



Brussels, **XXX**
SANTE/381534 &
990848_MERGED/2024 CIS
(POOL/G5/2024/381534 & 990848-EN
CIS.docx)
[...](2024) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the renewal of the authorisation of a preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive for turkeys for fattening, turkeys reared for breeding, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, and sows, its authorisation for Suidae for fattening, suckling piglets of all Suidae species and sows of minor Suidae species (holder of authorisation: Kemin Europa N.V.), amending Implementing Regulation (EU) 2023/366 and repealing Implementing Regulations (EU) No 306/2013, (EU) No 787/2013 and (EU) 2017/2276

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the renewal of the authorisation of a preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive for turkeys for fattening, turkeys reared for breeding, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, and sows, its authorisation for Suidae for fattening, suckling piglets of all Suidae species and sows of minor Suidae species (holder of authorisation: Kemin Europa N.V.), amending Implementing Regulation (EU) 2023/366 and repealing Implementing Regulations (EU) No 306/2013, (EU) No 787/2013 and (EU) 2017/2276

(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 nutrition¹, and in particular Article 9(2) and 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, modifying and renewing such an authorisation.
- (2) A preparation of *Bacillus velezensis* ATCC PTA-6737, previously taxonomically identified as *Bacillus subtilis* ATCC PTA-6737, was authorised for a period of 10 years as a feed additive for turkeys for fattening and turkeys reared for breeding by Commission Implementing Regulation (EU) No 787/2013², for weaned piglets and weaned Suidae other than *Sus scrofa domesticus* by Commission Implementing Regulation (EU) No 306/2013³, for sows by Commission Implementing Regulation (EU) 2017/2276⁴ and for chickens for fattening, chickens reared for laying and minor

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² Commission Implementing Regulation (EU) No 787/2013 of 16 August 2013 concerning the authorisation of a preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of authorisation Kemin Europa N.V.) (OJ L 220, 17.8.2013, p. 15, ELI: http://data.europa.eu/eli/reg_impl/2013/787/oj).

³ Commission Implementing Regulation (EU) No 306/2013 of 2 April 2013 concerning the authorisation of a preparation of *Bacillus subtilis* (ATCC PTA-6737) for weaned piglets and weaned Suidae other than *Sus scrofa domesticus* (holder of authorisation Kemin Europa N.V.) (OJ L 91, 3.4.2013, p. 5, ELI: http://data.europa.eu/eli/reg_impl/2013/306/oj).

⁴ Commission Implementing Regulation (EU) 2017/2276 of 8 December 2017 concerning the authorisation of a new use of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for sows (holder of the authorisation Kemin Europa N.V.) (OJ L 326, 9.12.2017, p. 50, ELI: http://data.europa.eu/eli/reg_impl/2017/2276/oj).

poultry species except minor poultry for laying by Commission Implementing Regulation (EU) 2023/366⁵.

- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive for turkeys for fattening and turkeys reared for breeding, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'gut flora stabilisers'. That application included a proposal for amending the conditions of the original authorisation, consisting in an increase of the minimum concentration of the active agent in the preparation from 1×10^{10} CFU/g additive to 8×10^{10} CFU/g additive and an addition of the possibility to use the additive in combination with the coccidiostat halofuginone. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, another application was submitted for the renewal of the authorisation of the preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive for weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, and sows, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'gut flora stabilisers'. That application included a proposal for amending the conditions of the original authorisations, consisting in an increase of the minimum concentration of the active agent in the preparation from 1×10^{10} CFU/g additive to 8×10^{10} CFU/g additive, and, as regards the use for sows, in a removal of the restriction of use in sows from three weeks before farrowing to whole lactation period. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (5) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of new uses of the preparation of *Bacillus velezensis* ATCC PTA-6737. That application concerns an extension of the authorisation of the preparation as a feed additive to all growing Suidae, sows and minor reproductive porcine species, which corresponds to a new use for Suidae for fattening, suckling piglets of all Suidae species and sows of minor Suidae species. The application requested that additive to be classified in the category 'zootechnical additives' and in the functional group 'gut flora stabilisers' and was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (6) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, an application was submitted for the modification of the terms of the authorisation of the preparation of *Bacillus velezensis* ATCC PTA-6737 as laid down in Implementing Regulation (EU) 2023/366 as regards the use for chickens for fattening, chickens reared for laying and minor poultry species except for laying. That application concerns a request to increase the minimum content of the additive from 1×10^7 CFU/kg of complete feed

⁵ Commission Implementing Regulation (EU) 2023/366 of 16 February 2023 concerning the renewal of the authorisation of a preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species except for laying purposes, its authorisation for ornamental birds, amending Implementing Regulation (EU) No 306/2013, Implementing Regulation (EU) No 787/2013, Implementing Regulation (EU) 2015/1020, Implementing Regulation (EU) 2017/2276 and repealing Regulation (EU) No 107/2010 and Implementing Regulation (EU) No 885/2011 (holder of authorisation Kemin Europa N.V.) (OJ L 50, 17.2.2023, p. 59, ELI: http://data.europa.eu/eli/reg_impl/2023/366/oj).

to 1×10^8 CFU/kg of complete feed and to add the possibility to use the additive in combination with the coccidiostat halofuginone.

