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COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of the preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger* (NRRL 25541) and alpha-amylase produced by *Aspergillus niger* (ATTC66222) as a feed additive for weaned piglets and minor porcine species (weaned) and amending Regulation (EC) No 1453/2004 (holder of authorisation Andrès Pintaluba S.A.)

(Text with EEA relevance)

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(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-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger* (NRRL 25541) and alpha-amylase produced by *Aspergillus niger* (ATTC66222) was authorised in accordance with Directive 70/524/EEC without a time limit as a feed additive for weaned piglets by Commission Regulation (EC) No 1453/2004[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 endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger* (NRRL 25541) and alpha-amylase produced by *Aspergillus niger* (ATTC66222) as a feed additive for weaned piglets and minor porcine species (weaned). 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 opinions of 8 October 2013[4], 16 May 2017[5] and 17 April 2018[6] that, under the proposed conditions

1 OJ L 268, 18.10.2003, p. 29.

2 Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

3 Commission Regulation (EC) No 1453/2004 of 16 August 2004 concerning the permanent authorisation of certain additives in feedingstuffs (OJ L 269, 17.8.2004, p. 3).

4 EFSA Journal 2013; 11(10):3430.

of use, of the preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger* (NRRL 25541) and alpha-amylase produced by *Aspergillus niger* (ATTC66222) 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 improve the final body weight and the feed to gain ratio [DG: ratio?]in weaned piglets and that conclusion can be can be extrapolated to minor porcine species (weaned). 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 endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger* (NRRL 25541) and alpha-amylase produced by *Aspergillus niger* (ATTC66222) 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 granting the authorisation for the preparation Regulation (EC) No 1453/2004 should be amended accordingly.

(7) Since there are no safety concerns requiring 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 ‘digestibility enhancers”, is authorised as an additive in animal nutrition, subject to the conditions laid down in the Annex.

Article 2
Amendment to Regulation (EC) No 1453/2004

In Annex II to Regulation (EC) No 1453/2004 entry E 1612 on the preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase and alpha-amylase is deleted.

Article 3
Transitional measures

The preparation specified in the Annex, and feed containing that preparation, which are produced and labelled before [*6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by*

[5] EFSA Journal 2017; 15(6):4856.
[6] EFSA Journal 2018; 1(5):5271.

the Service responsible for the publication] 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,

For the Commission
The President
Jean-Claude JUNCKER