Commission Implementing Regulation (EU) No 91/2012 of 2 February 2012 concerning the authorisation of Bacillus subtilis (CBS 117162) as a feed additive for weaned piglets and pigs for fattening (holder of authorisation Krka d.d.) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 91/2012

of 2 February 2012

concerning the authorisation of *Bacillus subtilis* (CBS 117162) as a feed additive for weaned piglets and pigs for fattening (holder of authorisation Krka d.d.)

(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 *Bacillus subtilis* (CBS 117162). The 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 *Bacillus subtilis* (CBS 117162) as a feed additive for weaned piglets and pigs for fattening, to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 7 September 2011[(2)] that, under the proposed conditions of use, *Bacillus subtilis* (CBS 117162) does not have an adverse effect on animal health, human health or the environment, and that its use can improve the weight gain in 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 Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of *Bacillus subtilis* (CBS 117162) 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 91/2012. (See end of Document for details)*

(6) 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.*

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

Done at Brussels, 2 February 2012.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 91/2012. (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.									
4b1824	Krka d.d.	*Bacillus subtilis* (CBS 117162)	*Additive composition:* Preparation of *Bacillus subtilis* (CBS 117162) containing a minimum of 4×10^9 CFU/g additive (granulated form) *Characterisation of the active substance:* Spores *Bacillus subtilis* (CBS 117162) *Analytical method*[a]:	Piglets (weaned) Pigs for fattening	—	2×10^9	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For piglets (weaned) up to 35 kg. 3. For safety: breathing protection, glasses and gloves shall be used during handling.	23 February 2022

Enumeration: spread plate method (EN 15787)
Identification: pulsed-

a Details of the analytical methods are available at the following address of the Community Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx