COMMISSION IMPLEMENTING REGULATION (EU) 2015/38

of 13 January 2015

concerning the authorisation of the preparation of *Lactobacillus acidophilus* CECT 4529 as a feed additive for laying hens and amending Regulation (EC) No 1520/2007 (holder of authorisation Centro Sperimentale del Latte)

(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 *Lactobacillus acidophilus* CECT 4529 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for laying hens by Commission Regulation (EC) No 1520/2007 ([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.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of the preparation of *Lactobacillus acidophilus* CECT 4529 as a feed additive for laying hens and, in accordance with Article 7 of that Regulation, for a new use in water for drinking, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was 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 opinion of 1 July 2014 ([4]) that, under the proposed conditions of use, the preparation of *Lactobacillus acidophilus* CECT 4529 does not have an adverse effect on animal health, human health or the environment. The Authority further concluded that the use of the preparation has the potential to increase laying intensity and improve the feed-to-egg mass ratio. It considered that the results are independent of the mode of administration provided that the exposure in water for drinking is the same by an equivalent dose to 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 *Lactobacillus acidophilus* CECT 4529 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) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulation (EC) No 1520/2007 should be amended accordingly.

(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.

([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 1520/2007 of 19 December 2007 concerning the permanent authorisation of certain additives in feedingstuffs (OJ L 335, 20.12.2007, p. 17).
([4]) *EFSA Journal* 2014; 12(7):3789.

(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 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

Amendments to Regulation (EC) No 1520/2007

Regulation (EC) No 1520/2007 is amended as follows:

(1) Article 4 is deleted.

(2) Annex IV is deleted.

Article 3

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 3 September 2015 in accordance with the rules applicable before 3 March 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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, 13 January 2015.

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	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.											
4b1715	Centro Sperimentale del Latte	*Lactobacillus acidophilus* CECT 4529	*Additive composition* Preparation of *Lactobacillus acidophilus* CECT 4529 containing a minimum of: 5×10^{10} CFU/g of additive (solid form). *Characterisation of the active substance* Viable cells of *Lactobacillus acidophilus* CECT 4529. *Analytical method* (1) Enumeration: spread plate method (EN 15787). Identification: Pulsed Field Gel Electrophoresis (PFGE).	Laying hens	—	1×10^9	—	5×10^8	—	1. In the directions for use of the additive, premixture and compound feed, indicate the storage conditions and stability to pelleting and in drinking water. 2. For safety: breathing protection shall be used during handling. 3. For use of the additive in water for drinking the homogeneous dispersion of the additive shall be ensured.	3 March 2025

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