SCIENTIFIC OPINION

efsa JOURNAL

ADOPTED: 11 May 2023

doi: 10.2903/j.efsa.2023.8047

Efficacy of a feed additive consisting of endo-1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 (Xygest™ HT) for all poultry species (Kemin Europa N.V.)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the efficacy of endo-1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 (Xygest™ HT) as a zootechnical feed additive (functional group: digestibility enhancers) for all poultry. In a previous opinion, the FEEDAP Panel concluded that Xygest™ HT is safe for all poultry, consumers, and the environment. The additive is not considered to be irritant to eyes and skin but a dermal and a respiratory sensitiser, although exposure by inhalation is unlikely. The Panel also concluded that the additive has the potential to be efficacious in laying hens at 45,000 U/kg complete feed and this conclusion was extrapolated to all laying poultry. However, the Panel could not conclude on the efficacy of the product in growing poultry at the proposed conditions of use. In the current application, the applicant provided an additional efficacy trial in chickens for fattening. The results showed a higher apparent metabolisable energy (nitrogen corrected) in chickens fed the additive at the minimum proposed level of 30,000 U/kg complete feed when compared to the control group. Considering the previously submitted studies in laying hens and chickens for fattening, and the newly submitted study in chickens for fattening, the Panel concluded that Xygest™ HT has the potential to be efficacious to enhance digestibility in all poultry at the corresponding proposed minimum levels in feed.

Keywords: zootechnical additives, digestibility enhancers, Xygest HT, endo-1,4-beta-xylanase, *K. phaffii* ATCC PTA-127053, poultry, efficacy

Requestor: European Commission

Question number: EFSA-Q-2022-00807

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Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

Acknowledgements: The Panel wishes to thank the following for the support provided to this scientific output (in alphabetical order of the last name): Daniel Pagés Plaza, Montserrat Anguita and the FEEDAP WG Panel on Animal Nutrition.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Durjava M, Dusemund B, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R and Ortuño Casanova J, 2023. Scientific opinion on the efficacy of a feed additive consisting of endo-1,4-beta-xylanase produced by *Komagataella phaffii* ATCC PTA-127053 (Xygest™ HT) for all poultry species (Kemin Europa N.V.). EFSA Journal 2023;21(6):8047, 7 pp. https://doi.org/10.2903/j.efsa.2023.8047

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant Kemin Europa N.V.,[2] is seeking a Community authorisation of endo-1,4-beta-xylanase (EC 3.2.1.8), as a feed additive to be used as a digestibility enhancer for chickens for fattening. (Table 1).

Table 1: Description of the substances

Category of additive	Zootechnical additives
Functional group of additive	Digestibility enhancer
Description	endo-1,4-beta-xylanase
Target animal category	Chickens for fattening
Applicant	Kemin Europa N.V.
Type of request	New opinion

On 29 June 2022[3], the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA), in its opinion on the safety and efficacy of the product, could not conclude on the efficacy for poultry.

The Commission gave the possibility to the applicant to submit supplementary information and data in order to complete the assessment and to allow a revision of the EFSA's opinion. The new data have been received on 15 November 2022 and the applicant has been requested to transmit them to EFSA as well.

In view of the above, the Commission asks EFSA to deliver a new opinion on the efficacy of endo-1,4-beta-xylanase (EC 3.2.1.8) as a feed additive for poultry, based on the supplementary data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

1.2. Additional information

The additive contains endo-1,4-beta-xylanase which is produced by a genetically modified strain of *Komagataella phaffii* ATCC PTA-127053 (Xygest™ HT) and it is intended to be used as a digestibility enhancer for all poultry species. The additive is currently authorised in all laying poultry[4] (4a36).

The FEEDAP Panel assessed the safety and the efficacy of endo-1,4-beta-xylanase in poultry (EFSA FEEDAP Panel, 2022). The Panel could not conclude on the efficacy of the additive in chickens for fattening. The applicant provided a new study to complement the previous assessment.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[5] to a previous application for the same product.[6]

In accordance with Article 38 of the Regulation (EC) No 178/2002[7] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Kemin Europa N.V., Toekomstlaan 42, 2020 Herentals, Belgium.
[3] It is noted that the adoption date was 29 June 202
[4] COMMISSION IMPLEMENTING REGULATION (EU) 2023/668 of 22 March 2023 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.).
[5] Dossier reference: EFSA-Q-2022-00807.
[6] Dossier reference: FAD-2020-0110.
[7] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[8] a non-confidential version of the supplementary information has been published on https://open.efsa.europa.eu/questions/EFSA-Q-2022-00807.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of endo-1,4-beta-xylanase (EC 3.2.1.8) is in line with the principles laid down in Regulation (EC) No 429/2008[9] and the relevant guidance documents: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3. Assessment

The additive under assessment (hereafter referred to as Xygest™ HT) is a product containing endo-1,4-beta-xylanase (IUBMB EC 3.2.1.8; xylanase) produced by a genetically modified strain of *K. phaffii* (ATCC PTA-127053) and it is intended to be used as a zootechnical additive (functional group: digestibility enhancers) for all poultry species.

Xygest™ HT ensures a guaranteed minimum endo-1,4-beta-xylanase activity of 3,000,000 U[10]/g of product and it is intended for use at a proposed minimum level of 30,000 U/kg complete feed for all poultry for fattening or reared for laying/breeding and at 45,000 U/kg complete feed for poultry for laying/breeding.

In the previous opinion (EFSA FEEDAP Panel, 2022), the FEEDAP Panel concluded that the additive is safe for the target species, consumer, and environment. Regarding the users, the additive is considered not to be irritant to eyes and skin but is considered a dermal sensitiser and a respiratory sensitiser, although exposure by inhalation is unlikely. The Panel also concluded that the additive has the potential to be efficacious in laying hens when added to feed at 45,000 U/kg feed and this conclusion was extrapolated to all laying poultry. However, the data provided were not sufficient to conclude on the efficacy of the additive in chickens for fattening and consequently in other poultry species for fattening/reared for laying or breeding.

3.1. Efficacy for all poultry species

In the previous assessment (EFSA FEEDAP Panel, 2022), five efficacy studies in laying hens and four studies in chickens for fattening were submitted to support the efficacy of the additive in all poultry species. Four of the five studies in laying hens showed positive effects allowing to conclude on its potential to be efficacious. Regarding the studies in chickens for fattening, only two studies were considered by the Panel and the two showed a positive effect on the zootechnical parameters at the minimum proposed level of 30,000 endo-1,4-beta-xylanase U/kg complete feed. In the absence of a third study with positive effects, the Panel could not conclude on the efficacy of the additive in chickens for fattening and consequently could not conclude on the efficacy in other poultry species for fattening/reared for laying or breeding.

The applicant has now submitted a balance trial in chickens for fattening to complement the previous assessment.[11]

