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Safety and efficacy of RONOZYME[®] WX (endo-1,4-beta-xylanase) as a feed additive for chickens and turkeys for fattening, minor poultry species for fattening, weaned piglets and pigs for fattening

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)

Abstract

The additive RONOZYME[®] WX is a preparation of endo-1,4-beta-xylanase produced with a genetically modified strain of *Aspergillus oryzae*, currently authorised for poultry for fattening, weaned piglets and pigs for fattening. The applicant has requested to change the production strain. The manufacturing process and the composition of the additive have not been modified and therefore the formulations of the additive remain as those previously reported. The new production strain derives from the same parental strain as the previous one and harbours the same xylanase gene, but the sequence of genetic modifications is different. The safety of the recipient strain was previously evaluated by EFSA. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) concluded that RONOZYME[®] WX, manufactured with the new production strain, does not give rise to safety concerns with regard to genetic modification. Neither the production strain nor its recombinant DNA was detected in the fermentation product used to formulate the additive. Based on tolerance and efficacy studies performed with the additive obtained with the previous production strain, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) concluded that the additive is safe for poultry for fattening at 200 FXU/kg feed and in weaned piglets and pigs for fattening at 400 FXU/kg feed and efficacious in poultry species for fattening at 100 FXU/kg feed and in weaned piglets and pigs for fattening at 200 FXU/kg. Based on toxicological studies performed with the fermentation product obtained with the new production strain, the Panel concluded that there is no reason for concern for consumer safety arising from the use of the product as a feed additive. The additive poses no risk to the environment. The additive is not a skin or an eye irritant but the Panel could not conclude on its skin sensitisation potential. Because of the proteinaceous nature of the active substance, the additive is considered a potential respiratory sensitiser.

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Note: The full opinion will be published in accordance with Article 8(6) of Regulation (EC) No 1831/2003 once the decision on confidentiality, in line with Article 18(2) of the Regulation, will be received from the European Commission.

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