

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)

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.

Status: Point in time view as at 19/07/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 2316/98. (See end of Document for details)

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.

Status: Point in time view as at 19/07/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 2316/98. (See end of Document for details)

ANNEX I

| No | EC No | Additive | Chemical formula, or description | Species or category of animal | Maximum age | Minimum content mg/kg of complete feedingstuff | Maximum content | Other provisions | Duration of authorisation |
|----|--------|--|--|-------------------------------|-------------|--|---|------------------|---------------------------|
| | | | | | | | | | |
| | | 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 xanthophylls) | — | Without a time limit |

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 2316/98. (See end of Document for details)

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| E 161c | Cryptoxanthin | $C_{40}H_{56}O$ | Poultry | — | — | 80 (alone or with the other carotenoids and xanthophylls) | — | Without a time limit |
| E 161g | Canthaxanthin | $C_{40}H_{52}O_2$ | Poultry | — | — | 80 (alone or with the other carotenoids and xanthophylls) | — | 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 | — | — | — | — | Without a time limit |

Status: Point in time view as at 19/07/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 2316/98. (See end of Document for details)

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| | | | | ornamental fish | | | | | |
| | | | | 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 | |
| E 161i | Citraxanthin | $C_{38}H_{44}O$ | 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 | Without a time limit | |

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 2316/98. (See end of Document for details)

| | | | | | | | | complete feedingstuff | |
|----|--|--|--|--------------------|---|---|-----|--|----------------------------|
| | | | | Ornamental fish | — | — | — | — | Without a time limit |
| 11 | | Astaxanthin rich <i>Phaffia</i> <i>rhodozyma</i> (CBS 116.94) | Concentrated biomass of the yeast <i>Phaffia</i> <i>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 |
| 12 | | Astaxanthin rich <i>Phaffia</i> <i>rhodozyma</i> (ATCC 74219) | Concentrated biomass of the yeast <i>Phaffia</i> <i>rhodozyma</i> (ATCC | Salmon, trout | — | — | 100 | The maximum content is expressed as astaxanthin | 30.9.1999 |

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| | | 74219), killed, containing at least 4,0 g astaxanthin per kilogram of additive and having a maximum ethoxyquin content of 2 000 mg/ kg | | | | 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 |
|--|--|--|--|--|--|---|

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 |

Status: Point in time view as at 19/07/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 2316/98. (See end of Document for details)

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| Basic cupric carbonate, monohydrate | $\text{CuCO}_3 \cdot \text{Cu(OH)}_2 \cdot \text{H}_2\text{O}$ | 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 | $\text{CuCl}_2 \cdot 2\text{H}_2\text{O}$ | | — | Without a time limit |
| [^{F1}] | | | | |
| Cupric oxide | CuO | in Member States where the mean density of the porcine population is lower than 175 pigs per 100 ha of utilisable agricultural land: | — | Without a time limit |
| Cupric sulphate, pentahydrate | $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ | | — up to 16 weeks: 175 (total) from 17th week up to slaughter: 35 (total) | Without a time limit |
| | | | — up to 16 weeks: 175 (total) from 17th week up | |

Status: Point in time view as at 19/07/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 2316/98. (See end of Document for details)

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| | | | to 6 months: 100 (total) — 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) | | |
| Cupric sulphate, monohydrate | $\text{CuSO}_4 \cdot \text{H}_2\text{O}$ | 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: | Denatured skimmed milk powder and compound feedingstuffs manufactured from denatured skimmed milk powder | — | Without a time limit |
| Cupric sulphate, pentahydrate | $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ | — up to | — subject to the relevant provisions of Commission | | |

Status: Point in time view as at 19/07/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 2316/98. (See end of Document for details)

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| | | | | 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 6 months: 100 (total) — over six months up to slaughter: 35 (total) Breeding pigs: 35 (total) | 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 |
|--|--|--|--|--|--|

Status: Point in time view as at 19/07/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 2316/98. (See end of Document for details)

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| | | | Ovines: 15 (total) Other species or categories of animals with the exception of calves: 35 (total) | |
| | Cupric chelate of amino acids hydrate | Cu (x) ₁₋₃ · nH ₂ 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 | 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 |

Status: Point in time view as at 19/07/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 2316/98. (See end of Document for details)

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| | | | | 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) | | |
| E5 | Manganese-Mn | [^{F1} Manganous carbonate] | [^{F1} MnCO ₃] | [^{F1} 250 (total)] | [^{F1} —] | [^{F1} Without a time limit] |
| | | Manganous chloride, tetrahydrate | MnCl ₂ · 4H ₂ O | 250 (total) | — | Without a time limit |
| | | [^{F1}] | | | | |
| | | Manganous oxide | MnO | 250 (total) | — | Without a time limit |

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| | | | | | | |
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| | | [^{F1}] | | | | |
| | | [^{F1}] | | | | |
| | | 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 |
| E6 | Zinc-Zn | [^{F1} Zinc lactate, trihydrate] | [^{F1} Zn(C ₃ H ₅ O ₃) ₂ · 3H ₂ O] | [^{F1} 250 (total)] | [^{F1} —] | [^{F1} Without a time limit] |
| | | Zinc acetate, dihydrate | Zn(CH ₃ COO) ₂ · 2H ₂ O | 250 (total) | — | Without a time limit |
| | | [^{F1}] | | | | |
| | | [^{F1}] | | | | |
| | | 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 | 250 (total) | Not more than 80 mg/kg of zinc in the complete feedingstuff may come from zinc chelate of | Without a time limit |

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| | | | soya protein) Molecular weight not exceeding 1500 | | amino acids hydrate | |
|--|--|--|--|--|---------------------|--|

Textual Amendments

- F1** Deleted by Commission Implementing Regulation (EU) 2017/1145 of 8 June 2017 on the withdrawal from the market of certain feed additives authorised pursuant to Council Directives 70/524/EEC and 82/471/EEC and repealing the obsolete provisions authorising those feed additives (Text with EEA relevance).

ANNEX III

| EC No | Additive | Chemical formula, or 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 feedingstuff | Without 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 | Without a time limit |
| E 321 | Butylated hydroxytoluene (BHT) | C ₁₅ H ₂₄ O | | — | — | | | |
| E 324 | Ethoxyquin | C ₁₄ H ₁₉ ON | Dogs | — | — | 100 | | |

Status: Point in time view as at 19/07/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 2316/98. (See end of Document for details)

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| | | | | | | | | complete feedingstuff |
|--|--|--|--|--|--|--|--|--------------------------|

ANNEX IV

| No | Additive | Chemical formula, or 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 ^a /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. | 30.9.1999 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 |

a 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.

Status:

Point in time view as at 19/07/2017.

Changes to legislation:

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