

Commission Regulation (EC) No 1334/2003 of 25 July 2003
amending the conditions for authorisation of a number of
additives in feedingstuffs belonging to the group of trace elements

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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 Regulation (EC) No 1756/2002⁽²⁾ and in particular Articles 3, 9d and 9e thereof,

Whereas:

- (1) Several additives belonging to the group of trace elements have been authorised under certain conditions in accordance with Directive 70/524/EEC, by means of Regulations (EC) No 2316/98⁽³⁾, (EC) No 639/1999⁽⁴⁾, (EC) No 2293/1999⁽⁵⁾, (EC) No 2200/2001⁽⁶⁾ and (EC) No 871/2003⁽⁷⁾.
- (2) In the light of the evolution of scientific and technical knowledge, the maximum content of trace elements authorised in feedingstuffs has been re-examined in order to ensure an optimal application of the conditions for authorisation laid down in Article 3a of Directive 70/524/EEC.
- (3) In the present state of scientific and technical knowledge it may be concluded that the maximum content of iron, cobalt, copper, manganese and zinc authorised in feedingstuffs in accordance with Directive 70/524/EEC should be reduced in order to better comply with the requirements laid down in Article 3a(a) and (b) of that Directive, in particular, the effects to satisfy nutritional needs, to improve animal production and to reduce harmful effects caused by animal excretions and also to minimise the adverse effects that the current levels of some trace elements have on human health and the environment
- (4) The maximum content of trace elements authorised in feedingstuffs must be calculated taking into consideration not only physiological requirements of animals but also other aspects such as average requirements and variability of the requirements in the diet, need to meet the needs of most members of animal populations and possible inefficiencies in the use of the nutrients.
- (5) The Scientific Committee on Animal Nutrition (SCAN) has delivered an opinion on the use of copper and zinc in feedingstuffs on 19 February 2003 and 14 March 2003 respectively. The SCAN concludes that the current maximum levels of these trace elements authorised in feedingstuffs are, in the majority of the cases, higher than

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 1334/2003. (See end of Document for details)

necessary as regards the effects of these additives and recommends a reduction of such levels in order to adapt them to the physiological animal requirements.

- (6) In accordance with the current scientific and technical knowledge concerning specifically iron in feedingstuffs, suckling pigs must retain 7 to 16 mg/kg of iron daily, or 21 mg of iron kg/body weight gain to maintain adequate levels of haemoglobin. Sows' milk contains an average of only 1 mg of iron per litre. Thus, pigs receiving only milk rapidly develop anaemia. Iron should therefore be given to piglets in complementary feedingstuffs with a high content of this element as far as, during the suckling period, piglets are only fed with milk.
- (7) It is appropriate to provide for a transitional period of six months for the implementation of the new requirements and for a transitional period of nine months for the disposal of existing stocks of feedingstuffs labelled according to the previous conditions established in accordance with Directive 70/524/EEC.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The conditions for the authorisation of the additives E1 Iron-Fe, E3 Cobalt-Co, E4 Copper-Cu, E5 Manganese-Mn and E6 Zinc-Zn belonging to the group 'trace elements'⁽⁸⁾, are hereby replaced by those set out in the Annex hereto in accordance with Directive 70/524/EEC.

Article 2

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

It shall apply from 26 January 2004. However, existing stocks of feedingstuffs labelled according to the previous conditions established in accordance with Directive 70/524/EEC may be used during a transitional period expiring 26 April 2004.

