COMMISSION REGULATION (EU) No 875/2010

of 5 October 2010

concerning the authorisation for 10 years of an additive in feedingstuffs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 an authorisation of nicarbazin as a feed additive for chickens for fattening 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. This 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 nicarbazin, CAS number 330-95-0, submitted an application for authorisation for 10 years, as a coccidiostat for chickens for fattening, in accordance with Article 4 of Directive 70/524/EEC.

(6) The European Food Safety Authority (the Authority) concluded in its opinion of 10 March 2010 [3] that nicarbazin does not have an adverse effect on animal health, consumer health or the environment, and that that additive is effective in controlling coccidiosis in chickens for fattening. Since p-nitroaniline, an impurity associated with nicarbazin, leads to possible residues of this substance, the Authority recommends that the content of that impurity be limited at the lowest achievable level.

(7) The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for the requested authorisation are satisfied. Accordingly, the use of that additive, as specified in the Annex to this Regulation, should be authorised. In view of the opinion of the Authority, it is, however, necessary to limit the content of the impurity p-nitroaniline. To give producers and users time to adapt, it is appropriate for this limitation to start to apply it three years after this Regulation becomes applicable.

(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 preparation specified in the Annex, belonging to the additive category 'coccidiostats and other medicinal substances', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the 20th day following 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] *EFSA Journal 2010*; 8(3):1551.

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

Done at Brussels, 5 October 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	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										
5 1 774	Phibro Animal Health SA Belgium	Nicarbazin 250 g/kg	*Additive composition* Nicarbazin: 250 g/kg Stearic acid: 126 ± 5 % g/kg Polysorbate 20: 13,90 ± 10 % g/kg Wheat middling to 100 % *Active substance* Nicarbazin, $C_{19}H_{18}N_6O_6$. CAS number: 330-95-0 equimolecular complex of 1,3-bis(4-nitrophenyl) urea and 4,6-dimethylpyrimidin-2-ol, in granular form Related impurities: p-nitroaniline: ≤ 0,3 %	Chickens for fattening	—	125	125	1. Use prohibited at least one day before slaughter. 2. Nicarbazin shall not be mixed with other coccidiostats except narasin. 3. The additive shall be incorporated in compound feed in form of a premixture. 4. From 26 October 2013 the p-nitroaniline content shall be ≤ 0,1 %. 5. A post-market monitoring program on the resistance to bacteria and *Eimeria* spp. shall be planned and executed by the holder of authorisation.	26 October 2020	15 000 µg of di-nitrocarbanilide (DNC)/kg of fresh liver; 6 000 µg of DNC/kg of fresh kidney; 4 000 µg of DNC/kg for fresh muscle and fresh skin/fat.