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Safety and efficacy of Bergazym[®] P100 (endo-1,4- β -xylanase) as a feed additive for other birds for fattening, ornamental birds and other growing Suidae

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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 Bergazym[®] P100 (endo-1,4- β -xylanase, produced by a non-genetically modified strain of *Trichoderma reesei*) as a feed additive for other birds for fattening, ornamental birds and other growing Suidae. Considering the high margin of safety observed in the tolerance studies in chickens for fattening and in weaned piglets, and that the recommended level is the same, the Panel extrapolates the conclusions reached in chickens for fattening to all poultry species for fattening and ornamental birds and extrapolates the conclusions reached in weaned piglets to other growing Suidae species. Therefore, Bergazym[®] P100 containing endo-1,4- β -xylanase as active substance is considered safe in other birds for fattening, ornamental birds and other growing Suidae at the recommended dose of 1,500 EPU/kg feed. The additive is considered safe for the consumer and the environment. The additive is not irritant to the eyes and the skin, but it is considered a potential skin and respiratory sensitiser. The additive has the potential to be efficacious as a zootechnical additive, functional group 'digestibility enhancers', in other birds for fattening, ornamental birds and other growing Suidae at the recommended dose of 1,500 EPU/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 Berg + Schmidt GmbH Co. KG,² for authorisation of the product Bergazym® P100 (endo-1,4- β -xylanase), when used as a feed additive for other birds for fattening, ornamental birds and other growing Suidae (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 4(1) (authorisation of a feed additive or new use of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 27 March 2019.

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 Bergazym® P100 (endo-1,4- β -xylanase), when used under the proposed conditions of use (see Section 3.1).

1.2. Additional information

Bergazym® P100 (endo-1,4- β -xylanase) produced by *Trichoderma reesei* (BCCM/MUCL 49755) is currently authorised in the European Union (EU) as a feed additive for pigs for fattening.³

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued an opinion on the safety and efficacy of Bergazym® P100 (endo-1,4- β -xylanase) when used as a feed additive for chickens for fattening, weaned piglets and pigs for fattening (EFSA FEEDAP Panel, 2017a) and a second opinion on its efficacy in chickens for fattening and weaned piglets (EFSA FEEDAP Panel, 2018a).

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁴ in support of the authorisation request for the use of Bergazym® P100 (endo-1,4- β -xylanase) as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA, to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.⁵

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Bergazym® P100 (endo-1,4- β -xylanase) is in line with the principles laid down in Regulation (EC) No 429/2008⁶ and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for

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 Berg + Schmidt GmbH Co. KG. An der Alster 81, 20099 Hamburg, Germany.

³ COMMISSION IMPLEMENTING REGULATION (EU) 2018/130 of 25 January 2018 concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) as a feed additive for pigs for fattening (holder of authorisation Berg and Schmidt GmbH Co. KG). OJ L 22, 26.1.2018, p. 25.

⁴ FEED dossier reference: FAD-2018-0082.

⁵ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/finirep-fad-2014-0029-bergazymp100.pdf>

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.

the target species (EFSA FEEDAP Panel, 2017b) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018b).

3. Assessment

The present opinion deals with the assessment of the safety and efficacy of Bergazym® P100 (endo-1,4- β -xylanase) produced by *T. reesei* (BCCM/MUCL 49755) as a zootechnical feed additive (functional group: digestibility enhancer) for other birds for fattening, ornamental birds and other growing Suidae.

3.1. Characterisation of the additive

The additive is available in a coated granular form which contains 2.6% of enzyme concentrate, wheat meal (96.7%) and starch (0.7%). The additive is specified to a minimum activity of 15,000 EPU⁷/g. The xylanase is produced by a non-genetically modified strain of *T. reesei* deposited at the Belgian Coordinated Collections of Microorganisms with the accession number BCCM/MUCL 49755. Information relating to the characterisation of the additive has been recently assessed by the FEEDAP Panel (EFSA FEEDAP Panel, 2017a).

Bergazym® P100 is intended to be added to feed for other birds for fattening, ornamental birds and other growing Suidae at a recommended dose of 1,500 EPU/kg feed.

