

Commission Implementing Regulation (EU) 2018/1569 of 18 October 2018 amending Implementing Regulation (EU) No 1110/2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for laying hens, minor poultry species and pigs for fattening (holder of authorisation Roal Oy) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1569

of 18 October 2018

amending Implementing Regulation (EU) No 1110/2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for laying hens, minor poultry species and pigs for fattening (holder of 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<sup>(1)</sup>, and in particular Article 13(3) 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) The use of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) was authorised as a feed additive for laying hens, minor poultry species and pigs for fattening by Commission Implementing Regulation (EC) No 1110/2011<sup>(2)</sup>.
- (3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed to modify the minimum content of the additive for laying hens and pigs for fattening. The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (hereinafter ‘the Authority’).
- (4) The Authority concluded in its opinions of 6 March 2018<sup>(3)</sup> that, the reduction of minimum content from 24 000 BXU to 12 000 BXU for laying hens and from 24 000 BXU to 20 000 BXU for pigs for fattening does not have an adverse effect on animal health, human health or the environment and the new proposed doses are efficacious for the target species.
- (5) The assessment of the new proposed doses shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.
- (6) Implementing Regulation (EU) No 1110/2011 should therefore be amended accordingly.

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**Changes to legislation:** Commission Implementing Regulation (EU) 2018/1569 is up to date with all changes known to be in force on or before 10 December 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

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- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Implementing Regulation (EU) No 1110/2011 is replaced by the text set out in the Annex to this Regulation.

*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, 18 October 2018.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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## ANNEX

ANNEX 1 BXU is the amount of enzyme which liberates 1 nmol reducing sugars as xylose from birch xylan per second at pH 5,3 and 50 °C. 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> 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. 4a8 Roal Oy Endo-1,4-beta-xylanase EC 3.2.1.8 Additive composition Preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) having a minimum activity of:

solid form:  $4 \times 10^6$  BXU<sup>a</sup>/g

liquid form:  $4 \times 10^5$  BXU/g

Characterisation of the active substance

endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044)

Analytical method

In the additive and the premixture: reducing sugar assay for endo-1,4- beta-xylanase by colorimetric reaction of dinitrosalicylic acid reagent on reducing sugar yield at pH 5,3 and 50 °C

In the feedingstuffs: colorimetric method measuring water soluble dye released by the enzyme from azurine crosslinked wheat arabinoxylan substrate

Minor poultry species other than laying birds—8 000 BXU—1.

In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.

2.

For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks to 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.

24 November 2021 Laying hens 12 000 BXU Laying birds of minor poultry species 24 000 BXU Pigs for fattening 20 000 BXU

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- (1) [OJ L 268, 18.10.2003, p. 29.](#)
- (2) Commission Implementing Regulation (EU) No 1110/2011 of 3 November 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for laying hens, minor poultry species and pigs for fattening (holder of authorisation Roal Oy) ([OJ L 287, 4.11.2011, p. 27](#)).
- (3) *EFSA Journal 2018*; 16(3):5216 and *EFSA Journal 2018*; 16(3):5217.

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**Changes and effects yet to be applied to :**

- Regulation revoked by [S.S.I. 2023/339 Sch. 14 para. 10](#)
- Regulation revoked by [S.I. 2023/1196 Sch. 14 Pt. 1](#)