COMMISSION IMPLEMENTING REGULATION (EU) No 403/2013

of 2 May 2013

concerning the authorisation of a preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* (ATCC 74444) as a feed additive for poultry for fattening and for laying and for weaned piglets and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005 and (EC) No 1876/2006 (holder of authorisation DSM Nutritional Products)

(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) A preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 74252) was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on chickens for fattening by Commission Regulation (EC) No 1259/2004 ([3]), on turkeys for fattening by Commission Regulation (EC) No 1206/2005 ([4]), and on laying hens and weaned piglets by Commission Regulation (EC) No 1876/2006 ([5]). 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 of that Regulation, an application was submitted for the re-evaluation of that preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* (ATCC 74444) (formerly ATCC 74252), as a feed additive for chickens for fattening, turkeys for fattening, laying hens and piglets and, in accordance with Article 7 of that Regulation, for a new use for all poultry species for fattening and laying, requesting 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 opinion of 17 October 2012 ([6]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* (ATCC 74444) does not have an adverse effect on animal health, human health or the environment, and that it has a potential to favourably affect animal performance in target species. However, based on the incomplete information provided by the applicant, the Authority was not in a position to specify the minimum enzyme activities. 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-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* (ATCC 74444) 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 new authorisation is granted in accordance with Regulation (EC) No 1831/2003, Regulations (EC) No 1259/2004, (EC) No 1206/2005 and (EC) No 1876/2006 should therefore be amended accordingly.

(7) 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.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) OJ L 239, 9.7.2004, p. 8.
([4]) OJ L 197, 28.7.2005, p. 12.
([5]) OJ L 360, 19.12.2006, p. 126.
([6]) *EFSA Journal 2012*; 10(11):2930.

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 1259/2004

Regulation (EC) No 1259/2004 is amended as follows:

1. Article 2 is replaced by the following:

   '*Article 2*

   The preparations belonging to the group "Enzymes", as set out in Annexes III, IV, V and VI are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in those Annexes.';

2. Annex II is deleted.

Article 3

Amendment to Regulation (EC) No 1206/2005

In the Annex to Regulation (EC) No 1206/2005 all the data contained in the entry E1602 are deleted.

Article 4

Amendments to Regulation (EC) No 1876/2006

Regulation (EC) No 1876/2006 is amended as follows:

1. Article 3 is deleted;

2. Annex III is deleted.

Article 5

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 23 November 2013 in accordance with the rules applicable before 23 May 2013, may continue to be placed on the market and used until the existing stocks are exhausted.

Article 6

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, 2 May 2013.

For the Commission
The President
José Manuel BARROSO

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 (Units of activity/kg of complete feedingstuff with a moisture content of 12 %)		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1602i	DSM Nutritional Products	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-glucanase EC 3.2.1.4	*Additive composition* Preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* (ATCC 74444) having a minimum activity of: endo-1,4-beta-xylanase 2 700 U ([1])/ml or g additive endo-1,3(4)-beta-glucanase 700 U ([2])/ml or g additive endo-1,4-beta-glucanase 800 U ([3])/ml or g additive (Liquid and solid form) *Characterisation of the active substance* endo-1,4-betaxylanase, endo-1,4-betaglucanase and endo-1,3(4)-betaglucanase, produced by *Trichoderma reesei* (ATCC 74444) *Analytical method* ([4]) Characterisation of the active substances in the feedingstuff: — Colorimetric method measuring water soluble dye released by the action of endo-1,4-beta-xylanase from cross-linked birchwood azoxylan substrate	Poultry for fattening other than turkeys for fattening	—	endo-1,4-beta-xylanase: 135 U endo-1,3(4)-beta-glucanase: 35 U endo-1,4-beta-glucanase: 40 U	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. For use in feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans). 3. For use in weaned piglets up to 35 kg. 4. For safety: breathing protection and gloves shall be used during handling.	23 May 2023
				Poultry for laying		endo-1,4-beta-xylanase: 216 U endo-1,3(4)-beta-glucanase: 56 U endo-1,4-beta-glucanase: 64 U			
				Turkeys for fattening Piglets (weaned)		endo-1,4-beta-xylanase: 270 U endo-1,3(4)-beta-glucanase: 70 U endo-1,4-beta-glucanase: 80 U			

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 %			
			— Colorimetric method measuring water soluble dye released by the action of endo-1,3(4)-beta-glucanase from cross-linked azobarley glucan substrate — Colorimetric method measuring water soluble dye released by the action of endo-1,4-beta-glucanase from cross-linked azocarboxymethylcellulose substrate.						

(1) 1 U is the amount of enzyme which liberates 1 micromoles of glucose from wheat arabinoxylan per minute at pH 5,0 and 40 °C.
(2) 1 U is the amount of enzyme which liberates 1 micromoles of glucose from barley beta-glucan per minute at pH 5,0 and 40 °C.
(3) 1 U is the amount of enzyme which liberates 1 micromoles of glucose from carboxymethylcellulose per minute at pH 5,0 and 40 °C.
(4) 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