Commission Implementing Regulation (EU) 2017/211 of 7 February 2017 concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Bacillus subtilis (LMG-S 15136) as a feed additive for poultry, weaned piglets and pigs for fattening, and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005, and (EC) No 322/2009 and repealing Regulation (EC) No 516/2007 (holder of authorisation Beldem, a division of Puratos NV) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/211

of 7 February 2017

concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* (LMG-S 15136) as a feed additive for poultry, weaned piglets and pigs for fattening, and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005, and (EC) No 322/2009 and repealing Regulation (EC) No 516/2007 (holder of authorisation Beldem, a division of Puratos NV)

(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 endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* (LMG-S 15136) 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 weaned piglets by Commission Regulation (EC) No 1206/2005[(4)], for pigs for fattening and turkeys for fattening by Commission Regulation (EC) No 516/2007[(5)] and for laying hens by Commission Regulation (EC) No 322/2009[(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. In accordance with Regulation (EC) No 1831/2003, that preparation was also authorised for 10 years for ducks by Commission Regulation (EC) No 242/2007[(7)].

(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 endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* (LMG-S 15136) as a feed additive for poultry, weaned piglets and pigs for fattening. The

applicant requested 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 13 July 2016[8] that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* (LMG-S 15136) does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the use of that preparation has the potential to be efficacious in chickens for fattening, laying hens, weaned piglets and pigs for fattening. This conclusion can be extended to chickens reared for laying and breeding hens. The Authority further considered that the conclusions on the efficacy can be extrapolated to minor poultry species for fattening, for breeding and for laying. It 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 Authority also concluded on turkeys for fattening that in two studies there was evidence of a positive effect on final body weight and on feed to gain ratio. A third one with a significant greater feed to gain ratio, as already evaluated and accepted in the previous evaluation for the authorisation, was not considered significant by the Authority. Since these evidences were judged a substantial indication of the improvement of zootechnical parameters, in addition to the long history of use, it was considered that the provided data meet the conditions for the demonstration of the efficacy of the additive for turkeys for fattening.

(6) The assessment of the preparation endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* (LMG-S 15136) 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) Regulations (EC) No 1259/2004, (EC) No 1206/2005, and (EC) No 322/2009 should be amended accordingly. Regulation (EC) No 516/2007 should be repealed.

(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:

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/211. (See end of Document for details)*

Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendment to Regulation (EC) No 1259/2004

Annex VI to Regulation (EC) No 1259/2004 is deleted.

Article 3

Amendment to Regulation (EC) No 1206/2005

In Annex I to Regulation (EC) No 1206/2005, the entry E 1606 endo-1,4-beta-xylanase (EC 3.2.1.8), is deleted.

Article 4

Amendment to Regulation (EC) No 322/2009

Annex I to Regulation (EC) No 322/2009 is deleted.

Article 5

Repeal

Regulation (EC) No 516/2007 is repealed.

Article 6

Transitional measures

The preparation specified in the Annex, and feed containing that preparation, which are produced and labelled before 28 August 2017 in accordance with the rules applicable before 28 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

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, 7 February 2017.

For the Commission

The President

Jean-Claude JUNCKER