

## COMMISSION IMPLEMENTING REGULATION (EU) No 775/2013

of 12 August 2013

concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens reared for laying and minor poultry species other than those used for laying (holder of authorisation Lactosan GmbH & Co KG)

(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<sup>(1)</sup>, 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 a new use of a preparation of *Enterococcus faecium* DSM 7134. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns a request of a new use of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens reared for laying and minor poultry species other than those used for laying, to be classified in the additive category 'zootechnical additives'.
- (4) The use of that preparation of *Enterococcus faecium* DSM 7134 was authorised for 10 years, for piglets and pigs for fattening by Commission Regulation (EC) No 538/2007<sup>(2)</sup>, for sows by Commission Regulation (EC) No 1521/2007<sup>(3)</sup>, and for chickens for fattening by Commission Regulation (EU) No 998/2010<sup>(4)</sup>.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 March 2013<sup>(5)</sup> that, under the proposed conditions of use, the preparation

of *Enterococcus faecium* DSM 7134 does not have an adverse effect on animal health, human health or the environment, and that since the potential to improve zootechnical parameters was already demonstrated in chickens for fattening, this conclusion can be extended to chickens reared for laying and extrapolated to minor poultry species other than those used for laying. 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 *Enterococcus faecium* DSM 7134 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 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, 12 August 2013.

For the Commission  
The President

José Manuel BARROSO

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> OJ L 128, 16.5.2007, p. 16.

<sup>(3)</sup> OJ L 335, 20.12.2007, p. 24.

<sup>(4)</sup> OJ L 290, 6.11.2010, p. 22.

<sup>(5)</sup> EFSA Journal 2013; 11(4):3167.

## 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 %			
<b>Category of zootechnical additives. Functional group: gut flora stabilisers</b>									
4b1841	Lactosan GmbH & Co KG	<i>Enterococcus faecium</i> DSM 7134	<p><i>Additive composition</i></p> <p>Preparation of <i>Enterococcus faecium</i> DSM 7134 containing a minimum of:</p> <p>Powder: <math>1 \times 10^{10}</math> CFU/g of additive</p> <p>Granulated (microencapsulated): <math>1 \times 10^{10}</math> CFU/g of additive</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Enterococcus faecium</i> DSM 7134</p> <p><i>Analytical method</i> <sup>(1)</sup></p> <p>Enumeration: spread plate method using bile esculin azide agar (EN 15788)</p> <p>Identification: Pulsed Field Gel Electrophoresis (PFGE).</p>	Chickens reared for laying	—	$5 \times 10^8$	—	<ol style="list-style-type: none"> <li>In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.</li> <li>The use is permitted in feed containing the authorised coccidiostats: diclazuril, halo-fuginone hydrobromide, robenidine hydrochloride, deco-quinone, lasalocid A sodium, maduramicin ammonium or monensin sodium, on conditions that this coccidiostat is authorised for the relevant species.</li> <li>For safety: it is recommended to use breathing protection and gloves during handling.</li> </ol>	2 September 2023

<sup>(1)</sup> 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](http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx)