



2023/2662

30.11.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2662

of 29 November 2023

amending Implementing Regulation (EU) 2017/447 as regards the terms of the authorisation of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) for turkeys for fattening (holder of authorisation: Chr. Hansen A/S)

(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(3) 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 and modifying such authorisation.
- (2) Commission Implementing Regulation (EU) 2017/447 ⁽²⁾ authorised the use of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) as a feed additive for sows, weaned piglets, pigs for fattening, calves for rearing and turkeys for fattening for a 10-year period.
- (3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, an application was submitted on 19 April 2018 for the modification of the terms of the authorisation of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) as regards turkeys for fattening. That application concerns the compatibility of the use of that preparation with the preservative formic acid and several coccidiostats and was accompanied by the relevant data supporting the request for the change.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 15 May 2019 ⁽³⁾ that the proposed modification in the conditions of the authorisation of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) would not modify the conclusions previously drawn regarding the safety of the additive. It also stated that the conclusions on the compatibility of the additive with several coccidiostats and the preservative formic acid which were drawn for chickens for fattening in its opinions of 22 October 2008 ⁽⁴⁾ and 6 January 2011 ⁽⁵⁾ apply also to turkeys for fattening provided that the maximum authorised concentrations of the coccidiostats semduramycin, maduramicin ammonium, lasalocid sodium and the preservative formic acid (when maximum authorised concentrations exist) are equal or lower than those for chickens for fattening. In addition, the Authority concluded that the use of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) is also compatible with the coccidiostats diclazuril and monensin sodium. Based on the available data, no conclusion could be drawn by the Authority on the compatibility of the use of that preparation with the coccidiostat robenidine hydrochloride and, in the absence of data, with the coccidiostat halofuginone.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) 2017/447 of 14 March 2017 concerning the authorisation of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) as a feed additive for sows, weaned piglets, pigs for fattening, calves for rearing and turkeys for fattening and amending Regulations (EC) No 1453/2004, (EC) No 2148/2004 and (EC) No 600/2005 (holder of authorisation Chr. Hansen A/S) (OJ L 69, 15.3.2017, p. 18).

⁽³⁾ EFSA Journal 2019;17(6):5726.

⁽⁴⁾ EFSA Journal (2008) 841, 1-7

⁽⁵⁾ EFSA Journal 2011;9(1):1953.

- (5) The coccidiostat lasalocid sodium is authorised, in accordance with Commission Implementing Regulation (EU) 2023/1172 ⁽⁶⁾, for chickens for fattening with a maximum content of 90 mg of active substance/kg of complete feedingstuff with a moisture content of 12 %. In order to fully take into account the conclusions of the Authority's opinion of 15 May 2019, the simultaneous use for turkeys for fattening of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) and of lasalocid sodium should therefore be authorised only where the maximum content of lasalocid sodium is 90 mg of active substance/kg of complete feedingstuff with a moisture content of 12 %.
- (6) In view of the above, the Commission considers that the authorisation of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) still meets the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 when modifying the terms thereof as regards turkeys for fattening, by specifying the compatibility of the use of that preparation with formic acid and, where authorised as feed additives for the same animal species and category, the coccidiostats semduramycin, maduramicin ammonium, diclazuril, monensin sodium and lasalocid sodium with a maximum content of 90 mg of lasalocid sodium/kg of complete feedingstuff with a moisture content of 12 %. Implementing Regulation (EU) 2017/447 should therefore be amended accordingly.
- (7) 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

Amendment to Implementing Regulation (EU) 2017/447

The following provision is added in the column 'Other provisions' of the Annex to Implementing Regulation (EU) 2017/447:

- '6. The additive may be used in turkeys for fattening in compound feed containing formic acid, or containing the following coccidiostats, where authorised as feed additives for the same animal species and category: semduramycin, maduramicin ammonium, diclazuril, monensin sodium and lasalocid sodium with a maximum content of 90 mg of lasalocid sodium/kg of complete feedingstuff with a moisture content of 12 %.'

Article 2

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, 29 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁶⁾ 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.) (OJ L 155, 16.6.2023, p. 22).