COMMISSION REGULATION (EU) No 885/2010

of 7 October 2010

concerning the authorisation of the preparation of narasin and nicarbazin as a feed additive for chickens for fattening (holder of authorisation Eli Lilly and Company Ltd) and amending Regulation (EC) No 2430/1999

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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 ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) The preparation of narasin, CAS number 55134-13-9, and nicarbazin, CAS number 330-95-0, was authorised for ten years in accordance with Directive 70/524/EEC as a feed additive for use on chickens for fattening by Commission Regulation (EC) No 2430/1999 ([3]). That additive was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of that additive, requesting that additive to be classified in the additive category 'coccidiostats and histomonostats'. That application was accompanied by the particulars and documents required pursuant to Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 7 April 2010 that, under the proposed conditions of use, the preparation of narasin and of nicarbazin do not have an adverse effect on animal health, consumer health or the environment and that these additives are effective in controlling coccidiosis in chickens for fattening ([4]). It considers that there is a need for specific requirements of post-market monitoring to control the possible development of bacterial and/or *Eimeria* spp resistances. 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. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of narasin and nicarbazin shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation. 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 three years after this Regulation becomes applicable.

(6) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, the provisions on that preparation in Regulation (EC) No 2430/1999 should be deleted.

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

Article 2

In Annex I to Regulation (EC) No 2430/1999, the entry under the registration number of additive E 772, concerning Narasin 80 g/kg — Nicarbazin 80 g/kg (Maxiban G160), is deleted.

Premixture and compound feed containing the feed additive labelled in accordance with Regulation (EC) No 2430/1999 may continue to be placed on the market and remain on the market and used until stocks are exhausted.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) OJ L 296, 17.11.1999, p. 3.
([4]) EFSA Journal 2010; 8(4):1574.

Article 3

This Regulation shall enter into force on the 20th day following 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, 7 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 histomonostats										
5 1 772	Eli Lilly and Company Ltd	Narasin 80 g activity/kg Nicarbazin 80 g/kg (Maxiban G160)	*Additive composition* Narasin: 80 g activity/kg Nicarbazin: 80 g/kg (Ratio 1:1) Vegetal or mineral oil: 10-30 g/kg Vermiculite: 0-20 g/kg Micro tracer red: 11 g/kg Corn cob grits or rice hulls qs 1 kg *Active substance* 1. 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: ≥ 85 % 2. 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	—	40 mg Narasin 40 mg Nicarbazin	50 mg Narasin 50 mg Nicarbazin	1. Indicate in the instructions for use: 'Dangerous for equine species, turkeys and rabbits' 'This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances can be contraindicated'. 2. The additive shall be incorporated in compound feed in form of a premixture. 3. The preparation of narasin and nicarbazin shall not be mixed with other coccidiostats. 4. A post-market monitoring program on the resistance to bacteria and *Eimeria* spp. shall be planned and executed by the holder of authorisation. 5. From 28 October 2013 the p-nitroaniline content shall be ≤ 0,1 %. 6. For safety: breathing protection shall be used during handling.	28 October 2020	50 µg of narasin/kg for fresh liver, muscle, kidney and skin/fat. 15 000 µg of dinitrocarbanilide (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.

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 %				
			Analytical methods (1) For the determination of narasin: reversed-phase high performance liquid chromatography (HPLC) using post-column derivatisation with vanillin and detection at 520 nm - ISO 14183:2005. For determination of nicarbazin: high performance liquid chromatography method and ultraviolet detection (HPLC-UV) spectrometry (LC-MS/MS)							

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives