

SCIENTIFIC OPINION

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 sows¹

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) and EFSA Panel on Genetically Modified Organisms (GMO)

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 a 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 poultry minor species, piglets (weaned), pigs for fattening and sows.

Finase[®] EC is a feed additive with 6-phytase as its declared enzymatic activity. The production strain is a genetically modified *Trichoderma reesei*. The final enzyme preparations contain no cultivable production organisms or recombinant DNA above the limits of detection. The products do not have antimicrobial activity or mycotoxins.

The additive Finase[®] EC is presented in solid (Finase[®] EC P) and liquid (Finase[®] EC L) forms; the solid form ensures a minimum activity of 40000 PPU/g and the liquid 10000 PPU/g. Finase[®] EC is intended to be used at a dose range of 250–1000 PPU/kg complete feed for pigs (all categories), chickens for fattening or reared for laying and turkeys for fattening or reared for breeding and at a dose range of 125–1000 PPU/kg complete feed in laying hens, ducks and other minor poultry species.

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

Based on the results obtained from the tolerance studies, it is concluded that Finase[®] EC is safe at the maximum recommended dose of 1000 PPU/kg feed for chickens for fattening and laying hens, which can be extrapolated to all minor poultry species, and for piglets and pigs for fattening. A conclusion on the safety for the turkeys and for sows could not be drawn due to the limitations of the trials provided.

Based on the absence of genotoxicity as demonstrated in two mutagenicity/clastogenicity tests and lack of any relevant effects in a subchronic oral toxicity study, it is concluded that the use of Finase[®] EC as feed additive is of no concern for consumer safety.

Finase[®] EC is not irritant to skin or eye and is not a skin sensitizer, but it is considered to be a respiratory sensitizer.

¹ On request from the European Commission, Question No EFSA-Q-2008-748 and Question No EFSA-Q-2009-00676, adopted on 11 November 2009 by the FEEDAP Panel and on 21 October 2009 by the GMO Panel.

No risk for the environment is expected from the use of Finase[®] EC as a feed additive under the conditions specified.

From the efficacy studies provided it can be concluded that Finase[®] EC is efficacious in pigs (all categories), chickens for fattening and chickens reared for laying, and in turkeys for fattening and turkeys reared for breeding at a minimum dose of 250 PPU/kg, and in laying hens at a dose of 125 PPU/kg. The conclusions on the efficacy data provided for major poultry species can be extrapolated to all minor poultry species. The minimum dose is then 250 PPU/kg for growing minor poultry species and 125 PPU/kg feed for laying minor poultry species.

KEY WORDS: zootechnical additive, 6-phytase, genetically modified microorganism, *Trichoderma reesei*, poultry, pigs, safety, efficacy