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

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ANNEX

| EEC No | Element | Additive | Chemical formula and description | [^{X1} Maximum content of the element in mg/kg of the complete feedingstuff] | Other provisions | Period of authorisation |
|---|--|--|--|---|------------------|-------------------------|
| [^{F1}Trace elements | | | | | | |
| E 1 | Iron-Fe | Ferrous carbonate | [^{F2} [^{X2} FeCO ₃]] | Ovine: 500 (total) mg/kg of the complete feedingstuff Pet animals: 1 250 (total) mg/kg of the complete feedingstuff Pigs: — piglets up to one week before weaning: 250 mg/day other pigs: 750 (total) mg/kg of the complete feedingstuff Other species: 750 (total) mg/kg of the complete feedingstuff | | Without a time limit |
| | | [^{F3} [^{F4} Ferrous chloride, tetrahydrate]] | [^{F3} [^{F4} FeCl ₂ · 4H ₂ O]] | | | |
| | | Ferric chloride, hexahydrate | [^{F2} [^{X2} FeCl ₃ · 6H ₂ O]] | | | |
| | | [^{F3} [^{F4} Ferrous citrate, hexahydrate]] | [^{F3} [^{F4} Fe ₃ (C ₆ H ₅ O ₇) ₂ · 6H ₂ O]] | | | |
| | | Ferrous fumarate | [^{F2} [^{X2} FeC ₄ H ₂ O ₄]] | | | |
| | | [^{F3} [^{F4} Ferrous lactate, trihydrate]] | [^{F3} [^{F4} Fe(C ₃ H ₅ O ₃) ₂ · 3H ₂ O]] | | | |
| | | Ferric oxide | [^{F2} [^{X2} Fe ₂ O ₃]] | | | |
| | | Ferrous sulphate, monohydrate | [^{F2} [^{X2} FeSO ₄ H ₂ O]] | | | |
| | | Ferrous sulphate, heptahydrate | [^{F2} [^{X2} FeSO ₄ · 7H ₂ O]] | | | |
| Ferrous chelate of amino acids, hydrate | [^{F2} [^{X2} Fe(x) ₁₋₃ · nH ₂ O (x = anion of any amino acid derived from hydrolysed soya protein)] | | | | | |

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| | | | Molecular weight not exceeding 1 500]] | | | | |
|-----|-----------|--|--|-----------------------|---|--|--|
| E 3 | Cobalt-Co | [^{F5} [^{F6} Cobaltous acetate, tetrahydrate]] | Co(CH ₃ COO) ₂ ·2H ₂ O | 146 (total) | — | Without a time limit | |
| | | [^{F5} [^{F6} Basic cobaltous carbonate, monohydrate]] | 2CoCO ₃ ·3Co(OH) ₂ ·H ₂ O | complete feedingstuff | | | |
| | | [^{F7} Cobaltous chloride, hexahydrate] | CoCl ₂ ·6H ₂ O | | | | |
| | | [^{F5} [^{F6} Cobaltous sulphate, heptahydrate]] | CoSO ₄ ·7H ₂ O | | | | |
| | | [^{F7} Cobaltous sulphate, monohydrate] | CoSO ₄ ·H ₂ O | | | | |
| | | [^{F7} Cobaltous nitrate, hexahydrate] | Co(NO ₃) ₂ ·6H ₂ O | | | | |
| E 4 | Copper-Cu | [^{F8} Cupric acetate, monohydrate] | Cu(CH ₃ COO) ₂ ·H ₂ O | 178 | — | The following declarations shall be inserted in the labelling (total) and accompanying documents: For pigs: 25 (total) For sheep: 10 (total) For bovine before the start of rumination: — | Without a time limit Where the level of copper in feedingstuffs exceeds 15 mg/kg (total) the complete |
| | | [^{F8} Basic cupric carbonate, monohydrate] | CuCO ₃ ·Cu(OH) ₂ ·H ₂ O | 121 | | | |
| | | [^{F8} Cupric chloride, dihydrate] | CuCl ₂ ·2H ₂ O | 170 | | | |
| | | [^{F3} Cupric methionate] | [^{F3} Cu(C ₅ H ₁₀ N ₂ S ₂) ₂] | Bovine 1. | | | |
| | | [^{F8} Cupric oxide] | CuO | | | | |
| | | [^{F8} Cupric sulphate, pentahydrate] | CuSO ₄ ·5H ₂ O | | | | |
| | | [^{F8} Cupric chelate of amino acids hydrate] | Cu (x) ₁₋₃ ·nH ₂ O (x = anion of any | | | | |

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| | | | | | | |
|--|--|--|---|---|--|--|
| | | amino acid derived from hydrolysed soya protein) Molecular weight not exceeding 1 500. | 2. — | | other bovine: 35 (total). | feedingstuffs: 15 copper (total). this feedingstuff may cause poisoning in certain breeds of sheep.' copperlysine sulphate |
| | [^{F8} Copperlysine sulphate] | $Cu(C_6H_{13}N_2O_2)_2 \cdot SO_4$ | Ovine: 15 (total) Fish: 25 (total) Crustaceans: 50 (total) Other species: 25 (total) | — | For bovines after the start of rumination: | 31.3.2004 for sheep.' copperlysine sulphate Where the level of copper in feedingstuffs is less than 20 mg/kg: 'the level of copper in this feedingstuff may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum |

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| | | | | | or sulphur.? | |
|-----|--------------|---|---|--|--------------|----------------------|
| E 5 | Manganese-Mn | [^{F3} Manganous carbonate] | [^{F3} MnCO ₃] | Fish: 100 (total) Other species: 150 (total) | — | Without a time limit |
| | | Manganous chloride, tetrahydrate | MnCl ₂ ·4H ₂ O | | | |
| | | [^{F3} Manganous hydrogen phosphate, trihydrate] | [^{F3} MnHPO ₄ ·3H ₂ O] | | | |
| | | Manganous oxide | MnO | | | |
| | | [^{F3} Manganic oxide] | [^{F3} Mn ₂ O ₃] | | | |
| | | [^{F3} Manganous sulphate, tetrahydrate] | [^{F3} MnSO ₄ ·4H ₂ O] | | | |
| | | Manganous sulphate, monohydrate | MnSO ₄ ·H ₂ O | | | |
| | | 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. | | | |
| | | [^{F3} Manganomanganic oxide] | [^{F3} Mn ₂ O ₃] | | | |
| E 6 | Zinc-Zn | [^{F3} Zinc lactate, trihydrate] | [^{F3} Zn(C ₃ H ₅ O ₃) ₂ ·3H ₂ O] | animals: 250 (total) Fish: 200 (total) Milk replacers: 200 (total) | — | Without a time limit |
| | | [^{F9} Zinc acetate, dihydrate] | [^{F9} Zn(CH ₃ COO) ₂ ·2H ₂ O] | | | |
| | | [^{F3} Zinc carbonate] | [^{F3} ZnCO ₃] | | | |

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| | | | | |
|--|--|--|----------------------------|--|
| | [^{F3} Zinc chloride, monohydrate] | [^{F3} ZnCl ₂ ·H ₂ O] | Other species: 150 (total) | |
| | [^{F9} Zinc oxide] | [^{F9} ZnO [^{F10} Maximum content of lead: 600 mg/kg.]] | | |
| | [^{F9} Zinc sulphate, heptahydrate] | [^{F9} ZnSO ₄ ·7H ₂ O] | | |
| | [^{F9} Zinc sulphate, monohydrate] | [^{F9} ZnSO ₄ ·H ₂ O] | | |
| | [^{F9} Zinc chelate of amino acids hydrate] | [^{F9} Zn (x) ₁₋₃ ·nH ₂ O (x = anion of any amino acid derived from hydrolysed soya protein) Molecular weight not exceeding 1 500.] | | |

Editorial Information

- X1** Substituted by [Corrigendum to Commission Regulation \(EC\) No 1334/2003 of 25 July 2003 amending the conditions for authorisation of a number of additives in feedingstuffs belonging to the group of trace elements \(Official Journal of the European Union L 187 of 26 July 2003\)](#).
- X2** Deleted by [Corrigendum to Commission Implementing Regulation \(EU\) 2017/2330 of 14 December 2017 concerning the authorisation of Iron\(II\) carbonate, Iron\(III\) chloride hexahydrate, Iron\(II\) sulphate monohydrate, Iron\(II\) sulphate heptahydrate, Iron\(II\) fumarate, Iron\(II\) chelate of amino acids hydrate, Iron\(II\) chelate of protein hydrolysates and Iron\(II\) chelate of glycine hydrate as feed additives for all animal species and of Iron dextran as feed additive for piglets and amending Regulations \(EC\) No 1334/2003 and \(EC\) No 479/2006 \(Official Journal of the European Union L 333 of 15 December 2017\)](#).

Textual Amendments

- F1** Substituted by [Commission Regulation \(EC\) No 2112/2003 of 1 December 2003 correcting Regulation \(EC\) No 1334/2003 amending the conditions for authorisation of a number of additives in feedingstuffs belonging to the group trace elements \(Text with EEA relevance\)](#).
- F2** Deleted by [Commission Implementing Regulation \(EU\) 2017/2330 of 14 December 2017 concerning the authorisation of Iron\(II\) carbonate, Iron\(III\) chloride hexahydrate, Iron\(II\) sulphate monohydrate, Iron\(II\) sulphate heptahydrate, Iron\(II\) fumarate, Iron\(II\) chelate of amino acids hydrate, Iron\(II\) chelate](#)

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of protein hydrolysates and Iron(II) chelate of glycine hydrate as feed additives for all animal species and of Iron dextran as feed additive for piglets and amending Regulations (EC) No 1334/2003 and (EC) No 479/2006 (Text with EEA relevance).

- F3** 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).
- F4** Deleted by Commission Implementing Regulation (EU) 2018/353 of 9 March 2018 correcting Implementing Regulation (EU) 2017/1145 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).
- F5** Deleted by Commission Implementing Regulation (EU) No 601/2013 of 24 June 2013 concerning the authorisation of cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate and coated granulated cobalt(II) carbonate hydroxide (2:3) monohydrate as feed additives (Text with EEA relevance).
- F6** Deleted by Commission Implementing Regulation (EU) No 131/2014 of 11 February 2014 amending Implementing Regulation (EU) No 601/2013 concerning the authorisation of cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate and coated granulated cobalt(II) carbonate hydroxide (2:3) monohydrate as feed additives (Text with EEA relevance).
- F7** Deleted by Commission Implementing Regulation (EU) No 107/2014 of 5 February 2014 on the withdrawal from the market of the feed additives cobaltous chloride hexahydrate, cobaltous nitrate hexahydrate and cobaltous sulphate monohydrate and amending Regulation (EC) No 1334/2003 (Text with EEA relevance).
- F8** Deleted by Commission Implementing Regulation (EU) 2018/1039 of 23 July 2018 concerning the authorisation of Copper(II) diacetate monohydrate, Copper(II) carbonate dihydroxy monohydrate, Copper(II) chloride dihydrate, Copper(II) oxide, Copper(II) sulphate pentahydrate, Copper(II) chelate of amino acids hydrate, Copper(II) chelate of protein hydrolysates, Copper(II) chelate of glycine hydrate (solid) and Copper(II) chelate of glycine hydrate (liquid) as feed additives for all animal species and amending Regulations (EC) No 1334/2003, (EC) No 479/2006 and (EU) No 349/2010 and Implementing Regulations (EU) No 269/2012, (EU) No 1230/2014 and (EU) 2016/2261 (Text with EEA relevance).
- F9** Deleted by Commission Implementing Regulation (EU) 2016/1095 of 6 July 2016 concerning the authorisation of Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate, Zinc chelate of protein hydrolysates, Zinc chelate of glycine hydrate (solid) and Zinc chelate of glycine hydrate (liquid) as feed additives for all animal species and amending Regulations (EC) No 1334/2003, (EC) No 479/2006, (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013 (Text with EEA relevance).
- F10** Deleted by Commission Regulation (EC) No 1980/2005 of 5 December 2005 amending the conditions for authorisation of a feed additive belonging to the group of trace elements and of a feed additive belonging to the group of binders and anti-caking agents (Text with EEA relevance).

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 1334/2003. (See end of Document for details)

- (1) OJ L 270, 14.12.1970, p. 1.
- (2) OJ L 265, 3.10.2002, p. 1.
- (3) OJ L 289, 28.10.1998, p. 4.
- (4) OJ L 82, 26.3.1999, p. 6.
- (5) OJ L 284, 6.11.1999, p. 1.
- (6) OJ L 299, 15.11.2001, p. 1.
- (7) OJ L 125, 21.5.2003, p. 3.
- (8) The list of authorised additives, including trace elements, is published in OJ C 329/1, 31.12.2002, as amended by Regulation (EC) No 871/2003 (L 123, 21.5.2003, p. 3).

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EC) No 1334/2003.