# 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 in the European Union by Pen & Tec Consulting S.L.U.) (Text with EEA relevance)

## 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 **[**[F1]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 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

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/2312. (See end of Document for details)*

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.

(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) 2017/2312. (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* DSM 15544 | *Additive composition* Preparation of *Bacillus subtilis* C-3102 DSM 15544 containing a minimum of $1 \times 10^{10}$ CFU/g additive in solid form *Characterisation of the active substance* Viable cells of Bacillus subtilis DSM 15544 *Analytical method* Enumeration: spread plate method using tryptone soya agar in all target | Sows Suckling piglets | — | $3 \times 10^{8}$ | — | 1. the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.<br>2. Indicate in the instruction for the use: The additive shall be fed to lactating sows and suckling piglets simultaneously<br>3. For users of the additive | 3 January 2028 |
| | | | | Dogs | | $1 \times 10^{9}$ | | | |