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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

(OJ L 187, 26.7.2003, p. 11)

Amended by:

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► <u>M1</u>	Commission Regulation (EC) No 2112/2003 of 1 December 2003	L 317	22	2.12.2003
► <u>M2</u>	Commission Regulation (EC) No 1980/2005 of 5 December 2005	L 318	3	6.12.2005

Corrected by:

► **C1** Corrigendum, OJ L 014, 21.1.2004, p. 54 (1334/2003)

**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**

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 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

⁽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.

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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' ⁽¹⁾, 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.

⁽¹⁾ 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).

ANNEX

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EEC No	Element	Additive	Chemical formula and description	►C1 Maximum content of the element in mg/kg of the complete feedingsstuff ▼	Other provisions	Period of authorisation
Trace elements						
E 1	Iron-Fe	Ferrous carbonate	FeCO ₃	Ovine: 500 (total) mg/kg of the complete feedingsstuff Pet animals: 1 250 (total) mg/kg of the complete feedingsstuff Pigs: — piglets up to one week before weaning: 250 mg/day — other pigs: 750 (total) mg/kg of the complete feedingsstuff Other species: 750 (total) mg/kg of the complete feedingsstuff		Without a time limit
		Ferrous chloride, tetrahydrate	FeCl ₂ · 4H ₂ O			
		Ferric chloride, hexahydrate	FeCl ₃ · 6H ₂ O			
		Ferrous citrate, hexahydrate	Fe ₃ (C ₆ H ₅ O ₇) ₂ · 6H ₂ O			
		Ferrous fumarate	FeC ₄ H ₂ O ₄			
		Ferrous lactate, trihydrate	Fe(C ₃ H ₅ O ₃) ₂ · 3H ₂ O			
		Ferric oxide	Fe ₂ O ₃			
		Ferrous sulphate, monohydrate	FeSO ₄ H ₂ O			
		Ferrous sulphate, heptahydrate	FeSO ₄ · 7H ₂ O			
		Ferrous chelate of amino acids, hydrate	Fe(x) ₁₋₃ · nH ₂ O (x = anion of any amino acid derived from hydrolysed soya protein) Molecular weight not exceeding 1 500			
E 3	Cobalt-Co	Cobaltous acetate, tetrahydrate	Co(CH ₃ COO) ₂ ·4H ₂ O	►C1 2 (total) mg/kg of the complete feedingsstuff ▼	—	Without a time limit
		Basic cobaltous carbonate, monohydrate	2CoCO ₃ ·3Co(OH) ₂ ·H ₂ O			
		Cobaltous chloride, hexahydrate	CoCl ₂ ·6H ₂ O			
		Cobaltous sulphate, heptahydrate	CoSO ₄ ·7H ₂ O			

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EEC No	Element	Additive	Chemical formula and description	►C1 Maximum content of the element in mg/kg of the complete feedingstuff ▼	Other provisions	Period of authorisation
E 4	Copper-Cu	Cobaltous sulphate, monohydrate	$\text{CoSO}_4 \cdot \text{H}_2\text{O}$	<p>Pigs</p> <ul style="list-style-type: none"> — piglets up to 12 weeks: 170 (total) — other pigs: 25 (total) <p>Bovine</p> <ol style="list-style-type: none"> 1. — bovine before the start of rumination: <ul style="list-style-type: none"> — milk replacers: 15 (total) — other complete feeding-stuffs: 15 (total). 2. — other bovine: 35 (total). <p>Ovine: 15 (total)</p> <p>Fish: 25 (total)</p> <p>Crustaceans: 50 (total)</p> <p>Other species: 25 (total)</p>	<p>The following declarations shall be inserted in the labelling and accompanying documents:</p> <ul style="list-style-type: none"> — For sheep: <p>Where the level of copper in feedingsuffs exceeds 10 mg/kg: 'the level of copper in this feedingsuff may cause poisoning in certain breeds of sheep.'</p> — For bovines after the start of rumination: <p>Where the level of copper in feedingsuffs is less than 20 mg/kg: 'the level of copper in this feedingsuff may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.'</p> 	Without a time limit
		Cobaltous nitrate, hexahydrate	$\text{Co}(\text{NO}_3)_2 \cdot 6\text{H}_2\text{O}$			
		Cupric acetate, monohydrate	$\text{Cu}(\text{CH}_3\text{COO})_2 \cdot \text{H}_2\text{O}$			
		Basic cupric carbonate, monohydrate	$\text{CuCO}_3 \cdot \text{Cu}(\text{OH})_2 \cdot \text{H}_2\text{O}$			
		Cupric chloride, dihydrate	$\text{CuCl}_2 \cdot 2\text{H}_2\text{O}$			
		Cupric methionate	$\text{Cu}(\text{C}_5\text{H}_{10}\text{NO}_2\text{S})_2$			
		Cupric oxide	CuO			
		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.			
		Copperlysine sulphate	$\text{Cu}(\text{C}_6\text{H}_{13}\text{N}_2\text{O}_2)_2 \cdot \text{SO}_4$			
		E 5	Manganese-Mn			
Manganous chloride, tetrahydrate	$\text{MnCl}_2 \cdot 4\text{H}_2\text{O}$					
Manganous hydrogen phosphate, trihydrate	$\text{MnHPO}_4 \cdot 3\text{H}_2\text{O}$					
Manganous oxide	MnO					
Manganic oxide	Mn_2O_3					

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EEC No	Element	Additive	Chemical formula and description	►C1 Maximum content of the element in mg/kg of the complete feedingstuff ▼	Other provisions	Period of authorisation
		Manganous sulphate, tetrahydrate	$\text{MnSO}_4 \cdot 4\text{H}_2\text{O}$			
		Manganous sulphate, monohydrate	$\text{MnSO}_4 \cdot \text{H}_2\text{O}$			
		Manganese chelate of amino acids hydrate	$\text{Mn}(\text{x})_{1,3} \cdot \text{nH}_2\text{O}$ (x = anion of any amino acid derived from hydrolysed soya protein) Molecular weight not exceeding 1 500.			
		Manganomanganic oxide	$\text{MnO Mn}_2\text{O}_3$			
E 6	Zinc-Zn	Zinc lactate, trihydrate	$\text{Zn}(\text{C}_3\text{H}_5\text{O}_3)_2 \cdot 3\text{H}_2\text{O}$	Pet animals: 250 (total) Fish: 200 (total) Milk replacers: 200 (total) Other species: 150 (total)	—	Without a time limit
		Zinc acetate, dihydrate	$\text{Zn}(\text{CH}_3\text{COO})_2 \cdot 2\text{H}_2\text{O}$			
		Zinc carbonate	ZnCO_3			
		Zinc chloride, monohydrate	$\text{ZnCl}_2 \cdot \text{H}_2\text{O}$			
		Zinc oxide	ZnO ► M2 ————— ▼			
		Zinc sulphate, heptahydrate	$\text{ZnSO}_4 \cdot 7\text{H}_2\text{O}$			
		Zinc sulphate, monohydrate	$\text{ZnSO}_4 \cdot \text{H}_2\text{O}$			
		Zinc chelate of amino acids hydrate	$\text{Zn}(\text{x})_{1,3} \cdot \text{nH}_2\text{O}$ (x = anion of any amino acid derived from hydrolysed soya protein) Molecular weight not exceeding 1 500.			