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COMMISSION IMPLEMENTING REGULATION (EU) No 900/2011

of 7 September 2011

concerning the authorisation of lasalocid A sodium as a feed additive for pheasants, guinea fowl, quails and partridges other than laying birds (holder of authorisation ►M2 Zoetis Belgium SA ◄)

(Text with EEA relevance)

(OJ L 231, 8.9.2011, p. 15)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Implementing Regulation (EU) No 118/2012 of 10 February 2012	L 38	36	11.2.2012
►M2	Commission Implementing Regulation (EU) No 1014/2013 of 22 October 2013	L 281	1	23.10.2013

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(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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of lasalocid A sodium, CAS number 25999-20-6. The application was accompanied by the particulars and documents required pursuant to Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of lasalocid A sodium, CAS number 25999-20-6, as a feed additive for pheasants, guinea fowl, quails and partridges other than laying birds, to be classified in the additive category ‘coccidiostats and histomonostats’.

(4) The use of that preparation was authorised for 10 years for chickens for fattening and for chickens reared for laying up to 16 weeks by Commission Regulation (EC) No 1455/2004 ([2]), and for turkeys up to 16 weeks by Commission Regulation (EU) No 874/2010 ([3]).

(5) New data were submitted in support of the application for authorisation of lasalocid A sodium, CAS number 25999-20-6, for pheasants, guinea fowl, quails and partridges other than laying birds. The European Food Safety Authority (‘the Authority’) concluded in its opinion of 16 March 2011 ([4]) that, under the proposed conditions of use, lasalocid A sodium, CAS number 25999-20-6, does not have an adverse effect on animal health, human health or the environment and that it is efficacious to control coccidiosis in the target species. It considers that there is a need for specific requirements of a post-market monitoring program on the resistance to bacteria and *Eimeria* spp. It 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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 269, 17.8.2004, p. 14.
([3]) OJ L 263, 6.10.2010, p. 1.
([4]) *The EFSA Journal* 2011; 9(4):2116.

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(6) The assessment of lasalocid A sodium, CAS number 25999-20-6, shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(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 'coccdiostats and histomonostats' 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.*

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

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/kg of complete feedingstuff with a moisture content of 12 %				
Category of coccidiostats and histomonostats										
5 1 763	►**M2** Zoetis Belgium SA ◄	Lasalocid A sodium 15 g/100 g (Avatec 150 G)	*Additive composition:* Lasalocid A sodium: 15 g/100 g Calcium sulphate dihydrate: 80,9 g/100 g Calcium lignosulphonate: 4 g/100 g Ferric oxide: 0,1 g/100 g *Active substance:* Lasalocid A sodium, $C_{34}H_{53}NaO_8$, CAS number: 25999-20-6, sodium salt of 6-[(3R, 4S, 5S, 7R)-7-[(2S, 3S, 5S)-5-ethyl-5-[(2R, 5R, 6S)-5-ethyl—5-hydroxy-6-methyl-tetrahydro-2H-pyran2-yl]-tetrahydro-3-methyl-2-furyl]-4-hydroxy-3,5-dimethyl-6-oxononyl]-2 hydroxy-3-methyl benzoate, produced by *Streptomyces lasaliensis* subsp. *Lasaliensis* (ATCC 31180) Related impurities: Lasalocid sodium B-E: ≤ 10 % *Analytical methods* (1): Reversed-phase high performance liquid chromatography (HPLC) with spectrofluorometric detector (Commission Regulation (EC) No 152/2009) (2)	Pheasants, guinea fowl, quails and partridges except laying birds thereof.	—	75	125	1. Use prohibited at least 5 days before slaughter. 2. Indicate in the instructions for use: 'Dangerous for equine species' 'This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances can be contra-indicated'. 3. A post-market monitoring program on the resistance to bacteria and *Eimeria* spp. shall be planned and executed by the holder of authorisation. 4. The additive shall be incorporated in compound feed in the form of a premixture. 5. Lasalocid A sodium shall not be mixed with other coccidiostats.	28 September 2021	Commission Regulation (EU) No 37/2010 (3)

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx
(2) OJ L 54, 26.2.2009, p. 1.
(3) OJ L 15, 20.1.2010, p. 1.