- (7) The European Food Safety Authority ('the Authority') concluded in its opinions of 5 January 2024⁶ and 2 February 2024⁷ that, under the current authorised conditions of use and considering the fact that the composition and manufacturing process of the additive has not been substantially modified, the preparation of *Bacillus velezensis* ATCC PTA-6737 remains safe for all poultry species, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, and sows, the consumers and the environment. It also concluded that the additive is safe for all Suidae and for the consumers and the environment. The Authority also concluded that the preparation is not irritant to the skin and eyes, but that it should be considered a respiratory sensitiser, while no conclusion could be drawn on the potential of the additive to be a skin sensitiser. The Authority considered that the additive has the potential to be efficacious in poultry for fattening and reared for laying/breeding ('all growing poultry') at the minimum use level of 1×10^8 CFU/kg complete feed and in all growing Suidae (suckling, weaned and fattening categories) at the minimum inclusion level of 1×10^7 CFU/kg complete feed and in sows and minor reproductive Suidae species at 1×10^8 CFU/kg of complete feed. The Authority further concluded in its opinion of 2 February 2024 concerning the use of the additive for poultry that the additive is compatible with the coccidiostat halofuginone. The Authority did not consider that there is a need for specific requirements for a post-market monitoring.
- (8) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of *Bacillus velezensis* ATCC PTA-6737 as a feed additive in the context of the previous authorisations are valid and applicable for the current applications. In accordance with Article 5(4), points (a), (b) and (c), of Commission Regulation (EC) No 378/2005⁸, an evaluation report of the Reference Laboratory is therefore not required.
- (9) In view of the above, the Commission considers that the preparation of *Bacillus velezensis* ATCC PTA-6737 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed for turkeys for fattening, turkeys reared for breeding, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, and sows. Furthermore, the use of the additive should be authorised for Suidae for fattening, suckling piglets of all Suidae species and sows of minor Suidae species. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive. Those protective measures should be without prejudice to other workers' safety requirements under Union law.
- (10) In addition, in view of the above, the Commission considers that the authorisation of the preparation of *Bacillus velezensis* ATCC PTA-6737 still meets the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 when modifying the terms thereof as regards the use for chickens for fattening, chickens reared for laying and

⁶ EFSA Journal; 2024;22:e8562.

⁷ EFSA Journal; 2024;22:e8650.

⁸ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

minor poultry species except for laying, by increasing the minimum content of the additive to 1×10^8 CFU/kg of complete feed and by adding the possibility to use the additive in combination with the coccidiostat halofuginone. Implementing Regulation (EU) 2023/366 should therefore be amended accordingly.

- (11) As a consequence of the renewal of the authorisation of the preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive for turkeys for fattening, turkeys reared for breeding, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, and sows, Implementing Regulations (EU) No 306/2013, (EU) No 787/2013 and (EU) 2017/2276 should be repealed.
- (12) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Bacillus velezensis* ATCC PTA-6737 for turkeys for fattening, turkeys reared for breeding, chickens for fattening, chickens reared for laying, minor poultry species except for laying, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, and sows, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal or the modification of the authorisations concerned.
- (13) 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

Renewal of the authorisation

The authorisation of the preparation specified in Annex I, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is renewed for turkeys for fattening, turkeys reared for breeding, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, and sows, subject to the conditions laid down in that Annex.

Article 2

Authorisation

The preparation specified in Annex I, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition for Suidae for fattening, suckling piglets of all Suidae species and sows of minor Suidae species, subject to the conditions laid down in that Annex.

Article 3

Amendment to Implementing Regulation (EU) 2023/366

The Annex to Implementing Regulation (EU) 2023/366 is replaced by Annex II to this Regulation.

Article 4

Repeal

Implementing Regulations (EU) No 306/2013, (EU) No 787/2013 and (EU) 2017/2276 are repealed.

Article 5

Transitional measures

1. The feed additive *Bacillus velezensis* ATCC PTA-6737, as authorised by Implementing Regulations (EU) No 306/2013, (EU) No 787/2013, (EU) 2017/2276 and (EU) 2023/366, and premixtures containing that additive, which are intended for turkeys for fattening, turkeys reared for breeding, chickens for fattening, chickens reared for laying, minor poultry species except for laying, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, and sows, and which are produced and labelled before [6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred in paragraph 1, which are intended for turkeys for fattening, turkeys reared for breeding, chickens for fattening, chickens reared for laying, minor poultry species except for laying, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, and sows, and which are produced and labelled before [12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the stocks concerned are exhausted.

Article 6

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,

For the Commission
The President
Ursula VON DER LEYEN