

ADOPTED: 27 February 2019

doi: 10.2903/j.efsa.2019.5652

Assessment of the application for renewal of authorisation of Natugrain[®] Wheat TS and TS L (endo-1,4-beta-xylanase) as a feed additive for chickens for fattening, ducks, turkeys for fattening, turkeys reared for breeding, minor avian species (except ducks and laying birds) and ornamental birds

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Abstract

Natugrain[®] Wheat TS is the trade name for a feed additive that contains endo-1,4-beta-xylanase produced [REDACTED]. The product is currently authorised for use as a feed additive in chickens for fattening, turkeys for fattening or reared for breeding, ducks, ornamental birds and minor avian species (except ducks and laying birds). This scientific opinion concerns the renewal of the authorisation of this additive for those species. The applicant provided evidence that the additive in the market complies with the conditions of the authorisation. According to the information provided by the applicant, no new evidence has been identified that would make the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) reconsider the previous conclusions regarding the safety for the target species, consumer, user and environment under the authorised conditions of use. The additive is safe for the target species for which there is an authorisation, the consumers and the environment. The additive is a potential skin and dermal sensitiser. The present application for renewal of the authorisation did not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there was no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

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Keywords: zootechnical additives, digestibility enhancers, endo-1,4-beta-xylanase, safety, efficacy and poultry

Requestor: European Commission

Question number: EFSA-Q-2017-00025

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Acknowledgements: The Panel wishes to thank the following for the support provided to this scientific output: Jaume Galobart and Paola Manini.

Legal notice: Relevant information or parts of this scientific output have been blackened in accordance with the confidentiality requests formulated by the applicant pending a decision thereon by the European Commission. The full output has been shared with the European Commission, EU Member States and the applicant. The blackening will be subject to review once the decision on the confidentiality requests is adopted by the European Commission.

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, Dusemund B, Kouba M, Kos Durjava M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Aquilina G, Brantom P, Cocconcelli PS, Dierick NA, Glandorf B, Herman L, Rychen G, Saarela M and Anguita M, 2019. Scientific Opinion on the assessment of the application for renewal of authorisation of Natugrain® Wheat TS and TS L (endo-1,4-beta-xylanase) as a feed additive for chickens for fattening, ducks, turkeys for fattening, turkeys reared for breeding, minor avian species (except ducks and laying birds) and ornamental birds. *EFSA Journal* 2019;17(3):5652, 13 pp. <https://doi.org/10.2903/j.efsa.2019.5652>

ISSN: 1831-4732

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



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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 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from BASF SE² for renewal of the authorisation of the product Natugrain® Wheat TS (endo-1,4-beta-xylanase), when used as a feed additive for chickens for fattening, ducks, turkeys reared for breeding, turkeys for fattening, ornamental birds, minor avian species (except ducks and laying birds) (category: zootechnical additives; functional group: digestibility enhancers).

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 14(1) (renewal of the authorisation). 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 10 March 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 Natugrain® Wheat TS (endo-1,4-beta-xylanase), when used under the proposed conditions of use (see Section 3.1.1).

1.2. Additional information

The additive Natugrain® Wheat TS is a preparation of endo-1,4-β-xylanase produced by [REDACTED]. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has issued four opinions on the product. The first was on the safety of Natugrain Wheat + (former name of the product) as feed additive for chickens for fattening (EFSA, 2005) which included the assessment of the safety aspects of the genetic modification, safety for the consumer, user and environment. The second regarded the use of the product in turkeys for fattening (EFSA, 2007), the third considered the re-evaluation of the product for use in chickens for fattening and an extension of use to ducks (EFSA FEEDAP Panel, 2009) and the fourth considered a modification on the conditions of use in chickens for fattening and the extension of use to chickens reared for laying, turkeys reared for breeding, minor avian species (except laying birds) and ornamental birds (EFSA FEEDAP Panel, 2012).

The additive is authorised for use in turkeys for fattening,³ chickens for fattening and ducks⁴ and for turkeys reared for breeding, ornamental birds, minor avian species for fattening and reared for laying or breeding and ornamental birds (except ducks and laying birds).⁵

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 BASF SE, ENS/LR – F31, Chemiestrasse 22, 68623 Lampertheim, Germany.

³ Commission Regulation (EC) No 1380/2007 of 26 November 2007 concerning the authorisation of endo-1,4-beta-xylanase (Natugrain Wheat TS) as a feed additive. OJ L 309, 27.11.2007, p. 21 and amendments.

⁴ Commission Regulation (EC) No 1096/2009 of 16 November 2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by [REDACTED] as a feed additive for chickens for fattening and the authorisation of a new use of this preparation as a feed additive for ducks (holder of authorisation BASF SE) and amending Regulation (EC) No 1458/2005. OJ L 301, 17.11.2009, p. 3. Amended by Commission Regulation (EC) No 1019/2012 of 6 November 2012 amending Commission Regulation (EC) No 1096/2009 as regards the minimum content of endo-1,4-beta-xylanase produced by [REDACTED] as a feed additive in feed for chickens for fattening and for ducks (holder of authorisation BASF SE). OJ L 307, 7.11.2012, p. 60.

⁵ Commission Implementing Regulation (EU) No 843/2012 of 18 September 2012 concerning the authorisation of endo-1,4-beta-xylanase produced by [REDACTED] as a feed additive for turkeys reared for breeding, minor avian species for fattening and reared for laying or breeding and ornamental birds (holder of authorisation BASF SE).

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 Natugrain® Wheat TS 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

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of product/active substance is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013) and Guidance on the risk assessment of genetically modified microorganisms and their products intended for food and feed use (EFSA GMO Panel, 2011).

3. Assessment

The additive Natugrain® Wheat TS is a preparation of endo-1,4-β-xylanase produced [REDACTED]. The additive is authorised for use as a zootechnical additive in turkeys for fattening, chickens for fattening and ducks and for turkeys reared for breeding, ornamental birds, minor avian species for fattening and reared for laying or breeding and ornamental birds (except ducks and laying birds). This opinion deals with the renewal of the authorisation of Natugrain® Wheat TS and TS L as a zootechnical additive (functional group of digestibility enhancers) for poultry.

3.1. Characterisation of the additive

The additive is authorised in two different formulations, solid (Natugrain® Wheat TS) and liquid (Natugrain® Wheat TS L).

The information submitted regarding the manufacturing process confirms that it is the same as the one described in the first assessment of the product produced by this strain (EFSA, 2005) and the applicant stated that no antimicrobial substances are used during the process.

[REDACTED]

⁶ FEED dossier reference: FAD-2016-0079.

⁷ The full report is available on the EURL website: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2016-0079>.

[REDACTED]

safety aspects related to the genetic modification of the production strain, safety for the consumers, users and environment. The Panel concluded that the genetic modification is of no concern, that the additive is safe for the target species at the recommended conditions of use and that the use of the product as a feed additive would be of no concern for the consumers of products derived from animals fed with the additive, or for the environment. Regarding the safety for the user, the Panel concluded that the additive should be considered as a potential skin and respiratory sensitiser.

3.2.2. Further evidence

In line with the requirements established in the EFSA guidance on the renewal (EFSA FEEDAP Panel, 2013), the applicant performed a literature search in order to provide evidence that in the light of the current knowledge, the additive remains safe under the approved conditions for target species, consumers, users and the environment.

[REDACTED] no safety issues were reported for the use of the additive for the animals, consumers, users or the environment.

The applicant claims that no adverse effects, including accidents, for target animals, consumers, users or environment have been reported in the framework of its quality management system.

3.2.3. Conclusions on the safety of the additive

Based on the above and the fact that the manufacturing of additive, the additive and the conditions of use for the species/categories have not been modified, the Panel considers that there is no evidence to reconsider the conclusions reached in previous assessments. The additive is safe for the target species under the conditions of use currently authorised, for the consumer and the environment. The additive is a potential respiratory and skin sensitiser.

3.3. Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

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 Regulation¹⁹ and Good Manufacturing Practice.

4. Conclusions

The Panel concludes that the additive currently in the market complies with the existing conditions of authorisation.

The FEEDAP Panel confirms its previous conclusion that Natugrain® Wheat TS/TS L is safe for the target species/categories for which it is authorised, consumers of products from animals fed the additive and the environment. The additive is to be considered a potential dermal and respiratory sensitiser.

There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

Documentation provided to EFSA

- 1) Natugrain Wheat TS renewal dossier. December 2016. Submitted by BASF SE

¹⁸ Technical dossier/Section III [REDACTED]

¹⁹ 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.

- 2) Natugrain Wheat TS renewal dossier. Supplementary information. March 2018. Submitted by BASF SE.
- 3) Evaluation report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for Natugrain Wheat TS.
- 4) Comments from Member States.

Chronology

Date	Event
15/12/2016	Dossier received by EFSA
23/12/2016	Reception mandate from the European Commission
10/03/2017	Application validated by EFSA – Start of the scientific assessment
31/10/2017	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 and safety</i>
10/06/2017	Comments received from Member States
04/07/2017	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
14/03/2018	Reception of supplementary information from the applicant - Scientific assessment re-started
05/12/2018	Reception of an amendment to the Evaluation report of the European Union Reference Laboratory for Feed Additives
27/02/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

- EFSA (European Food Safety Authority), 2005. Scientific Opinion of the Panel on Additives and Products or Substances used in Animal feed on a request from the Commission on the safety of the enzyme preparation Natugrain Wheat + for chickens for fattening. EFSA Journal 2005;3(4):198, 8 pp. <https://doi.org/10.2903/j.efsa.2005.198>
- EFSA (European Food Safety Authority), 2007. Opinion of the Scientific Panel on Additives and Products or Substance used in Animal Feed on the safety and efficacy of the enzymatic preparation Natugrain® Wheat TS (endo-1,4-beta-xylanase) as a feed additive for turkeys for fattening according to Regulation (EC) No 1831/2003. EFSA Journal 2007;5(4): 474, 11 pp. <https://doi.org/10.2903/j.efsa.2007.474>
- EFSA (European Food Safety Authority), 2009. Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on a request from the European Commission on the safety and efficacy of Natugrain® Wheat TS (endo-1,4-β-xylanase) as feed additive for chickens for fattening and ducks. EFSA Journal 2009;7(6):1155, 14 pp. <https://doi.org/10.2903/j.efsa.2009.1155>
- 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), 2013. Outcome of the public consultation on the draft guidance on the renewal of the authorisation of feed additives. EFSA Journal 2013;498, 14 pp. Available online: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2013.EN-498>
- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2011. Scientific Opinion on Guidance on the risk assessment of genetically modified microorganisms and their products intended for food and feed use. EFSA Journal 2011;9(6):2193, 54 pp. <https://doi.org/10.2903/j.efsa.2011.2193>

Abbreviations

- EURL European Union Reference Laboratory
 FEEDAP Panel on Additives and Products or Substances used in Animal Feed

Appendix A – List of references retrieved from the literature search provided by the applicant to support safety of the additive

[Redacted content]

[REDACTED]

[REDACTED]

[Redacted content]

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for Natugrain® Wheat TS and TS L

Natugrain® Wheat TS is the trade name of a *feed additive* containing as active substance *endo-1,4-beta-xylanase* (EC 3.2.1.8) produced from *Aspergillus niger* (CBS 109.173). This *feed additive* is currently authorised by different Commission Regulations under the category/functional 4(a) 'zootechnical additives'/ 'digestibility enhancers' according to the classification system of Annex I of Regulation (EC) No 1831/2003 (*feed additive* identification number 4a62). In the current application, a renewal of the *feed additive* authorisation under article 14 of the Regulation (EC) No 1831/2003 is requested for different avian species.

The *endo-1,4-beta-xylanase* activity is expressed in TXU units, where 'one TXU is the amount of enzyme, which liberates five micromoles per minute of reducing sugars, expressed as xylose equivalents, from wheat arabinoxylan at pH 3.5 and 40°C'. The *feed additive endo-1,4-beta-xylanase (4a62)* is intended to be marketed as a fine yellow-brown powder with a minimum activity of [REDACTED] TXU/g. *Endo-1,4-beta-xylanase (4a62)* is intended to be incorporated directly or through *premixtures* at a minimum *endo-1,4-beta-xylanase* activity in *feedingstuffs* of 280 or 560 TXU/kg depending on the target species.

For the quantification of the activity of *endo-1,4-beta-xylanase* in the *feed additive, premixtures* and *feedingstuffs*, the Applicant submitted a single-laboratory validated and further verified viscometric method. External calibration is performed using an *endo-1,4-beta-xylanase* standard with a known enzyme activity expressed in TXU, determined by colorimetry under the conditions specified in the TXU definition (i.e. pH 3.5 and 40°C). Based on the performance characteristics available the EURL recommends for official control this method for the quantification of the total *endo-1,4-beta-xylanase* activity in these three matrices.

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, as last amended by Regulation (EU) 2015/1761) is not considered necessary.

And its amendment:

Upon request from EFSA, the EURL evaluated the supplementary information provided in the frame of the FAD-2016-0079 dossier for the quantification of the activity of *endo-1,4-beta-xylanase* in the liquid form of the *feed additive*, while the original EURL report related to this dossier focused on the solid form of the same *feed additive*. The Applicant submitted a single-laboratory validated and further verified viscometric method.

The *endo-1,4-beta-xylanase* catalyses the hydrolysis of xylosidic bonds in the wheat arabinoxylan substrate to yield xylose, and reduces consequently the viscosity of sample solution. In the frame of the validation and verification studies, the Applicant reported precisions ranging from 2.4 to 4.5% for the liquid form of the *feed additive*. Similar performance characteristics were reported when the method was applied to the solid form of the *feed additive*.

Based on the performance characteristics available, the EURL recommends for official control the validated and further verified viscometric method for the quantification of *endo-1,4-beta-xylanase* in the liquid form of the *feed additive*. Moreover, the principle of the methods for the solid and liquid forms of the *feed additive* is identical. In consequence, also the recommended text for the register entry included in the original report applies to this amendment.