

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.)****(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 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, denying or suspending 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 (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 category of coccidiostats 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 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.
- (4) The European Food Safety Authority ('the Authority') stated in its opinions of 16 May 2017 ⁽⁴⁾ and 1 July 2020 ⁽⁵⁾ that the assessment of the particulars and documents submitted by the applicant makes it impossible to conclude on the safety and the efficacy of the feed additive lasalocid A sodium (Avatec 150 G) for chickens for fattening and chickens reared for laying. The Authority indicated that no safe level of the active substance lasalocid A sodium, when added to feed, could be identified for the target species. It also concluded that, due to the insufficient number of studies with positive results, the coccidiostatic efficacy of the feed additive was insufficiently demonstrated at the lowest proposed dose level of 75 mg lasalocid A sodium per kg of complete feed. 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.
- (5) Consequently, it has not been established that the feed additive 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. This conclusion can be extended to the existing authorisation of the feed additive lasalocid A sodium (Avatec 15 % cc), which contains the same concentration of the active substance lasalocid A sodium.
- (6) The existing authorisation of the feed additives lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) for chickens for fattening and chickens reared for laying therefore no longer meets the conditions set out by Article 5 of Regulation (EC) No 1831/2003.

⁽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.

- (7) It is possible that supplementary data concerning the safety of use and the efficacy of lasalocid A sodium (Avatec 150 G) for the target species bring new elements that would allow a re-consideration of the assessment carried out for that feed additive. In this respect, the applicant for the authorisation of lasalocid A sodium (Avatec 150 G) argues that additional studies may be performed in order to demonstrate the safety and efficacy of the feed additive for the target species. To this end, the applicant committed itself to produce supplementary data according to a time schedule, listing the studies to be carried out and planning that the outcome thereof will be available by 31 December 2021. Those studies would consist of tolerance and 'floor pen' efficacy studies for chickens for fattening and chickens reared for laying.
- (8) In accordance with Article 13(2) of Regulation (EC) No 1831/2003, the authorisation of the feed additives lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) should be suspended, pending the submission and assessment of the supplementary data. The suspension measure should be reviewed after due assessment of those data by the Authority.
- (9) Since further use of the feed additives lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) might cause a risk to animal health, the feed additives and feed containing them should be withdrawn from the market as soon as possible. For practical reasons, however, a limited transitional period should be allowed for the withdrawal from the market of the products concerned in order to enable operators to comply properly with the withdrawal obligation.
- (10) 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

Suspension of the authorisation

The authorisation of the feed additives lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) for use for chickens for fattening and chickens reared for laying shall be suspended.

Article 2

Transitional measures

1. Existing stocks of the feed additives lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) for use for chickens for fattening and chickens reared for laying, and of premixtures containing them, may continue to be placed on the market until 30 July 2021 and may be used until 30 August 2021 in accordance with the rules applicable before 30 June 2021.
2. Feed materials and compound feed produced with the feed additives or with premixtures referred to in paragraph 1 may continue to be placed on the market until 30 August 2021 and may be used until 30 September 2021 in accordance with the rules applicable before 30 June 2021.

Article 3

Review

This Regulation shall be reviewed by 31 December 2023, after the adoption by the Authority of a new opinion on the safety and efficacy of the feed additive lasalocid A sodium (Avatec 150 G) for use for chickens for fattening and chickens reared for laying.

*Article 4***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, 9 June 2021.

For the Commission
The President
Ursula VON DER LEYEN
