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Safety and efficacy of 3-phytase FSF10000 as a feed additive for chickens for fattening or reared for laying, laying hens and minor poultry species

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Abstract

The additive 3-phytase FSF10000 is a solid product that contains a 3-phytase produced by a genetically modified strain of *Komagataella phaffii*. A liquid formulation of the additive has been previously assessed by the EFSA Panel on Additives and Products of Substances used in Animal Feed (FEEDAP) and is currently authorised as a feed additive for poultry species. The applicant requested for the use of this new formulation of the additive in chickens for fattening or reared for laying/breeding, laying hens and minor poultry species for fattening or reared for laying/breeding. Therefore, in this assessment, the new formulation of the product has been characterised and its safety and efficacy has been evaluated. The production strain and its DNA were not detected in the solid formulation. Therefore, the additive poses no concerns with regard to the genetic modification of the production strain. The Panel concluded, based on studies conducted with the liquid formulation, that the additive 3-phytase FSF10000 is safe for the target species at 1,000 FTU/kg feed. Also, considering the production strain and composition of the final additive the Panel concluded that the additive raises no safety concerns for the consumer of products obtained from animals fed the additive or for the environment. The additive 3-phytase FSF10000 is not irritant to skin and eyes but it is a skin dermal sensitiser and is considered to be a respiratory sensitiser. Based on studies conducted with the liquid formulation, the Panel concluded that the 3-phytase FSF10000 has a potential to be efficacious in chickens for fattening or reared for laying and in minor poultry species for fattening or reared for laying/breeding at 500 FTU/kg feed and in laying hens at 1,000 FTU/kg feed.

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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 FSF10000 (3-phytase), when used as a feed additive for chickens for fattening or reared for laying, laying hens, minor poultry species, pigs for fattening and minor porcine species for growing (category: zootechnical additives; functional group: digestibility enhancers, substances 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 19 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 FSF10000 (3-phytase), when used under the proposed conditions of use (see Section 3.1.5).

1.2. Additional information

The additive 3-phytase FSF10000 is a solid formulation that contains 3-phytase (Enzyme Commission number 3.2.1.8) produced by a genetically modified strain of *Komagataella phaffii*⁴ (CECT 13094). The same enzyme is present in a liquid formulation 3-phytase FLF1000 which is authorised as a feed additive for chickens for fattening and laying hens.⁵

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) and another one on the use of the product as a feed additive for chickens reared for laying and minor poultry species (EFSA FEEDAP Panel 2018). The product assessed and authorised is available in liquid form. The applicant has now requested to evaluate a new formulation of the additive.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁶ in support of the authorisation request for the use of 3-phytase FSF10000 as a feed additive.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active substance in animal feed. The Executive Summary of the EURL report can be found in Annex A.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 course of the assessment, the applicant expressed its will to withdraw from this application the following target species: minor poultry species for laying purposes, pigs for fattening and minor porcine species.

⁴ Previously referred as *Komagataella pastoris*.

⁵ 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.

⁶ FEED dossier reference: FAD-2017-0043.

⁷ The full report is available on the EURL website: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of 3-phytase FSF10000 is in line with the principles laid down in Regulation (EC) No 429/2008⁸ 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 for authorisation of a new formulation of the additive 3-phytase FLF1000. The new formulation is solid, 3-phytase FSF10000, and it is to be used in feed for poultry species.

3.1. Characterisation of the additive

3.1.1. Characterisation of the production strain

The additive contains 3-phytase (Enzyme Commission number 3.2.1.8; phytase) produced by a genetically modified strain of *Komagataella phaffii* (CECT 13094, previously identified as *K. pastoris*). The production strain was characterised in full and its safety was evaluated (EFSA FEEDAP Panel, 2016). The species *K. phaffii* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment when used for enzyme production (EFSA BIOHAZ Panel, 2018).

3.1.2. Manufacturing process

The phytase is obtained by submerged aerobic fermentation of the production strain followed by a recovery and downstream processing. The manufacturing of the phytase is the same as the one used for the liquid formulation but it has a further concentration step using a 10-kDa membrane. The resulting product is then mixed with wheat bran, dried and milled.

3.1.3. Characterisation of the solid formulation

The new formulation of the additive is solid and contains protein (1.2%), sodium citrate (5%), wheat bran (90%) and water (2–8%). It ensures a minimum activity of 10,000 FTU⁹/g. The study of the batch to batch variation in five batches showed a mean value of 11,774 FTU/g (range: 11,550–12,009) with a coefficient of variation (CV) of 1.9%.¹⁰ Particle size distribution was measured in three batches of the additive by laser diffraction. Results showed 22% (v/v) of particles < 100 µm, 13% of particles < 50 µm and 3% < 10 µm.¹¹ The dusting potential was measured in two batches of the additive by the International Organization for Standardization (ISO) method 15051 and showed a low dusting potential (45 mg/m³ for inhalable particles and 0.5 mg/m³ for respirable particles).¹² The bulk density of this formulation is 640–656 kg/m³.¹³

Three batches of 3-phytase FSF10000 were analysed for chemical and microbiological contamination.¹⁴ The analyses of chemical contamination included arsenic (< 0.10 mg/kg), cadmium (< 0.039 mg/kg), lead (< 30 mg/kg), mercury (< 0.02 mg/kg), copper (12 mg/kg), zinc (< 70 mg/kg), total chromium (< 30 mg/kg), antimony (< 0.10 mg/kg) and barium (< 8.2 mg/kg). The following mycotoxins were also analysed: aflatoxin B1 (< 0.2 µg/kg), aflatoxin B2 (< 0.2 µg/kg), aflatoxin G1 (< 0.5 µg/kg), aflatoxin G2 (< 0.2 µg/kg), zearalenone (< 50 µg/kg), and fumonisin (< 5 µg/kg). Microbiological analysis included *Salmonella* spp. (absent in 25 g), *Escherichia coli* (< 3 colony forming units (CFU)/g), coliforms (< 3 CFU/g), total aerobic plate counts (< 7 × 10³ CFU/g at 22°C;

⁸ 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.

⁹ 1 FTU is the amount of enzyme which releases one micromole of inorganic phosphate from sodium phytate per minute at pH 5.5 and 37°C.

¹⁰ Technical dossier/Section II/Annex II.2.

¹¹ Technical dossier/Section II/Annex II.4.

¹² Technical dossier/Section II/Annex II.5.

¹³ Technical dossier/Section II/Annex II.6.

¹⁴ Technical dossier/Section II/Annex II.3.

$< 4 \times 10^3$ CFU/g at 37°C), coagulase-positive staphylococci (< 10 CFU/g), yeasts (< 100 CFU/g) and moulds (< 100 CFU/g).

Viable cells of the production strain were not detected in three batches of 3-phytase FSF10000.¹⁵ The analysis included incubation in a non-selective medium at 30°C for 4 h, followed by plating in selective medium and cultivation for 10–15 days at 30°C. A positive control with viable cells of the production strain was also included.

No recombinant DNA was detected in three batches of 3-phytase FSF10000.¹⁶ The samples were analysed in triplicate by polymerase chain reaction (PCR) targeting two different fragments, the method included a lysis step and the limit of detection of the method was verified.

3.1.4. Stability and homogeneity

The shelf-life of 3-phytase FSF10000 was studied in samples of three batches (mean initial activity was 10,934 FTU/g) stored for 6 months at 25°C or 40°C or room temperature (no details).¹⁷ Enzyme recovery after 6 months showed no decreases in the initial activity.

The stability of the solid formulation mixed with either dicalcium phosphate or a complete vitamin/mineral premixture (with choline chloride) was studied in three batches of 3-phytase FSF10000 stored at room temperature for 6 months.¹⁸ After 6 months, the enzyme recovery of the initial enzyme activity ranged from 67% to 86% in the dicalcium phosphate premix and from 81% to 88% in the complete premixture.

Three batches of 3-phytase FSF10000 were added to complete feed for chickens for fattening (based on maize, wheat and soybean meal) to provide 500 FTU/kg. The feeds were pelleted (at 80–85°C). Samples of the feed, mash and pelleted forms, were stored at 25°C or 35°C for 3 months.¹⁹ Recovery after pelleting showed a reduction of a 12% of the initial enzyme activity. No modifications were found on the initial enzyme activity in the mash or pelleted feed stored at 25°C, or in mash feed stored at 35°C. The samples of the pelleted feed stored at 35°C showed a reduction of enzyme activity around 20%.

The mash and the pelleted feeds tested for stability in feed were used to study the capacity of 3-phytase FSF10000 to homogeneously distribute.²⁰ Ten subsamples of each batch were analysed for enzyme activity and the CV was calculated. The CV was $< 6\%$ in mash feed and $< 19\%$ in the pelleted.

3.1.5. Conditions of use

3-Phytase FSF10000 is to be used in feed for chickens for fattening or reared for laying and for minor poultry species for fattening or reared for laying/breeding at the range of 500–1,000 FTU/kg feed and in feed for laying hens at 1,000 FTU/kg feed.

