Commission Regulation (EC) No 1464/2004 of 17 August 2004 concerning the authorisation for 10 years of the additive 'Monteban' in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1464/2004

of 17 August 2004

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

(Text with EEA relevance)

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)], and in particular Article 9g(5)(b) thereof,

Whereas:

(1) In accordance with 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. The narasin product, Monteban, is an additive belonging to the group 'Coccidiostats and other medicinal substances' listed in Chapter I of Annex B to Directive 70/524/EEC.

(2) The person responsible for putting into circulation Monteban submitted an application for authorisation and a dossier, according to Article 9g(2) and (4) of that Directive.

(3) 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 cases where, 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 Monteban. The Commission requested a full risk evaluation from the Scientific Committee for Animal Nutrition on 26 April 2001 and this request was consequently transferred to the European Food Safety Authority. Several requests for additional information were made during the re-evaluation process, making it impossible to complete the re-evaluation within the time limits required by Article 9g.

(4) The Scientific Panel on Additives and Products or Substances used in Animal Feed attached to the European Food Safety Authority has delivered a favourable opinion with regard to the safety and to the efficacy of Monteban for chickens for fattening.

(5) The re-evaluation of Monteban carried out by the Commission showed that the relevant conditions laid down in Directive 70/524/EEC are satisfied. Monteban should therefore be authorised for 10 years as an additive linked to the person responsible for putting

it into circulation and included in Chapter I of the list referred to Article 9t(b) of that Directive.

(6) As the authorisation for the additive is now linked to a person responsible for putting it into circulation, and replaces the previous authorisation which was not linked to any specific person, it is appropriate to delete the latter authorisation.

(7) Since there are no safety reasons for withdrawing the product narasin from the market immediately, it is appropriate to allow a transitional period of six months for the disposal of existing stocks of the additive.

(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

Chapter I of Annex B to Directive 70/524/EEC is amended as follows:

the additive narasin, belonging to the group ‘Coccidiostats and other medical substances’, is deleted.

Article 2

The additive Monteban belonging to the group ‘Coccidiostats and other medical substances’, as set out 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 narasin.

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.

[F1ANNEX

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 545/2006 of 31 March 2006 amending Regulation (EC) No 1464/2004 as regards the conditions for authorisation of the feed additive 'Monteban', belonging to the group of coccidiostats and other medicinal substances (Text with EEA relevance).

Registration number of additive	Name and registration number of person responsible for putting additive into circulation	Additive (Trade name)	Composition, chemical formula, description	Species or category of animal	Maximum age	Minimum content (mg of active substance/kg of complete feedingstuff)	Maximum content (mg of active substance/kg of complete feedingstuff)	Other provisions	End of period of authorisation	Maximum residue limits (MRLs) set in the relevant foodstuffs of animal origin from species or category of animal concerned
Coccidiostats and other medicinal substances										
E 765	[F2Elanco GmbH]	Narasin 100 g/kg (Monteban, Monteban G 100)	Additive composition: Narasin: 100 g activity/kg Soybean oil or mineral oil: 10-30 g/kg Vermiculite: 0-20 g/kg Soybean mill run or rice	Chickens for fattening	—	60	70	[F3Use prohibited at least one day before slaughter.] Indicate in the instructions for use: 'Dangerous for equine species, turkeys and rabbits' 'This feedingstuff contains an ionophore:	21.8.2013	30 µg Narasin/kg for all wet tissues from chickens for fattening]

					hulls qs 1 kg Active substance: Narasin, $C_{43}H_{72}O_{11}$ CAS number: 55134-13-9 polyether monocarboxylic acid produced by *Streptomyces aureofaciens* (NRRL 8092), in granular form Narasin A activity: ≥ 90 %				simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated’	

Textual Amendments

F2 Substituted by Commission Implementing Regulation (EU) 2019/138 of 29 January 2019 amending Regulations (EC) No 1356/2004, (EC) No 1464/2004, (EC) No 786/2007, (EC) No 971/2008, (EU) No 1118/2010, (EU) No 169/2011 and Implementing Regulations (EU) No 888/2011 and (EU) No 667/2013 as regards the name of the holder of the authorisation for feed additives (Text with EEA relevance).

F3 Deleted by Commission Regulation (EU) No 884/2010 of 7 October 2010 amending Regulation (EC) No 1464/2004 as regards the withdrawal time of the additive ‘Monteban’, belonging to the group of coccidiostats and other medicinal substances (Text with EEA relevance).

(**1**) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1289/2004 (OJ L 243, 15.7.2004, p. 15).

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 1464/2004.