

COMMISSION IMPLEMENTING REGULATION (EU) 2022/703

of 5 May 2022

concerning the renewal of the authorisation of a preparation of *Bacillus velezensis* DSM 15544 as a feed additive for weaned piglets, the authorisation for all avian species and categories, amending Implementing Regulation (EU) 2016/897, Implementing Regulation (EU) 2017/2312 and Implementing Regulation (EU) 2018/1081 and repealing Regulation (EU) No 333/2010, Regulation (EU) No 184/2011 and Implementing Regulation (EU) 2019/893 (holder of the authorisation: Asahi Biocycle Co. Ltd., represented in the Union by Pen & Tec Consulting S.L.U.)

(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) 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 renewing such an authorisation.
- (2) A preparation of *Bacillus velezensis* DSM 15544, previously taxonomically identified as *Bacillus subtilis* C-3102 (DSM 15544), was authorised for 10 years as a feed additive for weaned piglets by Commission Regulation (EU) No 333/2010 ⁽²⁾, for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds by Commission Regulation (EU) No 184/2011 ⁽³⁾, for laying hens and ornamental fish by Commission Implementing Regulation (EU) 2016/897 ⁽⁴⁾, for sows, suckling piglets and dogs by Commission Implementing Regulation (EU) 2017/2312 ⁽⁵⁾, for pigs for fattening by Commission Implementing Regulation (EU) 2018/1081 ⁽⁶⁾ and for chickens for fattening by Commission Implementing Regulation (EU) 2019/893 ⁽⁷⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EU) No 333/2010 of 22 April 2010 concerning the authorisation of a new use of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for weaned piglets (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.) (OJ L 102, 23.4.2010, p. 19).

⁽³⁾ Commission Regulation (EU) No 184/2011 of 25 February 2011 concerning the authorisation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.) (OJ L 53, 26.2.2011, p. 33).

⁽⁴⁾ Commission Implementing Regulation (EU) 2016/897 of 8 June 2016 concerning the authorisation of a preparation of *Bacillus subtilis* (C-3102) (DSM 15544) as a feed additive for laying hens and ornamental fish (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.) and amending Regulations (EC) No 1444/2006, (EU) No 333/2010 and (EU) No 184/2011 as regards the holder of the authorisation (OJ L 152, 9.6.2016, p. 7).

⁽⁵⁾ Commission Implementing Regulation (EU) 2017/2312 of 13 December 2017 concerning the authorisation of a new use of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for sows, suckling piglets and dogs (holder of the authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.) (OJ L 331, 14.12.2017, p. 41).

⁽⁶⁾ Commission Implementing Regulation (EU) 2018/1081 of 30 July 2018 concerning the authorisation of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for pigs for fattening (holder of the authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.) (OJ L 194, 31.7.2018, p. 17).

⁽⁷⁾ Commission Implementing Regulation (EU) 2019/893 of 28 May 2019 concerning the renewal of the authorisation of *Bacillus subtilis* DSM 15544 as a feed additive for chickens for fattening and repealing Regulation (EC) No 1444/2006 (Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.) (OJ L 142, 29.5.2019, p. 60).

- (3) The authorisation of the preparation of *Bacillus velezensis* DSM 15544 for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds expired on 18 March 2021.
- (4) In accordance with Article 13(3) and Article 14(1) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, two applications were submitted for the renewal of the authorisation of a preparation of *Bacillus velezensis* DSM 15544 as a feed additive for weaned piglets, for a new authorisation for chickens reared for laying and for breeding, turkeys for rearing, fattening, breeding and laying, minor poultry species and all other avian species for rearing, fattening, laying and breeding, requesting the additive to be classified in the additive category 'zootechnical additives' and for the modification of the terms of the authorisation. The modification relates to change of the name of the additive. The applications were accompanied by the particulars and documents required under Articles 7(3), 13(3) and 14(2) of that Regulation.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 30 September 2020 ⁽⁸⁾ and 29 September 2021 ⁽⁹⁾ that the applicant has provided data demonstrating that the preparation of *Bacillus velezensis* DSM 15544 complies with the existing conditions of authorisation under the proposed conditions of use. The Authority concluded that the preparation of *Bacillus velezensis* DSM 15544 does not have an adverse effect on animal health, consumer safety or the environment. It also stated that the preparation is not a dermal/eye irritant or a skin sensitiser but should be considered a respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards users of the additive. The Authority also concluded that the additive should be taxonomically designated as *Bacillus velezensis* DSM 15544 and that the preparation has the potential to be efficacious as a zootechnical additive in feedingstuffs. The Authority does not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) On 2 December 2020, the applicant, represented in the Union by Pen & Tec Consulting S.L.U., submitted relevant supporting data concerning a change of the name of the holder of authorisation in accordance with Article 13(3) of Regulation (EC) No 1831/2003. The applicant claimed that the current name of the company, holder of the authorisation, has been changed to 'Asahi Biocycle Co. Ltd.'
- (7) That proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The Authority was informed of the application.
- (8) Implementing Regulation (EU) 2016/897, Implementing Regulation (EU) 2017/2312 and Implementing Regulation (EU) 2018/1081 should therefore be amended accordingly.
- (9) The assessment of the preparation of *Bacillus velezensis* DSM 15544 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (10) As a consequence of the renewal of the authorisation of a preparation of *Bacillus velezensis* DSM 15544 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EU) No 333/2010, and Regulation (EU) No 184/2011 should be repealed.
- (11) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Bacillus velezensis* DSM 15544, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁸⁾ EFSA Journal 2020;18(11):6283.

⁽⁹⁾ EFSA Journal 2021;19(10):6903.

