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

of **XXX**

concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469 as a feed additive for chickens for laying or breeding, turkeys for breeding, minor poultry species for fattening and minor poultry species for laying or breeding (holder of authorisation: Kaesler Nutrition GmbH) and amending Implementing Regulation (EU) 2018/1090 as regards the terms of the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469 as a feed additive for chickens for fattening and chickens reared for laying

(Text with EEA relevance)

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

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concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469 as a feed additive for chickens for laying or breeding, turkeys for breeding, minor poultry species for fattening and minor poultry species for laying or breeding (holder of authorisation: Kaesler Nutrition GmbH) and amending Implementing Regulation (EU) 2018/1090 as regards the terms of the authorisation of the preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469 as a feed additive for chickens for fattening and chickens reared for laying

(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) and 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 an authorisation.
- (2) A preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* (previously allocated to the species *Komagataella pastoris*) DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* (previously allocated to the species *Komagataella pastoris*) DSM 26469 was authorised for a period of 10 years as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, all avian species reared for laying or for breeding purposes, weaned piglets and minor porcine species (weaned) by Commission Implementing Regulation (EU) 2018/1090².
- (3) 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 with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469. That application was accompanied by the

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² Commission Implementing Regulation (EU) 2018/1090 of 31 July 2018 concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Komagataella pastoris* (CBS 25376) and *Komagataella pastoris* (CBS 26469) as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, all avian species reared for laying or for breeding purposes, weaned piglets and minor porcine species (weaned) (holder of the authorisation Kaesler Nutrition GmbH) (OJ L 195, 01/08/2018, p. 23, ELI: http://data.europa.eu/eli/reg_impl/2018/1090/oj).

particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

- (4) The application concerns the authorisation of the preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469 as a feed additive for chickens for laying or breeding, turkeys for breeding, minor poultry species for fattening and minor poultry species for laying or breeding, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'.
- (5) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, an application was submitted for the modification of the terms of the authorisation of the preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469 as regards the use for chickens for fattening and chickens reared for laying. That application concerns the modification of the terms of the existing authorisation by reduction of the minimum recommended use level from 4250 xylanase enzyme activity (LXU) and 375 glucanase enzyme activity (LGU)/kg complete feed to 1400 LXU and 120 LGU/kg complete feed.
- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 18 March 2025³ that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469 is safe for all poultry, as well as for consumers and the environment. The Authority also concluded that the preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469, in either formulation is not a skin or eye irritant or a dermal sensitiser but is considered a respiratory sensitiser. The Authority further concluded that the preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469 has the potential to be efficacious in all poultry at 1400/120 LXU/LGU per kg complete feed. It did not consider that there is a need for specific requirements of post-market monitoring.
- (7) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning another application for the authorisation of the same additive and verified by the Authority in its opinion of 30 November 2017⁴ are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁵, an evaluation report of the Reference Laboratory was therefore not required.
- (8) In view of the above, the Commission considers that the preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-

³ EFSA Journal. 2025;23:e9344. <https://doi.org/10.2903/j.efsa.2025.9344>

⁴ EFSA Journal 2017;15(12):5097. <https://doi.org/10.2903/j.efsa.2017.5097>

⁵ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

glucanase produced with *Komagataella phaffii* DSM 26469 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for chickens for laying or breeding, turkeys for breeding, minor poultry species for fattening and minor poultry species for laying or breeding. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

- (9) In addition, in view of the above, the Commission considers that the authorisation of the preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469 still meets the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 when modifying the terms thereof as regards the use for chickens for fattening and chickens reared for laying, by reduction of the minimum recommended use level from 4250 xylanase enzyme activity (LXU) and 375 glucanase enzyme activity (LGU)/kg complete feed to 1400 LXU and 120 LGU/kg complete feed. Implementing Regulation (EU) 2018/1090 should therefore be amended accordingly.
- (10) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469 for chickens for fattening and chickens reared for laying, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the modification of the authorisation concerned.
- (11) 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

Authorisation

The preparation specified in Annex I, 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

Amendment to Implementing Regulation (EU) 2018/1090

The Annex to Implementing Regulation (EU) 2018/1090 is replaced by the Annex II to this Regulation.

Article 3

Transitional measures

1. The feed additive endo-1,4-beta-xylanase produced with *Komagataella phaffii* DSM 25376 and endo-1,3(4)-beta-glucanase produced with *Komagataella phaffii* DSM 26469, as authorised by Implementing Regulation 2018/1090 and premixtures containing that additive, which are intended for chickens for fattening and chickens reared for laying, and which are produced and labelled before [6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service

responsible for the publication] may continue to be placed on the market and used until the stocks concerned are exhausted.

2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are intended for chickens for fattening and chickens reared for laying, and which are produced and labelled before [*12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the stocks concerned are exhausted.

Article 4

Entry into force

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