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)

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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/38. (See end of Document for details)*

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.

(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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/38. (See end of Document for details)*

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