

Safety and efficacy of the product Ronozyme[®] NP (6-phytase) for chickens for fattening

Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed and the Panel on Genetically Modified Organisms

(Question No EFSA-Q-2007-133)

Adopted on 18 November 2008 by the FEEDAP Panel
and on 29 October 2008 by the GMO Panel

SUMMARY

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) and the Panel on Genetically Modified Organisms (GMO) were asked to deliver a scientific opinion on Ronozyme[®] NP for chickens for fattening.

The additive Ronozyme[®] NP is a preparation of 6-phytase produced by a genetically modified strain of the micro-organism *Aspergillus oryzae*. It is intended to be used in feed for chickens for fattening at a dose range of 1500-3000 FYT kg⁻¹ complete feed.

Ronozyme[®] NP is produced by fermentation of *Aspergillus oryzae* PhME3-38. Multiple copies of the 6-phytase gene cassette sequences are inserted in the genome of the production strain. No exogenous antibiotic resistance marker sequences were added. The recipient organism is considered as safe and no harmful sequences have been introduced in the production strain. After fermentation, the enzyme is separated from the cells and concentrated. The final enzyme preparation contains no cultivable production organisms, no antimicrobial activity or mycotoxins, and the level of the newly introduced DNA is below the limit of detection of 0.4 ng of recombinant DNA g⁻¹ enzyme product.

The results of two balance and two growth trials show that Ronozyme[®] NP improves the utilisation of phytate-bound P in diets of chickens for fattening. The solid and liquid forms of the product are considered to be essentially equivalent in terms of efficacy. The data confirms the minimum recommended dose of 1500 FYT kg⁻¹.

The use of Ronozyme[®] NP, as other phytases, allows the use of diets with a lower level of inorganic P, which may in turn reduce the excretion of P to the benefit of the environment.

From the two tolerance studies performed at a 10X overdose of Ronozyme[®] NP (CT), it is concluded that the use of Ronozyme[®] NP, in either form, at the maximum recommended dose, is safe for chickens for fattening.

The tests for genotoxicity and sub-chronic toxicity demonstrated no adverse effects associated with treatment. Therefore, it is concluded that the use of Ronozyme[®] NP as a feed additive is of no concern regarding consumer safety.

Regarding user safety, the data suggest no additional precautions beyond those required by the labelling of Ronozyme[®] NP as a respiratory sensitiser.

The active ingredient of Ronozyme[®] NP is a protein and as such will be degraded/inactivated during the passage through the digestive tract of animals. Therefore, no further environmental risk assessment is required.

Key words: zootechnical additive, digestibility enhancer, substances which favourably affect the environment, chickens for fattening, 6-phytase, efficacy, safety, *Aspergillus oryzae*, genetically modified micro-organism