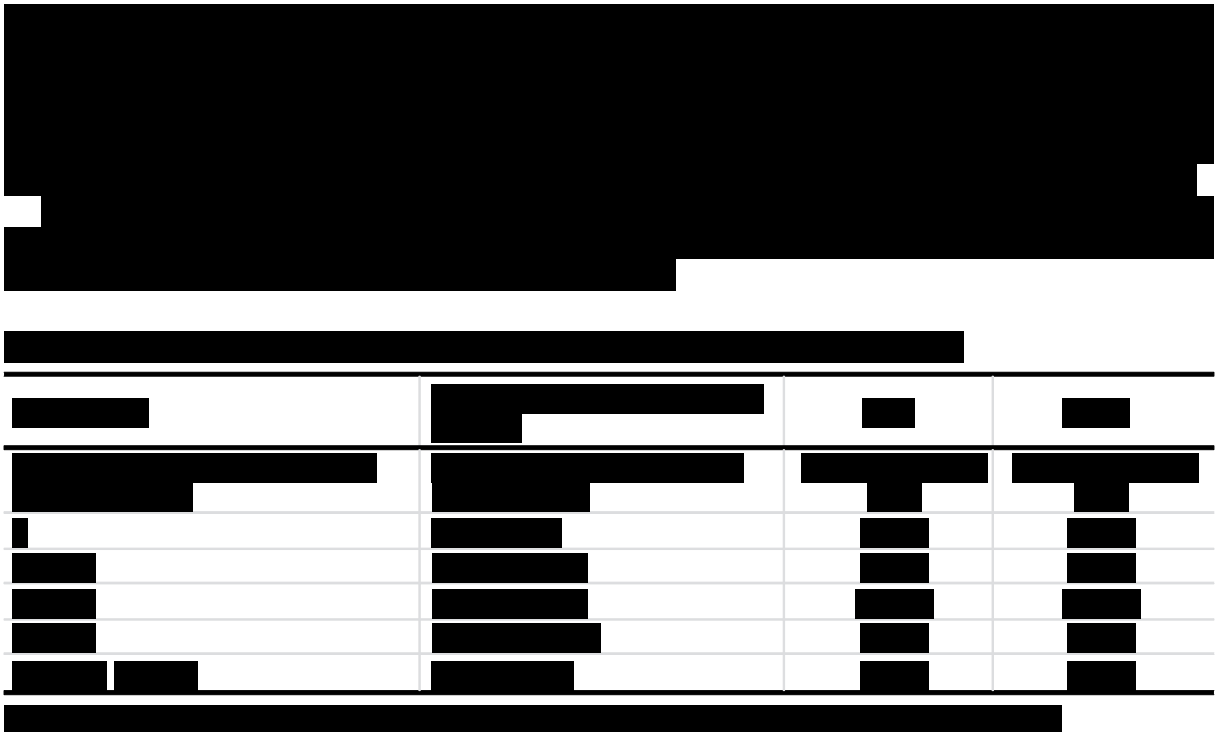
[redacted]

[8] Decision available online: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

[9] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

[10] One unit is the amount of enzyme that releases 0.0067 micromoles of reducing sugar (xylose equivalent) per minute and per gram of enzyme product at 50°C and pH 5.3.

[11] 'Annex 2. Study Report'.



3.1.1. Conclusions on efficacy

In the previous opinion, the Panel concluded that Xygest™ HT had the potential to be efficacious in laying hens at the proposed minimum level of 45,000 endo-1,4-beta-xylanase U/kg complete feed (EFSA FEEDAP Panel, 2022). In that opinion, two studies in chickens for fattening showed improvements on the zootechnical performance of chickens for fattening when the additive was added in feed to provide 30,000 endo-1,4-beta-xylanase U/kg complete feed. In the current assessment, a third study showed an improvement on the AME and AMEn of the diets when the birds were fed the additive at 30,000 U/kg complete feed. Therefore, the additive has the potential to be efficacious in chickens for fattening at 30,000 U/kg feed.

Considering all the data made available by the applicant, the FEEDAP Panel concludes that the additive is efficacious as a digestibility enhancer for all poultry species; the minimum efficacious level for poultry species for fattening or reared for laying/breeding is 30,000 U/kg complete feed, and for poultry species for laying/breeding is 45,000 U/kg complete feed.

4. Conclusions

The Panel concludes that Xygest™ HT has the potential to be efficacious as a digestibility enhancer in all poultry species for fattening and reared for laying/breeding at 30,000 U/kg complete feed, and in all poultry species for laying/breeding at 45,000 U/kg complete feed.

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Abbreviations

AME	apparent metabolisable energy
AMEn	Nitrogen corrected AME
ANOVA	analysis of variance
ATCC	American Type Culture Collection
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
IUBMB	International Union of Biochemistry and Molecular Biology