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the authorisation

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

Article 2

Amendments to Implementing Regulation (EU) 2016/897

Implementing Regulation (EU) 2016/897 is amended as follows:

- (1) in the title, the words 'Asahi Calpis Wellness Co. Ltd' are replaced by the words 'Asahi Biocycle Co. Ltd.', and the words '*Bacillus subtilis* C-3102 (DSM 15544)' are replaced by the words '*Bacillus velezensis* DSM 15544';
- (2) in the second column of the Annex, 'Name of the holder of authorisation', the words 'Asahi Calpis Wellness Co. Ltd' are replaced by the words 'Asahi Biocycle Co. Ltd.';
- (3) in the third column of the Annex, 'Additive', the words '*Bacillus subtilis* C-3102 (DSM 15544)' are replaced by the words '*Bacillus velezensis* DSM 15544';
- (4) in the fourth column of the Annex, 'Composition, chemical formula, description, analytical method', the words '*Bacillus subtilis* C-3102 (DSM 15544)' are replaced by the words '*Bacillus velezensis* DSM 15544';
- (5) in the fifth column of the Annex, Species or category of animal, 'Laying hens' is deleted;
- (6) in the seventh column, 'Minimum content', ' 3×10^8 ' is deleted.

Article 3

Amendments to Implementing Regulation (EU) 2017/2312

Implementing Regulation (EU) 2017/2312 is amended as follows:

- (1) in the title, the words 'Asahi Calpis Wellness Co. Ltd' are replaced by the words 'Asahi Biocycle Co. Ltd.' and the words '*Bacillus subtilis* C-3102 (DSM 15544)' are replaced by the words '*Bacillus velezensis* DSM 15544';
- (2) in the recitals, the words '*Bacillus subtilis* C-3102 (DSM 15544)' are replaced by the words '*Bacillus velezensis* DSM 15544';
- (3) in the second column of the Annex, 'Name of the holder of authorisation', the words 'Asahi Calpis Wellness Co. Ltd' are replaced by the words 'Asahi Biocycle Co. Ltd.';
- (4) in the third column of the Annex, 'Additive', the words '*Bacillus subtilis* DSM 15544' are replaced by the words '*Bacillus velezensis* DSM 15544';
- (5) in the fourth column of the Annex, 'Composition, chemical formula, description, analytical method', in the subparagraphs 'Additive composition' and 'Characterisation of the active substance' the words '*Bacillus subtilis* C-3102 DSM 15544' are replaced by the words '*Bacillus velezensis* DSM 15544'.

Article 4

Amendments to Implementing Regulation (EU) 2018/1081

Implementing Regulation (EU) 2018/1081 is amended as follows:

- (1) in the title, the words 'Asahi Calpis Wellness Co. Ltd' are replaced by the words 'Asahi Biocycle Co. Ltd.' and the words '*Bacillus subtilis* C-3102 (DSM 15544)' are replaced by the words '*Bacillus velezensis* DSM 15544';

- (2) in the recitals, the words '*Bacillus subtilis* C-3102 (DSM 15544)' are replaced by the words '*Bacillus velezensis* DSM 15544';
- (3) in the second column of the Annex, 'Name of the holder of authorisation', the words 'Asahi Calpis Wellness Co. Ltd' are replaced by the words 'Asahi Biocycle Co. Ltd.';
- (4) in the third column of the Annex, 'Additive', the words '*Bacillus subtilis* C-3102 (DSM 15544)' are replaced by '*Bacillus velezensis* DSM 15544';
- (5) in the fourth column of the Annex, 'Composition, chemical formula, description, analytical method', the words '*Bacillus subtilis* C-3102 (DSM 15544)' are replaced by the words '*Bacillus velezensis* DSM 15544'.

Article 5

Transitional period

1. The additive specified in the Annex to this Regulation, as well as in Implementing Regulation (EU) 2016/897, in Implementing Regulation (EU) 2017/2312, in Implementing Regulation (EU) 2018/1081 and in Implementing Regulation (EU) 2019/893, and premixtures containing it, which are produced and labelled before 26 November 2022 in accordance with the rules applicable before 26 May 2022 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the additive specified in the Annex to this Regulation, as well as in Implementing Regulation (EU) 2016/897, in Implementing Regulation (EU) 2017/2312, in Implementing Regulation (EU) 2018/1081 and in Implementing Regulation (EU) 2019/893, which are produced and labelled before 26 May 2023 in accordance with the rules applicable before 26 May 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the additive specified in the Annex to this Regulation, as well as in Implementing Regulation (EU) 2016/897 and in Implementing Regulation (EU) 2017/2312 which are produced and labelled before 26 May 2024 in accordance with the rules applicable before 26 May 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non food-producing animals.

Article 6

Repeal

Regulation (EU) No 333/2010, Regulation (EU) No 184/2011 and Implementing Regulation (EU) 2019/893 are repealed.

Article 7

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, 5 May 2022.

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

4b1820	Asahi Biocycle Co. Ltd, represented in the Union by Pen & Tec Consulting S.L.U.	<i>Bacillus velezensis</i> DSM 15544	<i>Additive composition</i> Preparation of <i>Bacillus velezensis</i> DSM 15544 containing a minimum of 1×10^{10} CFU/g	Weaned piglets All avian species and categories	-	3×10^8 3×10^8	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. May be used in feed containing the permitted coccidiostats for each avian species and categories. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its 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 eye and breathing protection.	26 May 2032
			<i>Characterisation of the active substance</i> Viable spores of <i>Bacillus velezensis</i> DSM 15544						
			<i>Analytical method</i> ⁽¹⁾ Enumeration: spread plate method using tryptone soya agar (EN 15784) Identification: pulsed-field gel electrophoresis (PFGE).						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>