Commission Regulation (EU) No 998/2010 of 5 November 2010 concerning the authorisation of Enterococcus faecium DSM 7134 as a feed additive for chickens for fattening (holder of the authorisation Lactosan GmbH & Co KG) (Text with EEA relevance)

COMMISSION REGULATION (EU) No 998/2010

of 5 November 2010

concerning the authorisation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens for fattening (holder of the 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[(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. The application was accompanied by the particulars and documents required pursuant to Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens for fattening, to be classified in the additive category ‘zootechnical additives’.

(4) The use of *Enterococcus faecium* DSM 7134 has been authorised for weaned piglets and pigs for fattening by Commission Regulation (EC) No 538/2007[(2)], for sows by Commission Regulation (EC) No 1521/2007[(3)] and was provisionally authorised for 4 years for chickens for fattening by Commission Regulation (EC) No 521/2005[(4)].

(5) New data were submitted in support of the application for the authorisation of the preparation for chickens for fattening. The European Food Safety Authority (‘the Authority’) concluded in its opinion of 27 May 2010[(5)] that *Enterococcus faecium* DSM 7134, under the proposed conditions of use, does not have an adverse effect on animal health, human health or the environment, and that it has the potential to be efficacious, when fed to the target species, by improving zootechnical parameters. 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 *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 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, 5 November 2010.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 998/2010. (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									
4b1841	Lactosan GmbH & Co KG	*Enterococcus faecium* DSM 7134	*Additive composition* Preparation of *Enterococcus faecium* DSM 7134 containing a minimum of: *Characterisation of the active substance* *Enterococcus faecium* DSM 7134 *Analytical method*[a]	*Chickens for fattening*	— Powder: 1×10^{10} CFU/g of additive Granulated (microencapsulated): 1×10^{10} CFU/g of additive Enumeration: spread	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. The use is permitted in feed containing the authorised coccidiostats: diclazuril, halofuginone hydrobromide, robenidine hydrochloride, decoquinate, lasalocid A sodium, maduramicin ammonium or	26 November 2020

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