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COMMISSION REGULATION (EC) No 1289/2004

of 14 July 2004

concerning the authorisation for 10 years of the additive Deccox® in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances

(Text with EEA relevance)

(OJ L 243, 15.7.2004, p. 15)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EC) No 552/2008 of 17 June 2008	L 158	3	18.6.2008
►M2	Commission Implementing Regulation (EU) No 118/2012 of 10 February 2012	L 38	36	11.2.2012
►M3	Commission Implementing Regulation (EU) No 1014/2013 of 22 October 2013	L 281	1	23.10.2013
►M4	Commission Implementing Regulation (EU) No 291/2014 of 21 March 2014	L 87	87	22.3.2014

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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 Council Regulation (EC) No 1756/2002 ([2]), and in particular Article 9g(5)(b) thereof,

Whereas:

(1) As provided for in Article 9g(1) of Directive 70/524/EEC, coccidiostats included in Annex I to that Directive before 1 January 1988 were provisionally authorised as from 1 April 1998 and transferred to Chapter I of Annex B with a view to their re-evaluation as additives linked to a person responsible for putting them into circulation.

(2) New applications for authorisation had to be submitted for the abovementioned additives. Furthermore, Article 9g(4) of Directive 70/524/EEC required that the dossiers in respect of these applications be submitted no later than 30 September 2000, with a view to re-evaluation. The data had to be produced as provided for in Article 4 of that Directive.

(3) Article 9g(5) of Directive 70/524/EEC provides that, after re-evaluation of the dossiers submitted, the provisional authorisation of the additives concerned be withdrawn or, as the case may be, be replaced by an authorisation linked to the person responsible for putting them into circulation for a period of 10 years through the adoption of a regulation taking effect no later than 1 October 2003.

(4) The person responsible for putting into circulation the *decoquinate* product (Deccox®), an additive belonging to the group 'Coccidiostats and other medicinal substances' listed in Chapter I of Annex B to Directive 70/524/EEC, submitted an application for authorisation and a dossier, in conformity with Article 9g(2) and (4) of that Directive.

(5) The Parliament and Council Regulation (EC) No 178 of 28 January 2002 regarding the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matter of food safety ([3]), as amended by Regulation (EC) No 1642/2003 ([4]), established the European Food Safety Authority (EFSA) took over the role of the Scientific Committees attached to the

([1]) OJ L 270, 14.12.1970, p. 1.
([2]) OJ L 265, 3.10.2002, p. 1.
([3]) OJ L 31, 1.2.2002, p. 1.
([4]) OJ L 245, 29.9.2003, p. 4.

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Commission in issuing scientific opinions in its field of competences. The Scientific Panel on Additives and Products or Substances used in Animal Feed has delivered a favourable opinion with regard to the safety and to the efficacy of Deccox® based on the *decoquinate* for chickens for fattening.

(6) The Commission took all necessary measures to ensure that re-evaluation of the *decoquinate* product (Deccox®) be completed within the time-frame provided by Article 9g(5) of Directive 70/524/EEC. Their evaluation showed that the relevant conditions laid down in Directive 70/524/EEC are satisfied in order to include Deccox® based on the *decoquinate* in Chapter I of the list referred to Article 9t(b) of the said Directive, as an additive linked to the person responsible for putting it into circulation authorised for a period of 10 years.

(7) Article 9g(6) of Directive 70/524/EEC allows the automatic extension of the period of authorisation of the additives concerned until the Commission takes a decision in case of, for reasons beyond the control of the authorisation holder, no decision may be taken on the application before the expiry date of the authorisation. This provision is applicable to the authorisation of Deccox® based on the *decoquinate*. Several requests for additional information were made during the re-evaluation process, extending the evaluation period for reason beyond the control of the person responsible for putting into circulation the product concerned.

(8) Article 9m of Directive 70/524/EEC foresees that an additive may continue to be authorised in order to use the stocks if the condition laid down in Article 3a(b) and (e) continue to be met. Since there are no safety reasons for withdrawing immediately the *decoquinate* product from the market, it is appropriate to allow a transitional period of six months for the disposal of existing stocks of the additive.

(9) The assessment of the application shows that certain procedures are required to protect workers from exposure to Deccox® based on the *decoquinate*. However, such protection is assured by the application of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ([1]).

(10) 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

Chapter I of Annex B to Directive 70/524/EEC shall be amended as follows: the additive *decoquinate*, belonging to the group ‘Coccidiostats and other medical substances’, shall be deleted.

([1]) OJ L 183, 29.6.1989, p. 1.

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Article 2

The additive Deccox® belonging to the group 'Coccidiostats and other medical substances' listed in the Annex to the present Regulation is authorised for use in animal nutrition under the conditions laid down in that Annex.

Article 3

A period of six months from the date of entry into force of this Regulation is permitted to use up the existing stocks of *decoquinate*.

Article 4

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

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

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ANNEX

Registration number of additive	Name and registration number of person responsible for putting the additive into circulation	Additive (Trade name)	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
Coccidiostats and other medicinal substances										
E756	Zoetis Belgium SA	Decoquinate (Deccox)	*Additive composition* Decoquinate: 60,6 g/kg Refined deodorised soya oil: 28,5 g/kg Wheat middling: q.s. 1 kg *Active substance* Decoquinate $C_{24}H_{35}NO_5$ Ethyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate CAS number: 18507-89-6 Related impurities: 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: < 0,5 % Methyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: < 1,0 % Diethyl-4-decycloxy-3-ethoxyanilinomethylenemalonate: < 0,5 %	Chickens for fattening		20	40	—	17 July 2014	1 000 µg of decoquinate/kg of wet liver and wet skin+fat; 800 µg of decoquinate/kg of wet kidney; 500 µg of decoquinate/kg wet muscle.

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Registration number of additive	Name and registration number of person responsible for putting the additive into circulation	Additive (Trade name)	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
			Analytical method (1) For the determination of decoquinate in feed additive, premixtures and feedingstuffs: Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) — EN 16162 For the determination of decoquinate in tissues: Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS)							

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx