Commission Implementing Regulation (EU) 2015/1053 of 1 July 2015 concerning the authorisation of the preparation of Enterococcus faecium DSM 10663/ NCIMB 10415 as a feed additive for calves for rearing, piglets, chickens for fattening, turkeys for fattening, cats and dogs and amending Regulations (EC) No 1259/2004, (EC) No 255/2005, (EC) No 1200/2005 and (EC) No 1520/2007 (holder of authorisation Chevita Tierarzneimittel-GmbH) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1053

of 1 July 2015

concerning the authorisation of the preparation of *Enterococcus faecium* DSM 10663/NCIMB 10415 as a feed additive for calves for rearing, piglets, chickens for fattening, turkeys for fattening, cats and dogs and amending Regulations (EC) No 1259/2004, (EC) No 255/2005, (EC) No 1200/2005 and (EC) No 1520/2007 (holder of authorisation Chevita Tierarzneimittel-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* DSM 10663/NCIMB 10415 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for chickens for fattening by Commission Regulation (EC) No 1259/2004[(3)], for calves by Commission Regulation (EC) No 255/2005[(4)], for piglets by Commission Regulation (EC) No 1200/2005[(5)], for turkeys for fattening and dogs by Commission Regulation (EC) No 1520/2007[(6)]. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) 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 *Enterococcus faecium* DSM 10663/NCIMB 10415 as a feed additive for calves for rearing, piglets, chickens for fattening, turkeys for fattening and dogs and, in accordance with Article 7 of that Regulation, for a new use for cats, requesting that additive to be classified in the additive category ‘zootechnical additives’. That

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1053. (See end of Document for details)*

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 opinions of 4 March 2014[7] and 21 May 2014[8] that, under the proposed conditions of use, the preparation of *Enterococcus faecium* DSM 10663/NCIMB 10415 does not have an adverse effect on animal health, human health or the environment. The Authority further concluded that the use of that preparation has the potential to improve zootechnical performance of calves for rearing, piglets (suckling and weaned), chickens for fattening and turkeys 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) Since small but significant effects on faecal quality were observed by the EFSA in cats and dogs, it is considered sufficient to confirm the efficacy in these species.

(6) The assessment of the preparation of *Enterococcus faecium* DSM 10663/NCIMB 10415 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.

(7) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulations (EC) No 1259/2004, (EC) No 255/2005, (EC) No 1200/2005 and (EC) No 1520/2007 should be amended accordingly.

(8) 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.

(9) 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 1259/2004

Regulation (EC) No 1259/2004 is amended as follows:

(1) Article 1 is deleted.

(2) Annex I is deleted.

Article 3

Amendment to Regulation (EC) No 255/2005

In Annex I to Regulation (EC) No 255/2005, the entry on E 1707, *Enterococcus faecium* DSM 10663/NCIMB 10415, is deleted.

Article 4

Amendment to Regulation (EC) No 1200/2005

In Annex II to Regulation (EC) No 1200/2005, the entry on E 1707, *Enterococcus faecium* DSM 10663/NCIMB 10415, is deleted.

Article 5

Amendments to Regulation (EC) No 1520/2007

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

(1) Articles 2 and 3 are deleted.

(2) Annexes II and III are deleted.

Article 6

Transitional measures

1 The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 22 January 2016 in accordance with the rules applicable before 22 July 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for calves, piglets, chickens for fattening and turkeys for fattening.

2 The preparation specified in the Annex and feed containing that preparation, which are produced and labelled [for dogs] before 22 July 2017 in accordance with the rules applicable before 22 July 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for dogs.

Article 7

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, 1 July 2015.

For the Commission

The President

Jean-Claude JUNCKER