COMMISSION IMPLEMENTING REGULATION (EU) 2023/1172

of 15 June 2023

concerning the authorisation of a preparation of lasalocid A sodium (Avatec 150 G) as a feed additive for chickens for fattening, the denial of authorisation of a preparation of lasalocid A sodium (Avatec 150 G) as a feed additive for chickens reared for laying, the withdrawal from the market of a preparation of lasalocid A sodium (Avatec 15 % cc) as a feed additive for chickens for fattening and chickens reared for laying and repealing Regulation (EC) No 1455/2004 and Implementing Regulation (EU) 2021/932 (holder of authorisation: Zoetis Belgium S.A.)

(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), Article 10(5) and Article 13(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 or denying such authorisation. Article 10(2) of that Regulation provides rules for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) The preparations of lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) were authorised by Commission Regulation (EC) No 1455/2004 ([3]) for 10 years as feed additives belonging to the group 'coccidiostats and other medicinal substances' for use for chickens for fattening and chickens reared for laying. Those feed additives were subsequently entered in the Register of feed additives as existing products, 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 thereof, an application was submitted for the authorisation of the preparation of lasalocid A sodium (Avatec 150 G) as a feed additive for chickens for fattening and chickens reared for laying, requesting the 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. No such application was submitted for the authorisation of the preparation of lasalocid A sodium (Avatec 15 % cc).

(4) The European Food Safety Authority ('the Authority') stated in its opinions of 16 May 2017 ([4]) and 1 July 2020 ([5]) that it could not conclude on the safety and efficacy of the preparation of lasalocid A sodium (Avatec 150 G) for chickens for fattening and chickens reared for laying, indicating that no safe level of the active substance lasalocid A sodium, when added to feed, could be identified for those target species. The Authority concluded that the coccidiostatic efficacy of the preparation was insufficiently demonstrated at the lowest proposed dose level of 75 mg lasalocid A sodium per kg of complete feed. Consequently, it had not been established that the preparation of

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) Commission Regulation (EC) No 1455/2004 of 16 August 2004 concerning the authorisation for 10 years of the additive 'Avatec 15 %' in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (OJ L 269, 17.8.2004, p. 14).
([4]) *EFSA Journal* 2017; 15(8):4857.
([5]) *EFSA Journal* 2020; 18(8):6202.

lasalocid A sodium (Avatec 150 G) does not have an adverse effect on animal health and that it has a coccidiostatic effect on the target species, when used under the proposed conditions. Therefore, the existing authorisation of the preparation of lasalocid A sodium (Avatec 150 G) was suspended by Commission Implementing Regulation (EU) 2021/932 ([6]).

(5) The authorisation of the preparation of lasalocid A sodium (Avatec 150 G) was suspended pending the submission and assessment of supplementary data to be produced by the applicant according to a time schedule listing the necessary studies to be carried out, consisting of tolerance and 'floor pen' efficacy studies for chickens for fattening and chickens reared for laying.

(6) In accordance with Implementing Regulation (EU) 2021/932, the suspension measure is to be reviewed by 31 December 2023 and in any event after the adoption by the Authority of a non-favourable opinion on the safety and efficacy of the preparation of lasalocid A sodium (Avatec 150 G) for use for chickens for fattening and chickens reared for laying.

(7) Since the adoption of the Authority's opinion of 1 July 2020, the applicant submitted to the Commission supplementary data on 29 June 2022, which were forwarded to the Authority.

(8) On 23 November 2022, the Authority adopted an opinion ([7]) following the assessment of the supplementary data submitted by the applicant and concluded that the preparation of lasalocid A sodium (Avatec 150 G) is safe and efficacious for chickens for fattening at the maximum and minimum dose level of 90 mg lasalocid A sodium per kg of complete feed. However, it also considered that an extrapolation of the results of the tolerance studies, all in chickens for fattening, to the chickens reared for laying is not possible, considering that, while zootechnical performance seems to be the most sensitive endpoint to evaluate the tolerance to lasalocid A sodium, negative effects were observed on performances of animals with low growth rate and a potential negative effect was noted on the breeding period with lasalocid A sodium when fed to chickens reared for breeding. The Authority could therefore still not conclude on the safety of that additive for chickens reared for laying.

(9) In its opinion of 16 May 2017, the Authority also concluded that the preparation of lasalocid A sodium (Avatec 150 G) is safe for the user, for the environment and for the consumer provided a withdrawal period of three days is applied for compliance with the maximum residue limits ('MRL'). In particular, the Authority stated that its previous conclusions that there is no likely risk to the user handling the additive, laid down in its opinion of 7 April 2010 ([8]), did not need to be reconsidered. The Authority further stated that the concurrent administration of lasalocid A sodium with tiamulin and certain other medicinal substances should be avoided, and recommended that a post-market monitoring of *Eimeria* spp. resistance to lasalocid A sodium be undertaken.

(10) In addition, the Authority verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003, including the addendum produced on 23 January 2023, recommending the addition of a new multi-analyte method based on liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS) for the determination of lasalocid A sodium in compound feed.

(11) The assessment of the preparation of lasalocid A sodium (Avatec 150 G) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied as regards the use for chickens for fattening. Accordingly, the use of that additive should be authorised for that use. It is appropriate to provide for post-market monitoring on the resistance of *Eimeria* spp. to lasalocid A sodium. The MRL established for lasalocid A sodium in Commission Regulation (EU) No 37/2010 ([9]) should apply to residues of that substance or its metabolites originating from the use thereof as a feed additive, in the relevant foodstuffs of animal origin.

([6]) Commission Implementing Regulation (EU) 2021/932 of 9 June 2021 suspending the authorisation of lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) as feed additives for chickens for fattening and chickens reared for laying (holder of authorisation Zoetis Belgium S.A.) (OJ L 204, 10.6.2021, p. 13).

([7]) *EFSA Journal* 2022; 20(12):7715.

([8]) *EFSA Journal* 2010;8(4):1575.

([9]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

(12) However, the Authority's opinions of 16 May 2017, 1 July 2020 and 23 November 2022 show that it has not been established that the preparation of lasalocid A sodium (Avatec 150 G) does not have an adverse effect on animal health, when used for chickens reared for laying. The assessment of that additive thus shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are not satisfied as regards the use for chickens reared for laying and accordingly, the authorisation of the preparation of lasalocid A sodium (Avatec 150 G) as a feed additive belonging to the category 'coccidiostats and histomonostats' should be denied for chickens reared for laying.

(13) Article 10(5) of Regulation (EC) No 1831/2003 imposes an obligation on the Commission to adopt a Regulation withdrawing from the market feed additives for which no applications as required by Article 10(2) of that Regulation were submitted before the deadline provided for in that provision. Therefore, the preparation of lasalocid A sodium (Avatec 15 % cc) should be withdrawn from the market. As Article 10(5) of Regulation (EC) No 1831/2003 does not differentiate between authorisations issued with a time limit and authorisations without a time limit, for clarity reasons it is appropriate to provide for the withdrawal from the market of feed additives whose limited authorisation periods pursuant to Directive 70/524/EEC have already expired.

(14) As a consequence of the above review and of the authorisation of the preparation of lasalocid A sodium (Avatec 150 G) for chickens for fattening, the denial of its authorisation for chickens reared for laying, and the withdrawal from the market of the preparation of lasalocid A sodium (Avatec 15 % cc), Regulation (EC) No 1455/2004 and Implementing Regulation (EU) 2021/932 should be repealed.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

Denial of authorisation

The authorisation of the preparation of lasalocid A sodium (Avatec 150 G) as an additive in animal nutrition belonging to the category 'coccidiostats and histomonostats' for use for chickens reared for laying, is denied.

Article 3

Withdrawal from the market

The feed additive lasalocid A sodium (Avatec 15 % cc) shall be withdrawn from the market.

Article 4

Repeals

Regulation (EC) No 1455/2004 and Implementing Regulation (EU) 2021/932 are repealed.

Article 5

Entry into force

This Regulation shall enter into force on the twentieth 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, 15 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

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 %				
Category: coccidiostats and histomonostats										
51763	Zoetis Belgium S. A.	Lasalocid A sodium 15 g/100 g (Avatec 150 G)	*Additive composition* Preparation of: Lasalocid A sodium: 15 g/100 g Calcium lignosulphonate: 4 g/100 g Ferric oxide: 0,1 g/100 g Calcium sulphate dihydrate: quantum satis *Characterisation of the active substance* Lasalocid A sodium: — $C_{34}H_{54}O_8Na$ — CAS number: 25999-20-6 — sodium 6-3R, 4S,5S,7R)-7-[2S,3S,5S)-5-ethyl-5-[(2R,5R,6S)-5-ethyl-5-hydroxy-6-methyltetrahydro-2H-pyran-2-yl]-tetrahydro-3-methyl-2-furyl]-4-hydroxy-3,5-dimethyl-6-oxononyl]-2,3-cresotate — produced by *Streptomyces lasaliensis* subsp. *lasaliensis* (ATCC 31180)	Chickens for fattening	-	90	90	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Use prohibited at least 3 days before slaughter. 3. Indicate in the directions for use of the additive, premixture and compound feed: 'Dangerous for equine species' 'This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances, including tiamulin, can be contra-indicated.' 4. A post-market monitoring program on the resistance of *Eimeria* spp. shall be planned and executed by the holder of authorisation, in accordance with Commission Regulation (EC) No 429/2008.	6 July 2033	Regulation (EU) No 37/2010

			Related impurities: lasalocid sodium B-E: ≤ 10 % *Analytical method* (1) For the determination of lasalocid A sodium in the feed additive and premixtures: Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) – Commission Regulation (EC) No 152/2009. For the determination of lasalocid A sodium in compound feed: — Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) – Commission Regulation (EC) No 152/2009 or — High Performance Liquid Chromatography coupled with tandem mass spectrometry (LC-MS/MS) – EN 17299					5. The additive shall be incorporated in compound feed in form of a premixture. 6. Lasalocid A sodium shall not be mixed with other coccidiostats.		

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en