

Brussels, XXX SANCO/10431/2018 CIS (POOL/E5/2018/10431/10431-EN CIS.doc) [...](2018) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) No .../..

of XXX

[...]

(Text with EEA relevance)

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COMMISSION IMPLEMENTING REGULATION (EU) .../..

of XXX

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 nutrition¹, 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 1110/2011².
- (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 applications were 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 2018³ 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.

³ EFSA Journal 2018; 16(3):5216 and EFSA Journal 2018; 16(3):5217.

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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).

(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,

For the Commission The President Jean-Claude JUNCKER