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.)

(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) 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 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 chickens for fattening by Commission Regulation (EU) No 107/2010 ([2]), for chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches by Commission Implementing Regulation (EU) No 885/2011 ([3]), for weaned piglets and weaned Suidae other than *Sus Scrofa domesticus* by Commission Implementing Regulation (EU) No 306/2013 ([4]), for turkeys for fattening and turkeys reared for breeding by Commission Implementing Regulation (EU) No 787/2013 ([5]), for laying hens and minor poultry species for laying by Commission Implementing Regulation (EU) 2015/1020 ([6]) and for sows by Commission Implementing Regulation (EU) 2017/2276 ([7]).

(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 for chickens for fattening, chickens reared for laying and minor poultry species except for laying purposes, including for a modification of the minimum concentration of the active agent in the preparation. In accordance with Article 7 of Regulation (EC) No 1831/2003, another application was submitted for a new use of that preparation for ornamental birds, sporting

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Regulation (EU) No 107/2010 of 8 February 2010 concerning the authorisation of *Bacillus subtilis* ATCC PTA-6737 as a feed additive for chickens for fattening (holder of authorisation Kemin Europa NV) (OJ L 36, 9.2.2010, p. 1).

([3]) Commission Implementing Regulation (EU) No 885/2011 of 5 September 2011 concerning the authorisation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches (holder of authorisation Kemin Europa N.V.) (OJ L 229, 6.9.2011, p. 3).

([4]) 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).

([5]) 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).

([6]) Commission Implementing Regulation (EU) 2015/1020 of 29 June 2015 concerning the authorisation of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for laying hens and minor poultry species for laying (holder of the authorisation Kemin Europa NV) (OJ L 163, 30.6.2015, p. 22).

([7]) 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).

and game birds. Those applications requested that additive to be classified in the additive category 'zootechnical additives' and the functional group 'gut flora stabilisers' and were accompanied by the particulars and documents required respectively under Article 14(2) and Article 7(3) of that Regulation.

(4) 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 subtilis* ATCC PTA-6737 as laid down in Implementing Regulation (EU) No 306/2013, Implementing Regulation (EU) No 787/2013, Implementing Regulation (EU) 2015/1020 and Implementing Regulation (EU) 2017/2276, in relation to the change of the name of the additive from *Bacillus subtilis* ATCC PTA-6737 to *Bacillus velezensis* ATCC PTA-6737, as regards the strain taxonomy. That application was accompanied by the relevant data supporting the request for change, as required by Article 13(3) of Regulation (EC) No 1831/2003.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 September 2020 ([8]) that the applicant has provided evidence that the preparation of *Bacillus velezensis* ATCC PTA-6737 remains safe for chickens for fattening, chickens reared for laying and minor poultry species (except for laying purposes) ([9]), consumers and the environment, taking notably into consideration the modification of the minimum concentration of the active agent in the preparation. It also concluded that the preparation is non-irritant to skin and eyes and is not a dermal sensitiser. In addition, the Authority concluded that the preparation has the potential to be efficacious as a zootechnical additive for ornamental, sporting and game birds. The Authority does not consider that there is a need for specific requirements of post-market monitoring.

(6) In its opinion of 23 March 2022 ([10]), the Authority concluded that the additive should be taxonomically designated as *Bacillus velezensis* ATCC PTA-6737. It further concluded that the additive is not a dermal or eye irritant or a skin sensitiser but should be considered a respiratory sensitiser.

(7) In accordance with Article 5(4), points (a), (b) and (c) of Commission Regulation (EC) No 378/2005 ([11]), the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment are applicable for the current applications.

(8) The assessment of the preparation of *Bacillus velezensis* ATCC PTA-6737 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. As for ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches, game and sporting birds should be considered as minor poultry species and should therefore be included in the scope of the renewal of authorisation. Accordingly, the authorisation of that additive should be renewed for chickens for fattening, chickens reared for laying and minor poultry species except for laying purposes and the use of that additive should be authorised for ornamental birds.

(9) The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. Those protective measures should comply with Union legislation on worker safety requirements.

(10) The name of the additive should be taxonomically designated as *Bacillus velezensis* ATCC PTA-6737 and Implementing Regulation (EU) No 306/2013, Implementing Regulation (EU) No 787/2013, Implementing Regulation (EU) 2015/1020 and Implementing Regulation (EU) 2017/2276 should therefore be amended accordingly.

([8]) EFSA Journal 2020;18(11):6280.

([9]) Chickens for fattening, chickens reared for laying and minor poultry species except for laying purposes.

([10]) EFSA Journal 2022;20(4):7244.

([11]) 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).

(11) As a consequence of the renewal of the authorisation of the preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive, Regulation (EU) No 107/2010 and Implementing Regulation (EU) No 885/2011 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, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation and from the change of the name of the additive.

(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 the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers' is renewed for chickens for fattening, chickens reared for laying and minor poultry species except for laying purposes, subject to the conditions laid down in that Annex.

Article 2

Authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers' is authorised for ornamental birds, subject to the conditions laid down in that Annex.

Article 3

Amendments to Implementing Regulation (EU) No 306/2013

Implementing Regulation (EU) No 306/2013 is amended as follows:

(1) In the title, the words '*Bacillus subtilis* (ATCC PTA-6737)' are replaced by the words '*Bacillus velezensis* ATCC PTA-6737'.

(2) In the third column of the Annex, 'Additive', the words '*Bacillus subtilis* (ATCC PTA-6737)' are replaced by the words '*Bacillus velezensis* ATCC PTA-6737';

(3) In the fourth column of the Annex, 'Composition, chemical formula, description, analytical method', the words '*Bacillus subtilis* (ATCC PTA-6737)' are replaced by the words '*Bacillus velezensis* ATCC PTA-6737'.

Article 4

Amendments to Implementing Regulation (EU) No 787/2013

Implementing Regulation (EU) No 787/2013 is amended as follows:

(1) In the title, the words '*Bacillus subtilis* (ATCC PTA-6737)' are replaced by the words '*Bacillus velezensis* ATCC PTA-6737';

(2) In the third column of the Annex, 'Additive', the words '*Bacillus subtilis* (ATCC PTA-6737)' are replaced by the words '*Bacillus velezensis* ATCC PTA-6737';

(3) In the fourth column of the Annex, 'Composition, chemical formula, description, analytical method', the words '*Bacillus subtilis* (ATCC PTA-6737)' are replaced by the words '*Bacillus velezensis* ATCC PTA-6737'.

Article 5

Amendments to Implementing Regulation (EU) 2015/1020

Implementing Regulation (EU) 2015/1020 is amended as follows:

(1) In the title, the words '*Bacillus subtilis* (ATCC PTA-6737)' are replaced by the words '*Bacillus velezensis* ATCC PTA-6737';

(2) In the third column of the Annex, 'Additive', the words '*Bacillus subtilis* ATCC PTA-6737' are replaced by the words '*Bacillus velezensis* ATCC PTA-6737';

(3) In the fourth column of the Annex, 'Composition, chemical formula, description, analytical method', the words '*Bacillus subtilis* (ATCC PTA-6737)' are replaced by the words '*Bacillus velezensis* ATCC PTA-6737'.

Article 6

Amendments to Implementing Regulation (EU) 2017/2276

Implementing Regulation (EU) 2017/2276 is amended as follows:

(1) In the title, the words '*Bacillus subtilis* (ATCC PTA-6737)' are replaced by the words '*Bacillus velezensis* ATCC PTA-6737';

(2) In the third column of the Annex, 'Additive', the words '*Bacillus subtilis* ATCC PTA-6737' are replaced by the words '*Bacillus velezensis* ATCC PTA-6737';

(3) In the fourth column of the Annex, 'Composition, chemical formula, description, analytical method', the words '*Bacillus subtilis* (ATCC PTA-6737)' are replaced by the words '*Bacillus velezensis* ATCC PTA-6737'.

Article 7

Repeal

Regulation (EU) No 107/2010 and Implementing Regulation (EU) No 885/2011 are repealed.

Article 8

Transitional measures

1. The preparation specified in the Annex, as well as in Implementing Regulation (EU) No 306/2013, Implementing Regulation (EU) No 787/2013, Implementing Regulation (EU) 2015/1020 and Implementing Regulation (EU) 2017/2276, and premixtures containing it, which are produced and labelled before 9 September 2023 in accordance with the rules applicable before 9 March 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before 9 March 2024 in accordance with the rules applicable before 9 March 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

Article 9

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, 16 February 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
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: gut flora stabilisers									
4b1823i	Kemin Europa N.V.	*Bacillus velezensis* ATCC PTA-6737	*Additive composition* Preparation of *Bacillus velezensis* ATCC PTA-6737 containing a minimum of 8×10^{10} CFU/g *Characterisation of the active substance* Viable spores of *Bacillus velezensis* ATCC PTA-6737 *Analytical method* (1) Enumeration: spread plate method using tryptone soya agar (EN 15784) Identification: pulsed-field gel electrophoresis (PFGE) method. or DNA sequencing methods	Chickens for fattening Chickens reared for laying Minor poultry species except minor poultry for laying Ornamental birds	-	1×10^7	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive is compatible with the following coccidiostats, provided they are authorised for the relevant species: diclazuril, decoquinate, salinomycin sodium, narasin/nicarbazin, lasalocid A sodium, maduramycin ammonium, monensin sodium, narasin or robenidine hydrochloride. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	9 March 2033

(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