3.2. Safety

The safety of Bergazym® P100 has been evaluated recently by the FEEDAP Panel (EFSA FEEDAP Panel, 2017a). The Panel concluded that the use of the product as a feed additive would not raise concern for the consumer and the environment. Regarding the safety for the user, the Panel concluded that the additive is not irritant to the eyes and the skin, but it is considered a potential skin and respiratory sensitiser. The Panel is not aware of any new information that would lead it to reconsider the conclusions drawn previously. Moreover, the Panel considers that the extension of use of the additive to a new target species do not introduce risks not already considered in the previous assessment. However, there is the need to consider the safety for the new target species.

3.2.1. Safety for the target species

The safety for chickens for fattening, weaned piglets and pigs for fattening was established in a previous assessment (EFSA FEEDAP Panel, 2017a). In tolerance studies submitted performed in chickens for fattening and in weaned piglets, the results showed no negative effects on the performance of the animals when fed 200 \times and 100 \times the level of 1,500 EPU/kg feed, respectively. Therefore, the FEEDAP Panel concluded that the additive is safe for these target species at the recommended level and the conclusions reached for weaned piglets can be extended to pigs for fattening.

Considering the high margin of safety observed in the tolerance studies in chickens for fattening and in weaned piglets, and that the recommended level is the same, the Panel extrapolates the conclusions reached in chickens for fattening to all poultry species for fattening and ornamental birds and extrapolates the conclusions reached in weaned piglets to other growing Suidae species.

3.2.1.1. Conclusions on safety for the target species

The FEEDAP Panel concludes that the additive is safe for all poultry species for fattening, ornamental birds and other growing Suidae species at the recommended level of 1,500 EPU/kg feed.

3.3. Efficacy

The efficacy of Bergazym® P100 as a zootechnical additive was previously established in pigs for fattening (EFSA FEEDAP Panel, 2017a), weaned piglets and chickens for fattening (EFSA FEEDAP Panel, 2018a) at the level of 1,500 EPU/kg feed.

Considering that the mode of action of the xylanase is well-known and can be reasonably assumed to be the same in all avian species and in all Suidae, the conclusions from the efficacy studies in

⁷ Endopentosanase unit. One EPU is defined as the amount of enzyme required to release 0.0083 μ mol of reducing sugar equivalents (xylose) equivalents from oat spelt xylan per minute at pH 4.7 and 50 °C.

chickens for fattening can be extrapolated to other birds for fattening and ornamental birds at the same use level and the conclusions from pigs for fattening and weaned piglets can be extrapolated to other growing Suidae. Therefore, the FEEDAP Panel concludes that the additive has the potential to be efficacious as a zootechnical additive in for other birds for fattening, ornamental birds and other growing Suidae when added to feed at of 1,500 EPU/kg feed.

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

Bergazym® P100 containing endo-1,4- β -xylanase (produced by a non-genetically modified strain of *T. reesei*) as active substance is considered safe in other birds for fattening, ornamental birds and other growing Suidae at the recommended dose of 1,500 EPU/kg feed.

The additive is considered safe for the consumer and the environment. The additive is not irritant to the eyes and the skin, but it is considered a potential skin and respiratory sensitiser.

The additive has the potential to be efficacious as a zootechnical additive, functional group 'digestibility enhancers', in other birds for fattening, ornamental birds and other growing Suidae at the recommended dose of 1,500 EPU/kg feed.

Documentation provided to EFSA and Chronology

Date	Event
22/11/2018	Dossier received by EFSA from Berg + Schmidt GmbH Co. KG on Bergazym® P100 (endo-1,4- β -xylanase) for other birds for fattening, ornamental birds and other growing Suidae
13/2/2019	Reception mandate from the European Commission
27/3/2019	Application validated by EFSA – Start of the scientific assessment
3/5/2019	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: Conditions of use
6/5/2019	Reception of supplementary information from the applicant - Scientific assessment re-started
27/6/2019	Comments received from Member States
2/7/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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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 35, 8.2.2005, p. 1.

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Abbreviations

EPU	Endopentosanase unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed