COMMISSION REGULATION (EC) No 167/2008

of 22 February 2008

concerning a new authorisation for ten years of a coccidiostat as an 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 Article 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 person responsible for putting into circulation Kokcisan 120G submitted an application for authorisation for ten years, as a coccidiostat for chickens for fattening, according to Article 4 of that Directive. The European Food Safety Authority (EFSA) has delivered an opinion on the safety of the use of this preparation for human, 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.

(6) The assessment of this application shows that certain procedures should be required to protect workers from exposure to the additive set out in the Annex. Such protection should be 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 [3].

(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.

[1] OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1800/2004 (OJ L 317, 16.10.2004, p. 37).

[2] OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

[3] OJ L 183, 29.6.1989, p. 1. Directive as last amended by Directive 2007/30/EC of the European Parliament and of the Council (OJ L 165, 27.6.2007, p. 21).

Article 2

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

Done at Brussels, 22 February 2008.

For the Commission
Markos KYPRIANOU
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 766	KRKA, d.d Novo mesto, Slovenia	Salinomycin sodium (Kokcisan 120G)	Additive composition: Salinomycin sodium: 120 g/kg Calcium carbonate to 1 000 g/kg Sucrose: 80-100 g/kg Corn starch: 20 g/kg Active substance: Salinomycin sodium, $C_{42}H_{69}O_{11}Na$, CAS number: 55721-31-8, sodium salt of a polyether monocarboxylic acid produced by fermentation of *Streptomyces albus* (CBS 101071) Related impurities: < 42 mg elaiophylin/kg salinomycin sodium < 40 g 17-epi-20-desoxy-salinomycin/kg salinomycin sodium	Chickens for fattening	—	60	70	Use prohibited at least three days before slaughter. Indicate in the instructions for use of compound feedingstuffs: 'Dangerous for equines and turkeys' 'This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated'	26 February 2018	5 µg salinomycin sodium/kg of all wet tissues