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)

(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 *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for chickens reared for laying, turkeys and minor avian species, to be classified in the additive category 'zootechnical additives'.

(4) The use of *Bacillus subtilis* C-3102 (DSM 15544) has been authorised for 10 years for chickens for fattening by Commission Regulation (EC) No 1444/2006 [2] and for weaned piglets by Commission Regulation (EU) No 333/2010 [3].

(5) New data were submitted in support of the application for the authorisation of the preparation for chickens reared for laying, turkeys and minor avian species. The European Food Safety Authority (the Authority) concluded in its opinion of 5 October 2010 [4] that *Bacillus subtilis* C-3102 (DSM 15544), under the proposed conditions of use, does not have an adverse effect on animal health, human health or the environment, and that its use can improve the weight gain of the target species. 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.

(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 this 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:

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*.

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 271, 30.9.2006, p. 19.
[3] OJ L 102, 23.4.2010, p. 19.
[4] EFSA Journal 2010; 8(10):1867.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 February 2011.

For the Commission
The President
José Manuel BARROSO

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	Calpis Co. Ltd Japan, represented by Calpis Co. Ltd Europe Representative Office, France	*Bacillus subtilis* C-3102 (DSM 15544)	*Additive composition* Preparation of *Bacillus subtilis* C-3102 DSM 15544 containing a minimum of 1×10^{10} CFU/g *Characterisation of active substance* Viable spores of *Bacillus subtilis* C-3102 (DSM 15544) *Analytical methods* (1) Enumeration: spread plate method using tryptone soya agar with preheat treatment of feed samples Identification: Pulsed Field Gel Electrophoresis (PFGE)	Chickens reared for laying	—	5×10^8	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. For safety: breathing protection, glasses and gloves shall be used during handling. 3. May be used in feed containing the following coccidiostats where authorised: decoquinate, monensin sodium, robenidine hydrochloride, diclazuril, lasalocid sodium, halofuginone, narasin, salinomycin sodium, maduramycin ammonium, narasin-nicarbazin, semduramycin sodium or nicarbazin.	18 March 2021
				Turkeys, minor avian species and other ornamental and game birds		3×10^8			

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives