Commission Implementing Regulation (EU) 2018/1566 of 18 October 2018 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 orizae (ATCC66222) 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1566

of 18 October 2018

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 **[**[X1]*Aspergillus orizae* (ATCC66222)**]** 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)

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* (ATCC66222) 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* (ATCC66222) as a feed additive for weaned piglets and minor porcine species (weaned). The applicant requested that additive to be classified in the additive category

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1566. (See end of Document for details)*

'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 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* (ATCC66222) 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 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* (ATCC66222) 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:

Editorial Information

X1 Substituted by Corrigendum to Commission Implementing Regulation (EU) 2018/1566 of 18 October 2018 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 (ATCC66222) 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.) (Official Journal of the European Union L 262 of 19 October 2018).

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 8 May 2019 in accordance with the rules applicable before 8 November 2018 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1566. (See end of Document for details)*

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species, or category of animal	Maximum age	Minimum content Units of activity/kg of complete feedingstuff with a moisture content of 12 %	Maximum content	Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1612i	Andrés Pintaluba S.A.	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Alpha-amylase EC 3.2.1.1	(4) *Additive composition* 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 [X1 *Aspergillus orizae* (ATCC66222)] having respectively a minimum activity of.	Weaned piglets Minor porcine species (weaned)		endo-1,3(4)-beta-glucanase 450 U beta-xylanase 500 U alpha-amylase 1 500 U	(4)-	1. the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures	8 November 2028

a 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,0 and 30 °C.

b 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from rye arabinoxylan per minute at pH 4,0 and 30 °C.

c 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from wheat starch per minute at pH 5,0 and 30 °C.

d Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1566. (See end of Document for details)*

			— Endo-1,3(4)-beta-glucanase 900 U[a]/g; — Endo-1,4-beta-xylanase 1 000 U[b]/g; — Alpha-amylase 3 000 U[c]/g Solid form *Characterisation of the active substance* endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger* (NRRL 25541) and alpha-amylase produced by *Aspergillus*			and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment including skin, eyes and breathing protections. 3. For use in weaned

a 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,0 and 30 °C.

b 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from rye arabinoxylan per minute at pH 4,0 and 30 °C.

c 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from wheat starch per minute at pH 5,0 and 30 °C.

d Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports