

## SCIENTIFIC OPINION

# Scientific Opinion on the safety and efficacy of Kemzyme<sup>®</sup> Plus Liquid (endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, alpha-amylase and endo-1,4-beta-xylanase) as a feed additive for poultry species and ornamental birds<sup>1</sup>

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)<sup>2,3</sup>

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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

The additive Kemzyme<sup>®</sup> Plus Liquid is an enzyme preparation with four glycosyl hydrolases to be used in poultry species and ornamental birds. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) considered that the additive is safe at the maximum dose of 200 mg additive/kg feed in chickens for fattening and laying hens and at a maximum dose of 150 mg additive/kg feed in turkeys for fattening. The conclusions can be extended to chickens reared for laying and turkeys reared for breeding at the corresponding dose. Similarly, the conclusions can be extrapolated to minor poultry species for fattening and laying and ornamental birds at 200 mg additive/kg feed. The Panel considers that the use of Kemzyme<sup>®</sup> Plus Liquid as a feed additive gives rise to no concerns for consumers. Kemzyme<sup>®</sup> Plus Liquid is not an irritant to skin and eyes but should be considered as a potential skin sensitiser. The additive is considered to be hazardous by inhalation. No risks to the environment are expected and no further environmental risk assessment is required. Owing to the incompleteness of the data on enzyme recovery, the FEEDAP Panel could not establish the efficacious dose in units of enzyme activity. The efficacy studies showed that supplementation of the diets with Kemzyme<sup>®</sup> Plus Liquid at a nominal dose of 50 mg additive/kg feed has the potential to be efficacious in chickens and turkeys for fattening and in laying hens. These conclusions can be extended at the same nominal dose to chickens reared for laying and turkeys reared for breeding and extrapolated to minor poultry species and ornamental birds.

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### KEY WORDS

zootechnical additive, digestibility enhancers, safety, efficacy, poultry

<sup>1</sup> On request from European Commission, Question No EFSA-Q-2010-01295, adopted on 9 September 2015.

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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<sup>®</sup> Plus Liquid (endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, alpha-amylase and endo-1,4-beta-xylanase) as a feed additive for poultry species and ornamental birds. It is proposed to be classified as a zootechnical additive, functional group of digestibility enhancers.

The additive Kemzyme<sup>®</sup> Plus liquid, formerly known as Kemzyme W liquid, 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), 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 as a feed additive in chickens for fattening, turkeys and laying hens and subject to re-evaluation.

Based on the results obtained in the tolerance studies provided, the FEEDAP Panel considered that the additive is safe for chickens for fattening and laying hens at the maximum dose of 200 mg additive/kg feed and for turkeys for fattening at a maximum dose of 150 mg additive/kg feed. The conclusions can be extended to chickens reared for laying and turkeys reared for breeding at the corresponding dose (200 mg/kg feed in chickens and 150 mg/kg feed in turkeys). Based on the wide margin of safety shown in the tolerance studies, the FEEDAP Panel considered that the conclusions can be extended to minor poultry species and ornamental birds at the maximum dose of 200 mg additive/kg feed.

The production organism of the alpha-amylase is considered suitable for the Qualified Presumption of Safety approach to safety assessment, and qualifications were met; consequently, the use of this product as a feed additive is considered safe for consumers. The genotoxicity studies and sub-chronic oral toxicity studies provided with this product support the conclusion. The results obtained in the genotoxicity studies and on the sub-chronic oral toxicity studies provided for the other enzyme components of the additive do not indicate any reason for concern regarding consumer safety. Therefore, the Panel considers that the use of Kemzyme<sup>®</sup> Plus Liquid as a feed additive gives rise to no concerns for consumers.

Kemzyme<sup>®</sup> Plus Liquid is not an irritant to skin and eyes but should be considered as a potential skin sensitiser. The additive is considered to be hazardous by inhalation.

The active substances of Kemzyme<sup>®</sup> Plus Liquid 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.

Owing to the incompleteness of the data on enzyme recovery, the FEEDAP Panel could not establish the efficacious dose in units of enzyme activity. The data showed that supplementation of the diets with Kemzyme<sup>®</sup> Plus Liquid at a nominal dose of 50 mg additive/kg feed has the potential to be efficacious in chickens and turkeys for fattening and in laying hens. These conclusions can be extended at the same nominal dose to chickens reared for laying and turkeys reared for breeding. The mode of action of the enzymes present in the additive is well known and can be considered to be similar in all avian species; thus, the conclusions on the efficacy in major poultry species can be extrapolated to minor poultry species and ornamental birds.