

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 by Asahi Calpis Wellness Co. Ltd Europe Representative Office)****(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, applications were submitted for a new use of the preparation *Bacillus subtilis* C-3102 (DSM 15544). Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The applications concern 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 to be classified in the additive category 'zootechnical additives'.
- (4) 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 weaned piglets by Commission Regulation (EU) No 333/2010 ⁽³⁾; for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds by Commission Regulation (EU) No 184/2011 ⁽⁴⁾, and for laying hens and ornamental fish by Commission Implementing Regulation (EU) 2016/897 ⁽⁵⁾.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 21 March 2017 ⁽⁶⁾ 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 health and the environment. It also concluded that the additive has the potential to improve the zootechnical performance parameters of sows and suckling piglets and to increase the faecal dry matter in dogs. 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.

⁽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⁾ 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 Calpis Co. Ltd Japan, represented in the European Union by Calpis Co. Ltd Europe Representative Office) (OJ L 102, 23.4.2010, p. 19).

⁽⁴⁾ 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 Calpis Co. Ltd Japan, represented by Calpis Co. Ltd Europe Representative Office) (OJ L 53, 26.2.2011, p. 33).

⁽⁵⁾ 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) 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).

⁽⁶⁾ EFSA Journal 2017; 15(4):4760 and EFSA Journal 2017; 15(4):4761.

- (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:

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.

Done at Brussels, 13 December 2017.

For the Commission
The President
Jean-Claude JUNCKER

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	Asahi Calpis Wellness Co. Ltd, represented by Asahi Calpis Wellness Co. Ltd Europe Representative Office	<i>Bacillus subtilis</i> DSM 15544	<p><i>Additive composition</i></p> <p>Preparation of <i>Bacillus subtilis</i> C-3102</p> <p>DSM 15544 containing a minimum of 1×10^{10} CFU/g additive in solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Bacillus subtilis</i> DSM 15544</p> <p><i>Analytical method</i></p> <p>Enumeration: spread plate method using tryptone soya agar in all target matrices (EN 15784:2009)</p> <p>Identification: pulsed-field gel electrophoresis (PFGE).</p>	Sows Suckling piglets Dogs	—	3×10^8	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Indicate in the instruction for the use: ‘The additive shall be fed to lactating sows and suckling piglets simultaneously’ 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 and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. 	3 January 2028