COMMISSION IMPLEMENTING REGULATION (EU) 2017/1008

of 15 June 2017

concerning the authorisation of the preparation of of *Lactococcus lactis* PCM B/00039, *Carnobacterium divergens* PCM KKP 2012p, *Lactobacillus casei* PCM B/00080, *Lactobacillus plantarum* PCM B/00081 and *Saccharomyces cerevisiae* PCM KKP 2059p as a feed additive for chickens for fattening (holder of authorisation JHJ Ltd)

(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 *Lactococcus lactis* PCM B/00039, *Carnobacterium divergens* PCM KKP 2012p, *Lactobacillus casei* PCM B/00080, *Lactobacillus plantarum* PCM B/00081 and *Saccharomyces cerevisiae* PCM KKP 2059p. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of the preparation of of *Lactococcus lactis* PCM B/00039, *Carnobacterium divergens* PCM KKP 2012p, *Lactobacillus casei* PCM B/00080, *Lactobacillus plantarum* PCM B/00081 and *Saccharomyces cerevisiae* PCM KKP 2059p 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 12 July 2016 ([2]) that, under the proposed conditions of use, the preparation of *Lactococcus lactis* PCM B/00039, *Carnobacterium divergens* PCM KKP 2012p, *Lactobacillus casei* PCM B/00080, *Lactobacillus plantarum* PCM B/00081 and *Saccharomyces cerevisiae* PCM KKP 2059p does not have an adverse effect on animal health, human health or the environment, and that it has a potential to improve zootechnical performance 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 Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of of *Lactococcus lactis* PCM B/00039, *Carnobacterium divergens* PCM KKP 2012p, *Lactobacillus casei* PCM B/00080, *Lactobacillus plantarum* PCM B/00081 and *Saccharomyces cerevisiae* PCM KKP 2059p 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 Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2016;14(9):4555.

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.

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, 15 June 2017.

For the Commission
The President
Jean-Claude JUNCKER

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									
4b1892	JHJ Ltd	*Lactococcus lactis* PCM B/00039, *Carnobacterium divergens* PCM KKP 2012p, *Lactobacillus casei* PCM B/00080, *Lactobacillus plantarum* PCM B/00081 and *Saccharomyces cerevisiae* PCM KKP 2059p	*Additive composition* Preparation of *Lactococcus lactis* PCM B/00039, *Carnobacterium divergens* PCM KKP 2012p, *Lactobacillus casei* PCM B/00080, *Lactobacillus plantarum* PCM B/00081 and *Saccharomyces cerevisiae* PCM KKP 2059p containing a minimum of $1{,}2 \times 10^9$ CFU/g of total Lactic Acid Bacteria (LAB) and *Saccharomyces cerevisiae* PCM KKP 2059p 1×10^7 CFU/g having a minimum of: *Lactococcus lactis* PCM B/00039 $\geq 5 \times 10^8$ CFU/g *Carnobacterium divergens* PCM KKP 2012p $\geq 3 \times 10^8$ CFU/g *Lactobacillus casei* PCM B/00080 $\geq 1 \times 10^8$ CFU/g *Lactobacillus plantarum* PCM B/00081 $\geq 3 \times 10^8$ CFU/g *Saccharomyces cerevisiae* PCM KKP 2059p $\geq 1 \times 10^7$ CFU/g	Chickens for fattening	—	5×10^8 (LAB) 5×10^6 (*Saccharomyces cerevisiae* PCM KKP 2059p)	—	1. In the directions for use of the additive and premixtures, indicate the storage temperature, storage life and stability to pelleting. 2. The use is permitted in feed containing the following authorised coccidiostats: narasin/nicarbazin, salinomycin sodium, diclazuril, decoquinate, or maduramicin 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 and skin protection.	6 July 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	Other provisions	End of period of authorisation
						CFU//kg of complete feedingstuff with a moisture content of 12 %			
			Characterisation of the active substance Viable cells of *Lactococcus lactis* PCM B/00039, *Carnobacterium divergens* PCM KKP 2012p, *Lactobacillus casei* PCM B/00080, *Lactobacillus plantarum* PCM B/00081 and *Saccharomyces cerevisiae* PCM KKP 2059p *Analytical method* (1) For the enumeration of *Lactococcus lactis* PCM B/00039 and *Carnobacterium divergens* PCM KKP 2012p in the feed additive and feedingstuffs: — Poured-plate method using de Man, Rogosa and Sharpe (MRS) agar ISO 15214 For the enumeration of *Lactobacilli* in the feed additive and feedingstuffs: — Poured-plate method using MRS agar EN 15787 For the enumeration of *Saccharomyces cerevisiae* PCM KKP 2059p in the feed additive and feedingstuffs: — Poured-plate method using chloramphenicol glucose yeast extract (CGYE) agar EN 15789						

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 %			
			For the identification of *Lactobacilli, Lactococcus lactis* PCM B/00039 and *Carnobacterium divergens* PCM KKP 2012p: — Identification: Pulsed-Field Gel Electrophoresis (PFGE) For the identification of *Saccharomyces cerevisiae* PCM KKP 2059p: — Polymerase Chain Reaction (PCR)						

([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