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 **[**F1Asahi 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.

(6) 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/893. (See end of Document for details)*

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 of zootechnical additives. Functional group: gut flora stabilisers									
4b1820	[F1Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.]	*Bacillus subtilis* C-3102 (DSM 15544)	*Additive composition:* *Bacillus subtilis* C-3102 (DSM 15544) with minimum of 1×10^{10} CFU/g *Characterisation of the active substance:* Viable spores (CFU) of *Bacillus subtilis* C-3102 (DSM 15544) *Analytical method*[a] Enumeration: spread plate method using tryptone soya agar (EN 15784:2009)	Chickens for fattening	—	[F1$3 \times 10^{8}$	—	1. the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The use is permitted in feed containing one of the following authorised coccidiostats: monensin sodium, salinomycin sodium, seduramycin sodium, lasalocid sodium, maduramycin ammonium,	18 June 2029

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