

Safety and efficacy of Ronozyme[®] ProAct (serine protease) for use as feed additive for chickens for fattening

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

(Question No EFSA-Q-2008-431a and EFSA-Q-2008-431b)

**Adopted on 7 July 2009 by the FEEDAP Panel
and on 2 July 2009 by the GMO Panel**

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 Ronozyme[®] ProAct when used as a feed additive for chickens for fattening.

Ronozyme[®] ProAct is a preparation of serine protease produced by a genetically modified strain of *Bacillus licheniformis*. It is produced by fermentation of a sporulation-deficient *Bacillus licheniformis* strain Rh-3 which expresses a synthetic gene encoding a serine protease (EC 3.4.21.-). The recipient organism is considered as safe. No antibiotic resistance remained in the final production strain as a result of the genetic modifications. After fermentation, the enzyme is separated from the cells and concentrated. The final enzyme preparation contains no cultivable production organisms in 1 g samples of the final product and the level of the newly introduced DNA is below the limit of detection.

The product is produced in solid (CT) and liquid (L) forms and is intended for use as feed additive in chickens for fattening at a proposed dose providing 15000 units of protease (PROT) kg⁻¹ complete feed. The two forms of the product Ronozyme[®] ProAct are considered to be equivalent in terms of safety and efficacy.

Ronozyme[®] ProAct is considered to be safe in chickens for fattening at the proposed dose.

Based on the absence of genotoxicity in two tests and the absence of treatment-related effects in a 90-day toxicity study in rats, it is concluded that the use of Ronozyme[®] ProAct as a feed additive would not pose a risk for the consumer.

The additive is a skin irritant and a potential skin and respiratory sensitiser.

The active ingredient of Ronozyme[®] ProAct is a protein and as such will be degraded/inactivated during the passage through the digestive tract of animals. Therefore, no risk for the environment is expected.

The potential efficacy of Ronozyme[®] ProAct has been demonstrated at dose level of 15000 PROT kg⁻¹ feed in chickens for fattening.

Key words: zootechnical additive, digestibility enhancer, enzyme, genetically modified micro-organism, serine protease, chickens for fattening, safety, efficacy