COMMISSION IMPLEMENTING REGULATION (EU) No 302/2014

of 25 March 2014

concerning the authorisation of a preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 126896) as a feed additive for chickens for fattening and weaned piglets (holder of the authorisation ROAL Oy)

(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-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 126896). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 126896) as a feed additive for chickens for fattening and weaned piglets, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 9 October 2013 [2] that, under the proposed conditions of use, the preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 126896) does not have an adverse effect on animal health, human health or the environment. It also concluded that the additive improves significantly the performance of the animals. 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 produced by *Trichoderma reesei* (CBS 126896) 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 the Food Chain and Animal Health,

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

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, 25 March 2014.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] *EFSA Journal* 2013; 11(10):3432.

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									
4a20	ROAL Oy	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	*Additive composition* Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 126896) having a minimum activity of: — solid form: endo-1,3(4)-beta-glucanase 200 000 BU [1]/g, — liquid form: endo-1,3(4)-beta-glucanase 400 000 BU/ml. *Characterisation of the active substance* endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 126896) *Analytical method* [2] For the quantification of endo-1,3(4)-beta-glucanase activity: spectrophotometric (DNS) method, based on the quantification of released sugars produced by the action of endo-1,3(4)-beta-glucanase on barley beta-glucan at pH 4,8 and 50 °C.	Chickens for fattening Piglets (weaned)	—	20 000 BU 10 000 BU	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. For use in (weaned) piglets up to approximately 35 kg. 3. For safety: breathing protection, glasses and gloves shall be used during handling.	15 April 2024

[1] 1 BU is the amount of enzyme which liberates 1 nanomole of reducing sugars (expressed as glucose equivalents) from barley beta-glucan substrate per second at 50 °C and pH 4,8.
[2] Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx