II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1896

of 17 October 2017

concerning the authorisation of a preparation o endo-1,3(4)-beta-glucanase (EC 3.2.1.6) and endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (NRRL 25541) as a feed additive for chickens for fattening, laying hens, pigs for fattening, minor poultry species and minor porcine species for fattening and amending Regulation (EC) No 255/2005 and repealing Regulation (EC) No 668/2003 (holder of the authorisation Andrés 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 (EC 3.2.1.6) and endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (NRRL 25541) 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 668/2003 ([3]) and as a feed additive for laying hens by Commission Regulation (EC) No 255/2005 ([4]). 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 thereof, an application was submitted for the re-evaluation of the preparation of endo-1,3(4)-beta-glucanase (EC 3.2.1.6) and endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (NRRL 25541) as a feed additive for chickens for fattening and for laying hens and, in accordance with Article 7 of that Regulation, for the authorisation for use for pigs for fattening, minor poultry and porcine species requesting that additive to be classified in the additive category of 'zootechnical additives'. The 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 11 July 2013 ([5]) and 25 January 2017 ([6]) that, under the proposed conditions of use, the preparation of endo-1,3(4)-beta-glucanase (EC 3.2.1.6) and endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (NRRL 25541) does not have

([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 668/2003 of 11 April 2003 concerning the permanent authorisation of an additive in feedingstuffs (OJ L 96, 12.4.2003, p. 14).
([4]) Commission Regulation (EC) No 255/2005 of 15 February 2005 concerning the permanent authorisations of certain additives in feedingstuffs (OJ L 45, 16.2.2005, p. 3).
([5]) *EFSA Journal* 2013; 11(8):3322.
([6]) *EFSA Journal* 2017; 15(3):4706.

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 improving zootechnical parameters in chickens for fattening, laying hens and pigs for fattening. The Authority further considered that the mode of action of the enzymes present in the additive can be considered to be similar in minor poultry species and minor porcine species, therefore the conclusions on the efficacy in chickens for fattening, laying hens and in pigs for fattening can be extrapolated to minor poultry species and minor porcine species 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) The assessment of the preparation of endo-1,3(4)-beta-glucanase (EC 3.2.1.6) and endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (NRRL 25541) 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) 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.

(7) Regulation (EC) No 255/2005 should be amended accordingly. Regulation (EC) No 668/2003 should be repealed.

(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 that Annex.

Article 2

Amendments to Regulation (EC) No 255/2005

In Annex II to Regulation (EC) No 255/2005, entry E 1601 on endo-1,3(4)-beta-glucanase EC 3.2.1.6 and endo-1,4-beta-xylanase EC 3.2.1.8 is deleted.

Article 3

Repeal

Regulation (EC) No 668/2003 is repealed.

Article 4

Transitional measures

The preparation specified in the Annex, and feed containing that preparation, which are produced and labelled before 7 May 2018 in accordance with the rules applicable before 7 November 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

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, 17 October 2017.

For the Commission
The President
Jean-Claude JUNCKER

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	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers.									
4a1601	Andrés Pintaluba S.A.	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 and endo-1,4-beta-xylanase EC 3.2.1.8	*Additive composition:* Preparation of endo-1,3(4)-beta-glucanase (EC 3.2.1.6) and endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (NRRL 25541) having a minimum activity of: endo-1,3(4)-beta-glucanase 1 100 U (1)/g and endo-1,4-beta-xylanase 1 600 U (2)/g. (solid form) *Characterisation of the active substance:* Endo-1,3(4)-beta-glucanase (EC 3.2.1.6) and endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (NRRL 25541). *Analytical method* (3) For the characterisation in the feed additive and premixtures of: — endo-1,3(4)-beta-glucanase activity: colorimetric method measuring reducing sugar (glucose equivalents) released by the action of endo-1,3(4)-beta-glucanase on barley beta-glucan substrate in presence of 3,5-dinitrosalicil acid (DNS);	Chickens for fattening Laying hens Pigs for fattening Minor poultry species Minor porcine species for fattening	—	Endo-1,3(4)-beta-glucanase 138 U Endo-1,4-beta-xylanase 200 U	—	1. In 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 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.	7.11.2027

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	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
			— endo-1,4-beta-xylanase activity: colorimetric method measuring reducing sugar (glucose equivalents) released by the action of endo-1,4-beta-xylanase on oat xylan substrate in presence of 3,5-dinitrosalicil acid (DNS). For the characterisation in the feed of: — endo-1,3(4)-beta-glucanase activity: colorimetric method measuring depolymerised soluble fragments released by the action of endo-1,3(4)-beta-glucanase on azo-barley-glucan; — endo-1,4-beta-xylanase activity: colorimetric method measuring depolymerised soluble fragments released by the action of endo-1,4-beta-xylanase on azo-xylan.						

(1) 1 U (unit) endo-1,3(4)-beta-glucanase is the amount of enzyme which liberates 1 µmole of reducing sugar (glucose equivalents) from oat beta-glucan per minute at 30 °C and pH 4.
(2) 1 U (unit) endo-1,4-beta-xylanase is the amount of enzyme which liberates 1 µmole of reducing sugar (xylose equivalents) from oat xylan per minute at 30 °C and pH 4.
(3) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports