

SCIENTIFIC OPINION

Scientific Opinion on the safety of Finase[®] EC (6-phytase) as a feed additive for turkeys for fattening¹

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the European Food Safety Authority (EFSA) was asked to deliver an opinion on the safety of Finase[®] EC (6-phytase) for turkeys for fattening.

Finase[®] EC is a feed additive with 6-phytase as its declared enzymatic activity and is produced by a genetically modified strain of *Trichoderma reesei*. The additive Finase[®] EC is presented in solid (Finase[®] EC 40 P) and liquid (Finase[®] EC 10 L) forms; the solid form ensures a minimum activity of 40000 PPU/g and the liquid form ensures a minimum of 10000 PPU/g. Finase[®] EC is intended to be used at a dose range of 250–1000 PPU/kg complete feed in turkeys for fattening or reared for breeding.

In a previous opinion, it was not possible to conclude on the safety of the preparation when used in turkeys. The applicant has provided a new tolerance study with turkeys for fattening.

Based on the results obtained from the tolerance study provided, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concludes that the 6-phytase contained in the product Finase[®] EC is safe at the maximum recommended dose of 1000 PPU/kg feed for turkeys for fattening. This conclusion can be extended to turkeys reared for breeding.

KEY WORDS

Zootechnical additive, 6-phytase, genetically modified microorganism, *Trichoderma reesei*, safety, turkeys

1 On request from the European Commission, Question No EFSA-Q-2010-00069, adopted on 10 March 2010.

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3 Acknowledgement: The Panel wishes to thank wishes to thank the members of the Working Group on Enzymes including Friedrich Schöne and Pieter Wester for the preparation of this opinion.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1831/2003 establishes rules governing the Community authorisation of additives for animal nutrition and in particular defines the conditions that a substance/product should meet to be granted the authorisation.

The Commission received directly from the company Roal Oy an application requesting to assess its product 6-phytase (FINASE EC), to obtain an authorisation as zootechnical additive for chickens for fattening, chickens for laying, laying hens, turkeys for fattening, turkeys for breeding, piglets (weaned), pigs for fattening, sows, ducks and other minor poultry species (ie. geese, quail, pigeon, pheasants and other game birds). The Authority in its opinion adopted on 11 November 2009 (Scientific Opinion on the safety and efficacy of FINASE EC (6-phytase) as a feed additive for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for laying, ducks and other minor species, piglets (weaned), pigs for fattening and sows), was not able to give a conclusive opinion on the safety of 6-phytase (FINASE EC) for turkeys for fattening and sows due to the lack of data provided by the company.

Therefore, the Commission gave the possibility to the company to submit complementary information to complete the assessment.

The Commission has now received a supplementary dossier from the applicant Roal Oy company containing new data on safety for turkeys for fattening of 6-phytase (FINASE EC) when used as feed additive under requested conditions.⁴

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In view of the above, the Commission asks to the European Food Safety Authority to deliver an opinion on the safety for turkeys for fattening under the requested condition of use.

⁴ EFSA Dossier Reference: FAD-2010-0004

ASSESSMENT

1. Introduction

The additive Finase[®] EC is a preparation of 6-phytase (E.C. 3.1.3.26) produced by a genetically modified strain of *Trichoderma reesei* (CBS 122001). The additive Finase[®] EC is presented in solid (Finase[®] EC 40 P) and liquid (Finase[®] EC 10 L) forms; the solid form ensures a minimum activity of 40000 PPU/g and the liquid form ensures a minimum of 10000 PPU/g. It is intended for use in feed for turkeys at a recommended dose range of 250–1000 PPU/kg complete feed and it is proposed to be classified as a zootechnical additive (functional group: digestibility enhancers and substances which favourably affect the environment). This additive is not authorised in the European Union.

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) and the Panel on Genetically Modified Organisms (GMO) issued an opinion (EFSA, 2009) on the safety and efficacy of Finase[®] EC (6-phytase) as a feed additive for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for laying, ducks and other minor poultry species, piglets (weaned), pigs for fattening and sows, including the safety aspects of the genetic modification. In the opinion it was stated that 'A conclusion on the safety for turkeys for fattening and for sows was not possible due to the limitations of the trials provided'. The applicant has now provided a new tolerance study aiming to demonstrate the safety of the product when administered to turkeys for fattening. Thus, the current opinion focuses on the assessment of that new study.

2. Tolerance for turkeys for fattening

A tolerance study was performed with a total of 297 one-day-old female turkeys (BUT Big 6) which were allocated in pens of nine birds each and distributed to one of the three dietary treatments (11 replicates per treatment). The basal diets (two phases), which were based on maize and soya bean meal (total phosphorus 8.0 and 7.9 g/kg, respectively), were supplemented with Finase[®] EC (diluted solid form) in order to provide 0, 1000 (1x) and 100000 (100x) PPU/kg complete feed (confirmed by analysis). The pelleted diets were offered *ad libitum* to the birds for 42 days. Animals were monitored for performance parameters during the experimental period.

No adverse effects on mortality (control: 5/99 turkeys) and performance (control body weight: 2.5 kg, 1.5 kg feed to 1 kg gain) of the birds were shown at the overdose level of 6-phytase compared to an unsupplemented group and a group supplemented at the maximum recommended dose.

CONCLUSIONS

Turkeys for fattening tolerated a 100-fold overdose of the 6-phytase contained in Finase[®] EC. Therefore, the FEEDAP Panel concludes that Finase[®] EC is safe for turkeys for fattening at the maximum recommended dose (1000 PPU/kg feed). This conclusion can be extended to turkeys reared for breeding.

The two forms of Finase[®] EC are considered to be equivalent in terms of safety when used at the same dose.

DOCUMENTATION PROVIDED TO EFSA

1. Supplementary dossier on the enzyme preparation Finase EC. Submitted by Roal Oy. January 2010.

REFERENCES

- EFSA (European Food Safety Authority), 2009. Scientific Opinion on the safety and efficacy of Finase[®] EC (6-phytase) as a feed additive for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, ducks and other minor poultry species, piglets (weaned), pigs for fattening and sows. EFSA Journal, 7(11):1380.