

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 authorisation of a new use of the preparation of *Enterococcus faecium* DSM 7134 (Bonvital), as a feed additive for piglets (weaned) and pigs for fattening, to be classified in the additive category 'zootechnical additives'.
- (4) The use of the preparation of *Enterococcus faecium* DSM 7134 (Bonvital) was authorised for piglets and pigs for fattening by Commission Regulation (EC) No 666/2003⁽²⁾ concerning the provisional authorisation of the use of certain micro-organisms in feedingstuffs, for sows by Commission Regulation (EC) No 2154/2003⁽³⁾ concerning the provisional authorisation of certain micro-organisms in feedingstuffs (*Enterococcus faecium* and *Lactobacillus acidophilus*), for chickens for

fattening by Commission Regulation (EC) No 521/2005⁽⁴⁾ concerning the permanent authorisation of an additive and the provisional authorisation of a new use of certain additives already authorised in feedingstuffs.

- (5) New data were submitted in support of the application for authorisation for piglets (weaned) and pigs for fattening. The European Food Safety Authority (the Authority) concluded in its opinion of 23 January 2007 that the preparation of *Enterococcus faecium* DSM 7134 (Bonvital) does not have an adverse effect on animal health, human health or the environment⁽⁵⁾. According to that opinion, the use of that preparation is efficacious in improving performance parameters according to doses recommended by the Authority in piglets and pigs for fattening. The Authority does not consider that there is a need for specific requirements of post market monitoring. That opinion 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 that preparation shows that the conditions for authorisation, 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 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

⁽²⁾ OJ L 96, 12.4.2003, p. 11.

⁽³⁾ OJ L 324, 11.12.2003, p. 11.

⁽⁴⁾ OJ L 84, 2.4.2005, p. 3.

⁽⁵⁾ Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the product 'Bonvital', a preparation of *Enterococcus faecium* as a feed additive for piglets and pigs for fattening. Adopted on 23 January 2007. *The EFSA Journal* (2007) 440, p. 1 to 9.

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, 15 May 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (Trade name)	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
Category of zotechnical additives. Functional group: gut flora stabilisers									
4b1841	Lactosan Starter-kulturen GmbH & Co KG	<i>Enterococcus faecium</i> DSM 7134 (Bonvital)	Additive composition: Preparation of <i>Enterococcus faecium</i> DSM 7134 containing a minimum of: Powder: 1×10^{10} CFU/g of additive Granules (microencapsulated): 1×10^{10} CFU/g of additive Characterisation of the active substance: <i>Enterococcus faecium</i> DSM 7134 Analytical method (1) Enumeration spread plate method using bile esculin azide agar and pulsed field gel electrophoresis (PFGE)	Piglets (weaned) Pigs for fattening	— —	$0,5 \times 10^9$ $0,2 \times 10^9$	4×10^9 1×10^9	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended doses per kilogram of complete feedingsuffs: — for piglets (weaned) up to 35 kg of body weight: 1×10^9 CFU — pigs for fattening: $0,5 \times 10^9$ CFU	5 June 2017

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/html/crlfaa/