COMMISSION REGULATION (EC) No 971/2008

of 3 October 2008

concerning a new use of a coccidiostat as additive in feedingstuffs

(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 Articles 3 and 9 thereof,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [2], and in particular Article 25 thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition.

(2) Article 25 of Regulation (EC) No 1831/2003 lays down transitional measures for applications for the authorisation of feed additives submitted in accordance with Directive 70/524/EEC before the date of application of Regulation (EC) No 1831/2003.

(3) The application for authorisation of the additive set out in the Annex to this Regulation was submitted before the date of application of Regulation (EC) No 1831/2003.

(4) Initial comments on that application, as provided for in Article 4(4) of Directive 70/524/EEC, were forwarded to the Commission before the date of application of Regulation (EC) No 1831/2003. That application is therefore to continue to be treated in accordance with Article 4 of Directive 70/524/EEC.

(5) The additive diclazuril (Clinacox 0,5 % Premix) is already authorised by Commission Regulations (EC) No 2430/1999 [3] for chickens for fattening, (EC) No 418/2001 [4] for turkeys for fattening and (EC) No 162/2003 [5] for chickens reared for laying.

(6) New data were submitted by the holder of the authorisation of the additive in support of an application for authorisation for ten years as coccidiostat for rabbits. The European Food Safety Authority ('the Authority') delivered two opinions [6] on the safety of the use of that coccidiostat for humans, animals and environment, under the conditions set out in the Annex to this Regulation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of this preparation, as specified in Annex, should be authorised for ten years.

(7) 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 preparation belonging to the group 'Coccidiostats and other medicinal substances', as specified in the Annex, is authorised for use for ten years as additive in animal nutrition under the conditions laid down in that Annex.

Article 2

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

[1] OJ L 270, 14.12.1970, p. 1.
[2] OJ L 268, 18.10.2003, p. 29.
[3] OJ L 296, 17.11.1999, p. 3.
[4] OJ L 62, 2.3.2001, p. 3.
[5] OJ L 26, 31.1.2003, p. 3.
[6] Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on a request from the European Commission on the safety and efficacy of 'Clinacox 0,5 %' based on diclazuril for rabbits for fattening and breeding, The EFSA Journal (2007) 506, 1-32.
Updated Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on a request from the European Commission on the safety of 'Clinacox 0,5 %' (diclazuril) used in rabbits for fattening and breeding, The EFSA Journal (2008) 697, 1-9.

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

Done at Brussels, 3 October 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

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	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				
Coccidiostats and other medicinal substances										
E 771	Janssen Pharmaceutica nv	Diclazuril 0,5 g/100 g (Clinacox 0,5 % Premix)	*Additive composition:* Diclazuril: 0,5 g/100 g Soybean meal: 99,25 g/100 g Polyvidone K 30: 0,2 g/100 g Sodium hydroxide: 0,0538 g/100 g *Active substance:* Diclazuril $C_{17}H_9Cl_3N_4O_2$, (±)-4-chlorophenyl[2,6-dichloro-4-(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl) phenyl]acetonitrile, CAS number: 101831-37-2 *Related impurities:* Degradation compound (R064318): < 0,2 % Other related impurities (R066891, R066896, R068610, R070156, R068584, R070016): < 0,5 % individually Total impurities: < 1,5 %	Rabbits	—	1	1	Use prohibited at least one day before slaughter.	24 October 2018	2 500 g diclazuril/kg of wet liver 1 000 g diclazuril/kg of wet kidney 150 g diclazuril/kg of wet muscle 300 g diclazuril/kg of wet fat