week up to slaughter: 35 (total) in Member States where the mean density of the porcine population is lower than 175 pigs per 100 ha of utilisable agricultural land: — up to 16 weeks: 175 (total) — from 17th week up to six months: 100 (total) — over six months up to slaughter: 35 (total) Breeding pigs: 35 (total) Other species or categories of animals, with the exception of calves prior to the start of rumination and sheep: 35 (total)	Not more than 20 mg/kg of copper in the complete feedingstuff may come from cupric chelate of amino acids hydrate	Without a time limit
E5	Manganese -Mn	Manganous carbonate	MnCO_3	250 (total)	—	Without a time limit
		Manganous chloride, tetrahydrate	$\text{MnCl}_2 \cdot 4\text{H}_2\text{O}$	250 (total)	—	Without a time limit
		Manganous hydrogen phosphate, trihydrate	$\text{MnHPO}_4 \cdot 3\text{H}_2\text{O}$	250 (total)	—	Without a time limit
		Manganous oxide	MnO	250 (total)	—	Without a time limit
		Manganic oxide	Mn_2O_3	250 (total)	—	Without a time limit
		Manganous sulphate, tetrahydrate	$\text{MnSO}_4 \cdot 4\text{H}_2\text{O}$	250 (total)	—	Without a time limit
		Manganous sulphate, monohydrate	$\text{MnSO}_4 \cdot \text{H}_2\text{O}$	250 (total)	—	Without a time limit

EC No	Element	Additive	Chemical formula	Maximum content of the element in mg/kg of the complete feedingstuff	Other provisions	Duration of authorisation
E6	Zinc-Zn	Manganese chelate of amino acids hydrate	$Mn(x)_{1-3} \cdot nH_2O$ (x = anion of any amino acid derived from hydrolysed soya protein) Molecular weight not exceeding 1 500	250 (total)	Not more than 40mg/kg of manganese in the complete feedingstuff may come from manganese chelate of amino acids hydrate	Without a time limit
		Zinc lactate, trihydrate	$Zn(C_3H_5O_3)_2 \cdot 3H_2O$	250 (total)	—	Without a time limit
		Zinc acetate, dihydrate	$Zn(CH_3COO)_2 \cdot 2H_2O$	250 (total)	—	Without a time limit
		Zinc carbonate	$ZnCO_3$	250 (total)	—	Without a time limit
		Zinc chloride, monohydrate	$ZnCl_2 \cdot H_2O$	250 (total)	—	Without a time limit
		Zinc oxide	ZnO	250 (total)	Maximum content of lead: 600 mg/kg	Without a time limit
		Zinc sulphate, heptahydrate	$ZnSO_4 \cdot 7H_2O$	250 (total)	—	Without a time limit
		Zinc sulphate, monohydrate	$ZnSO_4 \cdot H_2O$	250 (total)	—	Without a time limit
		Zinc chelate of amino acids hydrate	$Zn(x)_{1-3} \cdot nH_2O$ (x = anion of any amino acid derived from hydrolysed soya protein) Molecular weight not exceeding 1 500	250 (total)	Not more than 80 mg/kg of zinc in the complete feedingstuff may come from zinc chelate of amino acids hydrate	Without a time limit

ANNEX III

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content mg/kg of complete feedingstuff		Maximum content mg/kg of complete feedingstuff	Other provisions	Duration of authorisation
					Minimum content	Maximum content			
E 320	Butylated hydroxyanisole (BHA)	$C_{11}H_{16}O_2$	All species or categories of animals except dogs	—	—	150: alone or together	All feedingsuffs	Without a time limit	
E 321	Butylated hydroxytoluene (BHT)	$C_{13}H_{24}O$		—	—				
E 324	Ethoxyquin	$C_{14}H_{19}ON$		—	—				
E 320	Butylated hydroxyanisole (BHA)	$C_{11}H_{16}O_2$	Dogs	—	—	150: alone or together	The mixture of ethoxyquin with BHA and/or BHT is allowed provided the total concentration of the mixture does not exceed 150 mg/kg of complete feedingstuff	Without a time limit	
E 321	Butylated hydroxytoluene (BHT)	$C_{13}H_{24}O$		—	—				
E 324	Ethoxyquin	$C_{14}H_{19}ON$	Dogs	—	—	100			

ANNEX IV

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum activity		Maximum activity	Other provisions	Duration of authorisation
					Unit of activity per kg of complete feedingsuff	Unit of activity per kg of complete feedingsuff			
1	3-phytase (EC 3.1.3.8)	Preparation of 3-phytase produced by <i>Aspergillus niger</i> (CBS 114.94) having a minimum phytase activity of 5 000 FTU (1)/g for solid and liquid preparations	Pigs (all categories of animals) Chickens (all categories of animals) Turkeys	—	—	—	—	—	21. 4. 1999
				—	—	—	—	—	21. 4. 1999
				—	125 FTU	—	—	1. Indicate in the directions for use for the additive and the premixture the storage temperature, storage duration and stability on pelleting 2. Recommended dose per kg of complete feedingstuff: 200-800 FTU 3. For use in compound feedingstuffs with a minimum content of 0,3 % phytate, e.g. 20 % wheat	30. 9. 1999

(¹) 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from sodium phytate at pH 5,5 and 37 °C.