

ADOPTED: 21 February 2018

doi: 10.2903/j.efsa.2018.5203

Safety and efficacy of 3-phytase FLF1000 as a feed additive for chickens reared for laying and minor poultry species

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP),
Guido Rychen, Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis,
Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli,
Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Marta López-Alonso,
Secundino López Puente, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Maria Saarela,
Roberto Edoardo Villa, Robert John Wallace, Pieter Wester, Paul Brantom, Noël Albert Dierick
and Montserrat Anguita

Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of 3-phytase FLF1000 as a feed additive for chickens reared for laying and minor poultry species. Safety aspects regarding the use of this additive in feed including the safety for the consumer, for the users and for the environment have been previously evaluated by EFSA. The FEEDAP Panel considered that the new use requested by the applicant would not modify those conclusions. In the previous assessment, the Panel evaluated the safety and efficacy for chickens for fattening and laying hens. In the current evaluation, no new studies were submitted to support the safety and the efficacy in new species/categories. Therefore, the data on the tolerance and efficacy in major species previously evaluated was taken into consideration for this assessment. The results of the tolerance trial in chickens for fattening previously evaluated showed that chickens tolerated well 10-fold the maximum recommended dose. The Panel extended the conclusion reached in chickens for fattening to chickens reared for laying and extrapolated it to minor poultry species for fattening purposes or reared for laying/breeding. In the previous assessment, the FEEDAP Panel concluded that the additive has a potential to be efficacious in chickens for fattening at 500 FTU/kg feed. The Panel extended the conclusion on the efficacy in chickens for fattening to chickens reared for laying and extrapolated it to minor poultry species for fattening purposes or reared for laying/breeding.

© 2018 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: zootechnical additives, digestibility enhancers, substance which favourably affect the environment, safety, efficacy, 3-phytase, poultry

Requestor: European Commission

Question number: EFSA-Q-2017-00387

Correspondence: feedap@efsa.europa.eu

Panel members: Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester.

Acknowledgements: The EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed) wishes to thank the following for the support provided to this scientific output: Jaume Galobart, Gloria López-Gálvez and Maria Vittoria Vettori.

Suggested citation: EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Brantom P, Dierick NA and Anguita M, 2018. Scientific Opinion on the safety and efficacy of 3-phytase FLF1000 as a feed additive for chickens reared for laying and minor poultry species. *EFSA Journal* 2018;16(3):5203, 6 pp. <https://doi.org/10.2903/j.efsa.2018.5203>

ISSN: 1831-4732

© 2018 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs License](https://creativecommons.org/licenses/by/4.0/), which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.



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



Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference.....	4
1.2. Additional information.....	4
2. Data and methodologies.....	4
2.1. Data.....	4
2.2. Methodologies.....	5
3. Assessment.....	5
3.1. Characterisation.....	5
3.2. Safety.....	5
3.3. Efficacy for target species.....	5
3.4. Post-market monitoring.....	6
4. Conclusions.....	6
Documentation provided to EFSA.....	6
References.....	6
Abbreviation.....	6

1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Fertinagro Nutrientes S.L.² for authorisation of the product 3-phytase FLF1000 (3-phytase), when used as a feed additive for chickens reared for laying and minor poultry species (ducks, goose, pheasants) (category: zootechnical additives; functional groups: digestibility enhancers and substance which favourably affect the environment).³

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 27 October 2017.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product 3-phytase FLF1000 (3-phytase), when used under the proposed conditions of use (see Section 3.1).

1.2. Additional information

The additive 3-phytase FLF1000 contains 3-phytase (Enzyme Commission number 3.2.1.8) produced by a genetically modified strain of *Komagataella pastoris* (CECT 13094) and is authorised as a feed additive for chickens for fattening and laying hens.⁴

The FEEDAP Panel adopted an opinion on the safety and efficacy of the product as a feed additive for chickens for fattening and laying hens (EFSA FEEDAP Panel, 2016). The applicant is now requesting for an extension of the use of the additive to chickens reared for laying and minor poultry species (excluding minor poultry species for laying/breeding).

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁵ in support of the authorisation request for the new use of 3-phytase FLF1000 as a feed additive. The technical dossier was prepared following the provisions of Article 7 of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008⁶ and the applicable EFSA guidance documents.

The European Union Reference Laboratory considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.⁷

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

² Fertinagro Nutrientes S.L., Pol. Ind. La Paz parcela 185, 44195 Teruel, Spain.

³ During the risk assessment the applicant expressed the will to modify the application in order to exclude minor poultry species for laying/breeding purposes.

⁴ Commission implementing Regulation (EU) 2017/895 of 24 May 2017 concerning the authorisation of a preparation of 3-phytase produced by *Komagataella pastoris* (CECT 13094) as a feed additive for chickens for fattening and laying hens (holder of authorisation Fertinagro 0014 SL). OJ L 138, 25.5.2017, p. 120.

⁵ FEED dossier reference: FAD-2017-0014.

⁶ 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.

⁷ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/finirep-fad-2015-0026-preparation-3phytase.pdf>

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of 3-phytase FLF1000 is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012) and Technical Guidance: Extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition (EFSA, 2008).

3. Assessment

This assessment deals with a request from the applicant to extend the use of the additive 3-phytase FLF1000 to chickens reared for laying and minor poultry species (except minor poultry species for laying/breeding).

3.1. Characterisation

The additive was characterised in full in a previous assessment (EFSA FEEDAP Panel, 2016). The additive is presented in liquid form and contains 3-phytase (Enzyme Commission number 3.2.1.8) produced by a genetically modified strain of *K. pastoris* (CECT 13094) and has a minimum phytase activity of 1,000 FTU/mL. It is proposed to be used in chickens reared for laying and minor poultry species for fattening or reared for laying at a minimum level of 500 FTU/kg and a maximum dose of 1,000 FTU/kg feed.

3.2. Safety

Safety aspects regarding the use of this additive in feed including the safety for the consumer, for the users and for the environment have been previously evaluated (EFSA FEEDAP Panel, 2016). The FEEDAP Panel concluded that there were no concerns for the consumer safety and no risks for the environment were expected. Regarding the safety for the user, it was concluded that the additive was not irritant to eyes and skin and was not a dermal sensitiser; however, it should be considered a potential respiratory sensitiser.

The Panel is not aware of any new information that would lead it to reconsider the conclusions on the safety for the consumers, the users and the environment drawn previously. Moreover, the FEEDAP Panel considers that the above conclusions can be applied to the new use of the additive requested by the applicant.

Regarding the safety in the target species, no trials in the new target species/categories have been provided. In the previous assessment the FEEDAP Panel evaluated the safety for chickens for fattening, and the results of the tolerance trial in chickens for fattening showed that chickens tolerated well 10-fold the maximum recommended dose.

The Panel considers that the conclusion on the tolerance for chickens for fattening can be extended to chickens reared for laying. Taking into consideration the margin of safety established in the chickens for fattening, the Panel extrapolates the conclusions to minor poultry species for fattening purposes or reared for laying/breeding.

3.3. Efficacy for target species

Regarding the efficacy in the target species, no trials in the new target species/categories have been provided. Therefore, the conclusion will be based on the data from major species evaluated in the previous assessment (EFSA FEEDAP Panel, 2016). In that opinion, the FEEDAP Panel concluded that the additive had a potential to improve the phosphorus retention in chickens for fattening at a minimum dose of 500 FTU/kg feed. The Panel considers that the conclusion drawn in chickens for fattening can be extended to chickens reared for laying. The mode of action of a phytase is well-known and can reasonably be assumed to be the same in poultry species; therefore, the conclusion in the chickens for fattening can be extrapolated to minor poultry species for fattening purposes or reared for laying/breeding.

3.4. Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation⁸ and Good Manufacturing Practice.

4. Conclusions

The use of the product as a feed additive raises no concerns for the consumer safety nor for the environment. The additive should be regarded as a potential respiratory sensitiser.

The additive is considered safe for chickens reared for laying and minor poultry species for fattening or reared for laying/breeding.

The additive is considered to have a potential to be efficacious for chickens reared for laying and for minor poultry species for fattening or reared for laying/breeding at the minimum proposed dose of 500 FTU/kg.

Documentation provided to EFSA

- 1) Preparation of 3-phytase produced by *Komagataella pastoris* (CECT 13094), a zootechnical additives additive for chickens reared for laying and minor poultry species. March 2017. Submitted by Fertinagro Nutrientes S.L.
- 2) Preparation of 3-phytase produced by *Komagataella pastoris* (CECT 13094), a zootechnical additives additive for chickens reared for laying and minor poultry species. Supplementary information. January 2018. Submitted by Submitted by Fertinagro Nutrientes S.L.
- 3) Comments from Member States.

References

- EFSA (European Food Safety Authority), 2008. Technical Guidance: extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition. EFSA Journal 2008;6(9):803, 5 pp. <https://doi.org/10.2903/j.efsa.2008.803>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Guidance for the preparation of dossiers for zootechnical additives. EFSA Journal 2012;10(1):2536, 19 pp. <https://doi.org/10.2903/j.efsa.2012.2536>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Flachowsky G, Gropp J, Kolar B, Kouba M, López Puente S, López-Alonso M, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Brantom P, Dierick N, Herman L, Glandorf B, Kärenlampi S, Aguilera J, Anguita M and Cocconcelli PS, 2016. Scientific opinion on the safety and efficacy of 3-phytase FLF1000 as feed additive for chickens for fattening and laying hens. EFSA Journal 2016;14(11):4622, 15 pp. <https://doi.org/10.2903/j.efsa.2016.4622>

Abbreviation

FEEDAP EFSA Panel on Additives and Products or Substances used in Animal Feed

⁸ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 268, 8.2.2005, p. 1.