3.2. Safety

Safety aspects regarding the use of the liquid formulation of the additive in feed for poultry species, including the safety aspects of the genetic modification, have been previously evaluated (EFSA FEEDAP Panel, 2016, 2018).

3.2.1. Safety for the target species

No studies have been conducted with 3-phytase FSF10000 to support the safety for the target species. In a previous assessment, tolerance studies done with the liquid formulation of the additive in chickens for fattening and laying hens were evaluated (EFSA FEEDAP Panel, 2016). From the results, the FEEDAP Panel concluded that the use of the liquid formulation is safe for chickens for fattening and laying hens at 1,000 FTU/kg feed. The conclusion was extended/extrapolated, in another assessment (EFSA FEEDAP Panel, 2018), to chickens reared for laying and to minor poultry species for fattening or reared for laying/breeding.

The ingredients used to formulate the solid formulation raise no concerns for the target species. Therefore, the conclusions drawn from studies conducted with the liquid formulation apply to the solid.

¹⁵ Technical dossier/Supplementary information August 2018/Annex 2.

¹⁶ Technical dossier/Supplementary information August 2018/Annex 3.

¹⁷ Technical dossier/Section II/Annex II.16.

¹⁸ Technical dossier/Section II/Annex II.17 and supplementary information August 2018/Annex 4.

¹⁹ Technical dossier/Section II/Annex II.17.

²⁰ Technical dossier/Section II/Annex II.11 and supplementary information June 2016/Annex 7.

Consequently, the FEEDAP Panel concludes that 3-phytase FSF10000 is safe for chickens for fattening, chickens reared for laying, laying hens and minor poultry species for fattening or reared for laying/breeding at 1,000 FTU/kg feed.

3.2.2. Safety for the consumer

The enzyme is produced by a genetically modified strain of *K. phaffii*, which is considered to qualify for the QPS approach to safety assessment used for enzyme production. The identity of the strain was unambiguously established (see Section 3.1.1) and the genetic modification raised no concerns for the consumers. The ingredients used to formulate 3-phytase FSF10000 raise no concerns for the consumers and viable cells of the production strain and its recombinant DNA were not detected in the final additive. Therefore, the FEEDAP Panel concludes that the use of the solid formulation of the additive as a feed additive raises no concerns for the safety of the consumers.

3.2.3. Safety for the user

No specific studies were provided regarding the effects of the additive on the respiratory system. The inhalation exposure is likely to be limited due to the low dusting potential of this formulation. However, owing to the proteinaceous nature of the active substance, the additive is considered as a potential respiratory sensitiser.

The irritant properties of 3-phytase FSF10000 to skin and eyes were evaluated according to Organisation for Economic Co-operation and Development (OECD) test guidelines 439 and 437, respectively.²¹ Based on the results of these studies, the additive is not irritant to eyes or skin.

The skin sensitising potential of 3-phytase FSF10000 was evaluated in guinea pigs following OECD TG 406.²² After induction (intradermal injection with 10% and topical application with 50% test item), the challenge phase consisted in a single topical application of 50% and 25% test item under occlusive dressing for 24 h. From the results of that study, it is concluded that the solid formulation of the additive is a skin sensitiser.

3.2.3.1. Conclusions on safety for the user

3-Phytase FSF10000 is not irritant to eyes and skin but is a dermal sensitiser and should be considered a potential respiratory sensitiser.

3.2.4. Safety for the environment

The production strain and its recombinant DNA were not detected in the solid formulation. The active substance is a protein that will be degraded during the passage through the digestive tract of animals and the ingredients used for the formulation are of no concern for the environment. Consequently, the additive does not raise concerns for the environment.

3.3. Efficacy

Efficacy studies done with the solid formulation under assessment were not submitted. In a previous evaluation (EFSA FEEDAP Panel, 2016), the FEEDAP Panel assessed efficacy studies in chickens for fattening and laying hens fed with the liquid formulation. The FEEDAP Panel concluded that the additive has a potential to be efficacious in chickens for fattening at 500 FTU/kg feed and in laying hens at 1,000 FTU/kg feed. In a second opinion (EFSA FEEDAP Panel, 2018), these conclusions were extended/extrapolated to chickens reared for laying and minor poultry species for fattening (500 FTU/kg feed).

The solid and liquid formulations are considered equivalent in terms of efficacy, consequently, the FEEDAP Panel considers that the conclusions drawn for the liquid formulation apply to the solid.

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 Regulation²³ and Good Manufacturing Practice.

²¹ Technical dossier/Section III/Annex III.4 and III.5.

²² Technical dossier/Section III/Annex III.6.

²³ 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 35, 8.2.2005, p. 1.

4. Conclusions

The production strain and its recombinant DNA were not detected in the additive. Therefore, the additive poses no safety concerns with regard to the genetic modification of the production strain.

The additive 3-phytase FSF10000 is safe for the target species at 1,000 FTU/kg feed.

The additive raises no safety concerns for the consumer of products obtained from animals fed the additive or for the environment.

The additive 3-phytase FSF10000 is not irritant to skin and eyes but it is a skin dermal sensitiser and is considered to be a respiratory sensitiser.

The 3-phytase FSF10000 has a potential to be efficacious in chickens for fattening or reared for laying and in minor poultry species for fattening or reared for laying/breeding at 500 FTU/kg feed and in laying hens at 1,000 FTU/kg feed.

Documentation provided to EFSA

- 1) 3-phytase FSF10000. August 2017. Submitted by Fertinagro Biotech S.L.
- 2) 3-phytase FSF10000. Supplementary information. August 2018. Submitted by Fertinagro Biotech S.L.
- 3) Evaluation report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for a preparation of 3-phytase (FSF10000).
- 4) Comments from Member States.

Chronology

Date	Event
28/8/2017	Dossier received by EFSA
7/9/2017	Reception mandate from the European Commission
19/10/2017	Application validated by EFSA – Start of the scientific assessment
15/3/2017	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: characterisation, safety for target species, efficacy and methods of analysis</i>
19/1/2018	Comments received from Member States
12/7/2018	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
21/8/2018	Reception of supplementary information from the applicant - Scientific assessment re-started
27/11/2018	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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 BIOHAZ Panel (EFSA Panel on Biological Hazards), 2018. Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 7: suitability of taxonomic units notified to EFSA until September 2017. EFSA Journal 2018;16(1):5131, 43 pp. <https://doi.org/10.2903/j.efsa.2018.5131>
- 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), 2016. Scientific Opinion on the safety and efficacy of 3-phytase FLF1000 as a feed additive for chickens and laying hens. EFSA Journal 2016;14(11):4622. <https://doi.org/10.2903/j.efsa.2016.4622>
- EFSA FEEDAP Panel (EFSA Panel on additives and Products or Substances used in animal Feed), 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. <https://doi.org/10.2903/j.efsa.2018.5203>

Abbreviations

CFU	colony-forming unit
CV	coefficient of variation

EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products of Substances used in Animal Feed
ISO	International Organization for Standardization
OECD	Organisation for Economic Co-operation and Development
PCR	polymerase chain reaction
QPS	qualified presumption of safety

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Methods of Analysis for a preparation of 3-phytase (FSF10000)

In the current application authorisation is sought under article 4(1) of the Regulation (EC) No 1831/2003 for a *Preparation of 3-phytase (FSF10000)* under the category/functional groups 4 (a and c) 'zootechnical additives'/ 'digestibility enhancers' and 'substances which favourably affect the environment'. Specifically, authorisation is sought for the use of the *feed additive* for different poultry and porcine species. The liquid formulation of this *feed additive* is currently authorised by Commission Implementing Regulation (EU) 2017/895 for chickens for fattening and laying hens.

According to the Applicant, *FSF10000* is a solid formulation containing *3-phytase* (active agent), sodium citrate, water and wheat bran. The *3-phytase* enzymatic activity is expressed in FTU units, where 'one FTU is the amount of enzyme which releases one micromole of inorganic phosphate from sodium phytate per minute at pH 5.5 and 37°C'.

The product is intended to be marketed as a solid formulation having a guaranteed minimum *phytase* activity of 10000 FTU/g. *FSF10000* is intended to be used directly in *feedingstuffs* or through *premixtures* to obtain a minimum activity of 500 or 1000 FTU/kg *feedingstuffs* depending of the target species and a maximum activity of 1000 FTU/kg *feedingstuffs*.

For the quantification of the *phytase* activity in *feedingstuffs* the Applicant applied the colorimetric EN ISO 30024 method. Furthermore the Applicant applied this method with slight modifications to analyse of the *feed additive (FSF10000)* and *premixtures*, and obtained similar performance characteristics. Based on the performance characteristics obtained, the EURL recommends for official control these colorimetric methods for the quantification of the *phytase* activity in the *feed additive*, *premixtures* and *feedingstuffs*.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary.