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.) (Text with EEA relevance)

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 **[**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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a new use of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for weaned piglets, to be classified in the additive category ‘zootechnical additives’.

(4) The use of that micro-organism preparation has been authorised for chickens for fattening by Commission Regulation (EC) No 1444/2006(2).

(5) New data were submitted in support of the application for authorisation for weaned piglets. The European Food Safety Authority (the Authority) concluded in its opinion of 9 December 2009(3) that *Bacillus subtilis* C-3102 (DSM 15544) does not have an adverse effect on animal health, human health or the environment and that the use of that preparation can improve the performance of the animals. The Authority does not consider that there is a need for specific requirements of post market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 333/2010. (See end of Document for details)*

(6) 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 use of that preparation should be authorised, as specified in the Annex to this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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 preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the 20th day following 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 Regulation (EU) No 333/2010. (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 $1,0 \times 10^{10}$ 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	Piglets (weaned)	—	3×10^8	—	1. the directions for use of the additive, premixture and compound feedingstuff indicate the storage temperature, storage life and stability to pelleting 2. For use in weaned piglets up to approximately 35 kg. 3. For safety: breathing protection, glasses and gloves shall be used	13 May 2020

a Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.ec.europa.eu/crl-feed-additives