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.) (Text with EEA relevance)

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 **[**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) The preparation of *Bacillus subtilis* C-3102 (DSM 15544), belonging to the additive category of 'zootechnical additives', was authorised for 10 years as a feed additive for chickens for fattening by Commission Regulation (EC) No 1444/2006[(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 weaned piglets by Commission Regulation (EU) No 333/2010[(4)], for laying hens and ornamental fish by Commission Implementing Regulation (EU) 2016/897[(5)].for sows, suckling piglets and dogs by Commission Implementing Regulation (EU) 2017/2312[(6)].

(3) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for a new use of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) for pigs for fattening, requesting that the additive be classified in the additive category 'zootechnical additives'.

(4) The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 6 March 2018[(7)] that, under the proposed conditions of use, the preparation of *Bacillus subtilis* C-3102 (DSM 15544) does not have an adverse effect on animal health, human

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1081. (See end of Document for details)*

health and the environment and that it has the potential to improve the zootechnical performance of pigs for fattening. 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 Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the preparation 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 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 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 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) 2018/1081. (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, 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 × 10^{10} CFU/g Solid form *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 in all	Pigs for fattening	—	1,5 × 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. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures	20.8.2028

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