



EUROPEAN
COMMISSION

Brussels, XXX
SANTE/8279090/2022 CIS
G5/2022/8279090/8279090-EN
CIS.docx)
[...] (2022) XXX draft

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

of XXX

**concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by
Komagataella phaffii ATCC PTA-127053 as a feed additive for all laying poultry (holder
of authorisation: Kemin Europa N.V.)**

(Text with EEA relevance)

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(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 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 a preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053. The 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 a preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 as a feed additive for all laying poultry, to be classified in the additive category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’.
- (4) The European Food Safety Authority (‘the Authority’) concluded, in its opinion of 29 June 2022², that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 did not have an adverse effect on consumer safety or the environment. As regard the target species, the Authority concluded that the additive is safe and has the potential to be efficacious for laying hens when added to feed at 45,000 U/kg and that the conclusions on laying hens can be extrapolated to all laying poultry species.
- (5) The Authority concluded that that additive was not irritant to eyes and skin but was considered a dermal and respiratory sensitiser.
- (6) The Authority considered that there was no need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed.

¹ OJ L 268, 18.10.2003, p. 29.

² EFSA Journal 2022;20(7):7439.

additive in feed, submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (7) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 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. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (8) 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 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,

For the Commission
The President
Ursula VON DER LEYEN