

Brussels, XXX
SANTE/5278540/2026 CIS
(POOL/G5/2026/5278540/5278540-EN
CIS.docx)
[...](2026) XXX draft

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

of XXX

amending Implementing Regulations (EU) 2023/366 and (EU) 2024/3166 as regards the terms of the authorisation of a preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive for poultry (except poultry for laying or reproduction), ornamental birds and porcine species (holder of authorisation: Kemin Europa N.V.)

(Text with EEA relevance)

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

of **XXX**

amending Implementing Regulations (EU) 2023/366 and (EU) 2024/3166 as regards the terms of the authorisation of a preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive for poultry (except poultry for laying or reproduction), ornamental birds and porcine species (holder of authorisation: Kemin Europa N.V.)

(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 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) A preparation of *Bacillus velezensis* ATCC PTA-6737 was authorised for a period of 10 years as a feed additive for use in feed for ornamental birds by Commission Implementing Regulation (EU) 2023/366². The authorisation of that preparation was renewed for a period of 10 years by that Regulation for chickens for fattening, chickens reared for laying and minor poultry species except for laying purposes. Commission Implementing Regulation (EU) 2024/3166³ authorised that preparation for a period of 10 years as a feed additive for use in feed for pigs for fattening of all Suidae species, suckling piglets of all Suidae species and sows of minor Suidae species. That Regulation also renewed the authorisation of that preparation for the

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

² 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/2023/366/2025-01-08).

³ Commission Implementing Regulation (EU) 2024/3166 of 18 December 2024 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 pigs for fattening of all Suidae species, 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 (OJ L, 2024/3166, 19.12.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/3166/oj).

same period as a feed additive for use in feed for turkeys for fattening, turkeys reared for breeding, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, and sows.

- (3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, an application was submitted on 12 June 2025 for the modification of the terms of the authorisation of the preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive for use in feed for all poultry species for fattening or reared for laying/breeding, laying hens, minor poultry species for laying, ornamental birds and all pigs, requesting to allow the simultaneous use of that preparation with the coccidiostats amprolium, nicarbazin, a combination of monensin and nicarbazin, and semduramicin, which are authorised as feed additives. The request was accompanied by the relevant supporting data.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 April 2026⁴ that the proposed modification in the terms of the authorisation of the preparation of *Bacillus velezensis* ATCC PTA-6737 would not change the conclusions previously drawn regarding the safety of that additive for the target species, consumers and the environment. The Authority also concluded that the preparation of *Bacillus velezensis* ATCC PTA-6737 is not a skin or eye irritant but should be considered a skin and respiratory sensitiser, and inhalation and dermal exposure are considered a risk. It also concluded that the use of that preparation is compatible with the coccidiostats amprolium, nicarbazin, a combination of monensin and nicarbazin, and semduramicin, under the currently authorised conditions of use. The Authority did not consider that there is a need for specific requirements for a post-market monitoring.
- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning another application for the authorisation of the same additive and verified by the Authority in its opinion of 15 September 2009⁵ are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁶, an evaluation report of the Reference Laboratory was therefore not required.
- (6) In view of the above, the Commission considers that the preparation of *Bacillus velezensis* ATCC PTA-6737 still satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003, when modifying the terms of the authorisation laid down in Implementing Regulations (EU) 2023/366 and (EU) 2024/3166, by specifying the compatibility of the use of that preparation with the coccidiostats amprolium, nicarbazin, a combination of monensin and nicarbazin, and semduramicin. In addition, considering that those coccidiostats may not be authorised as feed additives for each of the species or categories listed in Annexes I and II their simultaneous use with the preparation of *Bacillus velezensis* ATCC PTA-6737 should only be possible in accordance with their respective conditions of authorisation as feed additives.
- (7) Implementing Regulations (EU) 2023/366 and (EU) 2024/3166 should therefore be amended accordingly.

⁴ EFSA Journal. 2026;24:e10075. <https://doi.org/10.2903/j.efsa.2026.10075>.

⁵ EFSA Journal 2009; 7(9):1314. <https://doi.org/10.2903/j.efsa.2009.1314>.

⁶ 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>).

- (8) 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 chickens for fattening, chickens reared for laying, minor poultry species except for laying purposes, ornamental birds, turkeys for fattening, turkeys reared for breeding, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, sows, pigs for fattening of all Suidae species, suckling piglets of all Suidae species and sows of minor Suidae species, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the modification of the authorisations concerned.
- (9) 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) 2023/366

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

Article 2

Amendment to Implementing Regulation (EU) 2024/3166

The Annex to Implementing Regulation (EU) 2024/3166 is replaced by Annex II to this Regulation.

Article 3

Transitional measures

1. The feed additive *Bacillus velezensis* ATCC PTA-6737, as authorised by Implementing Regulations (EU) 2023/366 and (EU) 2024/3166 and premixtures containing that additive, which are intended for chickens for fattening, chickens reared for laying, minor poultry species except for laying purposes, ornamental birds, turkeys for fattening, turkeys reared for breeding, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, sows, pigs for fattening of all Suidae species, suckling piglets of all Suidae species and sows of minor Suidae species, 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 to in paragraph 1, which are intended for chickens for fattening, chickens reared for laying, minor poultry species except for laying purposes, ornamental birds, turkeys for fattening, turkeys reared for breeding, weaned piglets, weaned Suidae other than *Sus scrofa domesticus*, sows, pigs for fattening of all Suidae species, suckling piglets of all Suidae species and sows of minor Suidae species, 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 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,

For the Commission

The President

Ursula VON DER LEYEN