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# COMMISSION REGULATION (EU) No 874/2010

## of 5 October 2010

## concerning the authorisation of lasalocid A sodium as a feed additive for turkeys up to 16 weeks (holder of authorisation Alpharma (Belgium) BVBA) and amending Regulation (EC) No 2430/1999

**(Text with EEA relevance)**

(OJ L 263, 6.10.2010, p. 1)

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 |

Corrected by:

►**C1** Corrigendum, OJ L 264, 7.10.2010, p. 19 (874/2010)

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# COMMISSION REGULATION (EU) No 874/2010

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## concerning the authorisation of lasalocid A sodium as a feed additive for turkeys up to 16 weeks (holder of authorisation Alpharma (Belgium) BVBA) 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) Lasalocid A sodium, CAS number 25999-20-6, was authorised for 10 years in accordance with Directive 70/524/EEC as a feed additive for use on chickens for fattening and chickens reared for laying by Commission Regulation (EC) No 1455/2004 ([3]) and for use on turkeys up to 12 weeks by Commission Regulation (EC) No 2430/1999 ([4]). 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 lasalocid A sodium as a feed additive for turkeys, extending the maximum age from 12 to 16 weeks and requesting that additive to be classified in the additive category ‘coccidiostats and histomonostats’. That application was accompanied by the particulars and documents required under 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, lasalocid A sodium does not have an adverse effect on animal health, consumer health or the environment, and that that additive is effective in controlling coccidiosis in turkeys ([5]). It considers that there is a need for specific requirements of post-market monitoring to control the possible development of

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) OJ L 269, 17.8.2004, p. 14.
([4]) OJ L 296, 17.11.1999, p. 3.
([5]) *The EFSA Journal 2010*; 8(4):1575.

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bacterial and/or *Eimeria* spp. resistances. 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 that additive 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 additive should be authorised as specified in the Annex to this Regulation.

(6) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, the provisions on that additive 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 763, concerning lasalocid A sodium, 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.

*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.

*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** | | | | | | | | | | |
| ►**C1** 5 1 763 ◄ | ►**M1** Pfizer Ltd ◄ | Lasalocid A sodium 15 g/100 g (Avatec 150 G) | *Additive composition*<br>Lasalocid A sodium: 15 g/100 g<br>Calcium sulphate dehydrate: 80,9 g/100 g<br>Calcium lignosulphonate: 4 g/100 g<br>Ferric oxide: 0,1 g/100 g<br>*Active substance*<br>Lasalocid A sodium, $C_{34}H_{53}NaO_8$,<br>CAS number: 25999-20-6,<br>sodium salt of 6-[(3R, 4S, 5S, 7R)-7-[(2S, 3S, 5S)-5-ethyl-5-[(2R, 5R, 6S)-5-ethyl-5-hydroxy-6-methyltetrahydro-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)<br>Related impurities:<br>Lasalocid sodium B-E: ≤ 10 %<br>*Analytical methods* (1)<br>Reversed-phase high performance liquid chromatography (HPLC) with spectrofluorometric detector (Regulation (EC) No 152/2009) | Turkeys | 16 weeks | 75 | 125 | 1. Use prohibited at least 5 days before slaughter.<br>2. Indicate in the instructions for use:<br>'Dangerous for equine species'<br>'This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances can be contra-indicated.'<br>3. A post-market monitoring program on the resistance to bacteria and *Eimeria* spp. shall be planned and executed by the holder of authorisation.<br>4. The additive shall be incorporated in compound feed in form of a premixture.<br>5. Lasalocid A sodium shall not be mixed with other coccidiostats. | 26 October 2020 | Regulation (EU) No 37/2010 |

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