Commission Implementing Regulation (EU) No 887/2011 of 5 September 2011 concerning the authorisation of a preparation of Enterococcus faecium CECT 4515 as feed additive for chickens for fattening (holder of the authorisation Evonik Nutrition & Care GmbH) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 887/2011

of 5 September 2011

concerning the authorisation of a preparation of *Enterococcus faecium* CECT 4515 as feed additive for chickens for fattening (holder of the authorisation [F1Evonik Nutrition & Care GmbH])

(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* CECT 4515. That 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 the preparation set out in the Annex as a feed additive for chickens for fattening, to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 16 March 2011(2) that *Enterococcus faecium* CECT 4515, under the proposed conditions of use, does not have an adverse effect on animal health, consumer health or the environment, and that this additive has the potential to improve the body weight gain and feed to gain ratio in chickens for fattening. 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.

(5) The assessment of the preparation of *Enterococcus faecium* CECT 4515 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.

(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:

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2017/173 of 1 February 2017 amending Regulation (EC) No 1292/2008 and Implementing Regulation (EU) No 887/2011, as regards the name of the holder of the authorisation of Bacillus amyloliquefaciens CECT 5940 and Enterococcus faecium CECT 4515 (Text with EEA relevance).

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 887/2011. (See end of Document for details)*

[F2ANNEX

Textual Amendments

F2 Substituted by Commission Implementing Regulation (EU) 2017/961 of 7 June 2017 concerning the authorisation of a preparation of Enterococcus faecium CECT 4515 as a feed additive for weaned piglets, and a new use in water for drinking for weaned piglets and chickens for fattening, and amending Regulation (EC) No 2036/2005 and Regulation (EU) No 887/2011 (holder of authorisation Evonik Nutrition & Care GmbH) (Text with EEA relevance).

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									
4b1713	Evonik Nutrition & Care GmbH)	*Enterococcus faecium* CECT 4515	*Additive composition* Preparation of *Enterococcus faecium* CECT 4515 containing a minimum of 1 × 10^9 CFU/g additive Solid forms *Characterisation of the active substance* Viable cells of *Enterococcus faecium* CECT 4515	Chickens for fattening	—	1 × 10^9	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The use is compatible in feed containing one	26 September 2021

a Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 887/2011. (See end of Document for details)*

			Analytical method[a] Enumeration: spread plate method using bile esculin azide agar (EN 15788) Identification: Pulsed-Field Gel Electrophoresis (PFGE)					3.	of the following authorised coccidiostats: monensin sodium, diclazuril, nicarbazin, decoquinate, robenidine hydrochloride, semduramycin sodium, narasin, salinomicin sodium, lasalocid A sodium, narasin/ nicarbazin or maduramycin ammonium. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where

a Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

									those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection and skin protection.

a Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

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/l of water for drinking			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1713	Evonik Nutrition & Care GmbH)	*Enterococcus faecium* CECT 4515	*Additive composition* Preparation of *Enterococcus faecium* CECT 4515	Chickens for fattening	—	5×10^8	—	1. The additive may be used in water	28 June 2027

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports**]**