Commission Implementing Regulation (EU) 2015/1399 of 17 August 2015 concerning the denial of authorisation of the preparation of Bacillus toyonensis (NCIMB 14858T) (formerly Bacillus cereus var. toyoi NCIMB 40112/CNCM I-1012) as a feed additive for cattle for fattening, rabbits for fattening, chickens for fattening, piglets (weaned), pigs for fattening, sows for reproduction and calves for rearing and the revocation of the authorisations of the preparation of Bacillus cereus var. toyoi (NCIMB 40112/CNCM I-1012) as a feed additive for turkeys for fattening and rabbit breeding does, amending Regulations (EC) No 256/2002, (EC) No 1453/2004, (EC) No 255/2005 and (EC) No 1200/2005 and repealing Regulations (EC) No 166/2008, (EC) No 378/2009 and Implementing Regulation (EU) No 288/2013 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1399

of 17 August 2015

concerning the denial of authorisation of the preparation of *Bacillus toyonensis* (NCIMB 14858^{T}) (formerly *Bacillus cereus* var. *toyoi* NCIMB 40112/CNCM I-1012) as a feed additive for cattle for fattening, rabbits for fattening, chickens for fattening, piglets (weaned), pigs for fattening, sows for reproduction and calves for rearing and the revocation of the authorisations of the preparation of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012) as a feed additive for turkeys for fattening and rabbit breeding does, amending Regulations (EC) No 256/2002, (EC) No 1453/2004, (EC) No 255/2005 and (EC) No 1200/2005 and repealing Regulations (EC) No 166/2008, (EC) No 378/2009 and Implementing Regulation (EU) No 288/2013

(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 Articles 9(2) and 13(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, denying or revoking 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 *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012) was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for piglets under 2 months and sows by Commission Regulation (EC) No 256/2002[(3)], for piglets from 2 to 4 months and pigs for fattening by Commission Regulation (EC) No 1453/2004[(4)], for cattle for fattening by Commission Regulation (EC) No 255/2005[(5)] and for rabbits for fattening and chickens for fattening by

Commission Regulation (EC) No 1200/2005[6]. The 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) That preparation was also authorised in accordance with Regulation (EC) No 1831/2003 for 10 years for turkeys for fattening by Commission Regulation (EC) No 166/2008[7] and for rabbit breeding does by Commission Regulation (EC) No 378/2009[8].

(4) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of the preparation of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012) as a feed additive for cattle for fattening, rabbits for fattening, chickens for fattening, piglets (weaned), pigs for fattening and sows for reproduction and, in accordance with Article 7 of that Regulation, an application was submitted for a new use of that preparation for calves for rearing, both applications requesting the additive to be classified in the additive category 'zootechnical additives'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) On the basis of the opinion of 16 October 2012 of the European Food Safety Authority ('the Authority')[9], Commission Implementing Regulation (EU) No 288/2013[10] suspended the existing authorisations of the preparation of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012).

(6) Implementing Regulation (EU) No 288/2013 refers to the possibility that supplementary data concerning the safety of use of the preparation of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012), to be submitted by the applicant, may bring new elements which would allow a re-consideration of the assessment carried out for that additive. That Regulation further provides for the review of the suspension measure.

(7) On 6 December 2013, the applicant submitted supplementary data to the Commission, which were subsequently forwarded to the Authority with a request to evaluate them in order to receive a new opinion on the safety and efficacy of the additive.

(8) In addition, the applicant, on his own initiative, submitted to the Authority additional documentation on 24 April 2014, on 14 May 2014 and on 17 June 2014.

(9) On 1 July 2014, the Authority adopted an opinion following the assessment of the supplementary data submitted by the applicant[11]. In its opinion, the Authority considered that the taxonomic re-classification of the strain of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012) as a new species named *Bacillus toyonensis* had no impact on the assessment thereof, as it still belongs to the *Bacillus cereus* group. As regards the antibiotic susceptibility of the *Bacillus toyonensis* strain, the Authority concluded that the supplementary data provided do not alter the previous conclusion that the strain poses a risk for the spread of genes coding for resistance to tetracycline and chloramphenicol, which are antibiotics of human and veterinary importance. On the toxigenic potential of the *Bacillus toyonensis* strain, the Authority concluded that it has the capacity to elaborate functional toxins and, thus, to pose a risk to those exposed to the organism, including those handling the additive and consumers exposed to contaminated animal products.

(10) On 30 August 2014, the applicant requested the administrative review of the opinion of the Authority of 1 July 2014 and on 17 October 2014 he supplemented his request with additional elements. By Decision of 20 May 2015[(12)], the Commission concluded that there was no reason to require that the Authority withdraw that opinion.

(11) Consequently, it has not been established that the preparation of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012), which has been re-classified as a new species named *Bacillus toyonensis* (NCIMB 14858^T), does not have an adverse effect on animal health or on human health, when used as feed additive.

(12) The conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are therefore not satisfied.

(13) Accordingly, the authorisation of the preparation of *Bacillus toyonensis* (NCIMB 14858^T) as a feed additive for cattle for fattening, rabbits for fattening, chickens for fattening, piglets (weaned), pigs for fattening, sows for reproduction and calves for rearing should be denied.

(14) For the same reasons, the conditions for authorisation of the preparation of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012) as a feed additive for use for turkeys for fattening and for rabbit breeding does are no longer fulfilled and those authorisations should be revoked.

(15) Regulations (EC) No 256/2002, (EC) No 1453/2004, (EC) No 255/2005 and (EC) No 1200/2005 should be amended accordingly, and Regulations (EC) No 166/2008 and (EC) No 378/2009 should be repealed.

(16) Implementing Regulation (EU) No 288/2013 should also be repealed.

(17) Since existing stocks of the preparation of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012), of premixtures containing that preparation and of feed materials and compound feed produced from that preparation were already to be withdrawn from the market according to Article 7 of Implementing Regulation (EU) No 288/2013, no transitional measures should be provided for.

(18) 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

Denial of authorisation

Authorisation of *Bacillus toyonensis* (NCIMB 14858^T) as an additive in animal nutrition for use for cattle for fattening, rabbits for fattening, chickens for fattening, piglets (weaned), pigs for fattening, sows for reproduction and calves for rearing is denied.