

**COMMISSION IMPLEMENTING REGULATION (EU) 2016/997****of 21 June 2016**

**concerning the authorisation of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase EC 3.2.1.6 produced by *Trichoderma reesei* (ATCC SD 2106) as a feed additive for lactating sows and minor porcine species (holder of authorisation Danisco (UK) Ltd)**

**(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 <sup>(1)</sup>, 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 endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase EC 3.2.1.6 produced by *Trichoderma reesei* (ATCC SD 2106). 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 endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase EC 3.2.1.6 produced by *Trichoderma reesei* (ATCC SD 2106) as a feed additive for lactating sows (including minor porcine species) and minor porcine species for weaning and fattening, to be classified in the additive category 'zootechnical additives'.
- (4) The additive was already authorised for use in poultry, weaned piglets and pigs for fattening by Commission Regulation (EU) No 337/2011 <sup>(2)</sup>.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 3 December 2015 <sup>(3)</sup> that, under the proposed conditions of use, endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase EC 3.2.1.6 produced by *Trichoderma reesei* (ATCC SD 2106) does not have an adverse effect on animal health, human health or the environment, and that it is efficacious for lactating sows and minor porcine species at the recommended dose. 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.
- (6) The assessment of the preparation of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase EC 3.2.1.6 produced by *Trichoderma reesei* (ATCC SD 2106) 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.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Regulation (EU) No 337/2011 of 7 April 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase as feed additive for poultry, weaned piglets and pigs for fattening (holder of the authorisation Danisco Animal Nutrition) (OJ L 94, 8.4.2011, p. 19).

<sup>(3)</sup> EFSA Journal 2016;14(1):4350.

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, 21 June 2016.

*For the Commission*

*The President*

Jean-Claude JUNKER

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| 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 active substance/kg of complete feedingstuff with a moisture content of 12 % |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
| Category: Zootechnical additives. Functional group: digestibility enhancers |                                                                                                                                                      |                            |                                                                                                                                                                                                                                                                                     |                                                |             |                                                                                       |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
| 4a15                                                                        | Danisco (UK) Ltd                                                                                                                                     | Endo-1,4-beta-xylanase     | Additive composition                                                                                                                                                                                                                                                                | Lactating sows                                 | —           | Endo-1,4-beta-xylanase                                                                | —               | 1. In the directions for use of the additive and pre-mixture, indicate the storage conditions and stability to heating treatment.<br><br>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment. | 12 July 2026                   |
|                                                                             |                                                                                                                                                      | EC 3.2.1.8                 | Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase produced by <i>Trichoderma reesei</i> (ATCC SD 2106) having respectively a minimum activity of 12 200 U <sup>(1)</sup> /g and 1 520 U <sup>(2)</sup> /g. | (including minor porcine species)              |             | 1 220 U                                                                               |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
|                                                                             |                                                                                                                                                      | Endo-1,3(4)-beta-glucanase |                                                                                                                                                                                                                                                                                     |                                                |             | Endo-1,3(4)-beta-glucanase                                                            |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
|                                                                             |                                                                                                                                                      | EC 3.2.1.6                 |                                                                                                                                                                                                                                                                                     |                                                |             | 152 U                                                                                 |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
|                                                                             |                                                                                                                                                      |                            | Solid and liquid form.                                                                                                                                                                                                                                                              | Minor porcine species weaned and for fattening |             | Endo-1,4-beta-xylanase                                                                |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
|                                                                             |                                                                                                                                                      |                            | Characterisation of the active substance                                                                                                                                                                                                                                            |                                                |             | 610 U                                                                                 |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
|                                                                             |                                                                                                                                                      |                            | Endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase produced by <i>Trichoderma reesei</i> (ATCC SD 2106).                                                                                                                   |                                                |             | Endo-1,3(4)-beta-glucanase                                                            |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
|                                                                             | Analytical methods <sup>(3)</sup>                                                                                                                    |                            | 76 U                                                                                                                                                                                                                                                                                |                                                |             |                                                                                       |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
|                                                                             | Characterisation of the active substance in the additive, premixtures and feedingstuffs:                                                             |                            |                                                                                                                                                                                                                                                                                     |                                                |             |                                                                                       |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
|                                                                             | — colorimetric method measuring water soluble dye released by action of endo-1,4-β-xylanase from azurine cross-linked wheat arabinoxylan substrates; |                            |                                                                                                                                                                                                                                                                                     |                                                |             |                                                                                       |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |

| Identifica-<br>tion<br>number of<br>the additive | Name of<br>the holder<br>of authoris-<br>ation | Additive | Composition, chemical formula,<br>description, analytical method                                                                                                      | Species or cat-<br>egory of animal | Maximum<br>age | Minimum<br>content                                                                          | Maximum<br>content | Other provisions | End of<br>period of<br>authoris-<br>ation |
|--------------------------------------------------|------------------------------------------------|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------|---------------------------------------------------------------------------------------------|--------------------|------------------|-------------------------------------------|
|                                                  |                                                |          |                                                                                                                                                                       |                                    |                | Units of active substance/kg of<br>complete feedingstuff with a<br>moisture content of 12 % |                    |                  |                                           |
|                                                  |                                                |          | — colorimetric method measuring<br>water soluble dye released by<br>action of endo-1,3(4)-β-gluca-<br>nase from azurine cross-linked<br>barley β — glucan substrates. |                                    |                |                                                                                             |                    |                  |                                           |

<sup>(1)</sup> 1 U is the amount of enzyme which releases 0,48  $\mu$ mol of reducing sugar (xylose equivalent) per minute from wheat arabino xylan at pH 4,2 and 50 °C.

<sup>(2)</sup> 1 U is the amount of enzyme which releases 2,4  $\mu$ mol of reducing sugar (glucose equivalent) per minute from glucan of barley at pH 5,0 and 50 °C.

<sup>(3)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>