COMMISSION IMPLEMENTING REGULATION (EU) No 1083/2014

of 15 October 2014

concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 (Bonvital) as a feed additive for sows

(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 of *Enterococcus faecium* DSM 7134 (Bonvital). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of the preparation of *Enterococcus faecium* DSM 7134 (Bonvital) as a feed additive for sows to be used for the duration of the entire reproductive cycle, to be classified in the additive category 'zootechnical additives'.

(4) The use of the preparation of *Enterococcus faecium* DSM 7134 was authorised provisionally for piglets and pigs for fattening by Commission Regulation (EC) No 666/2003 ([2]), provisionally for sows by Commission Regulation (EC) No 2154/2003 ([3]), provisionally for chickens for fattening by Commission Regulation (EC) No 521/2005 ([4]), for 10 years for weaned piglets and pigs for fattening by Commission Regulation (EC) No 538/2007 ([5]) and for 10 years for sows from day 90 of pregnancy to the end of lactation by Commission Regulation (EC) No 1521/2007 ([6]).

(5) The European Food Safety Authority (the Authority) concluded in its opinion of 18 February 2014 ([7]) that, under the proposed conditions of use, the preparation of *Enterococcus faecium* DSM 7134 (Bonvital) does not have an adverse effect on animal health, human health or the environment. It also concluded that the additive has the potential to increase litter weight gain or maintain sow condition. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the preparation of *Enterococcus faecium* DSM 7134 (Bonvital) 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) As a consequence of the authorisation being granted by this Implementing Regulation, Regulation (EC) No 1521/2007 should be repealed.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Commission Regulation (EC) No 666/2003 of 11 April 2003 provisionally authorising the use of certain micro-organisms in feedingstuffs (OJ L 96, 12.4.2003, p. 11).
([3]) Commission Regulation (EC) No 2154/2003 of 10 December 2003 provisionally authorising certain micro-organisms in feedingstuffs (*Enterococcus faecium* and *Lactobacillus acidophilus*) (OJ L 324, 11.12.2003, p. 11).
([4]) Commission Regulation (EC) No 521/2005 of 1 April 2005 concerning the permanent authorisation of an additive and the provisional authorisation of new uses of certain additives already authorised in feedingstuffs (OJ L 84, 2.4.2005, p. 3).
([5]) Commission Regulation (EC) No 538/2007 of 15 May 2007 concerning the authorisation of a new use of *Enterococcus faecium* DSM 7134 (Bonvital) as a feed additive (OJ L 128, 16.5.2007, p. 16).
([6]) Commission Regulation (EC) No 1521/2007 of 19 December 2007 concerning the authorisation of a new use of *Enterococcus faecium* DSM 7134 (Bonvital) as a feed additive (OJ L 335, 20.12.2007, p. 24).
([7]) EFSA Journal 2014; 12(2):3565

(8) 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 category 'zootechnical additives' and the functional group 'gut flora stabilisers' is authorised as an additive in animal nutrition subject to the conditions laid down in this Annex.

Article 2

Regulation (EC) No 1521/2007 is repealed.

Article 3

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, 15 October 2014.

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									
4b1841	Lactosan GmbH & Co KG	*Enterococcus faecium* DSM 7134	*Additive composition* Preparation of *Enterococcus faecium* DSM 7134 containing a minimum of: Powder: 1×10^{10} CFU/g of additive Granulated (microencapsulated): 1×10^{10} CFU/g of additive *Characterisation of the active substance* Viable cells of *Enterococcus faecium* DSM 7134 *Analytical method* (1) Enumeration: spread plate method using bile esculin azide agar (EN 15788) Identification: Pulsed Field Gel Electrophoresis (PFGE).	Sows	—	5×10^{8}	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. For safety: it is recommended to use breathing protection and gloves during handling.	5 November 2024

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx