

SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of Kemzyme[®] Plus Dry (endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, alpha-amylase, bacillolysins and endo-1,4-beta-xylanase) for poultry, ornamental birds and piglets (weaned)¹

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

European Food Safety Authority (EFSA), Parma, Italy

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

ABSTRACT

Kemzyme[®] Plus Dry is a preparation of four glycosyl hydrolases and a protease which is to be used as a feed additive for poultry, ornamental birds and weaned piglets. Based on the tolerance studies provided, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) considered that the additive is safe for chickens and turkeys for fattening and laying hens at the maximum dose of 1 000 mg additive/kg feed and in weaned piglets at a maximum dose of 500 mg additive/kg feed. The conclusion can be extended/extrapolated to avian species at the same dose. The Panel concluded that the additive is safe for consumers. The additive is not an irritant to skin or eyes but should be regarded as a potential skin sensitiser and as hazardous by inhalation. No risks to the environment are expected and no further environmental risk assessment is required. Owing to the lack of data, the efficacious dose in units of enzyme activity could not be established. The FEEDAP Panel concluded that the additive has the potential to be efficacious at a nominal dose of 500 mg additive/kg feed in chickens for fattening and laying hens and at a nominal dose of 250 mg additive/kg feed in turkeys for fattening. These conclusions can be extended to chickens reared for laying and turkeys reared for breeding at the corresponding dose. The conclusions on efficacy in poultry species can be extrapolated to minor poultry species and ornamental birds at the nominal dose of 250 mg/kg feed for fattening birds and of 500 mg/kg feed for laying birds. The FEEDAP Panel could not conclude on the efficacy in weaned piglets.

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KEY WORDS

zootechnical additive, digestibility enhancers, safety, efficacy, poultry, piglets

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SUMMARY

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of Kemzyme[®] Plus Dry as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, other minor poultry for fattening/laying and ornamental birds. It is proposed to be classified as a zootechnical additive, functional group of digestibility enhancers.

The additive Kemzyme[®] Plus Dry, formerly known as Kemzyme W Dry, is a preparation of endo-1,3(4)-beta-glucanase (EC 3.2.1.6) produced by *Aspergillus aculeatinus* (CBS 589.94, formerly classified as *A. aculeatus*), endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma reesei* (CBS 592.94, formerly classified as *T. longibrachiatum*), alpha-amylase (EC 3.2.1.1) produced by *Bacillus amyloliquefaciens* (DSM 9553), bacillolysin (EC 3.4.24.28) produced by *Bacillus amyloliquefaciens* (DSM 9554) and endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (NIBH FERM BP 4842, formerly classified as *T. viride*). This additive is currently authorised for use in chickens for fattening, laying hens, turkeys for fattening and weaned piglets and subject to re-evaluation.

Based on the tolerance studies provided, the FEEDAP Panel considered that the additive is safe for weaned piglets at a maximum dose of 500 mg additive/kg feed and for chickens and turkeys for fattening and laying hens at the dose of 1 000 mg additive/kg feed. Based on the wide margin of safety shown in the major poultry species, the conclusion can be extended/extrapolated to avian species (for growing and laying) at the same dose.

The production organisms of alpha-amylase and bacillolysin are considered suitable for the Qualified Presumption of Safety approach to safety assessment, and qualifications were met; consequently, the use of these products as feed additives is considered safe for consumers. The results obtained in the genotoxicity studies and on the sub-chronic oral toxicity studies provided for the other three enzymes do not indicate any reason for concern regarding consumer safety. Therefore, the Panel considered that the use of Kemzyme[®] Plus Dry as a feed additive gives rise to no concerns for the consumers.

The product is not an irritant to the skin or eyes but it should be considered a potential skin sensitiser. The additive is considered to be hazardous by inhalation.

The active substances of Kemzyme[®] Plus Dry are proteins, and as such will be degraded/inactivated during passage through the digestive tract of animals. Therefore, no risks to the environment are expected and no further environmental risk assessment is required.

The FEEDAP Panel could not establish the efficacious dose in units of enzyme activity owing to the incompleteness of the data on the enzyme recovery in feed. Based on the results obtained in the efficacy studies provided in chickens and turkeys for fattening and laying hens, the FEEDAP Panel concluded that the additive has the potential to be efficacious at a nominal dose of 500 mg additive/kg feed in chickens for fattening and laying hens and at a nominal dose of 250 mg additive/kg feed in turkeys for fattening. These conclusions can be extended to chickens reared for laying and turkeys reared for breeding at the corresponding dose. The mode of action of the enzymes present in the additive is very well known and can be considered to be similar in all avian species; thus, the conclusions on the efficacy in the major poultry species can be extrapolated to minor poultry species and ornamental birds at the nominal dose of 250 mg/kg feed for fattening birds and of 500 mg/kg feed for laying birds. The FEEDAP Panel could not conclude on the efficacy of the additive in weaned piglets owing to the lack of data.