REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1090

of 31 July 2018

concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Komagataella pastoris* (CBS 25376) and *Komagataella pastoris* (CBS 26469) as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, all avian species reared for laying or for breeding purposes, weaned piglets and minor porcine species (weaned) (holder of the authorisation Kaesler Nutrition GmbH)

(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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Komagataella pastoris* (CBS 25376) and *Komagataella pastoris* (CBS 26469). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Komagataella pastoris* (CBS 25376) and *Komagataella pastoris* (CBS 26469) as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, all avian species reared for laying or for breeding purposes, weaned piglets and all porcine species (weaned) to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 November 2017 ([2]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Komagataella pastoris* (CBS 25376) and *Komagataella pastoris* (CBS 26469) does not have an adverse effect on animal health, human health or the environment. It was concluded that the additive has a potential to improve zootechnical parameters in chickens for fattening, turkeys for fattening, and weaned piglets. This conclusion can be extended to chickens reared for laying and turkeys reared for breeding. The Authority also concluded that the effects of the additive on turkeys for fattening and on weaned piglets can be extrapolated respectively to all avian species up to the reared for laying and to weaned piglets of all porcine species. The Authority did 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-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Komagataella pastoris* (CBS 25376) and *Komagataella pastoris* (CBS 26469) 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) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal 2017*; 15(12):5097.

HAS ADOPTED THIS REGULATION:

Article 1

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

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, 31 July 2018.

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									
4a 28	Kaesler Nutrition GmbH	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6	*Additive composition* Preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Komagataella pastoris* (CBS 25376) and *Komagataella pastoris* (CBS 26469) having a minimum activity of: 25 000 LXU [1]/g and 2 200 LGU [2]/g Solid and liquid form. *Characterisation of the active substance* endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Komagataella pastoris* (CBS 25376) and *Komagataella pastoris* (CBS 26469) *Analytical method* [3] Determination in the feed additive, premixtures and feedingstuffs of xylanase — colorimetric method based on the quantification of water soluble dyed fragments produced by the action of endo-1,4-β-xylanase on cross-linked wheat arabinoxylan.	Chickens for fattening Chickens reared for laying	—	4 250 LXU 375 LGU	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For use in weaned piglets up to 35 kg of body weight. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks 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.	21.8.2028
				Turkeys for fattening All avian species reared for laying or for breeding purposes other than chickens reared for laying		1 400 LXU 120 LGU			
				Piglets (weaned) Minor porcine species (weaned)		700 LXU 60 LGU			

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 %			
			Determination in the feed additive, premixtures and feedingstuffs of endo-1,3(4)-beta-glucanase: — colorimetric method based on the quantification of water soluble dyed fragments produced by the action of endo-1,3(4)-beta-glucanase on cross-linked azo-barley-glucan.						

(1) 1 LXU is the amount of enzyme which releases one micromole of reducing sugars equivalents (as xylose) from birch xylan per minute at pH 5,5 and 50 °C.
(2) 1 LGU is the amount of enzyme which releases one micromole of reducing sugars equivalents (as glucose) from barley glucan per minute at pH 5,5 and 50 °C.
(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