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

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.

ANNEX

EEC No	Element	Additive	Chemical formula and description	[X1Maximum content of the element in mg/kg of the complete feedingstuff]	Other provisions	Period of authorisation
[F1Trace 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[F4Ferrous chloride, tetrahydrate]]	[F3[F4$FeCl_2 . 4H_2O$]]			
		Ferric chloride, hexahydrate	[F2[X2$FeCl_3 . 6H_2O$]]			
		[F3[F4Ferrous citrate, hexahydrate]]	[F3[F4$Fe_3(C_6H_5O_7)_2 . 6H_2O$]]			
		Ferrous fumarate	[F2[X2$FeC_4H_2O_4$]]			
		[F3[F4Ferrous lactate, trihydrate]]	[F3[F4$Fe(C_3H_5O_3)_2 . 3H_2O$]]			
		Ferric oxide	[F2[X2Fe_2O_3]]			
		Ferrous sulphate, monohydrate	[F2[X2$FeSO_4H_2O$]]			
		Ferrous sulphate, heptahydrate	[F2[X2$FeSO_4 . 7H_2O$]]			
		Ferrous chelate of amino acids, hydrate	[F2[X2$Fe(x)_{1-3} . nH_2O$ (x = anion of any amino acid derived from hydrolysed soya protein)			

			Molecular weight not exceeding 1 500]]]			
E 3	Cobalt-Co	[F5[F6Cobaltous acetate, tetrahydrate]]	$Co(CH_3COO)_2 \cdot 4H_2O$	[2 mg/kg of the complete feedingstuff]	—	Without a time limit
		[F5[F6Basic cobaltous carbonate, monohydrate]]	$2CoCO_3 \cdot 3Co(OH)_2 \cdot H_2O$			
		[F7Cobaltous chloride, hexahydrate]	$CoCl_2 \cdot 6H_2O$			
		[F5[F6Cobaltous sulphate, heptahydrate]]	$CoSO_4 \cdot 7H_2O$			
		[F7Cobaltous sulphate, monohydrate]	$CoSO_4 \cdot H_2O$			
		[F7Cobaltous nitrate, hexahydrate]	$Co(NO_3)_2 \cdot 6H_2O$			
E 4	Copper-Cu	[F8Cupric acetate, monohydrate]	$Cu(CH_3COO)_2 \cdot H_2O$	25 mg/kg of the complete feedingstuff	The following declarations shall be inserted in the labelling and accompanying documents: For sheep: Where the level of copper in feedingstuffs exceeds 10 mg/kg: ‘the complete	Without a time limit
		[F8Basic cupric carbonate, monohydrate]	$CuCO_3 \cdot Cu(OH)_2 \cdot H_2O$			
		[F8Cupric chloride, dihydrate]	$CuCl_2 \cdot 2H_2O$			
		[F3Cupric methionate]	[F3$Cu(C_5H_{10}NO_2S)_2$]			
		[F8Cupric oxide]	CuO			
		[F8Cupric sulphate, pentahydrate]	$CuSO_4 \cdot 5H_2O$			
		[F8Cupric chelate of amino acids hydrate]	Cu $(x)_{1-3} \cdot nH_2O$ (x = anion of any			

		amino acid derived from hydrolysed soya protein) Molecular weight not exceeding 1 500.	2. — Ovine: 15 (total) Fish: 25 (total) Crustaceans: 50 (total) Other species: 25 (total)	—	other bovine: 35 (total).	feedingstuffs: 15 (total).	copper (1): this feedingstuff may cause poisoning in certain breeds of sheep.’
		[F8Copperlysine sulphate]	$Cu(C_6H_{13}N_2O_2)_2.SO_4$	—	For bovines after the start of rumination:	31.3.2004 for 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