# COMMISSION REGULATION (EC) No 271/2009

## of 2 April 2009

## concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase as a feed additive for weaned piglets, chickens for fattening, laying hens, turkeys for fattening and ducks for fattening (holder of the authorisation BASF SE)

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 the preparation set out in the Annex to this Regulation. 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 enzyme preparation endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) and endo-1,4-beta-glucanase produced by *Aspergillus niger* (DSM 18404), as a feed additive for weaned piglets, chickens for fattening, laying hens, turkeys for fattening and ducks for fattening to be classified in the additive category 'zootechnical additives'.

(4) From the opinion of the European Food Safety Authority (the Authority) of 3 December 2008 and on 9 December 2008 [2] it results that the enzyme preparation endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) and endo-1,4-beta-glucanase produced by *Aspergillus niger* (DSM 18404), as produced by the applicant BASF SE, does not have an adverse effect on animal health, human health and the environment and that it is efficacious in increasing performance of piglets and chickens for fattening and in improving feed conversion in turkeys for fattening and laying hens. Based on the data provided for chickens for fattening, it was assumed efficacious also for ducks for fattening. It further concluded that the product may be a potential skin and respiratory sensitiser. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that preparation shows that the conditions for authorisation, 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*

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 20th day following 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 April 2009.

*For the Commission*
Androulla VASSILIOU
*Member of the Commission*

[1] OJ L 268, 18.10.2003, p. 29.
[2] The EFSA Journal (2008) 914, 1-21.

*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.** | | | | | | | | | |
| 4a7 | BASF SE | Endo-1,4-beta-xylanase<br>EC 3.2.1.8<br>Endo-1,4-beta-glucanase<br>EC 3.2.1.4 | **Additive composition:**<br>Preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713)<br>and endo-1,4-beta-glucanase produced by *Aspergillus niger* (DSM 18404) having a minimum activity of:<br>Solid form:<br>5 600 TXU [1] and 2 500 TGU [2]/g<br>Liquid form:<br>5 600 TXU and 2 500 TGU/g<br>**Characterisation of the active substance:**<br>endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) and endo-1,4-beta-glucanase produced by *Aspergillus niger* (DSM 18404)<br>**Analytical method** [3]<br>For quantification of endo-1,4-beta-xylanase activity:<br>viscosimetric method based on decrease of viscosity produced by action of endo-1,4-beta-xylanase on the xylan containing substrate (wheat arabinoxylan) at pH = 3,5 and 55 °C.<br>For quantification of endo-1,4-beta-glucanase activity:<br>viscosimetric method based on decrease of viscosity produced by action of endo-1,4-beta-glucanase on the glucan containing substrate (barley betaglucan) at pH = 3,5 and 40 °C. | Piglets (weaned) | - | 560 TXT<br>250 TGU | - | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.<br>2. For use in feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e. g. containing more than 30 % wheat, barley, rye and/or triticale.<br>3. Recommended doses for kilogram of complete feedingstuffs:<br>Piglets (weaned):<br>560-840 TXU/250-375 TGU;<br>Chickens for fattening:<br>280-840 TXU/125-375 TGU;<br>Laying hens:<br>560-840 TXU/250-375 TGU;<br>Turkeys for fattening:<br>560-840 TXU/250-375 TGU;<br>Ducks for fattening:<br>280-840 TXU/125-375 TGU.<br>4. For use in weaned piglets until approximately 35 kg.<br>5. For safety: breathing protection, glasses and gloves shall be used during handling. | *22 April 2019* |
| | | | | Chickens for fattening | | 280 TXT<br>125 TGU | | | |
| | | | | Laying hens | | 560 TXT<br>250 TGU | | | |
| | | | | Turkeys for fattening | | 560 TXT<br>250 TGU | | | |
| | | | | Ducks for fattening | | 280 TXT<br>125 TGU | | | |

[1] 1 TXU is the amount of enzyme which liberates 5 micromoles of reducing sugars (xylose equivalents) from wheat arabino-xylan per minute at pH 3,5 and 40 °C.
[2] 1 TGU is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley ß-glucan per minute at pH 3,5 and 40 °C.
[3] Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives