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Safety and efficacy of HOSTAZYM[®] X (endo-1,4- β -xylanase) as a feed additive for chickens reared for laying and minor poultry species reared for laying

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 Dierick and Montserrat Anguita

Abstract

The additive HOSTAZYM[®] X contains endo-1,4- β -xylanase and it is available in solid and liquid forms. This additive is authorised for use in piglets and pigs for fattening, chickens and turkeys for fattening, laying hens, minor poultry species for fattening and laying. The applicant has requested to extend the use of the additive to chickens reared for laying and minor poultry species reared for laying at a dose range of 1,500–3,000 EPU/kg feed. Safety aspects regarding the use of this additive in feed including the safety for the consumers, for the users and for the environment were previously assessed. The FEEDAP Panel concluded that there are no concerns for the consumer safety and no risks for the environment are expected, the additive should be considered a potential skin and eye irritant, and a potential skin and respiratory sensitiser. The FEEDAP Panel is not aware of any new information that would lead it to reconsider the conclusions drawn previously. The FEEDAP Panel had previously evaluated a tolerance trial carried out with chickens for fattening where it was considered that the animals tolerated well the dose of 3,000 EPU/kg feed. In that assessment, the FEEDAP Panel also evaluated the efficacy of the product in chickens for fattening and concluded that the additive has the potential to be efficacious in chickens for fattening at the dose of 1,500 EPU/kg feed. The tolerance and efficacy data in chickens for fattening evaluated previously was considered relevant for the use in the new target category/species proposed by the applicant. Consequently, the conclusions on the safety and efficacy drawn for chickens for fattening were extended to chickens reared for laying and extrapolated to minor poultry species reared for laying.

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Correspondence: feedap@efsa.europa.eu

Panel members: Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Coconcelli, 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.

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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 Huvepharma NV² for authorisation of the product HOSTAZYM® X (endo-1,4- β -xylanase), when used as a feed additive for chickens reared for laying and minor poultry species reared for laying (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). 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 2 February 2016.

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 HOSTAZYM® X (endo-1,4- β -xylanase), when used under the proposed conditions of use (see Section 3.1.1).

1.2. Additional information

The additive HOSTAZYM® X is a preparation of endo-1,4- β -xylanase available in liquid and solid formulations. This product is authorised as a feed additive for chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and laying, weaned piglets and pigs for fattening.³

The FEEDAP Panel adopted two opinions on the safety and efficacy of the product as a feed additive for poultry and pigs (EFSA FEEDAP Panel, 2013, 2015). The applicant is now requesting for an extension of use of the additive to chickens reared for laying and minor poultry species reared for laying.

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 HOSTAZYM® X (endo-1,4- β -xylanase) as a feed additive. The technical dossier was prepared following the provisions of Article 7 of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008 and the applicable EFSA guidance documents.

The 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 HOSTAZYM® X is in line with the principles laid down in Regulation (EC) No 429/2008⁶ and the relevant guidance

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 Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerp, Belgium.

³ Commission Implementing Regulation (EU) 2015/1043 of 30 June 2015 concerning the authorisation of the preparation of endo-1,4- β -xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IMI SD 135) as a feed additive for chickens for fattening, turkeys for fattening, laying hens, weaned piglets, pigs for fattening and minor poultry species for fattening and for laying, and amending Regulations (EC) No 2148/2004, (EC) No 828/2007 and (EC) No 322/2009 (holder of authorisation Huvepharma NV). OJ L 167, 1.7.2015, p.63–66.

⁴ FEED dossier reference: FAD-2015-0043.

⁵ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2010-0001.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, 22.05.2008, p. 1.

documents: Technical Guidance: extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition (2008) and Guidance on zotechnical additives (EFSA FEEDAP Panel, 2012).

3. Assessment

This assessment deals with a request from the applicant to extend the use of the additive HOSTAZYM® X to chickens reared for laying and minor poultry species reared for laying.

3.1. Characterisation

The additive HOSTAZYM® X is a preparation of endo-1,4- β -xylanase (xylanase; EC 3.2.1.8) produced by a non-genetically modified strain of *Trichoderma citrinoviride* (IMI SD135). This additive is available in two solid and two liquid formulations. The solid formulations are HOSTAZYM® X 6000 MicroGranulate and 30000 MicroGranulate which have a minimum guaranteed enzyme activity of 6,000 and 30,000 EPU units⁷/g of product, respectively. The liquid formulations are HOSTAZYM® X 6000 Liquid and 15000 Liquid with a minimum guaranteed enzyme activity of 6,000 and 15,000 EPU units/mL. The additive was characterised in full in a previous assessment (EFSA FEEDAP Panel, 2013). The production strain belongs to a species that is capable to produce peptaibols. The applicant submitted newly generated data on the presence of these secondary metabolites in the fermentation product.⁸ The method developed was a liquid chromatography–mass spectrometry (LC–MS) method in which alamethicin was used as standard to determine peptaibols. Three batches of the fermentation product were analysed and peptaibols were not detected (limit of detection 0.02 mg/kg).

3.1.1. Conditions of use

The additive is to be used in feed for chickens reared for laying or minor poultry species reared for laying at a dose range of 1,500–3,000 EPU/kg feed.

3.2. Safety

Safety aspects regarding the use of this additive in feed including the safety for the consumers, for the users and for the environment has been previously evaluated (EFSA FEEDAP Panel, 2013, 2015). The FEEDAP Panel concluded that there are no concerns for the consumer safety and no risks for the environment are expected. Considering the safety for the user, it was concluded that the additive should be considered a potential skin and eye irritant, and a potential skin and respiratory sensitiser.

The FEEDAP Panel is not aware of any new information that would lead it to reconsider the conclusions drawn previously. Moreover, the FEEDAP Panel considers that the new use requested by the applicant would not modify the above conclusions.

In the previous assessments, the FEEDAP Panel evaluated also the safety for the target species (EFSA FEEDAP Panel, 2013, 2015), including a tolerance trial in chickens for fattening. In that trial, the chickens tolerated well 100-fold the maximum dose of 3,000 EPU/kg feed, and therefore, the FEEDAP Panel concluded that the additive is safe for chickens for fattening at the maximum recommended dose of 3,000 EPU/kg feed. The FEEDAP Panel considers that the conclusion can be extended to chickens reared for laying and based on the wide margin of safety shown in chickens for fattening the conclusion can also be extrapolated to minor poultry species reared for laying.

3.3. Efficacy

In a previous assessment, the FEEDAP Panel evaluated the efficacy in chickens for fattening (EFSA FEEDAP Panel, 2013). Five long-term trials and one short-term trial were evaluated, and the Panel concluded that the additive has the potential to be efficacious in chickens for fattening at the dose of 1,500 EPU/kg feed. The Panel considers that this conclusion can be extended to chickens reared for laying at the same dose. The mode of action of the xylanases is well-known and can be reasonably assumed to be the same in poultry species; therefore, the conclusion can also be extrapolated to include minor poultry species reared for laying.

⁷ EPU: One EPU is the amount of enzyme which releases 0.0083 μ mol of reducing sugars (xylose equivalent) per minute from oat spelt xylan at pH 4.7 and 50°C.

⁸ Technical dossier/Supplementary information October 2016/Annex 2.

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 Regulation⁹ and Good Manufacturing Practice.

4. Conclusions

The new use of the additive would not change the previous conclusions regarding the safety for the consumer, user and environment. The FEEDAP Panel concluded that there are no concerns for the consumer safety and no risks for the environment are expected, the additive should be considered a potential skin and eye irritant, and a potential skin and respiratory sensitiser.

The additive is considered safe and efficacious for chickens reared for laying and minor poultry species reared for laying at the recommended dose range.

Documentation provided to EFSA

- 1) HOSTAZYM® X for chickens reared for laying, minor poultry species reared for laying. November 2015. Submitted by Huvepharma NV.
- 2) HOSTAZYM® X for chickens reared for laying, minor poultry species reared for laying. Supplementary information. October 2016. Submitted by Huvepharma NV.
- 3) Comments from Member States.

References

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- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2013. Scientific Opinion on the safety and efficacy of HOSTAZYM X (endo-1,4-beta-xylanase) as a feed additive for poultry, piglets and pigs for fattening. EFSA Journal 2013;11(2):3105, 19 pp. doi:10.2903/j.efsa.2013.3105
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015. Scientific Opinion on the safety of HOSTAZYM X as a feed additive for poultry and pigs. EFSA Journal 2015;13(1):3969, 10 pp. doi:10.2903/j.efsa.2015.3969

Abbreviations

EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
LC-MS	liquid chromatography–mass spectrometry

⁹ 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, 8.02.2005, p. 1.