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)

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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) The preparation of *Enterococcus faecium* CECT 4515 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for weaned piglets by Commission Regulation (EC) No 2036/2005 ([3]). That preparation was subsequently entered in the Register of Feed Additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003. That preparation has been authorised for chickens for fattening by Commission Implementing Regulation (EU) No 887/2011 ([4]).

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, applications were submitted for the re-evaluation of the preparation of *Enterococcus faecium* CECT 4515 as a feed additive in feed for weaned piglets and for a new use in water for drinking for weaned piglets and chickens for fattening. The applicant requested the additive to be classified in the additive category 'zootechnical additives'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 9 April 2014 ([5]), 29 April 2015 ([6]) and 8 September 2015 ([7]) that, under the proposed conditions of use, the preparation of *Enterococcus faecium* CECT 4515 does not have an adverse effect on animal health, human health or the environment. In its opinion of 29 April 2015, the Authority also concluded that the additive has the potential to improve the zootechnical performance of weaned piglets when used in feed. In its opinion of 8 September 2015, the Authority further concluded that the use of the preparation of *Enterococcus faecium* CECT 4515 in water for drinking for weaned piglets and chickens for fattening has the same efficacy as when it is used in feed. 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.

(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 that preparation should be authorised as specified in the Annexes to this Regulation.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).
([3]) Commission Regulation (EC) No 2036/2005 of 14 December 2005 concerning the permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of certain additives already authorised in feedingstuffs (OJ L 328, 15.12.2005, p. 13).
([4]) 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) (OJ L 229, 6.9.2011, p. 7).
([5]) *EFSA Journal* 2014;12(5):3672.
([6]) *EFSA Journal* 2015;13(5):4111.
([7]) *EFSA Journal* 2015; 13(9):4232.

(6) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulation (EC) No 2036/2005 should be amended accordingly. Furthermore, the existing authorisation of the preparation of *Enterococcus faecium* CECT 4515 for chickens for fattening in Implementing Regulation (EU) No 887/2011 should be supplemented by a new use in water for drinking by way of an amendment to that Implementing Regulation.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(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

Authorisation

The preparation specified in Annex I, 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

Amendment to Regulation (EC) No 2036/2005

In Annex I to Regulation (EC) No 2036/2005, the entry E 1713 on *Enterococcus faecium* CECT 4515 is deleted.

Article 3

Amendment to Regulation (EU) No 887/2011

The Annex to Regulation (EU) No 887/2011 is replaced by Annex II to this Regulation.

Article 4

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 28 December 2017 in accordance with the rules applicable before 28 June 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

Entry into force

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, 7 June 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		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 containing a minimum of 1×10^9 CFU/g additive in solid form *Characterisation of the active substance* Viable cells of *Enterococcus faecium* CECT 4515 *Analytical method* (1) Enumeration: spread plate method using bile esculin azide agar (EN 15788) Identification: Pulsed-Field Gel Electrophoresis (PFGE)	Weaned piglets		1×10^9	—	5×10^8	—	1. The additive may be used in water for drinking. 2. In the directions for use of the additive and premixtures stability in water for drinking shall be indicated. 3. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 4. For use of the additive in water for drinking a homogeneous dispersion of the additive shall be ensured. 5. For use in weaned piglets up to 35 kg of body weight.	28 June 2027

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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			
										6. 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 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.	

(1) 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

ANNEX II

'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									
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 *Analytical method* (1) Enumeration: spread plate method using bile esculin azide agar (EN 15788) Identification: Pulsed-Field Gel Electrophoresis (PFGE)	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 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. 3. 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 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.	26 September 2021

(1) 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 containing a minimum of 1×10^9 CFU/g additive Solid forms. *Characterisation of the active substance* Viable cells of *Enterococcus faecium* CECT 4515 *Analytical method* (1) Enumeration: spread plate method using bile esculin azide agar (EN 15788) Identification: Pulsed- Field Gel Electrophoresis (PFGE)	Chickens for fattening	—	5×10^8	—	1. The additive may be used in water for drinking. 2. In the directions for use of the additive and premixtures stability in water for drinking shall be indicated. 3. For use of the additive in water for drinking a homogeneous dispersion of the additive shall be ensured. 4. The use is compatible in feed containing one 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. 5. 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 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.	28 June 2027

(1) 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'