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 (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.) (Text with EEA relevance)

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 (holder of authorisation [^{FI}Asahi Calpis Wellness Co. Ltd, represented in the European 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 authorisation.
- (2) *Bacillus subtilis* C-3102 (DSM 15544) was authorised for 10 years as a feed additive for chickens for fattening by Commission Regulation (EC) No 1444/2006⁽²⁾.
- (3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for chickens for fattening, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 June 2018⁽³⁾ that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation.
- (5) The assessment of *Bacillus subtilis* C-3102 (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.

- As a consequence of the renewal of the authorisation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 1444/2006 should be repealed.
- (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:

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2020/146 of 3 February 2020 amending Regulation (EU) No 333/2010, Implementing Regulation (EU) 2017/2312, Implementing Regulation (EU) 2018/1081, Implementing Regulation (EU) 2016/897, Implementing Regulation (EU) 2019/893 and Regulation (EU) No 184/2011 concerning the authorisations of the preparation of Bacillus subtilis C-3102 (DSM 15544) as a feed additive (Text with EEA relevance).

Article 1

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

Regulation (EC) No 1444/2006 is repealed.

Article 3

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.

ANNEX

Identifi number of the additive	of the holder	Additiv	chemica	alor a,categor	age	u h linim content CFU/kg comple		u tô ther provisio	End onsf period of
	authori		analytic method	ca a nimal		feeding with a moistur content %	stuff re t of 12		authorisation
Categor			1	Functiona		gut flora s	stabilisers		
4b1820		Bacillus subtilis C-3102 (DSM 15544) ted	Additive composit	Chickens titor: fattening n erisation e: al		[^{F1} 3 × 10 ⁸]		1.	18 June 2029 the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. The use is permitted in feed containing one of the following authorised coccidiostats:
	641 1-	4	(EN 15784:20	, ,	ing address	of the Pafer	ence Laborato	mu https://co	monensin sodium, salinomycin

a 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

Commission Implementing Regulation (EU) 2019/893. (See end of Document for details)

	Identification: pulsed- field gel electrophoresis (PFGE).			sodium, seduramycin sodium, lasalocid sodium, maduramycin ammonium, narasin/ nicarbazin, diclazuril.			
			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			
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							

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				measures,
				the additive
				and
				premixtures
				shall
				be
				used
				with
				personal
				protective
				equipment,
				including
				eye
				and
				breathing
				protection.

a 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

- (**1**) OJ L 268, 18.10.2003, p. 29.
- (2) Commission Regulation (EC) No 1444/2006 of 29 September 2006 concerning the authorisation of *Bacillus subtilis* C-3102 (Calsporin) as a feed additive (OJ L 271, 30.9.2006, p. 19).
- (**3**) *EFSA Journal* 2018;16(7):5340.

Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/893.