

**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)***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.

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.

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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.

ANNEX I

No	EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Duration of authorisation
						mg/kg of complete feedingstuff			
		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 carotenoids and xanthophylls)	—	Without a time limit
	E 160e	Beta-apo-8'-carotenal	C ₃₀ H ₄₀ O	Poultry	—	—	80 (alone or with the other carotenoids and xanthophylls)	—	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 carotenoids and xanthophylls)	—	Without a time limit
	E 161b	Lutein	C ₄₀ H ₅₆ O ₂	Poultry	—	—	80 (alone or with the other carotenoids and xantho-phylls)	—	Without a time limit

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No	EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Duration of authorisation
						mg/kg of complete feedingstuff			
	E 161c	Cryptoxanthin	C ₄₀ H ₅₆ O	Poultry	—	—	80 (alone or with the other carotenoids and xantho-phylls)	—	Without a time limit
	E 161g	Canthaxanthin	C ₄₀ H ₅₂ O ₂	Poultry	—	—	80 (alone or with the other carotenoids and xantho-phylls)	—	Without a time limit
				Salmon, trout	—	—	80	Use permitted from the age of six months onwards The mixture of canthaxanthin 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
				Dogs, cats and ornamental fish	—	—	—	—	Without a time limit
				Pet and ornamental birds	—	—	—	—	30.9.1999
	E 161h	Zeaxanthin	C ₄₀ H ₅₆ O ₂	Poultry	—	—	80 (alone or with the other carotenoids and xanthophylls)	—	Without a time limit

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No	EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Duration of authorisation
						mg/kg of complete feedingstuff			
	E 16li	Citraxanthin	C ₃₃ H ₄₄ O	Laying hens	—	—	80 (alone or with the other carotenoids and xanthophylls)	—	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 astaxanthin 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
				Ornamental fish	—	—	—	—	Without a time limit
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	Salmon, trout	—	—	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	21.4.1999

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No	EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Duration of authorisation
						mg/kg of complete feedingstuff			
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	<p>The maximum content is expressed as astaxanthin</p> <p>Use permitted only from the age of six months onwards</p> <p>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</p> <p>Ethoxyquin content to be declared</p>	30.9.1999

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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	$\text{Cu}(\text{CH}_3\text{COO})_2 \cdot \text{H}_2\text{O}$	Pigs for fattening:	—	Without a time limit
		Basic cupric carbonate, monohydrate	$\text{CuCO}_3 \cdot \text{Cu}(\text{OH})_2 \cdot \text{H}_2\text{O}$	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:	—	Without a time limit
		Cupric chloride, dihydrate	$\text{CuCl}_2 \cdot 2\text{H}_2\text{O}$	— up to 16 weeks: 175 (total) — from 17th week up to slaughter: 35 (total)	—	Without a time limit
		_____		in Member States where the mean density of the porcine population is lower than 175 pigs per 100 ha of utilisable agricultural land:		
		Cupric oxide	CuO	— up to 16 weeks: 175 (total) — from 17th week up to 6 months: 100 (total)	—	Without a time limit
		Cupric sulphate, pentahydrate	$\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$	— over six months up to slaughter: 35 (total) Breeding pigs: 35 (total) Calves: — milk replacers: 30 (total) — other complete feedingstuffs: 50 (total) Ovines: 15 (total) Other species or categories of animals: 35 (total)	—	Without a time limit

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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:</p> <p>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 feedingstuffs 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	$\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$			
		Cupric chelate of amino acids hydrate	$\text{Cu} (\text{x})_{1-3} \cdot \text{nH}_2\text{O}$ (x = anion of any amino acid derived from hydrolysed soya protein) Molecular weight not exceeding 1 500	<p>Pigs for fattening:</p> <p>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 six months: 100 (total) — over six months up to slaughter: 35 (total) <p>Breeding pigs: 35 (total)</p> <p>Other species or categories of animals, with the exception of calves prior to the start of rumination and sheep: 35 (total)</p>	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

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EC No	Element	Additive	Chemical formula	Maximum content of the element in mg/kg of the complete feedingstuff	Other provisions	Duration of authorisation
E5	Manganese-Mn	► <u>M1</u> ——— ◀	► <u>M1</u> ——— ◀	► <u>M1</u> ——— ◀	► <u>M1</u> ——— ◀	► <u>M1</u> ——— ◀
		Manganous chloride, tetrahydrate	MnCl ₂ · 4H ₂ O	250 (total)	—	Without a time limit

		▼ <u>M1</u>				
		▼ <u>B</u>				
		Manganous oxide	MnO	250 (total)	—	Without a time limit

▼ <u>M1</u>						
▼ <u>B</u>						
		Manganous sulphate, monohydrate	MnSO ₄ · H ₂ O	250 (total)	—	Without a time limit
		Manganese chelate of amino acids hydrate	Mn (x) ₁₋₃ · nH ₂ O (x = anion of any amino acid derived from hydrolysed soya protein) Molecular weight not exceeding 1 500	250 (total)	Not more than 40 mg/kg of manganese in the complete feedingstuff may come from manganese chelate of amino acids hydrate	Without a time limit

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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	► <u>M1</u> ——— ◀	► <u>M1</u> ——— ◀	► <u>M1</u> ——— ◀	► <u>M1</u> ——— ◀	► <u>M1</u> ——— ◀
		Zinc acetate, dihydrate	Zn(CH ₃ COO) ₂ · 2H ₂ O	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 · 7H ₂ O	250 (total)	—	Without a time limit
		Zinc sulphate, monohydrate	ZnSO ₄ · H ₂ O	250 (total)	—	Without a time limit
		Zinc chelate of amino acids hydrate	Zn (x) ₁₋₃ · nH ₂ O (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

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ANNEX III

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Duration of authorisation
					mg/kg of complete feedingstuff			
E 320	Butylated hydroxyanisole (BHA)	C ₁₁ H ₁₆ O ₂	All species or categories of animals except dogs	—	—	150: alone or together	All feedingstuffs	Without a time limit
E 321	Butylated hydroxytoluene (BHT)	C ₁₅ 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 ₁₅ 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 feedingstuff			
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)	—	—	—	—	21.4.1999
			Chickens (all categories of animals)	—	—	—	—	21.4.1999
			Turkeys	—	125 FTU	—	1. Indicate in the directions for use for the additive and the pre-mixture 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 feeding-stuffs 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.